EUROPEAN UNION AGENCY FOR RAILWAYS

ASZ Agencija za sigurnost željezničkog prometa

REPUBLIKA HRVATSKA
MINISTARSTVO MORA, PROMETA I INFRASTRUKTURE

Fakultet prometnih znanosti

Workshop on the technical pillar of the 4RP

WORKSHOP PROCEEDINGS



Zagreb, 1st and 2nd of October 2019

PROCEEDINGS OF THE WORKSHOP ON THE TECHNICAL PILLAR OF THE 4TH RAILWAY PACKAGE

Publisher: University of Zagreb
Faculty of Transport and Traffic Sciences
Vukelićeva 4, HR-10000 Zagreb, Croatia
https://www.fpz.unizg.hr/

For Publisher: Tomislav Josip Mlinarić, Dean
Faculty of Transport and Traffic Sciences

Editors: Danijela Barić
Martin Starčević

URL: https://www.fpz.unizg.hr/web/dogadanja/zbornici-radova

ISBN 978-953-243-112-4

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Agencija Europske unije za željeznice

Croatian Railway Safety Agency

Ministry of the Sea, Transport and Infrastructure

REPUBLIKA HRVATSKA
MINISTARSTVO MORA,
PROMETA I INFRASTRUKTURE

University of Zagreb
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TŽV Gredelj d.o.o. u stečaju
UNIFE

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4th Railway Package – INTRO

The 4th Railway Package (4RP)* is a set of legislative texts designed to complete the single market for rail services (Single European Railway Area). It should revitalise the rail sector and make it more efficient and more competitive vis-à-vis other modes of transport. The 4RP comprises a technical pillar and a market pillar. This brochure highlights the new tasks arising from the 'technical pillar' of the 4RP. The 'technical pillar', which was adopted by the European Parliament and the Council in April 2016, enhances the role of the EU Agency for Railways ('the Agency') by introducing new tasks to ensure a uniform implementation of the EU framework. Further information on the legislation can be found in all EU languages on EUR-LEX website: https://eur-lex.europa.eu

What are the benefits of the 4RP technical pillar?

The technical pillar is designed to boost the competitiveness of the European railway sector by significantly reducing the costs and the administrative burden for cross-border rail services. In particular, it will:

- save businesses from having to file costly multiple applications for vehicle authorisations and safety certificates in the case of operations beyond one single member state
- create a 'one-stop shop' IT tool which will act as a single entry point for all such applications, using easy, transparent and consistent procedures
- ensure that European Rail Traffic Management System (ERTMS) equipment is interoperable
- reduce the large number of remaining national rules, which create a risk of insufficient transparency and disguised discrimination against new railway undertakings.

What are the main changes?

- A renewed framework for railway safety aiming at promoting safety culture.
- A harmonised approach to safety certification where single safety certificates are granted. to railway undertakings for the whole area of operation rather than having Part A and Part B certificates.
- A new harmonised framework for vehicle authorisation.
- A harmonised implementation of ERTMS in the Union with a prior check that the ERTMS trackside technical solutions envisaged are fully compliant with the relevant Technical Specifications for Interoperability (TSIs) and are therefore fully interoperable.
- An enhanced role for the Agency in the EU rail system:
    - ✓ The Agency will issue vehicle authorisations and safety certificates, and approve ERTMS trackside technical solutions

- ✓ The Agency will also be responsible for managing the 'one-stop shop' IT tool through which all application files for vehicle authorisations, safety certificates and ERTMS trackside approvals shall be submitted.

- New approach for checking the technical compatibility of the vehicle with the route
- Clearer safety responsibilities for the different actors of the railway system
- More transparent identification of national rules.

When do the new processes apply?

The member states shall transpose the 4th Railway Package by the 16th of June 2019 or, if notified to the Commission and the Agency, by the 16th of June 2020. During the period between these two dates, it is possible that different legal regimes will be in place in adjacent countries. This will affect the arrangements for the assessment of applications for vehicle authorisations or safety certificates. Please contact your national safety authority or the Agency to request more information about your options.

Practical arrangements: streamlining the processes of vehicle authorisation, safety certification and ERTMS trackside approval

In order to reduce the complexity, length and cost of the vehicle authorisation and safety certification processes, and foster collaboration among all the parties involved in these processes, both the recast Interoperability Directive and the recast Safety Directive have identified the need for practical arrangements harmonising the approach to vehicle authorisation and safety certification. These practical arrangements have materialised into new EU Regulations applicable to all parties involved in the vehicle authorisation and safety certification processes, respectively:

- **Commission Implementing Regulation (EU) 2018/545** of 4 April 2018 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process
- **Commission Implementing Regulation (EU) 2018/763** of 9 April 2018 establishing practical arrangements for issuing single safety certificates to railway undertakings

To ensure the harmonised implementation and interoperability of ERTMS, the recast Interoperability Directive requires that the Agency checks the compliance of the technical solutions envisaged with the relevant Technical Specifications for Interoperability (TSI) and gives its approval by means of a decision. The approval process to be followed by the Agency and the applicants is described in an EC Recommendation.

What are the key changes brought by the new processes?

Safety Certification

- Introduction of the notion of 'single safety certificate' valid within the area of operation of the concerned railway undertaking to reduce administrative burdens (Part A and Part B safety certificates will no longer exist).
- The new 'single safety certificate' covers one or several member states. In the former case, the applicant can choose the safety certification body between the Agency and the national safety authority of the member state concerned. In the latter case, the Agency is the safety certification body.
- Single harmonised EU process for safety certification.
- All applications for a single safety certificate are submitted through the 'one-stop shop' IT tool.
- The Agency acting as safety certification body is responsible for assessing the part of the application related to the EU requirements (i.e. the safety management system requirements). It coordinates with the national safety authority or authorities concerned with the intended area of operation for the assessment of compliance with the national rules notified by the relevant member state(s).
- Single safety certificates can be updated with restrictions or conditions of use, renewed or revoked.
- The applicant can request pre-engagement with the concerned authorities before the submission of its application for a single safety certificate. Such pre-engagement should help clarify how the safety assessment process will be conducted, including the process of decision-making, and verify that the applicant has received sufficient information to know what is expected of it.

Vehicle Authorisation

- Introduction of the notion of 'vehicle authorisation for placing on the market' to allow for commercial transactions of vehicles anywhere in the Union and to reduce administrative burdens.
- The new notion of 'vehicle authorisation for placing on the market' covers one or several member states. In the former case, the applicant can choose the authorising entity between the Agency and the national safety authority of the member state concerned. In the latter case, the Agency is the authorising entity.
- Single harmonised EU process for vehicle authorisation for placing on the market and vehicle type authorisation.
- All applications for a vehicle type authorisation are submitted through the 'one-stop shop' IT tool.
- The Agency acting as authorising entity is responsible for assessing the part of the application related to the EU requirements (i.e. TSIs). It coordinates with the national safety authority or authorities concerned with the intended area of use for the assessment of compliance with the national rules notified by the relevant member state(s).

- National safety authorities may issue a temporary authorisation to use the vehicle for tests on the network.
- The applicant is responsible, as part of its application for a vehicle type authorisation, for capturing the applicable requirements and ensuring that they are met.
- Clarification of the definition of 'vehicle type version' and introduction of a new definition for 'vehicle type variant' to accommodate the concept of 'platforms' in vehicle type authorisations.
- Vehicles already authorised under a previous regime remain authorised until a change is made that makes it necessary to apply for a new authorisation. When a new authorisation is required, only the change and the interface with the unchanged parts are assessed.
- Vehicle type authorisation and/or vehicle authorisation for placing on the market can be suspended, revoked or amended.
- The applicant can request pre-engagement with the concerned authorities before the submission of its application for a vehicle type authorisation. Such pre-engagement should help clarify how the vehicle authorisation process will be conducted, including the process of decision-making, and verify that the applicant has received sufficient information to know what is expected of it.

ERTMS Trackside Approval

- ERTMS trackside approval is part of the application file for an authorisation for placing in service trackside control-command and signalling subsystems, involving the European Train Control System (ETCS) and/or the Global System for Mobile Communications – Railway (GSM-R) equipment.
- Following a request for approval, the applicant provides the complete application file that describes the envisaged technical solution.
- The Agency evaluates the application file to make a positive decision on the technical solution envisaged and issue an approval when appropriate.
- The approval decision is based on the demonstration of controlling issues identified in previous ERTMS projects that may hinder interoperability.
- National safety authorities may be involved in this process by issuing an opinion at any stage (but are still responsible for the authorisation of the placing into service of the trackside equipment) and will have full visibility through the 'one-stop shop' IT tool.
- Prospective applicants are invited to engage with the Agency as soon as possible and provide information on any possible ERTMS (including GSM-R only) project that may be subject to the approval process.

**Source: The 4th Railway Package - What does it mean for me?, European Union Agency for Railways, Luxembourg: Publications Office of the European Union, 2018*

Invitation

EUROPEAN UNION AGENCY FOR RAILWAYS
Making the railway system work better for society.

Agencija za sigurnost željezničkog prometa
Croatian Railway Safety Agency

REPUBLIKA HRVATSKA
MINISTARSTVO MORA, PROMETA I INFRASTRUKTURE
Ministry of the Sea, Transport and Infrastructure

Fakultet prometnih znanosti
University of Zagreb Faculty of Transport and Traffic Sciences

Workshop on the technical pillar of the 4RP

Zagreb, Faculty of Transport and Traffic Science, 1st and 2nd of October 2019

We are delighted to announce a two-day workshop, organized by European Union Agency for Railways (ERA), Croatian National Safety Authority (ASŽ), Ministry of the Sea, Transport and Infrastructure (MMPI) and University of Zagreb Faculty of Transport and Traffic Sciences (FPZ), which gives answers on the changes in the context of the 4th Railway Package.

This event is part of our joint effort to clarify the changes to the European Railways Safety Regulatory structure which will take place in the next year when the 4th Railway Package will be introduced in the Croatian railway system.

In this workshop NSA HR and ERA are delivering presentations on the changes of the 4th Railway Package (4th RP), SSC, VA processes, the OSS, organizational aspects, fees and charges, appeal and review process.

The first day will be dedicated to the safety certification for railway undertakings while the second day will focus on the vehicle and vehicle type authorization. The workshop will be in Croatian/English.

Other presentations will be given by representatives of the Croatian regulatory authority for network industries (HAKOM) and The European Rail Supply Industry Association (UNIFE).

In addition to presentations on the main changes introduced by the 4th RP, sufficient time will be available on both days for discussions and prepared questions from the audience.

We would like to deliver as much information as possible, therefore we kindly ask you to have all your questions prepared for the Workshop registration inside the registration form!

If you will have any questions, please do not hesitate to contact us.

We are looking forward to welcoming you in Zagreb!

EUROPEAN UNION AGENCY FOR RAILWAYS
Making the railway system work better for society.

ASŽ Agencija za sigurnost željezničkog prometa
Croatian Railway Safety Agency

REPUBLIKA HRVATSKA MINISTARSTVO MORA, PROMETA I INFRASTRUKTURE
Ministry of the Sea, Transport and Infrastructure

Fakultet prometnih znanosti
University of Zagreb Faculty of Transport and Traffic Sciences

Radionica na temu 4. Željezničkog paketa

Zagreb, Fakultet prometnih znanosti, 1. i 2. listopada 2019.

Posebno nam je zadovoljstvo najaviti dvodnevnu radionicu, u organizaciji Agencije Europske unije za željeznice (ERA), Agencije za sigurnost željezničkog prometa (ASŽ), Ministarstva mora, prometa i infrastrukture (MMPI) i Fakulteta prometnih znanosti Sveučilišta u Zagrebu (FPZ), koja će dati odgovore na pitanja vezana za promjene u sklopu 4. Željezničkog paketa.

Ova je radionica dio naših zajedničkih nastojanja, da se razjasne promjene u europskoj regulativi koje će nastupit sljedeće godine uvođenjem 4. Željezničkog paketa u hrvatski željeznički sustav.

U ovoj će radionici ASŽ i ERA prezentirati promjene koje dolaze s 4. Željezničkim paketom, jedinstvenim potvrdama o sigurnosti (SSC), odobrenjima za stavljanje vozila (tipova vozila) na tržište (VA), OSS-om (One-stop-shop; jedinstvena informatička točka), organizacijskim aspektima, troškovima i naknadama, žalbama i procesu nadzora.

Prvi će dan biti posvećen postupcima vezanim uz potvrde o sigurnosti za željezničke prijevoznike, dok će drugi dan biti fokusiran na odobrenja za stavljanje vozila (tipova vozila) na tržište.

Radionica će biti na hrvatskom i engleskom jeziku. Ostale će prezentacije držati Hrvatska regulatorna agencija za mrežne djelatnosti (HAKOM) i Udruženje europske željezničke industrije (UNIFE).

Pored prezentacija vezanih za glavne promjene koje donosi 4. Željeznički paket, bit će osigurano vrijeme za diskusiju na temelju unaprijed pripremljenih pitanja.

Sa željom da Vam pružimo što više informacija, molimo da pripremite pitanja za Radionicu koja ćete nam dostaviti s obrascem za registraciju!

Ako imate pitanja, slobodno nam se obratite.

Očekujemo Vas s radošću u Zagrebu!

Programme

Making the railway system work better for society.

Croatian Railway Safety Agency

Ministry of the Sea, Transport and Infrastructure

University of Zagreb Faculty of Transport and Traffic Sciences

Agenda

Workshop on the technical pillar of the 4RP

Zagreb, 01 and 02 October 2019

Workshop venue:

Faculty of Transport and Traffic Sciences at the University of Zagreb, University Campus Borongaj, *Borongajska 83a, Building 69, Amphitheatre,* https://www.fpz.unizg.hr/web/naslovna/novosti

Target audience:

Frontline and clerical staff engaged in activities related to applications for:

- Safety Certificates
- Vehicle (Type) Authorisations

Type of organisations:

National Safety Authority, Railway Undertakings, Infrastructure managers, Manufacturers, other organisations at discretion of the NSA.

Type of event:

Raise awareness, generate knowledge on principles applied to Safety certification and Vehicle (type) authorisation;

Trigger actions on the use of the One Stop Shop and preparation of application files

Question and answer session included

Official languages:

English, Croatian

Member State:

Croatia, transposition date: 2020

Live-Streaming:

Both days the Workshop will be broadcast live on this link

https://www.fpz.unizg.hr/web/dogadanja/streaming/workshop-4rp

Workshop on the technical pillar of the 4RP

organized by

EUROPEAN UNION AGENCY FOR RAILWAYS

Making the railway system work better for society.

ASŽ *Agencija za sigurnost željezničkog prometa*

Croatian Railway Safety Agency

REPUBLIKA HRVATSKA
MINISTARSTVO MORA,
PROMETA I INFRASTRUKTURE

MINISTRY OF THE SEA,
TRANSPORT AND
INFRASTRUCTURE

Fakultet prometnih znanosti

University of Zagreb
Faculty of Transport and
Traffic Sciences

WORKSHOP AGENDA

Tuesday, 1st of October 2019, SSC

Moderator: **Danijela Barić**

Time	*Item*	*Speaker(s)*
08:15 – 09:00	**Registration**	
09:00 – 09:30	**Opening and introduction**	UNIZG-FPZ: **Mladen Nikšić**, Vice Dean NSA HR: **Želimir Delač**, Director ERA: **Dragan Jovičić,** Project Officer - Safety and Operations Unit
09:30 – 10:00	**Overview on the 4RP – technical pillar**	ERA: **Dragan Jovičić**, Project Officer - Safety and Operations Unit
10:00 – 11:00	**The safety certification process under 4th RP**	ERA: **Dragan Jovičić**, Project Officer - Safety and Operations Unit
11:00 – 11:30	Coffee break	
11:30 -12:00	**Main differences with current national process for safety certification. Changes in the legal framework**	NSA HR: **Želimir Delač**, Director **Tihomir Pleša**, Deputy Director
12:00 - 12:30	**The fourth railway package – market pillar**	HAKOM: **Dragica Flam,** Senior Specialist
12:30 – 13:30	Lunch	
13:30 – 14:15	**Single Safety Certificate delivery by ERA: organisational aspects. Fees and charges. Appeal and review process**	ERA: **Dragan Jovičić**, Project Officer - Safety and Operations Unit
14:15 – 15:15	**The One Stop Shop – simulation SSC**	ERA: **Stijn Michiels**, Project Officer - Safety and Operations Unit
15:15 – 15:45	Coffee break	
15:45 – 17:00	**Open Q & A session**	NSA HR/ERA
17:00 – 17:30	**Laboratory for Modelling and Simulation Railway System – Tour & Visit**	Faculty of Transport and Traffic Sciences (FPZ): **Denis Šipuš**, Head of Laboratory **Ivica Ljubaj**, Head of Laboratory

Wednesday, 2nd of October 2019, VA

Moderator: **Želimir Delač**

Time	*Item*	*Speaker(s)*
08:15 – 09:00	**Registration**	
09:00 – 09:30	**Opening and introduction**	UNIZG-FPZ: **Tomislav Josip Mlinarić**, Dean NSA HR: **Želimir Delač**, Director ERA: **Antoine Defossez,** Project Officer - Rolling stock and Fixed installations Unit
09:30 – 10:00	**Overview on the 4RP – technical pillar**	ERA: **Antoine Defossez,** Project Officer - Rolling stock and Fixed installations Unit
10:00 – 11:00	**The vehicle (type) authorisation process under 4th RP**	ERA: **Nordine Boussouf**, Project Officer - Rolling stock and Fixed installations Unit
11:00 – 11:30	Coffee break	
11:30 - 12:00	**The vehicle (type) authorisation process under 4th RP (continuation)**	ERA: **Nordine Boussouf,** Project Officer - Rolling stock and Fixed installations Unit
12:00 -12:30	**Main differences with current national process for vehicle authorization. Changes in the legal framework**	NSA HR: **Vili Milković**, Chief Engineer at Vehicle Administration
12:30 – 13:30	Lunch	
13:30 – 14:30	**Vehicle (type) authorization delivery by ERA: organisational aspects. Fees and charges. Appeal and review process**	ERA: **Antoine Defossez,** Project Officer - Rolling stock and Fixed installations Unit
14:30 – 15:30	**The One Stop Shop – simulation VA**	ERA: **Nordine Boussouf,** Project Officer - Rolling stock and Fixed installations Unit
15:30 – 15:45	**Industry's expectations regarding the 4th RP**	UNIFE: **David Kupfer**, Technical Affairs Manager
15:45 – 16:00	Coffee break	
16:00 – 17:00	**Open Q & A session**	NSA HR/ERA

Workshop – Day 1

Tuesday, October 1st

1. Dragan Jovicic: *SSC in the framework of the 4th RP*

Workshop on the Technical Pillar of the 4th RP SSC in the framework of the 4th RP

Dragan JOVICIC

Zagreb, 01 October 2019

EUROPEAN UNION AGENCY FOR RAILWAYS

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Outline

- What is new?
- EU legal framework
- Transition period
- How to apply for a single safety certificate?
- Outline of the safety assessment process
- Update and renewal of the certificate

Slide 2

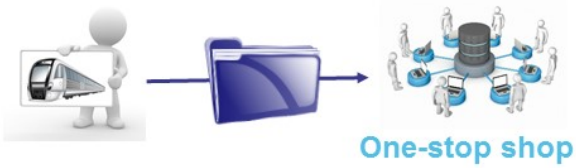
What is new?

What is new?

ERA as new authority

June 2019

Area of operation in more than one Member State or in one Member State if the applicant so requests



OR

NSA

Single safety certificate

Area of operation limited to one Member State if the applicant so requests

Slide 4

Main changes

Before	After
Safety certificate part A issued by the relevant NSA	Single safety certificate issued by a safety certification body: either the NSA or the Agency
One or more safety certificates part B issued by the relevant NSAs	
Applications managed in accordance with national arrangements	All applications managed through the one-stop shop IT tool in accordance with arrangements set out in EU law
Assessment process defined by each NSA in accordance with its own rules	Harmonised assessment process set out in EU law
Assessment based on EU criteria (to be applied by NSAs) and national rules	Homogeneous safety management system requirements (aligned with ISO management system standards, to be applied by both the authorities and the applicants) and cleaning up of national rules
No obligation from authorities to pre-engage with the applicant	Authorities must pre-engage on request of the applicant

Slide 5

EU legal framework

EU legal framework

Applicable legislation

Directive

2016/798 – Railway Safety Directive

Regulations

2018/762 – Common safety methods on safety management system requirements

2018/763 – Practical arrangements for issuing single safety certificates to railway undertakings

2015/995 – Technical specification for interoperability relating to the 'operation and traffic management' subsystem

2019/xxx – Technical specification for interoperability relating to the 'operation and traffic management' subsystem

402/2013 – Common safety method for risk evaluation and assessment

1078/2012 – Common safety method for monitoring

2018/761 – Common safety method for supervision

eur-lex.europa.eu

Slide 7

Auxiliary legislation

Directives

2016/797 – Interoperability Directive

2007/59 – Train Drivers Directive

Regulations

445/2011 – Certification of entities in charge of maintenance

2016/796 – Agency (ERA) Regulation

2018/764 – Fees and charges payable to the Agency (ERA) and their conditions of payment

2018/867 – Rules of procedure of the Board(s) of Appeal of the Agency (ERA)

Regulation concerning the International Carriage of Dangerous Goods by Rail (RID)

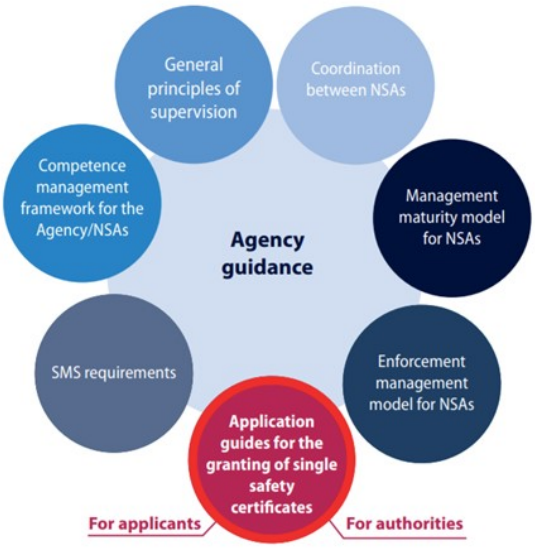
Technical specifications for interoperability relating to the structural subsystems (ETCS, wagons, etc.)

eur-lex.europa.eu

Slide 8

Compendium of Agency guidance

- New set of guidance to support the implementation of the new EU safety regulatory framework



Slide 9

Where can you get the information from?

- ERA website

ERA > Applicants > Applications for single safety certificates

ERA > Activities > Common Safety Methods

- Common Safety Methods on safety management system requirements
- Common Safety Methods on supervision

ERA > Can we help you? > FAQ

era.europa.eu

Slide 10

Transition period

Transition period?

Transitional period

- As of 16 of June 2019, ERA is responsible for issuing single safety certificates **when the area of operation entails at least one Member State** that has transposed Directive (EU) 2016/798 by that date
- The national safety authorities of the Member States that postponed the transposition of the new legal framework by one year continue to issue safety certificates in accordance with Directive 2004/49/EC until 16 June 2020

Transposition by 16/06/2019



Transposition by 16/06/2020

Slide 12

Transitional period

16/06/2019
16/06/2020



- Safety Directive allowed Member States to chose one of the two possible transposition dates
- Notification of chosen dates was to be done by 16/12/18
- Single safety certificate to be issued when any part of the certificate (A or B) expires in the Member State that transposed Directive (EU) 2016/798 in 2019
- During that period some of the railway undertakings need to follow two different regimes at the same time

Slide 13

Transitional period

(1)	**MS 1** (PART A/B) 06/2019	**MS 2** (PART B) 06/2019	**ERA** issues SSC
(2)	**MS 1** (PART A/B) 06/2019	**MS 2** (PART B) 06/2020	**ERA** issues SSC **MS 2** issues certificate Part B
(3)	**MS 1** (PART A/B) 06/2020	**MS 2** (PART B) 06/2019	**MS 1** issues certificates Part A and B **ERA** issues SSC
(4)	**MS 1** (PART A/B) 06/2020	**MS 2** (PART B) 06/2020	**MS 1** issues certificates Part A and B **MS 2** issues certificate Part B **ERA** involved as of 06/2020

EXPLANATION:

MS 1 (PART A) 06/2019
- Member State X issuing certificate Part X
- Transposition date in the Member State
- Color reflects the transposition date

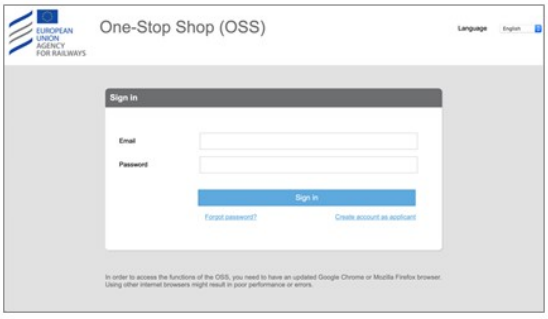
Slide 14

How to apply?

How to apply?

Submission of the application

- Railway undertakings submit any application for a single safety certificate through the **one-stop shop** IT tool, available from the Agency website or by using the following URL: https://oss.era.europa.eu/logon.html



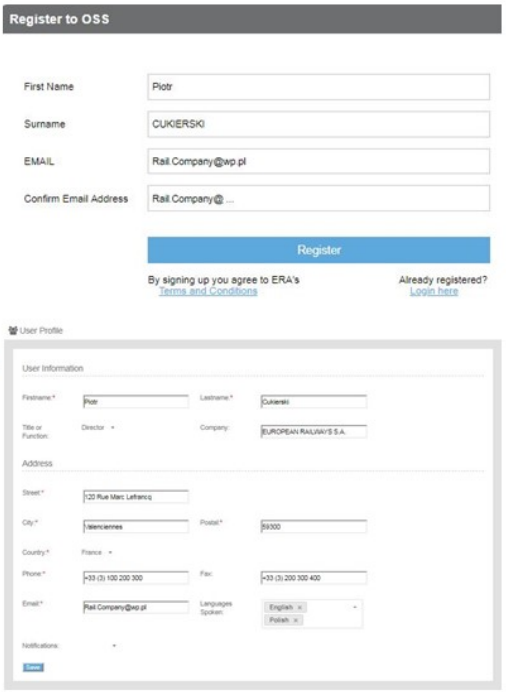
- It is recommended that an application for a single safety certificate is submitted in advance to any possible deadline (at least 6 months)

Slide 16

Application Process in the OSS

1. Register yourself
2. Log in to the OSS
3. Complete user profile
4. Registered user:
   - → Can draft application in the OSS
   - → Can submit application in the OSS
   - → Can share application with other user
   - → Is automatically a contact person

You have to decide internally how to manage the access rights in your organisation



Slide 17

Application Process in the OSS

Submit your application in seven steps:

1. • Fill in the application form
2. • Upload evidence for compliance with the SMS requirements
   • Cross reference the evidence with the SMS / TSI OPE requirements
3. • Upload evidence for compliance with the national rules
   • Cross reference evidence with the national rules
4. • Upload additional documents (e.g. financial)
5. • Review + sign + submit your application

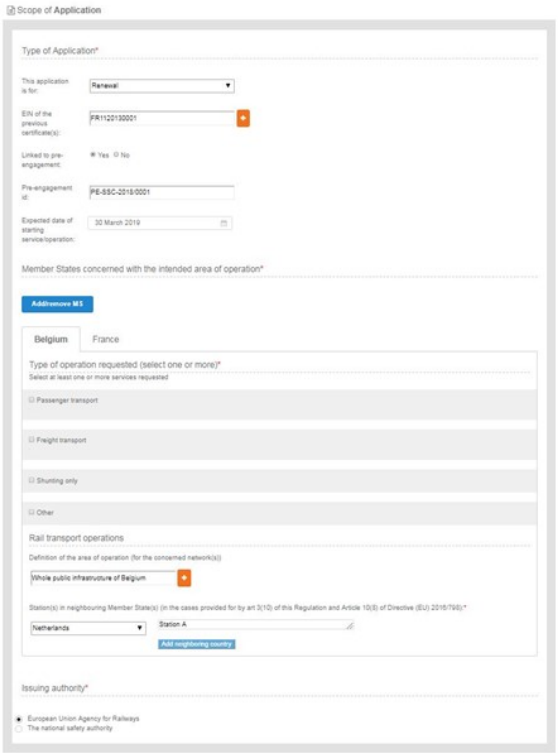
Slide 18

Application Process in the OSS: **step 1**

Fill in the application form:

- type of request
- area of operation
- type of operation
- networks concerned
- border stations (if any)
- information on the applicant
- information on the contact person

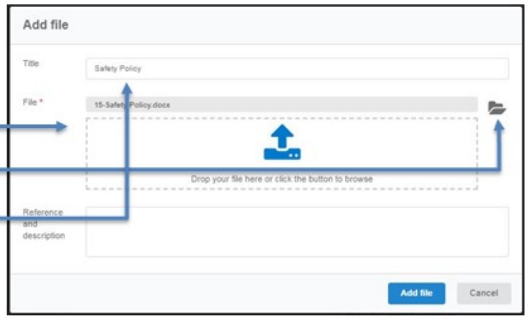
This is covered by the Annex I to Practical Arrangements



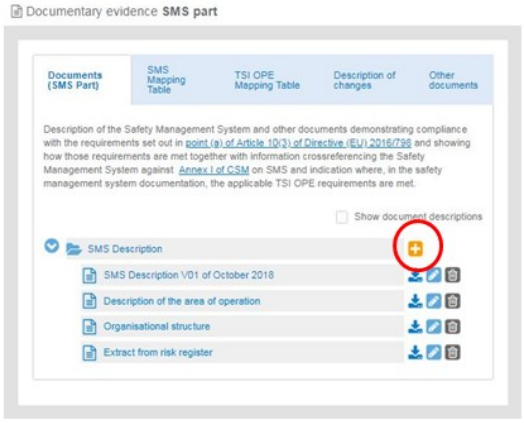
Application Process in the OSS: **step 2/1**

Upload your evidence for the SMS part:

- use drag and drop function
- or upload from your folders
- provide clear titles



You decide how to structure your evidence but clear structure and not too extensive documents facilitate assessment

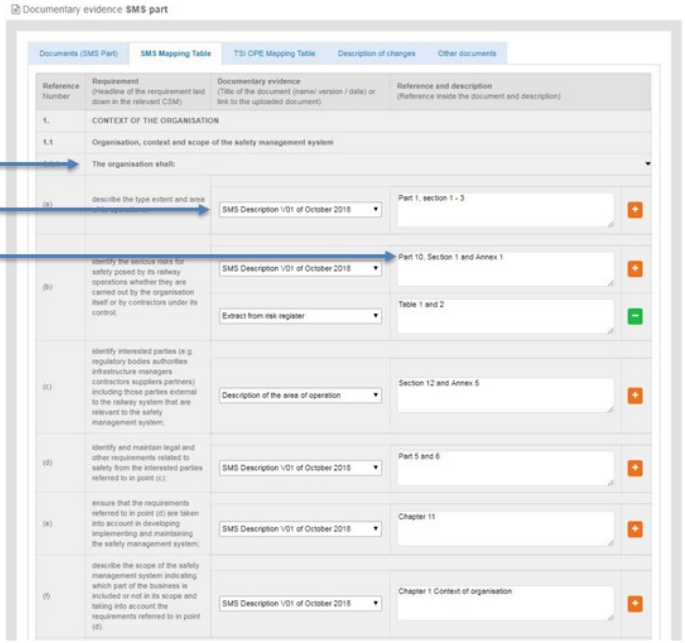


Application Process in the OSS: step 2/2

Cross reference you evidence with relevant requirements:

SMS Requirements

- SMS Requirement
- Your evidence
- Description



TSI OPE Requirements

- Under development



Slide 21

Application Process in the OSS: step 3/1

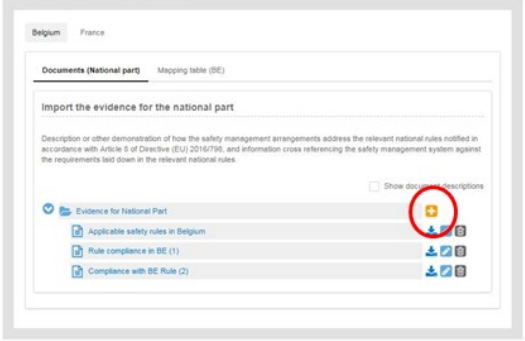
Upload evidence for the national parts:

National requirements

- use drag and drop function
- or upload from your folders
- provide clear titles



Documentary evidence: **National part**



Check National Application Guides to find out the list of applicable rules

Upload information separately for each of the areas of operation

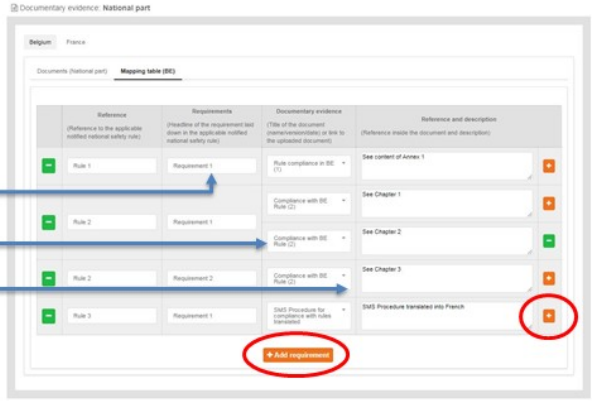
Slide 22

Application Process in the OSS: step 3/2

Cross reference your evidence with the national requirements

Option 1:

- Build your own mapping table
- Complete the table providing:
  - Requirements captured in guides
  - The evidence you have uploaded
  - Reference and description



Option 2:

- Complete the table in paper
- Upload it as a file



Slide 23

Application Process in the OSS: step 4

Upload additional documents:

- Legal Entity Form (LEF)
- Any other document



Do not upload here any evidence for SMS or national parts. It's only for administrative and financial documents

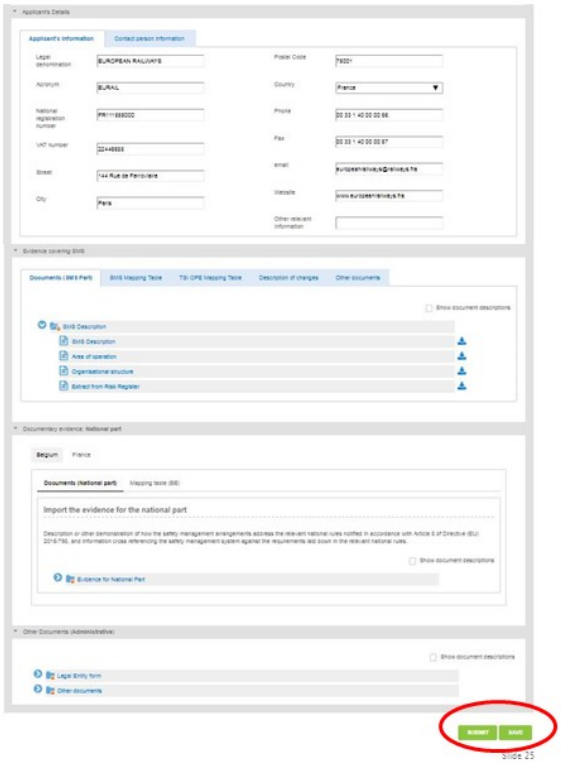
Slide 24

Application Process in the OSS: step 5

Review + sign + submit:

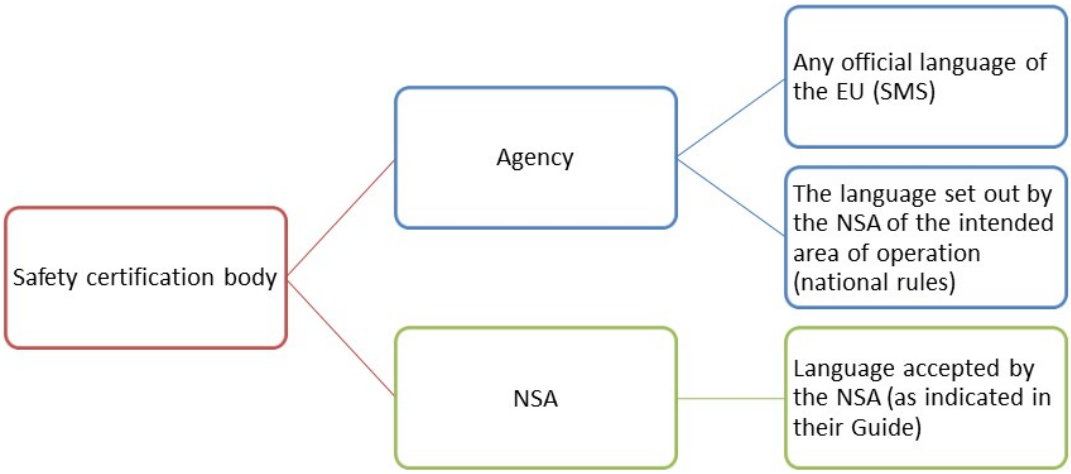
- Check quality of data
- Check completeness of file
- Check uploaded documents
- and
- Submit your application

You will be automatically notified about receipt of your application and about the starting date of the assessment
Submitted file will be frozen and you will be able to update it only in reply to issue logged in by the assessors



Slide 25

Language policy



Slide 26

EUROPEAN UNION AGENCY FOR RAILWAYS

The safety assessment process

The safety assessment process

EUROPEAN UNION AGENCY FOR RAILWAYS

Safety assessment process



Slide 28

Pre-engagement stage (optional)

Advantages
Facilitating early contact
Developing the relationship between assessors and applicant
Gaining familiarity with applicant's SMS level of maturity
Mitigating the embryonal risks of delays in issuing the SSC
One-stop shop used to submit the request, info can be re-used for later submission
Not mandatory, but highly recommended



Disadvantages
Long-time perspective
Extra and constant commitment by the applicant
Subject to charges

The applicant chooses a safety certification body when requesting pre-engagement but this can be changed at later stage

Slide 29

Initial screen stage

Aim:

- To check that the documents submitted by the applicant (i.e. the evidence) are sufficient, relevant and consistent
- If not, the safety certification body (and the NSA(s) concerned with the area of operation) may request for additional information
- The timeframe for the provision of missing information is agreed with the applicant
- The request is managed through the issue log of the one-stop shop

Slide 30

Detailed assessment stage

Aim:

- To check that the evidence complies with the legal requirements (both EU and national)
- If not, the authority or authorities concerned with the area of operation may request for additional information
- The timeframe for the provision of missing information is agreed with the applicant
- The request is managed through the issue log of the one-stop shop
- An assessment report is issued by the authority or authorities concerned; If the Agency is the safety certification body, it aggregates the different reports to produce a final assessment report available in the language of the applicant

Slide 31

Decision stage

Aim:

- To notify the applicant of the safety certification body's decision
- Negative decision means:
  - Rejection of the application
  - Inclusion of restrictions/conditions of use
- Negative decision can be subject to review, appeal and actions before the Court of Justice (EU/national)

Slide 32

Communication arrangements

- The exchange of information between the applicant, the Agency and the NSA(s) concerned with the area of operation is managed through the one-stop stop or via other communication channels (phone, videoconferencing, email etc.)

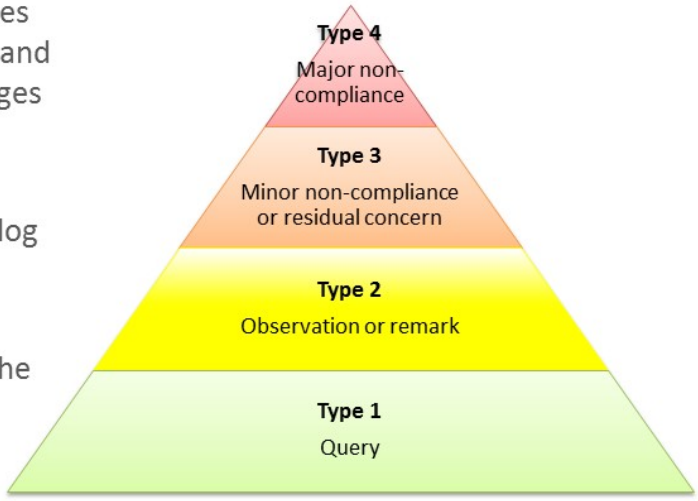




- A project manager is responsible for the coordination of the assessment. S/he is the point of contact for the applicant and the NSA(s) concerned

Management of issues

- Assessors may raise issues during the initial screen and detailed assessment stages
- Issues are recorded and categorised in the issue log of the one-stop shop
- The applicant provides the requested information through the issue log



Audits, inspections or visits

- The authorities involved in the safety assessment may conduct audits, inspections or visits on the site of the applicant

Aim:

- To collect additional evidence and to ascertain the applicant's awareness on some areas of concern





- These activities do neither replace nor duplicate the supervision carried out by the NSA

Slide 35

Update and renewal of a single safety certificate

Update and renewal of a single safety certificate

Update and renewal

- **Update** in case of:
  - substantial change to the type or extent of the operation, or
  - extension of the area of operation, or
  - substantial change to the legal framework if the Agency or the NSA so requires

The railway undertaking is responsible for engaging with the safety certification body when it plans a change to the conditions under which the single safety certificate was issued. Changes can be of technical, operational or organisational nature.

- **Renewal** at the expiry of the certificate

Slide 37

Type & extent of operation

- Changing the type of operation means adding or removing:
  - Passenger transport (including high speed services)
  - Freight transport (including dangerous good services)
  - Shunting services
- Changing the extent of operation means increasing or decreasing:
  - The number of passengers and/or volume of goods
  - The estimated size (micro, small, medium sized, large) of the company in terms of employees

Slide 38

Restricting or revoking a single safety certificate

- A SSC may be restricted or revoked by the safety certification body that has issued it
- Such a restriction or revocation happens when the safety certification body is notified by a NSA that, following its supervision activities, the holder of the certificate no longer satisfies the conditions under which it has been certified
- If the NSA identifies a serious safety risk it may decide to take proportionate enforcement action, including where necessary suspending the rail operations





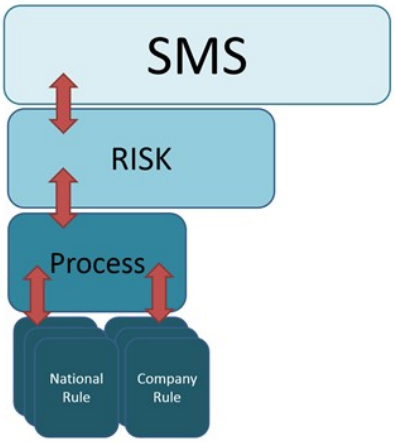


Slide 39

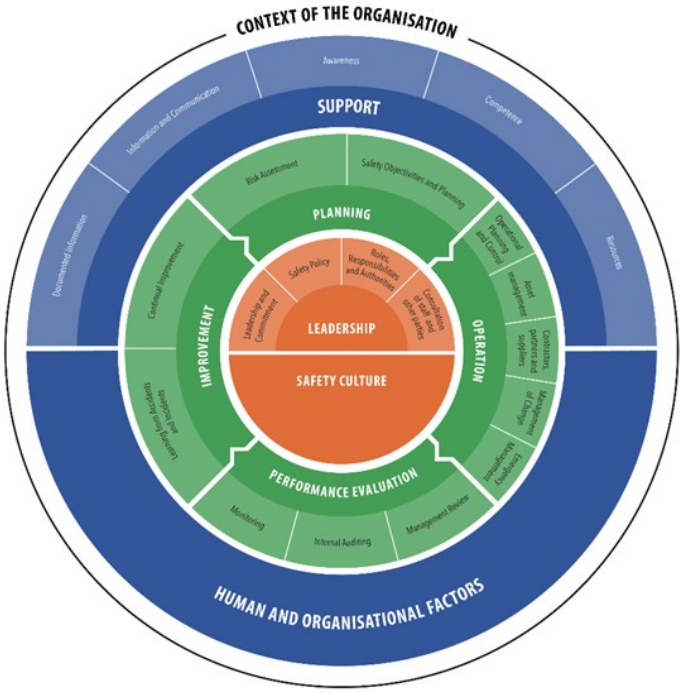
Safety management systems

What is a safety management system (SMS)?

- The **safety management system (SMS)** is a living system of linked processes and procedures, which control **risk** to ensure the safe management of rail operations
- **Risk** means the frequency of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of severity of that harm (*Regulation (EU) 402/2013, Art. 3(1)*)



ERA SMS wheel/Mobile App

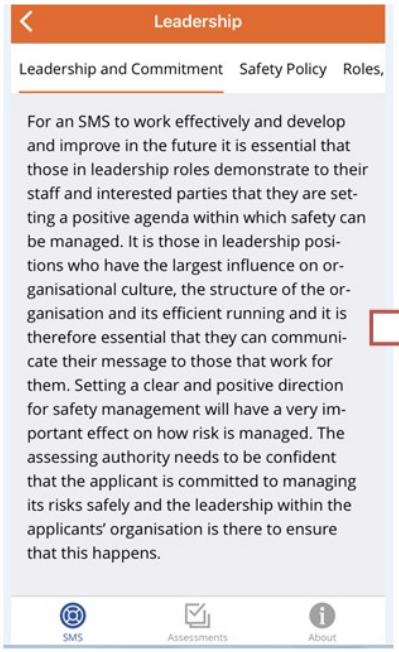


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Slide 42

SMS application - leadership





Demonstration of commitment

Communication

Safety culture

Risk management and responsibility

Slide 43

SMS application – safety culture

MANAGE MAJOR RAILWAY RISKS WITH ANTICIPATION AND RESILIENCE

F1.1 Individuals at all levels and positions are aware of major railway risks and understand their personal contribution.

F1.2 Individuals at all levels and positions are aware that complex technologies and systems can fail in unpredictable ways.

F1.3 The capability to operate safely under unexpected situations, which relies on the competence and flexibility of frontline operators and managers, is recognised and developed.

F1

UNDERSTAND WORKPLACE REALITY

F2.1 Any design and change of equipment, tasks, working conditions and organisational arrangements takes into account human characteristics and limitations.

F2.2 Normal and abnormal deviations from anticipated performance are recognised, reported and analysed. Human and organisational factors, including frontline experience, are systematically considered. Results are used to define and adapt those conditions that allow work to succeed safely.

F2.3 Measures to mitigate organisational blindness and organisational silence are implemented.

F2

CULTIVATE A CONTINUOUS LEARNING ENVIRONMENT

F3.1 Safety is learning driven. Individuals at all levels and positions avoid complacency, challenge assumptions and support organisational learning.

F3.2 Appropriate relationships within and across organisational boundaries are nurtured to operate safely.

F3.3 Any deviation from a rule or procedure is considered as an opportunity to understand how working conditions influence actual individual activities and to improve safety processes.

F3

INTEGRATE SAFETY INTO BUSINESS AT ALL LEVELS

F4.1 Individuals at all levels and positions are convinced that safety and operations go hand in hand. They demonstrate their commitment to safety through their behaviours and decisions.

F4.2 Safety is a primary consideration in the allocation of resources.

F4.3 Individuals at all levels and positions understand that working conditions influence safe behaviours. Good working conditions exist with regard to time pressures, workload and stress.

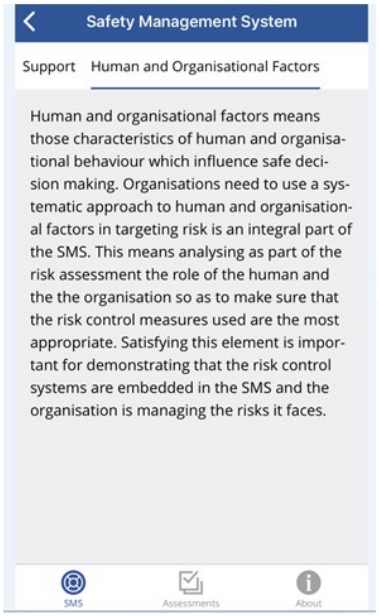
F4

era.europa.eu

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SMS application – Human and organisational factors (HOF)





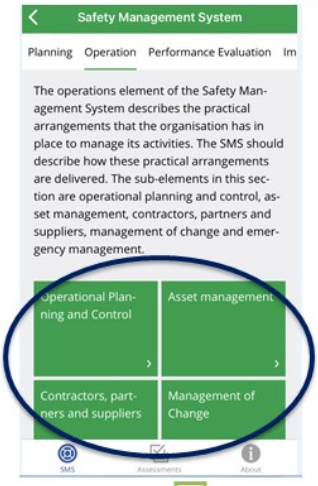
Those HOF factors which influence safe decision making

Ensuring HOF is included in the risk analysis

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SMS application - operations





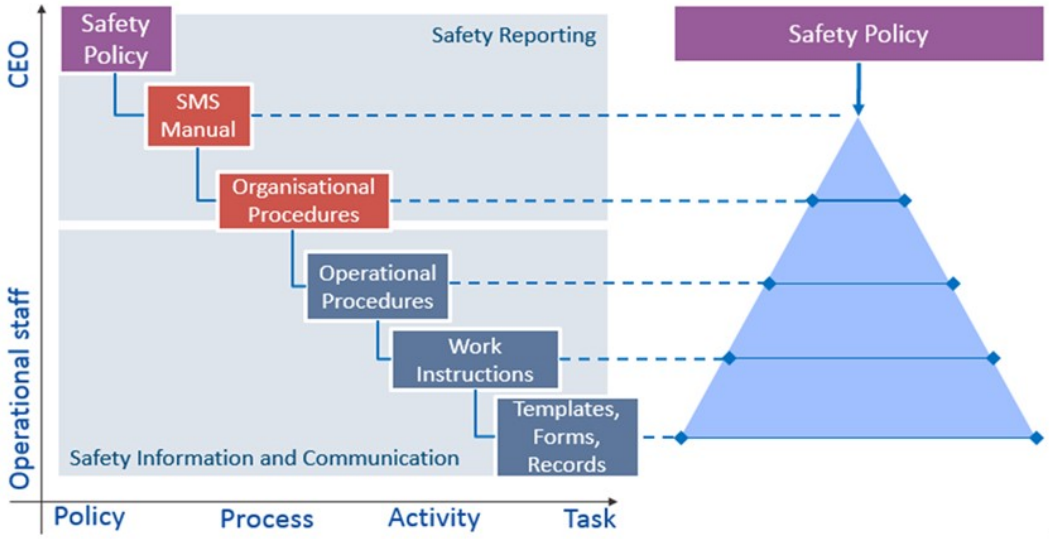


Arrangements to manage activities
Processes to manage risks
Staff understand and apply
Vehicles are operated safely under different operating conditions

Slide 46

SMS document architecture

- SMS is a process document, which needs to link to more detailed operational procedures/company operational rules/work instructions



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SMS and operations

Framework for operations:

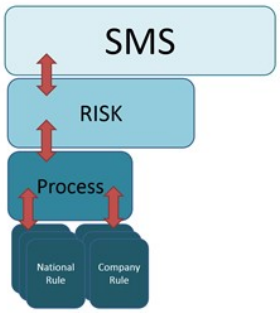
- The operational requirements of the railway is the starting point for deciding the suitability of operational procedures
- It should include a description of how standards, performance data, management system, risk assessment
- National Rules can be used providing they control the risks, are relevant, up to date and can be applied
- For planning reviewing or developing any new or updated operational the information from the risk assessment should be used to ascertain whether the existing or new operation is safe and the risks can be controlled by either procedures or rules
- The issue of normal, degraded and emergency operations should also be based on outputs from the risk assessment including control measures (i.e. rules or working instructions) for what is needed to prevent unsafe operations
- The SMS process for the operational requirements should be regularly monitored and reviewed as part of the CSM Monitoring requirements

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SMS and operational rules

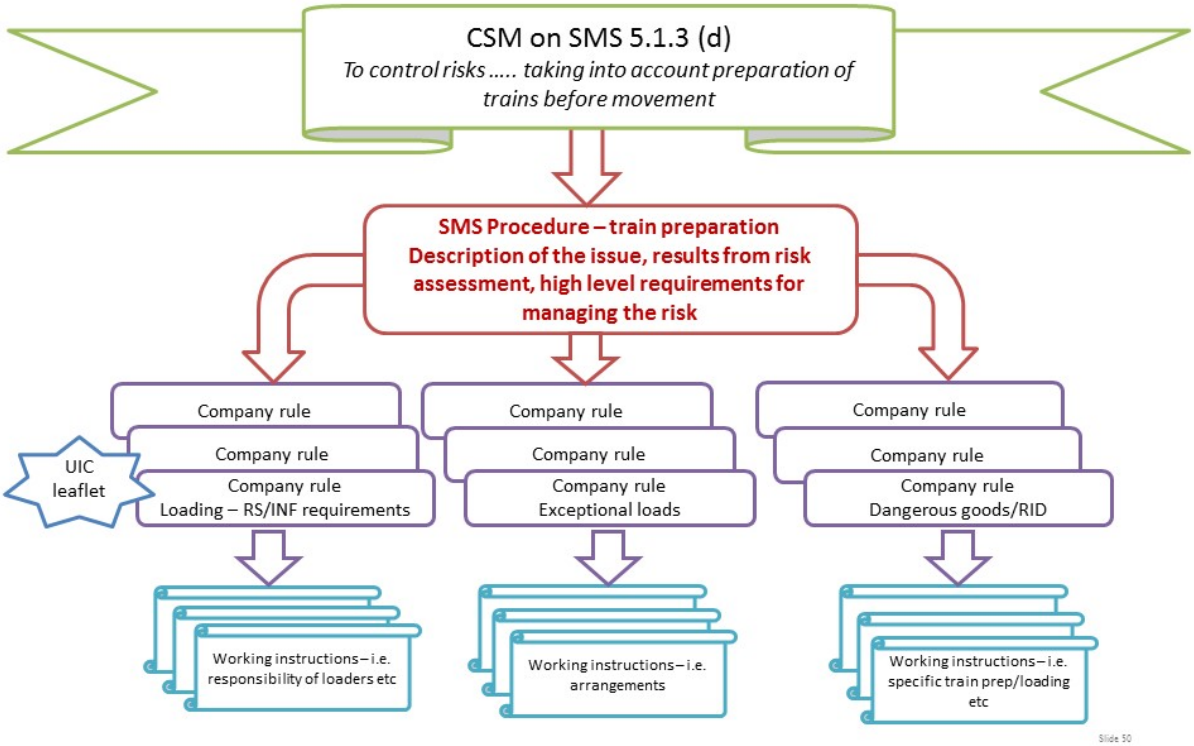
- The operational requirements are linked to a number of SMS processes and it is important that these are risk based and clearly identifiable in the SMS procedures/company rules

- For example:
  - Tasks to be performed by safety critical staff (e.g. train driving, accompanying train, preparing train, testing train, shunting, authorising train movements)
  - Train Preparation
  - Loading/RID
  - Train composition,
  - Tests and checks before departure,
  - Maintenance, diagnostic and repairs,
  - …



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SMS and operations – an example



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EUROPEAN UNION AGENCY FOR RAILWAYS

FAQ & Questions

The FAQ webpage in the Agency website provides further explanations about the issuing of single safety certificates



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EUROPEAN UNION AGENCY FOR RAILWAYS

Making the railway system work better for society.

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ISO 9001:2015 BUREAU VERITAS Certification

2. Dragan Jovicic: *ERA organisation, BoA, Fees and charges*

Workshop on the Technical pillar of the 4th RP
ERA organization, BoA, Fees and charges

Zagreb, 01 – 02 October 2019

EUROPEAN UNION AGENCY FOR RAILWAYS

EUROPEAN UNION AGENCY FOR RAILWAYS

Outline

- ERA organisation
- Board of Appeal
- Fees and charges

Slide 2

EUROPEAN UNION AGENCY FOR RAILWAYS

ERA organisation

ERA organisation

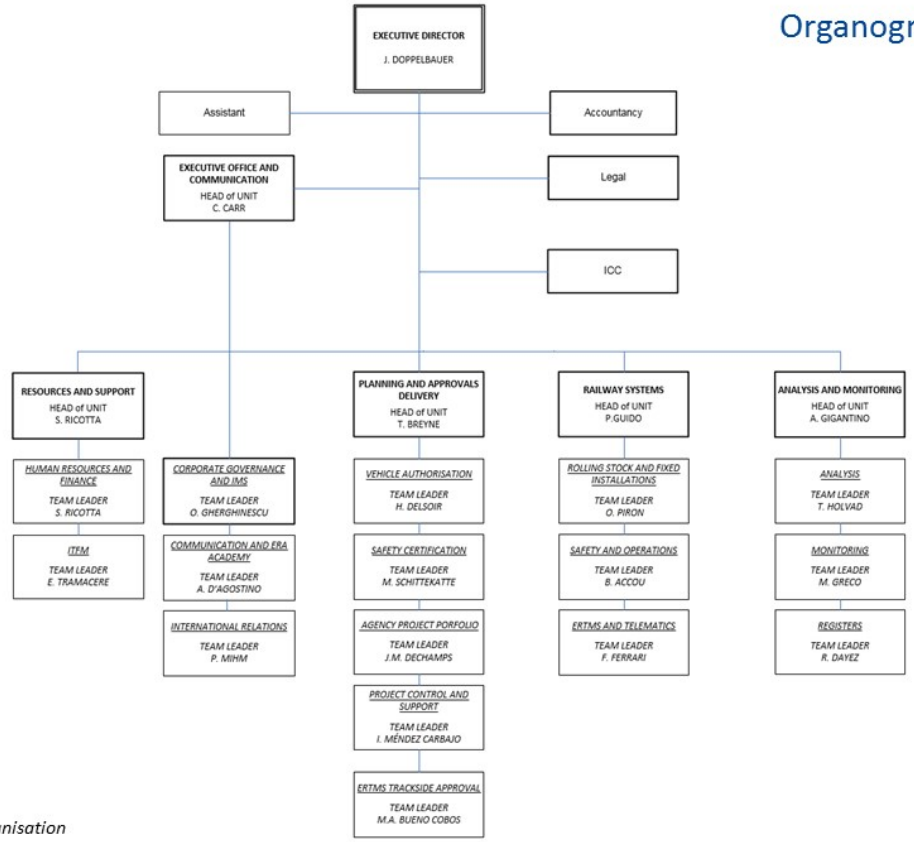
EUROPEAN UNION AGENCY FOR RAILWAYS

ERA organisation

- **Matrix based organisation** in place since July 2018
- **Planning and Approvals Delivery Unit** in charge of the portfolio of programme, projects and services at ERA and management of certification/authorisation/approval activities
- **Technical coordinator** for the technical coordination of SSC projects and **programme manager** for the planning and monitoring of SSC projects
- Close coordination with other Units for the assignment of staff to SSC projects
- Decision taken by the Executive Director (or one of his delegates)

Slide 4

Organogram



* *Temporary organisation*

Slide 5

ERA organisation

- **All applications** for single safety certificates or vehicles authorisations are **projects**.
- ERA appoints a project team for the part of the assessment it is responsible for (i.e. the assessment of the safety management system).
- The **project manager** is responsible for the coordination of the assessment. S/he is the **contact point** for the applicant and the NSA(s) concerned.
- The **decision** to issue (or not) the single safety certificate, including a link to the final assessment report, is **notified to the applicant via the one-stop shop**.

Slide 6

Board of Appeal

Board of Appeal

Remedies

- Different remedies against the decisions taken by an authority issuing single safety certificates or vehicle authorisations:
  - **Review** of the negative decision (only for the applicant)
  - **Appeal** before an appeal body (for the applicant or any natural or legal person for which the decision is addressed to that person, or of direct and individual concern to that person)
  - **Actions for the annulment or for failure to act** before the Court of Justice of the EU (ERA) or a national court (NSA)
- The applicant must first submit a request for the review of the decision taken by the authority before lodging an appeal

Slide 8

Appeal body

- The competent appeal body depends on the authority responsible for taking the decision:
  - The **Board(s) of Appeal** established by the Agency (ERA)
  - **An appeal body in accordance with national law**
- The members of the Board(s) of Appeal established by ERA are independent of any parties involved and cannot assume other roles within the Agency

Slide 9

Board of Appeal

- The Board of Appeal of the Agency plays a role during:
  - the **arbitration procedure** on request of the NSA(s) during the assessment
  - the **appeal lodged by the applicant** after the decision has been taken by ERA
- The NSA(s) concerned may request an **arbitration** before the Board of Appeal when ERA disagrees with a negative assessment carried out by the NSA(s) if a mutually acceptable assessment cannot be agreed within a month following the notification of its disagreement by ERA to the NSA(s)
- As regards **arbitration**, the Board of Appeal decides whether to confirm the Agency's draft decision.

Slide 10

Board of Appeal

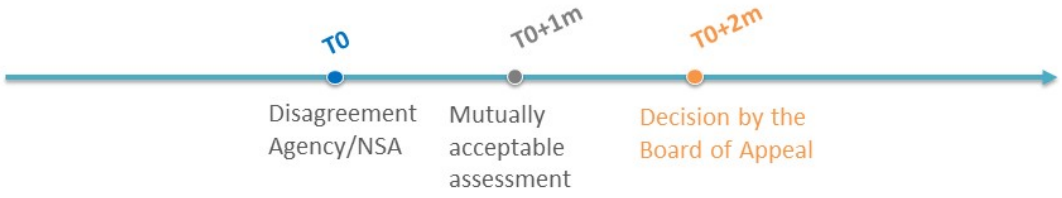
- Where the Board of Appeal finds that the grounds for **appeal** are founded, it remits the case to the Agency. The Agency takes its final decision in compliance with the findings of the Board of Appeal and provides a statement of reasons for that decision. The Agency informs the parties to the appeal proceedings accordingly.

- An lodged **appeal** does not suspend the application. However, upon request by the parties involved, the Board of Appeal may decide that the appeal in question is to have suspensory effect, if it considers that circumstances, such as impact on safety, so permit. In such a case, the Board of Appeal provides a statement of reasons for its decision.

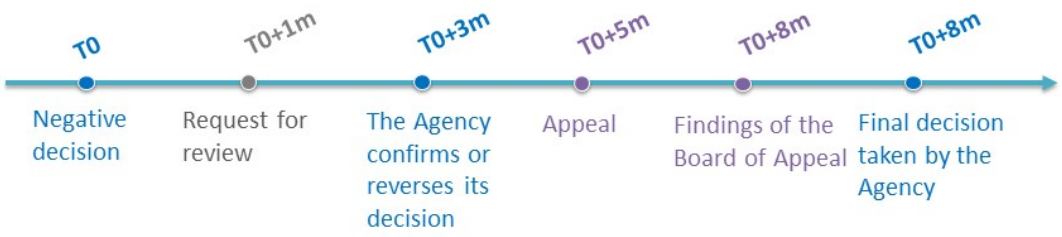
Slide 11

Chambre de recours

- Timeframe for the arbitration procedure



- Timeframe for an appeal



Slide 12

** Deadlines*

Chambre de recours

- Any request for arbitration or appeal before the Board of Appeal must be submited to the Registrar of the Board of Appeal (BoA@era.europa.eu)
- The findings of the Board of Appeal will be available in the one-stop shop by the Registrar
- Commission Implementing Regulation (EU) 2018/867 of 13 June 2018 laying down the rules of procedure of the Board(s) of Appeal of the European Union Agency for Railways

Slide 13

Fees and charges

Fees and charges

Fees and charges

- The fees and charges levied by the Agency should cover the full costs of the services rendered by the Agency.
- The fees and charges payable to the Agency should be set in a transparent, fair and uniform manner, in particular with the objective of simplification. They should not result in the imposition of unnecessary financial burden on enterprises and should not jeopardise the competitiveness of the European railway sector.
- The fees and charges are calculated based on:
  - The time spent by the Agency staff (and external experts when applicable), multiplied by an hourly rate of 130€
  - The statement of costs provided by the NSA(s) concerned

Slide 15

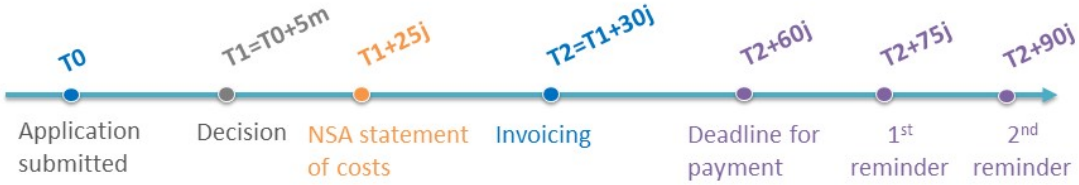
Fees and charges

- The Agency shall, at the request of the applicant, issue a **non-binding estimate** of the amount of the fees and charges related to the application (including pre-engagement as appropriate) and provide information on when the invoices will be issued
- Applicants shall ensure that the Agency receives **payment of the amounts due**, including any bank charges related to that payment, **within 60 calendar days** from the date of notification of the invoice
- The Agency may invoice interim amounts every 6 months (during pre-engagement stage)
- Where the applicant is a small or medium-sized enterprise, the Agency shall take into account requests for a r**easonable extension of the time limit for payment and payment by instalments**

Slide 16

Fees and charges

- Payment plan



* Deadlines

Slide 17

Fees and charges

- Commission Implementing Regulation (EU) 2018/764 of 2 May 2018 on the fees and charges payable to the European Union Agency for Railways and their conditions of payment

Slide 18


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Certification

3. Želimir Delač: *Implementation of the 4th Railway Package and the main differences with current national process*

Croatian Railway Safety Agency

Agencija za sigurnost željezničkog prometa

Implementation of the 4th Railway Package and the main differences with current national process.

Workshop on the technical pillar of the 4RP,

Zagreb, 1st and 2nd of October 2019

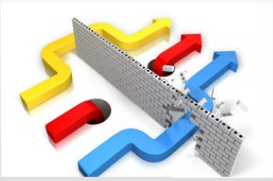


ASŽ

Objectives of the Technical Pillar of the 4th RP



"Safety First"



Facilitate the completion of the

Single European Railway Area

- removing the remaining technical barriers

ASŽ

EU legal framework for the 4th RWP – Technical Pillar

European Parliament

Croatia extended the transposition period by one year. For that purpose, on 16th of December 2018, our Ministry notified the Agency and the Commission thereof and presented the reasons for such extensions.



Member State shall bring into force the laws, regulations and administrative provisions necessary to articles….., and annexes…

by 16. June 2020. (Directives (EU) 797/798/2016)

The transposition of directives into national legal framework

European Parliament

Directives - (EU) 797 i 798/2016) for railway safety and interoperability

Regulation (EU) 2016/796 on the European Union Agency for Railways

Implementing regulation on fees and charges… (EU) 2018/764,

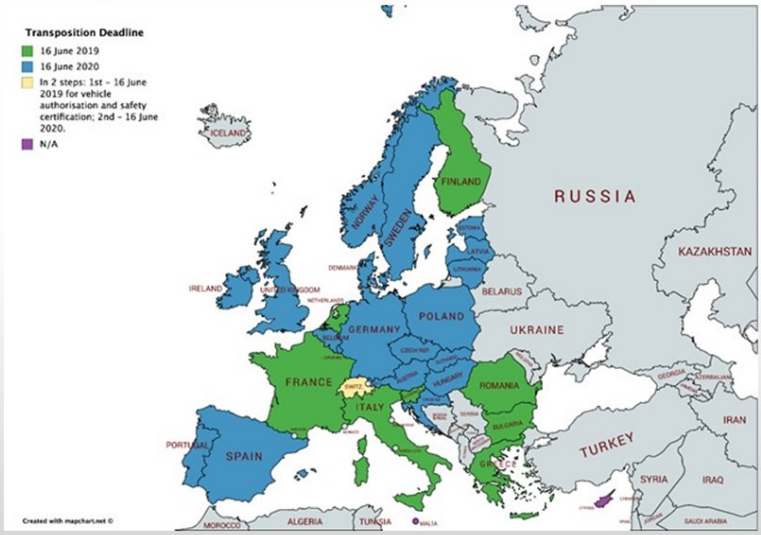
Implementing regulation (EU) 2018/545 – Establishing practical arrangements for VA…SSC…



The transposition of the directives into the Safety and Interoperability Railway System Act (SIRS act), cleaning and harmonization of the national rules – Zakon o sigurnosti i interoperabilnosti željezničkog sustava

The Ministry of the See, Transport and Infrastructure established the Task Force to amending the SIRS act

The transposition of directives into national legal framework



NSA will have to cooperate with the Agency in tasks which were before in their domain of responsibility



AV – Vehicle authorization

The Agency shall issue authorisations for the placing on the market of railway vehicles, and shall be empowered to renew, amend, suspend and revoke authorisations issued by it. For that purpose, **the Agency shall cooperate with national safety authorities** in accordance with Article 21 of Directive (EU) 2016/797.



SSC – Single Safety Certification

The Agency shall issue, renew, suspend and amend single safety certificates and **cooperate with national safety authorities** in that respect in accordance with Articles 10, 11 and 18 of Directive (EU) 2016/798.

Main differences when issuing entity is a national safety authority

In accordance to the ERA's letter (12 July 2019) any applicant has the right to prepare and submit at any time valid application in the OSS in line with the applicable EU railway legislation.



ASŽ Agencija za sigurnost željezničkog prometa

Main differences when issuing entity is a national safety authority

Notwithstanding the requirements of EU legislation, the **compliance with any complementary national rules, requirements…, fall under the responsibility of the competent NSA…**



ASŽ Agencija za sigurnost željezničkog prometa

Main differences when issuing entity is a national safety authority

…, such as:

- finalisation and formal submission of an application,
- content of formal acknowledgement of receipt of an application,



ASŽ Agencija za sigurnost željezničkog prometa

Main differences when issuing entity is a national safety authority

…, such as:

- signature of reports and/or final decisions/acts,
- any other, relevant national administrative issue.



ASŽ Agencija za sigurnost željezničkog prometa

Main differences when issuing entity is a national safety authority

NSA may take all necessary actions to ensure compliance with the national requirements **not contradicting EU law.**



ASZ Agencija za sigurnost željezničkog prometa

Main differences when issuing entity is a national safety authority

Such actions could be the preparation, scanning and uploading in OSS of any additional documentation, information or elements required by national law.



ASZ Agencija za sigurnost željezničkog prometa

Main differences when issuing entity is a national safety authority

The NSA shall publish and keep up to date an application guide for both, SSC (Reg. (EU) 2018/763) and VA (Reg. (EU) 2018/545)…



Agencija za sigurnost željezničkog prometa

Main differences when issuing entity is a national safety authority

…, describing and where necessary explaining the national rules that apply in respect of the intended area of operation and applicable national procedural rules.



Agencija za sigurnost željezničkog prometa

Main differences when issuing entity is a national safety authority

NSA hr is getting ready to issue a guidance to applicants for their compliance with any complementary national requirements.



Agencija za sigurnost željezničkog prometa

Main differences when issuing entity is a national safety authority

The application for SSC/VA

Formal submission of an application

General Administrative Procedure Act (NN 47/09) - ZUP

omega software Centrix PISMOHRANA

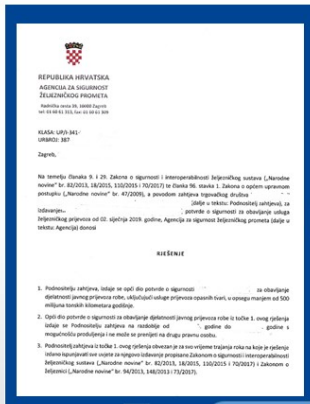
Administrative fees Act (NN 115/16)
Low on archives (NN 61/18)



Content of the application for SSC/VA (Reg. (EU) 2018/763 (Annex I); Reg. (EU) 2018/545 (Annex I))

Upload to OSS

Main differences when issuing entity is a national safety authority



Final decisions/acts

omega software Centrix PISMOHRANA

RJEŠENJE – Zakon o upravnom postupku
General Administrative Procedure Act (NN 47/09)



Content of the single safety certificate (Reg. (EU) 2018/763 (Anex III)

Upload to OSS

Main differences when issuing entity is a national safety authority



Signature of final decisions/acts
General Administrative Procedure Act (NN 47/09)

omega software Centrix PISMOHRANA

Administrative fees Act (NN 115/16)
Administrative procedure dispute Act (NN 20/10, 143/12, 152/14, 94/16, 29/17)



Content of the single safety certificate (Reg. (EU) 2018/763 (Anex III)

Upload to OSS

Main differences when issuing entity is a national safety authority

Transitional period – Reg. (EU) 2018/545 (art. 55); 2018/763 (15)



Where a national safety authority recognizes that it will not be able to issue SSC/AV in accordance with Directives 2004/49/EC or 2008/57/EC before the relevant date in the MS, it shall inform the applicant and the Agency (ERA) immediately.

We warmly recommend to our applicants to submit their applications (with completed documents) to the NSA hr at latest to 15th of February 2020, if they want their cases/projects to be finished in accordance to the „old procedures (3RP)". Otherwise it is more likely that the cases to be finished in accordance to the „new procedures (4RP)", what would cause additional time and costs for the applicant.

OSS – One Stop Shop



All applications for VA/SSC/ERTMS will have to be submitted through the Information and Communication System with a virtual One Stop Shop (OSS) which will be developed and managed by the ERA (Agency).



According to the ERA' s Education and Training Plan (all stakeholders - ERA, NSAs, RUs,…) will be involved in training activities (target groups: applicants, assessment teams, program managers, user managers,…)

Cooperation with the Agency – Cooperation agreement



The Agency and the national safety authorities shall conclude cooperation agreement …(Article 76; EU Regulation 2016/796)

EUROPEAN UNION AGENCY FOR RAILWAYS

NSA sent its nominations for Pool of Experts (Assessors and Project managers for VA/SSC) to the ERA by the end of August 2018.

Cooperation with the Railway Sector



In the preparation and in the execution of the new tasks given by the 4RWP to the NSA, there is a need for the NSA to have a close collaboration with all stakeholders in the Sector…



One of the NSA's Programme Plan for implementation of the 4RWP objectives is to ensure that all applicants for SSC and VA will have the necessary information for the 4RWP to be effective for the implementation process from the 1st day of application of the 4RWP

NSA's Competence Management



Identification of hard and soft skills necessary for operational processes – VA, SSC and ERTMS. These inputs are necessary for both the competence within the NSA and for the establishment of the Pool of Experts (PoE)



The Agency shall provide the necessary training to the experts of the NSA nominated in the Pool of Experts in order to ensure efficient assessment of applications (**Cooperation agreements: draft clauses for "Technical Elements"**)

Croatian Railway Safety Agency (CRSA)

Thank you for your attention!

Agency Director
Želimir Delač, dipl.ing.el.

zelimir.delac@asz.hr

4. Dragica Flam: *IV Željeznički paket – tržišni dio*

HAKOM

IV. Željeznički paket – tržišni dio



Zagreb,
1. listopada 2019.

HAKOM

TEME

1. UVOD
2. IV. ŽELJEZNIČKI PAKET – TRŽIŠNI DIO
3. UPRAVLJANJE INFRASTRUKTUROM
4. REGULATORNO TIJELO
5. PSO

HAKOM

UVOD – ŽELJEZNIČKI PAKETI

- ***Prvi željeznički paket:***
  - *Direktiva 2001/12/EZ o izmjeni Direktive 91/440/EEZ o razvoju željeznica Zajednice*
  - *Direktiva 2001/13/EZ o izmjeni Direktive 95/18/EZ o licenciranju željezničkih prijevoznika*
  - ***Direktiva 2001/14/EZ** o raspodjeli kapaciteta željezničke infrastrukture, nametanju pristojbi za korištenje željezničke infrastrukture te potvrdama o sigurnosti,*
  - *Direktiva 2001/16/EZ o interoperabilnosti trans-europskog konvencionalnog željezničkog sustava*

HAKOM

UVOD – ŽELJEZNIČKI PAKETI

- ***Drugi željeznički paket:***
  - *Direktiva 2004/49/EZ o sigurnosti željeznica Zajednice, izmijeni Direktive 95/18/EZ o licenciranju željezničkih prijevoznika i Direktive 2001/14/EZ o raspodjeli kapaciteta želj. infr., nametanju pristojbi za korištenje želj. infr. te potvrdama o sigurnosti (Direktiva o sigurnosti),*
  - *Direktiva 2004/50/EZ o izmjeni Direktive 96/48/EZ o interoperabilnosti trans-europskog sustava velikih brzina i Direktive 2001/16/EZ o interoperabilnosti trans-europskog konvencionalnog želj. sustava,*
  - ***Direktiva 2004/51/EZ** o izmjeni Direktive 91/440/EEC o razvoju željeznica Zajednice,*
  - *Uredba 881/2004/EZ o osnivanju Europske željezničke agencije (ERA)*

HAKOM

UVOD – ŽELJEZNIČKI PAKETI

- ***Treći željeznički paket:***
  - *Direktiva 2007/58/EZ o izmjeni Direktive 91/440/EEZ o razvoju želj. Zajednice i Direktive 2001/14/EZ o raspodjeli kapaciteta želj. infr., nametanju pristojbi za korištenje želj. infr. te potvrdama o sigurnosti (**Direktiva o liberalizaciji međun. putn. prometa**),*
  - *Direktiva 2007/59/EZ o izdavanju potvrda strojovođama koji upravljaju lok. i vlak. u želj. sustavu Zajednice,*
  - *Uredba 1370/2007/EZ o jav. usl. prijevoza putnika želj. i cestom i prestanku važenja Uredbi 1191/69 i 1107/70,*
  - *Uredba 1371/2007/EZ o pravima i obvezama putnika,*
  - *Uredba 1372/2007/EZ o izmjeni Uredbe 577/98 o provedbi ankete o radnoj snazi na uzorku u Zajednici*

HAKOM

UVOD – ŽELJEZNIČKI PAKETI

- ***Tehnički paket:***
  - *Direktiva 2008/110/EZ o izmjeni Direktive 2004/49/EZ o sigurnosti željeznica Zajednice,*
  - *Direktiva 2008/57/EZ o interoperabilnosti željezničkog sustava unutar Zajednice,*
  - *Uredba 1335/2008 o izmjeni Uredbe 881/2004/EZ o osnivanju Europske željezničke agencije (ERA)*
- ***Revizija direktiva prvog željezničkog paketa iz 2001.***
  - *Direktiva 2012/34/EU o uspostavi jedinstvenog Europskog željezničkog prostora (**Recast**)*

HAKOM

IV. ŽELJEZNIČKI PAKET – TRŽIŠNI DIO

Četvrti željeznički paket:

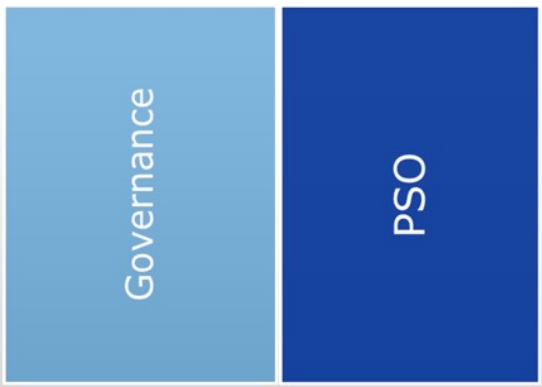
1) tehnički dio (engl. technical pillar)

*2) **politički/tržišni dio (engl. market pillar)***

- ***Direktiva (EU) 2016/2370** Europskog Parlamenta i Vijeća od 14. prosinca 2016. o izmjeni Direktive 2012/34/EU **u pogledu otvaranja tržišta za usluge domaćeg željezničkog prijevoza putnika i upravljanja željezničkom infrastrukturom**,*
- ***Uredba (EU) 2016/2338** Europskog Parlamenta i Vijeća od 14. prosinca 2016. o izmjeni Uredbe (EZ) br. 1370/2007 **u pogledu otvaranja tržišta za usluge domaćeg željezničkog prijevoza putnika***
- *implementacija 25.12.2018.*

HAKOM

ČETVRTI ŽELJEZNIČKI PAKET – TRŽIŠNI DIO



HAKOM

UPRAVLJANJE INFRASTRUKTUROM

- ***otvaranje tržišta za usluge domaćeg željezničkog prijevoza putnika – 1.1.2019. (VR 2020/2021 - 14.12.2020.)***

- pravo pristupa željezničkoj infrastrukturi u svim državama članicama u svrhu pružanja usluga željezničkog prijevoza putnika pod pravičnim, nediskriminirajućim i transparentnim uvjetima - podrazumijeva i pravo ukrcaja putnika na bilo kojem kolodvoru i iskrcaja na nekom drugom kolodvoru, te pravo pristupa infrastrukturi kojom se povezuju uslužni objekti

- *ograničenje pristupa ! – ekon. ravnoteža ugovora o javnim uslugama/isključiva prava (bez naknade)*

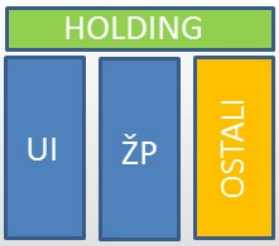
HAKOM

IV. ŽELJEZNIČKI PAKET – TRŽIŠNI DIO

- ***Odvojena struktura***
  - *UI i ŽP potpuno odvojene pravne osobe*



- ***Vertikalno integrirano društvo - holding***
  - *UI and ŽP su odvojene pravne osobe*
  - *pojam "kontrola" prema regulaciji spajanja koja se primjenjuje za ocjenu vert. integracija*



- ***Vertikalno integrirana "monolitna" struktura***
  - *s eksternalizacijom osnovnih funkcija*



IV. ŽELJEZNIČKI PAKET – TRŽIŠNI DIO

HAKOM



- *članovi Upravljačkog/Nadzornog odbora UI i osobe zadužene za donošenje odluka UI - moraju postupati na nediskriminrajući način i bez sukoba interesa*
- *nijedan od drugih pravnih subjekata unutar vertikalno integriranog poduzeća nema odlučujući utjecaj na odluke UI u pogledu osnovnih funkcija*
- *Zabrana određenih dvostrukih mandata*
  - *Upravljački odbor UI - ŽP, Nadzorni odbor UI – ŽP*
  - *osobe zadužene za donošenje odluka o osnovnim funkcijama i kao članovi upravljačkog odbora ŽP*
  - *kao članovi nadzornog odbora poduzeća koje je dio vertikalno integriranog poduzeća i koje vrši kontrolu i nad ŽP i nad UI te kao članovi upravljačkog odbora tog UI*

IV. ŽELJEZNIČKI PAKET – TRŽIŠNI DIO

HAKOM



- *Pravila o bonusima i naknadama UI*
- *Zaštita povjerljivih informacija u vezi s osn. funkcijama – samo ovlašteno osoblje UI*
- *ŽP ili bilo koji drugi pravni subjekt*
  - *ne ostvaruje odlučujući utjecaj na UI u vezi s osnovnim funkcijama*
  - *nema odlučujući utjecaj imenovanje/razrješenje osoba zaduženih za osnovne funkcije*
- *mobilnošću osoba zaduženih za osnovne funkcije ne stvara sukob interesa*
- ***tijelo za ubiranje pristojbi i/ili tijelo za dodjelu kapaciteta***

HAKOM

IV. ŽELJEZNIČKI PAKET – TRŽIŠNI DIO

Eksternalizacija, dijeljenje i raspodjela funkcija UI

- *Izvedba radova i povezani zadaci – ŽP*
- *Druge funkcije UI – a – subjektu koji nije ŽP, ne kontrolira ŽP-a ili nije kontroliran od ŽP-a*

- *Između dvoje ili više UI*
- *uvjet: svi UI moraju udovoljavati uvjetima neovisnosti i preuzimaju punu odgovornost za navedene funkcije*

- *Obvezna eksternalizacija za osnovne funkcije neovisnom tijelu kad UI ne ispunjava uvjete (npr. nema odvojene pravne osobe)*
- *Uvjet: neovisno tijelo obavlja te funkcije potpuno neovisno*

HAKOM

IV. ŽELJEZNIČKI PAKET – TRŽIŠNI DIO

Financijska transparentnost

Holding

- *odvojeni računi, transparentni fin. tokovi*
- *nema zajmova između UI i ŽP*
- *zajmovi od holdinga: po tržišnim cijenama, odražavaju individualni rizični profil subjekta*
- *pravila o naplati usluga među subjektima vertikalno integriranog poduzeća*
- *odvojeno servisiranje dugova*

Odvojena struktura

- *odvojeni računi, transparentni financijski tokovi*
- *nema zajmova između UI i ŽP*

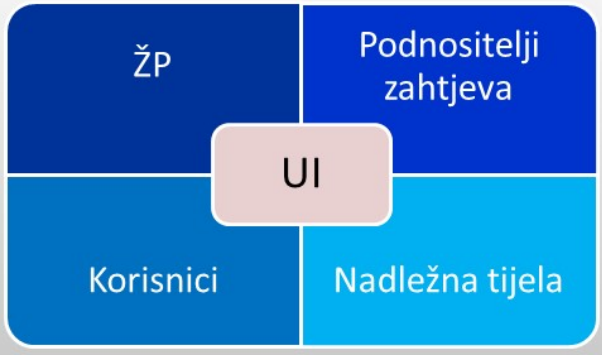
IV. ŽELJEZNIČKI PAKET – TRŽIŠNI DIO

HAKOM

Mehanizmi koordinacije UI – korisnici mreže

RT - promatrač

- *održavanje i razvoj infrastrukturnog kapaciteta*
- *intermodalnost i interoperabilnost*
- *sadržaj i provedba IoM*
- *uvjeti pristupa, kvaliteta usluga UI*



IV. ŽELJEZNIČKI PAKET – TRŽIŠNI DIO

HAKOM

Jače regulatorne ovlasti:

- *Kriteriji neovisnosti za UI (dvostruki mandati, sukob interesa itd.)*
- *Financijski tokovi unutar ver. intg. poduzeća (zajmovi, pružanje usluga, itd.)*
- *Upravljanje prometom (neovisnost, pristup informacijama i prostorijama itd.)*
- *Planiranje obnove, najavljeno i nenajavljeno održavanje (nepristranost, transparentnost, nediskriminacija)*



HAKOM

PSO Uredba

- *obveza pružanja javne usluge*
- *konkurentni natječajni postupak - osnovni postupak za dodjelu ugovora o javnim uslugama*
- *specifikacija obveza obavljanja javnih usluga*
- *željeznička vozila*
- *izravna dodjela ugovora o javnim uslugama - IZNIMKE:*
  1) *iznimne okolnosti,*
  2) *tzv. de minimis pragovi*
  3) *strukturnih i zemljopisnih značajki dotičnog tržišta i mreže*

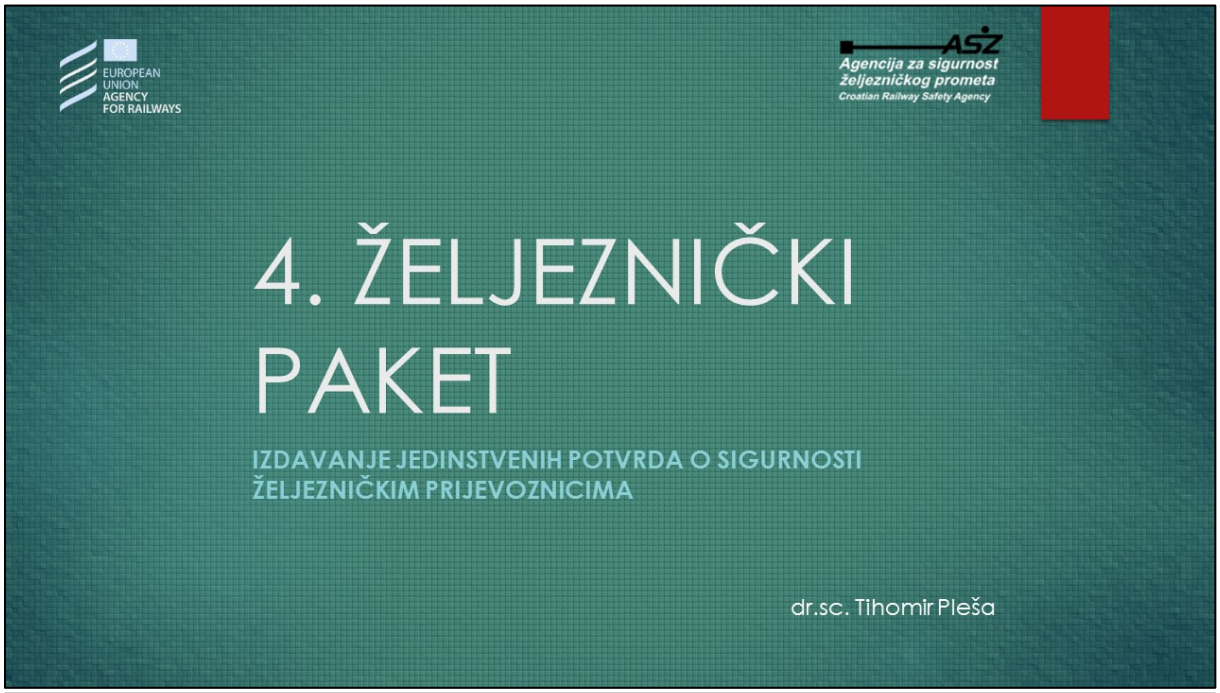
HAKOM



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HAKOM
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10110 Zagreb, HRVATSKA
Tel: 01/7007 007
Fax: 01/7007 070
www.hakom.hr

5. Tihomir Pleša: *4. Željeznički paket – izdavanje jedinstvenih potvrda o sigurnosti željezničkim prijevoznicima*



Pravni okvir

- DIREKTIVA 2008/57/EZ EUROPSKOG PARLAMENTA I VIJEĆA od 17. lipnja 2008. o interoperabilnosti željezničkog sustava unutar Zajednice
- DIREKTIVA (EU) 2016/798 EUROPSKOG PARLAMENTA I VIJEĆA od 11. svibnja 2016. o sigurnosti željeznica
- DIREKTIVA (EU) 2016/797 EUROPSKOG PARLAMENTA I VIJEĆA od 11. svibnja 2016. o interoperabilnosti željezničkog sustava u Europskoj uniji
- UREDBA KOMISIJE (EU) br. 1078/2012 od 16. studenoga 2012. o zajedničkoj sigurnosnoj metodi za kontrolu koju će primjenjivati željeznički prijevoznici i upravitelji infrastrukture nakon izdanog rješenja o sigurnosti za upravljanje željezničkom infrastrukturom i rješenja o sigurnosti za obavljanje usluga željezničkog prijevoza te subjekti nadležni za održavanje
- UREDBA (EU) 2016/796 EUROPSKOG PARLAMENTA I VIJEĆA od 11. svibnja 2016. o Agenciji Europske unije za željeznice i stavljanju izvan snage Uredbe (EZ) br. 881/2004
- PROVEDBENA UREDBA KOMISIJE (EU) br. 402/2013 od 30. travnja 2013. o zajedničkoj sigurnosnoj metodi za vrednovanje i procjenu rizika i stavljanju izvan snage Uredbe (EZ) br. 352/2009
- PROVEDBENA UREDBA KOMISIJE (EU) 2015/1136 od 13. srpnja 2015. o izmjeni Provedbene uredbe (EU) br. 402/2013 o zajedničkoj sigurnosnoj metodi za vrednovanje i procjenu rizika
- ODLUKA KOMISIJE od 14. studenoga 2012. o tehničkoj specifikaciji za interoperabilnost podsustava „odvijanje i upravljanje prometom" željezničkog sustava u Europskoj uniji i o izmjeni Odluke 2007/756/EZ
- UREDBA KOMISIJE (EU) 2015/995 od 8. lipnja 2015. o izmjeni Odluke 2012/757/EU o tehničkoj specifikaciji za interoperabilnost podsustava „odvijanje i upravljanje prometom" željezničkog sustava u Europskoj uniji
- DELEGIRANA UREDBA KOMISIJE (EU) 2018/761 od 6. veljače 2018. o utvrđivanju zajedničkih sigurnosnih metoda za nadzor koji provode nacionalna tijela nadležna za sigurnost nakon izdavanja jedinstvene potvrde o sigurnosti ili uvjerenja o sigurnosti u skladu s Direktivom (EU) 2016/798 Europskog parlamenta i Vijeća te stavljanju izvan snage Uredbe Komisije (EU) br. 1077/2012
- PROVEDBENA UREDBA KOMISIJE (EU) 2018/763 od 9. travnja 2018. o utvrđivanju praktičnih aranžmana za izdavanje jedinstvenih potvrda o sigurnosti željezničkim prijevoznicima u skladu s Direktivom (EU) 2016/798 Europskog parlamenta i Vijeća te o stavljanju izvan snage Uredbe Komisije (EZ) br. 653/2007
- PROVEDBENA UREDBA KOMISIJE (EU) 2019/776 od 16. svibnja 2019. o izmjeni uredaba Komisije (EU) br. 321/2013, (EU) br. 1299/2014, (EU) br. 1301/2014, (EU) br. 1302/2014, (EU) br. 1303/2014 i (EU) 2016/919 te Provedbene odluke Komisije 2011/665/EU u pogledu usklađivanja s Direktivom (EU) 2016/797 Europskog parlamenta i Vijeća i provedbe posebnih ciljeva utvrđenih u Delegiranoj odluci Komisije (EU) 2017/1474
- **Zakon o sigurnosti i interoperabilnosti željezničkog sustava**
- Zakon o općem upravnom postupku

Osnovni uvjeti

- Direktiva (EU) 2016/798 - željeznički prijevoznici moraju posjedovati jedinstvenu potvrdu o sigurnosti kako bi mogli dobiti pristup željezničkoj infrastrukturi jedne ili više država članica u skladu sa svojim prijavljenim područjem djelovanja
- Zahtjev za jedinstvenu potvrdu o sigurnosti - teretni i/ili putnički prijevoz, SUS
- Održavatelj infrastrukture – vlastita jedinstvena potvrda ili kroz SUS upravitelja infrastrukture
- Prekogranična djelatnost - do graničnih postaja u susjednim državama članicama – navesti u zahtjevu
  - Uvjeti usuglašeni sa NSA ili drugim mjerodavnim tijelom članice

Svrha jedinstvene potvrde o sigurnosti

Dokaz da je željeznički prijevoznik:

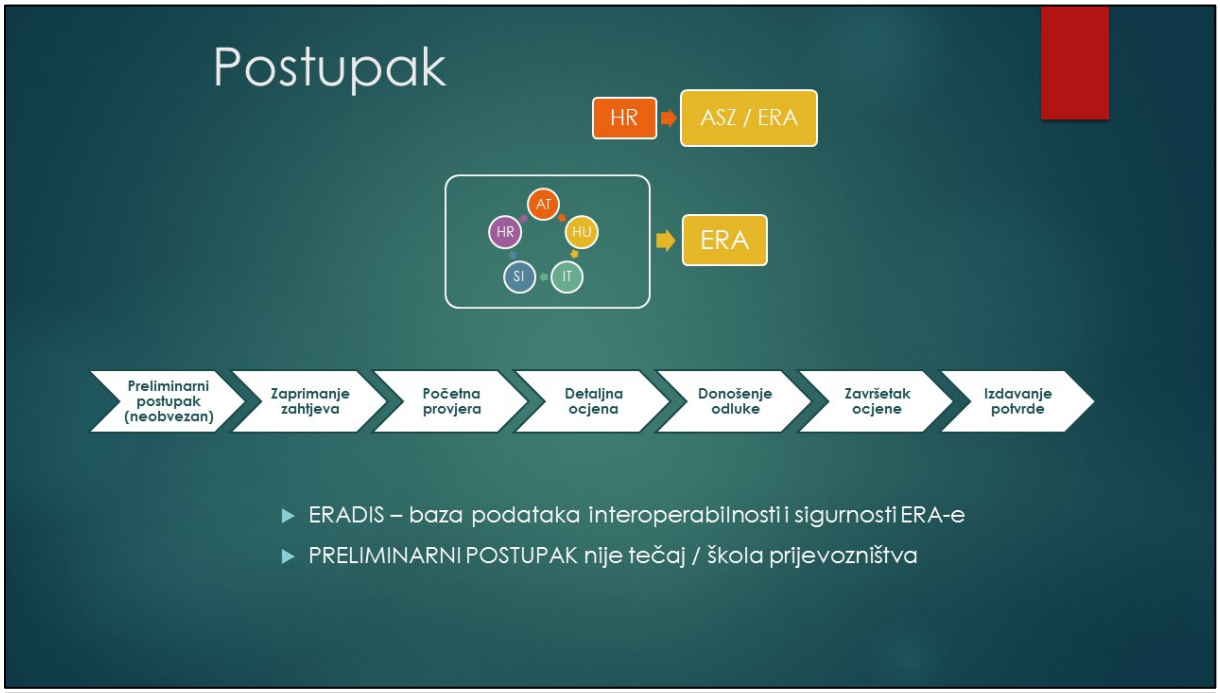
- Uspostavio SUS prema čl.9. Direktive EU 2016/798,
- Ispunio zahtjeve propisane mjerodavnim priopćenim nacionalnim pravilima,
- Sposoban sigurno obavljati djelatnost željezničkog prijevoznika.

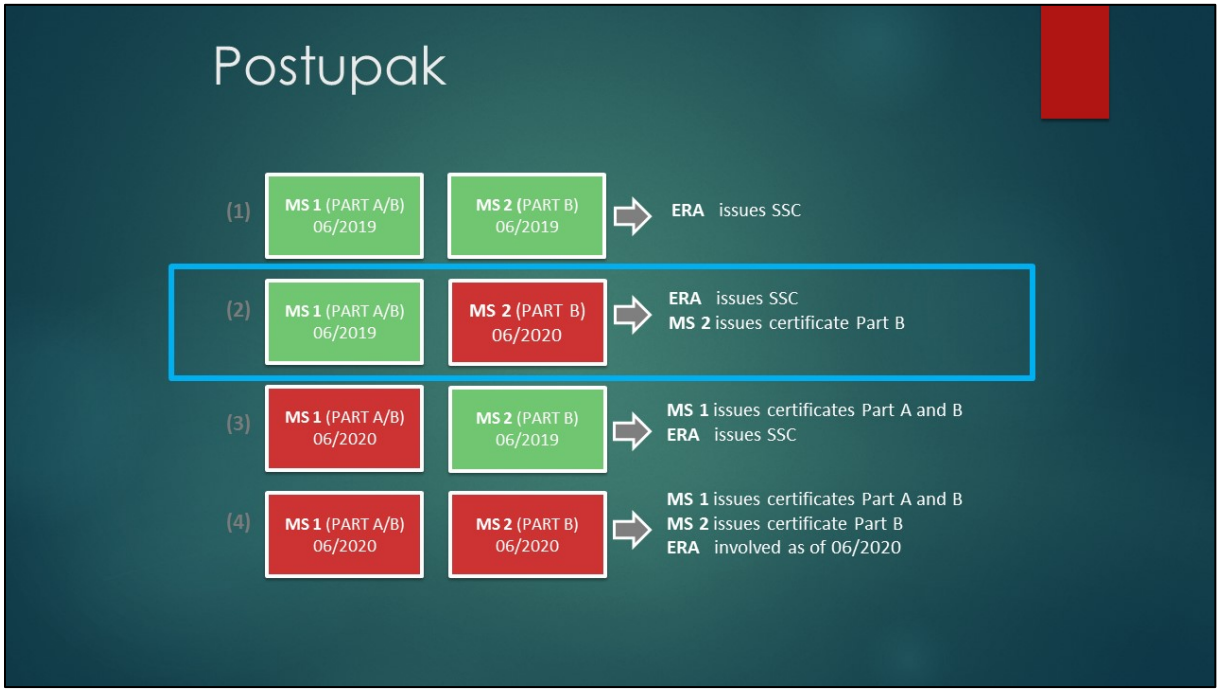
Podnošenje zahtjeva

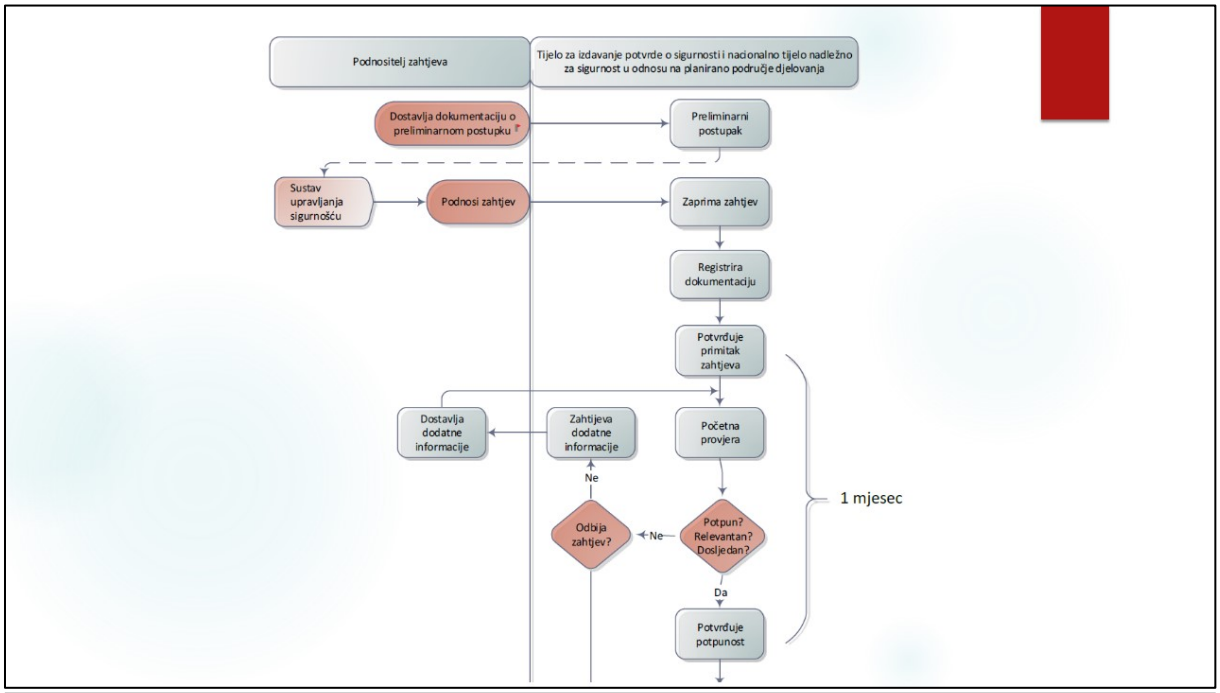
- OSS – jedinstvena pristupna točka – informatička platforma (ERA)
- Svi jezici EU
- Priručnik za OSS
- Preporuka 6 mj. prije:
  - *planiranog početka djelatnosti prijevoza,*
  - *planiranog ažuriranja postojeće jedinstvene potvrde,*
  - *kraja roka važenja trenutačne jedinstvene potvrde.*
- Komunikacija i obavijesti putem OSS
- ERA – NSA ugovor o suradnji (CA)
- Odabir tijela za izdavanje jedinstvene potvrde obvezujući do kraja postupka (nakon preliminarnog postupka)
- Jezik – službeni države članice, kvalitetan, mogući zahtjev za prevođenjem dokumentacije

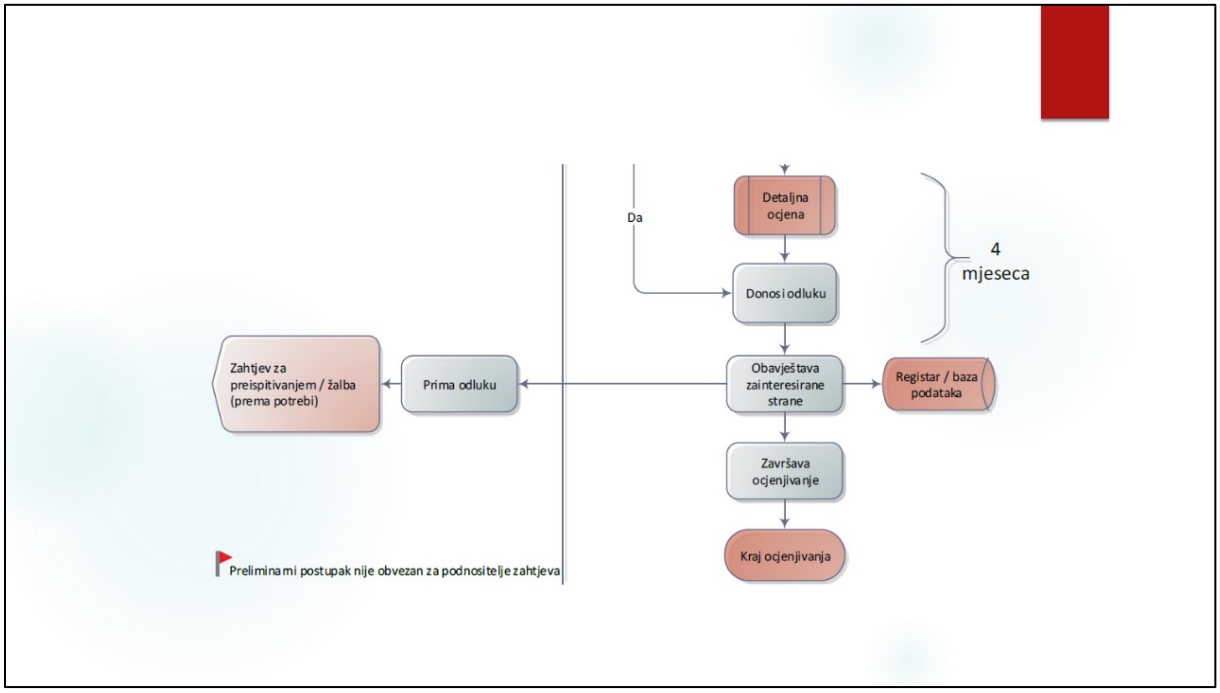
Podnošenje zahtjeva

- OSS
  - Svi zahtjevi i administracija
  - PREDMET > PROJEKT
  - Uloge dodijeljene stručnjacima:
    - voditelj programa, voditelj projekta, procjenitelj…


Postupak
HR
ASZ / ERA
AT
HR
HU
SI
IT
ERA
Preliminarni postupak (neobvezan)
Zaprimanje zahtjeva
Početna provjera
Detaljna ocjena
Donošenje odluke
Završetak ocjene
Izdavanje potvrde
ERADIS – baza podataka interoperabilnosti i sigurnosti ERA-e
PRELIMINARNI POSTUPAK nije tečaj / škola prijevozništva


Postupak
(1)
MS 1 (PART A/B) 06/2019
MS 2 (PART B) 06/2019
ERA issues SSC
(2)
MS 1 (PART A/B) 06/2019
MS 2 (PART B) 06/2020
ERA issues SSC
MS 2 issues certificate Part B
(3)
MS 1 (PART A/B) 06/2020
MS 2 (PART B) 06/2019
MS 1 issues certificates Part A and B
ERA issues SSC
(4)
MS 1 (PART A/B) 06/2020
MS 2 (PART B) 06/2020
MS 1 issues certificates Part A and B
MS 2 issues certificate Part B
ERA involved as of 06/2020


Podnositelj zahtjeva
Tijelo za izdavanje potvrde o sigurnosti i nacionalno tijelo nadležno za sigurnost u odnosu na planirano područje djelovanja
Dostavlja dokumentaciju o preliminarnom postupku
Preliminarni postupak
Sustav upravljanja sigurnošću
Podnosi zahtjev
Zaprima zahtjev
Registrira dokumentaciju
Potvrđuje primitak zahtjeva
Dostavlja dodatne informacije
Zahtijeva dodatne informacije
Početna provjera
Ne
Odbija zahtjev?
Ne
Potpun? Relevantan? Dosljedan?
1 mjesec
Da
Potvrđuje potpunost

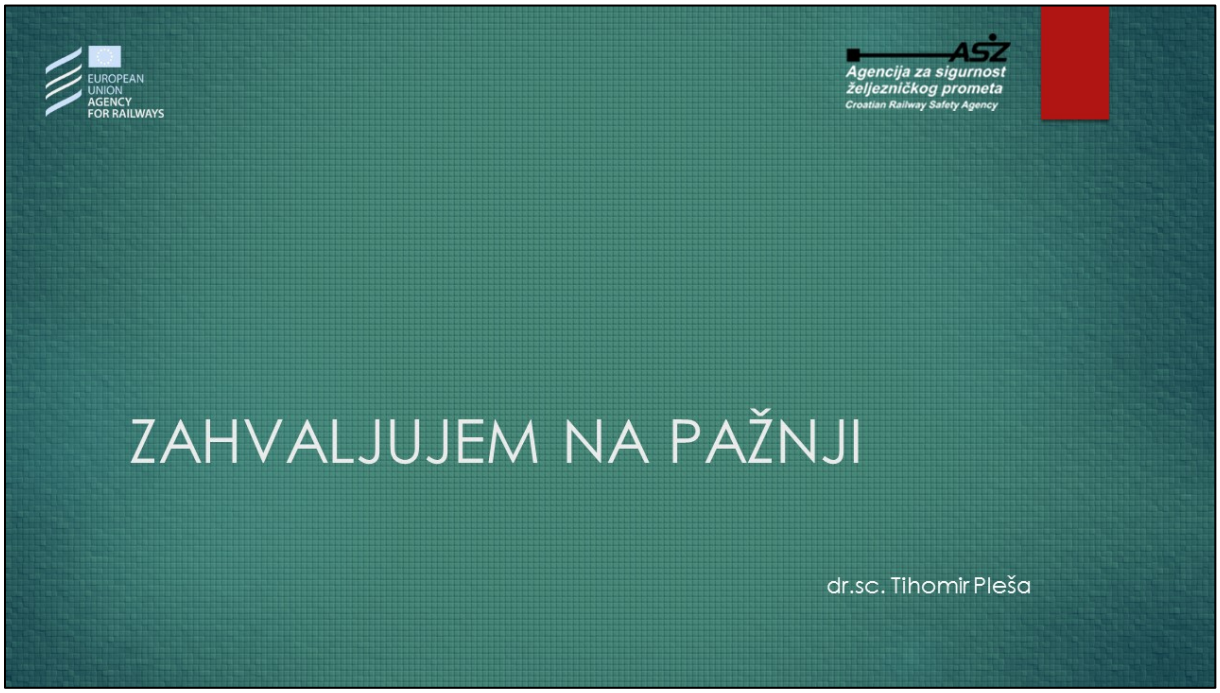

Da
Detaljna ocjena
4 mjeseca
Donosi odluku
Zahtjev za preispitivanjem / žalba (prema potrebi)
Prima odluku
Obavještava zainteresirane strane
Registar / baza podataka
Završava ocjenjivanje
Kraj ocjenjivanja
Preliminarni postupak nije obvezan za podnositelje zahtjeva

Ocjena – kategorije nedostataka

1. **Upit**- pružiti dodatne informacije kako bi razjasnio neke aspekte zahtjeva
2. **Opažanje ili napomena o kojima treba prosuditi podnositelj zahtjeva** - ne ugrožavaju sigurnost, no podnositelj zahtjeva ih mora riješiti.
3. **Manje neusklađenosti ili preostali problemi** – ocjena može li se rješavanje nedostatka odgoditi do izdavanja jedinstvene potvrde o sigurnosti. Podnositelj zahtjeva mora riješiti problem prije podnošenja sljedećeg zahtjeva za obnavljanje ili ažuriranje. Podaci u zapisnik radi ponovne ocjene tijekom podnošenja sljedećeg zahtjeva za obnavljanje ili ažuriranje.
4. **Veća neusklađenost** - problem uslijed nedostatka informacija ili nedovoljne jasnoće informacija. Tolike važnosti da se zahtjev ne može prihvatiti kao takav i da se jedinstvena potvrda o sigurnosti ne može izdati ako se problem ne riješi.

Preispitivanje odluke

- Kada nacionalno tijelo nadležno za sigurnost djeluje kao tijelo za izdavanje potvrde o sigurnosti, njegove odluke podliježu sudskom preispitivanju u skladu s odredbama nacionalnog zakonodavstva.


EUROPEAN UNION AGENCY FOR RAILWAYS
Agencija za sigurnost željezničkog prometa
Croatian Railway Safety Agency
ZAHVALJUJEM NA PAŽNJI
dr.sc. Tihomir Pleša

Workshop – Day 2

Wednesday, October 2nd

1. **Antoine Defosses, Nordine Bousouff**: Vehicle authorisation in the framework of *the 4th Railway Package*

Vehicle authorisation in the framework of the 4th Railway Package

Antoine DEFOSSEZ, Nordine BOUSSOUF
Zagreb, 01-02 October 2019

EUROPEAN UNION AGENCY FOR RAILWAYS

The 4th Railway Package

- January 2013: EC proposes 6 legislative texts under the **4th railway package** to be negotiated and adopted by the Council and the European Parliament.
- They include:
  - A " **governance and market opening pillar**" to open up domestic passenger railways to new entrants : not relevant for ERA
  - A "**technical pillar**" (3 legislative proposals) to reduce administrative costs for rail operators + to ease entrance of new operators on the rail market + to remove remaining administrative and technical barriers in the single European railway area

The Technical Pillar (1/2)

- Technical pillar adopted by the European Parliament and the Council in April 2016.
- It includes three legislative texts dated of 11 May 2016 (OJEU of 26 May 2016):
  - Regulation (EU) 2016/796 on the European Union Agency for Railways
  - Directive (EU) 2016/797 on the interoperability of the rail system within the European Union
  - Directive (EU) 2016/798 on railway safety

The Technical Pillar (2/2)

- Regulation 2016/796 (« AR ») entered into force on 15 June 2016. As from such date, the **European Union Agency for Railways** replaced and succeeded **the European Railway Agency**



- Directives 2016/797 (IOD") and 2016/798 ("RSD") have to be **transposed by MS by 16 June 2019**. MS may however decide to **postpone the transposition by 16 June 2020** if they notify such decision and the reasons thereof to the Commission and the Agency **by 16 December 2018**

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Map of the transposition date



Slide 5

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New concepts and new terms introduced by the 4th Railway Package

Slide 6 of 00

EUROPEAN UNION AGENCY FOR RAILWAYS

We'll be talking about…



AUTORISATION OF PLACING ON THE MARKET

Slide 7

EUROPEAN UNION AGENCY FOR RAILWAYS

We'll be talking about…



AREA OF USE OF A VEHICLE

Slide 8

EUROPEAN UNION AGENCY FOR RAILWAYS

We'll be talking about…

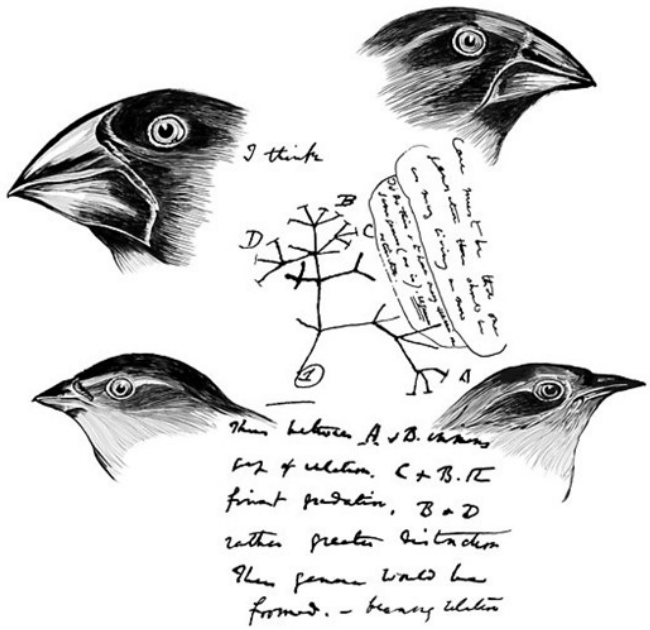


ROUTE COMPATIBILITY CHECK

Slide 9

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We'll be talking about…

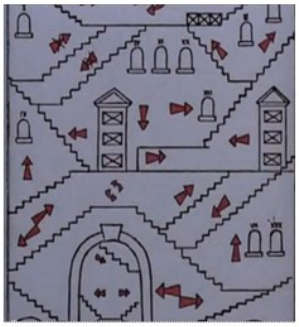


TYPES, VARIANTS AND VERSIONS

Slide 10

We'll be talking about…

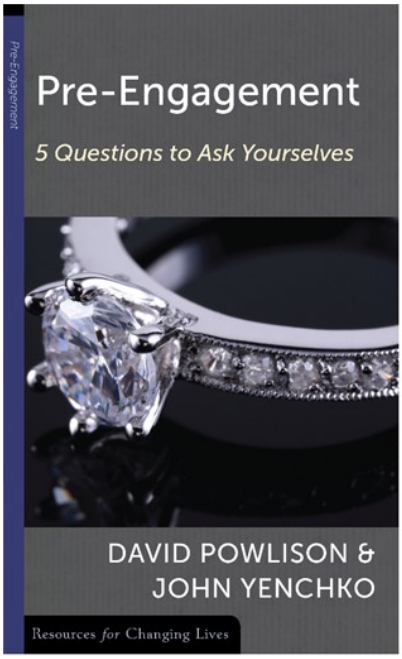




THE
ONE STOP SHOP

Slide 11

We'll be talking about…



THE PRE-ENGAGEMENT

Slide 12

EUROPEAN UNION AGENCY FOR RAILWAYS

And of course, we'll be talking about…



THE ROLES AND RESPONSIBILITIES OF THE 'USUAL SUSPECTS'

Slide 13

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Making the railway system work better for society.

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Discover our job opportunities on **era.europa.eu**

ISO 9001:2015 BUREAU VERITAS Certification

2. **Antoine Defosses, Nordine Bousouff**: The vehicle (type) authorisation process under 4th RP

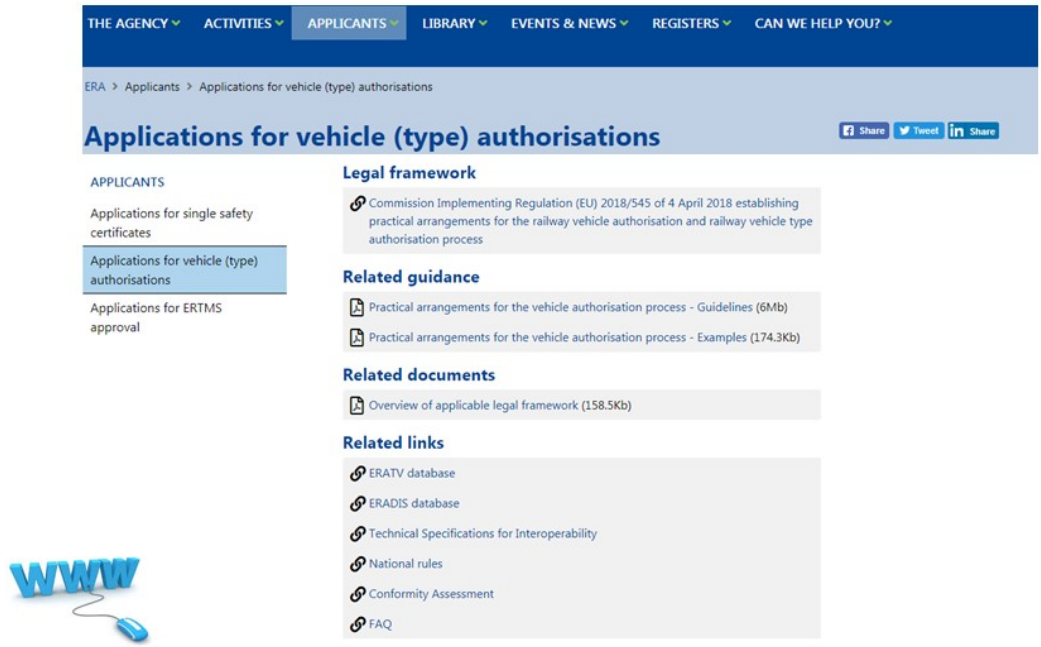
The vehicle (type) authorisation process under 4th RP

EU legal framework for Vehicle Authorisation

Zagreb, 01-02 October 2019

EUROPEAN UNION AGENCY FOR RAILWAYS

VA documents in ERA website



EU legal framework

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

2007
- **3rd 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
- **4th 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

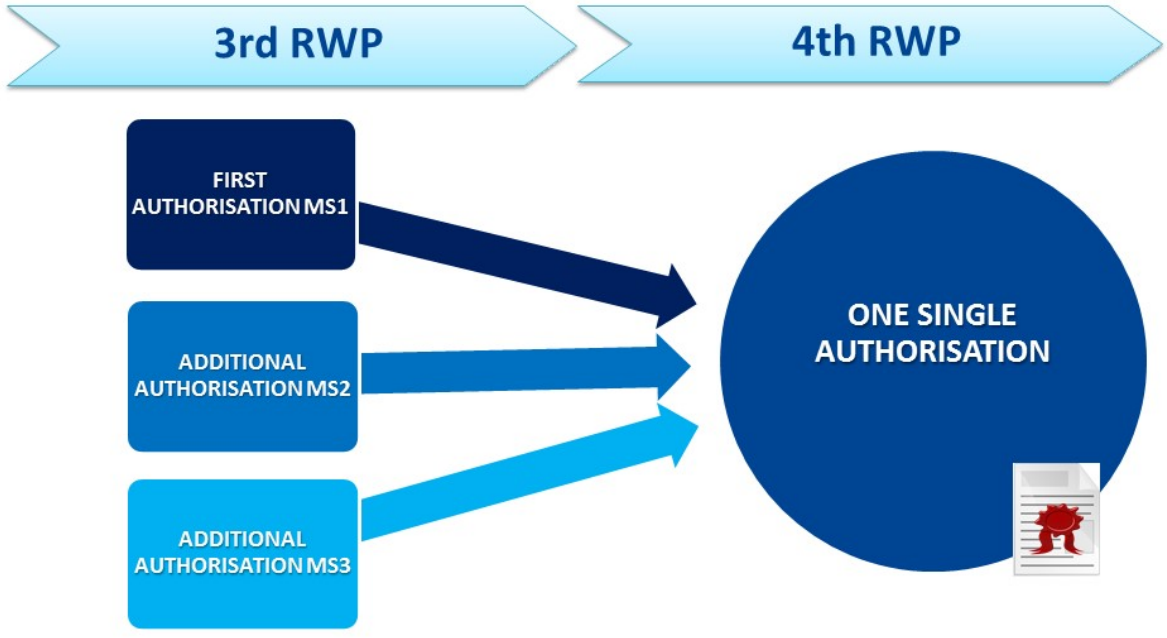
Technical pillar of the 4RP (1/2)

Directives & Regulations	• Regulation (EU) 2016/796 The Agency regulation • Directive (EU) 2016/797 Interoperability • Directive (EU) 2016/798 Safety
Commission Implementing Regulations	• (EU) 2018/545 Practical arrangements for VA • EC declaration of verification (voted RISC 83) • Cross-acceptance (draft) • Other (Fees & Charges, Board of Appeal)
Guidance	• ERA-PRG-005/02_361 Guidelines for the practical arrangements for the vehicle authorisation process • ERA-PRG-005/02_374 Catalogue of examples • Guidance to the IA EC declaration of verification (draft)
Agreements	• Cooperation agreements between Agency and NSAs • Multilateral agreements

Technical pillar of the 4RP (2/2)

Revised TSIs	• Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 amending LOC&PAS, WAG, SRT, CCS, INF, ENE TSIs and ERATV specification • Commission Implementing Regulation (EU) 2019/773 of 16 May 2019 (OPE TSI, voted RISC 85)
Other legal texts	• Regulation (EU) 402/2013 CSM RA • Decision 2010/713/EU conformity assessment modules • Regulation (EU) 1300/2014 PRM
Other	• Decision (EU) 2018/1614 EVR specification • Commission Implementing Regulation (EU) 2019/777 of 16 May 2019 (Revised RINF specification) • RDD: decision 2011/155/EU on the reference document • RDD: ERA/GUI/XA v3.0 Part 1 reference document • Guidance to TSIs and Registers

Key aspects of the 4RP: single authorisation



Key aspects of the 4RP: APOM

3rd RWP → 4th RWP

APIS → **APOM**

Authorisation for placing **in service**

Authorisation for placing **on the market** for an area of use

Key aspects of the 4RP: Authorising entity

The authorising entity depends on the area of use

Area of use = more than one Member State
ERA authorising entity, collaboration with NSAs

Area of use = one Member State
The applicant can choose the Agency or the NSA

All requests addressed via the OSS

Key aspects of the 4RP: main steps







Applicant submits request for VA to the One-Stop-Shop

- Specifying the area of use
- Including relevant documentation

ERA/NSA issues APOM (or communicate negative decision)

- Within 4 months from reception of complete documentation
- Following detailed rules established in Reg. **(EU) 2018/545**

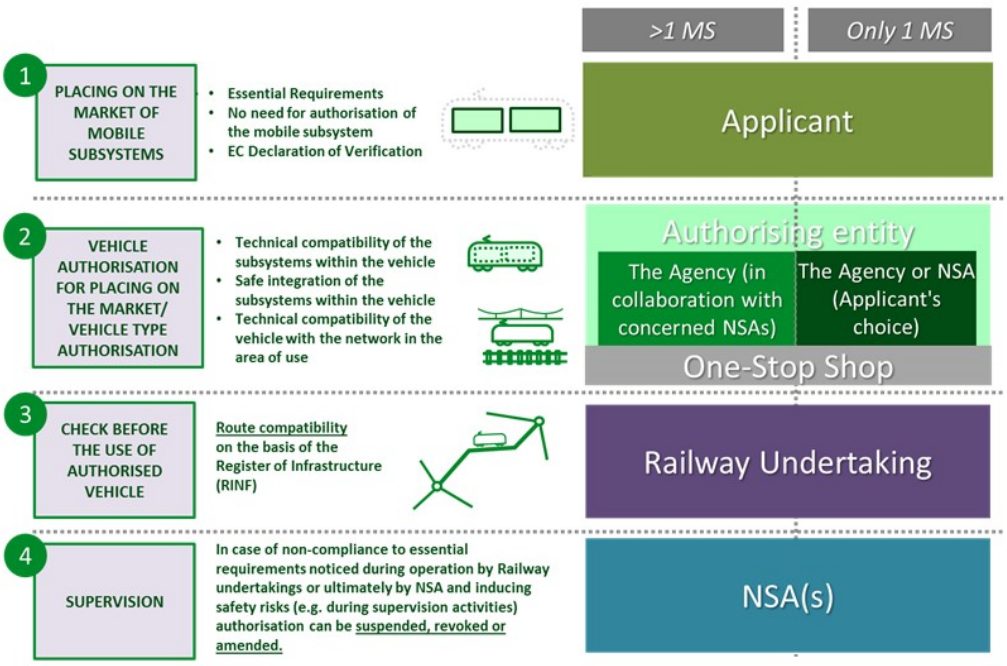
Vehicle registration

RU checks, including:

- Route compatibility
- Proper integration in the train composition

⇒ No need of „additional authorisations“ if vehicle stays within area of use, conditions for use and restrictions

EU legal framework for VA



EUROPEAN UNION AGENCY FOR RAILWAYS

Questions?



The vehicle (type) authorisation process under 4th RP

Regulation (EU) 2018/545

EUROPEAN UNION AGENCY FOR RAILWAYS

Overview of the Process




Stage 1 Preparation of the application


Stage 2 Pre-engagement


Stage 3 Conformity assessment


Stage 4 Submitting the application


Stage 5 Processing the application


Stage 6 Final documentation


Suspension, revocation or amendment

EU HARMONISED PROCESS

What is authorisation?

Reasonable assurance: Authorising entity has reached the confidence that actors have fulfilled their responsibilities

1. Not necessary to have an absolute certainty
2. Level of engagement should be proportional and take into account:
   - Complexity and risk associated with the vehicle/type being authorised
   - Quality of the evidence provided by the applicant
   - Return of experience
   - Confidence gained in the applicant
3. Detailed assessments are to be performed by applicant & assessment bodies; avoid duplication of assessments

Area of use (AoU)

- Area of Use of a Vehicle = MSs & list of networks
- An issued authorisation contains:
  - Area of use (MSs & Network(s))
  - Values of the parameters checked for technical compatibility
  - Conditions for use of the vehicle and other restrictions
- This means that **the actual lines on which a vehicle can operate can be smaller than the Area of use.**

Area of use (AoU)

(a) Area of Use: Networks of Belgium, France, UK, CT

(b) Values of parameters checked for technical compatibility btw Vehicle and the Networks of the AoU:

Parameter*	Value(s)*
INF	
• Nominal track gauge	• 1435 m
• Axle load	• 22,5 T
• Gauge	• GB, GC
• Minimum radius of horizontal curve	• 100 m
• Rail inclination	• 1/20, 1/30
ENE	
• Voltage and frequency	• 1,5kV,3kV, 25kV-50Hz
• Pantograph gauge	• 1950 mm
CCS	
• ETCS baseline	B3R2
• Class B	TBL1+, KVB
• Radio System	GSM-R BL 1

** Illustrating purpose : list of parameters/values non exhaustive*

Area of use (AoU)

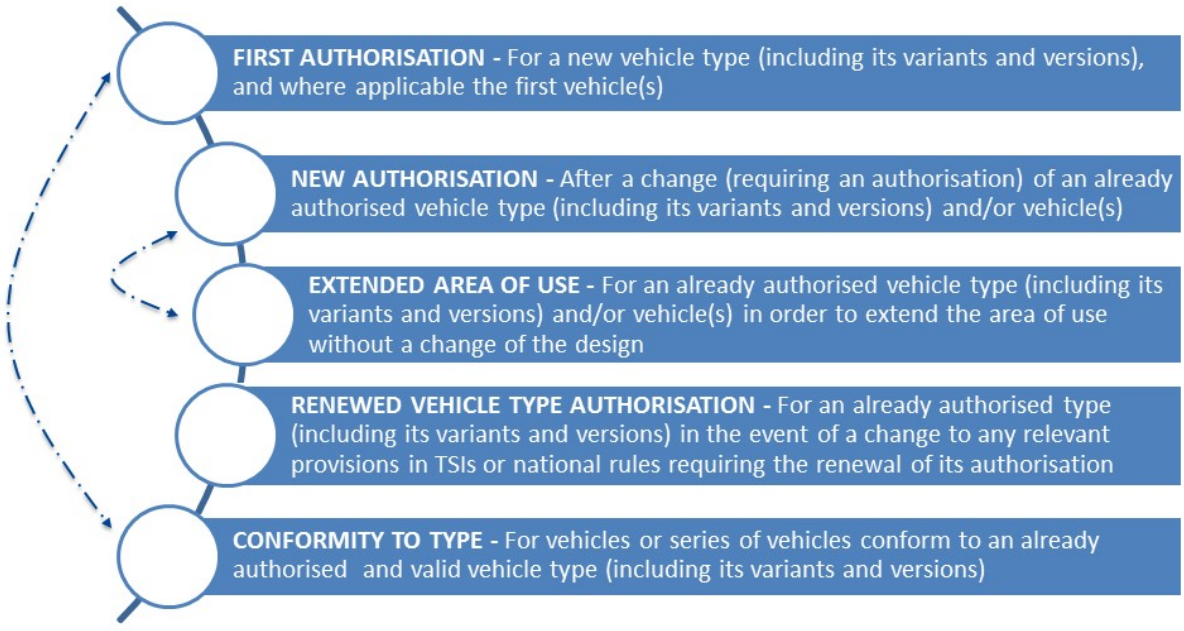
(c) Vehicle's compliance with the relevant TSIs and sets of national rules

- TSIs: 1302/2014 Loc&Pas TSI, 1300/2014 PRM TSI, 1304/2014 NOI TSI, 2016/919 CCS TSI
- National Rules: France, Belgium, UK, Channel Tunnel

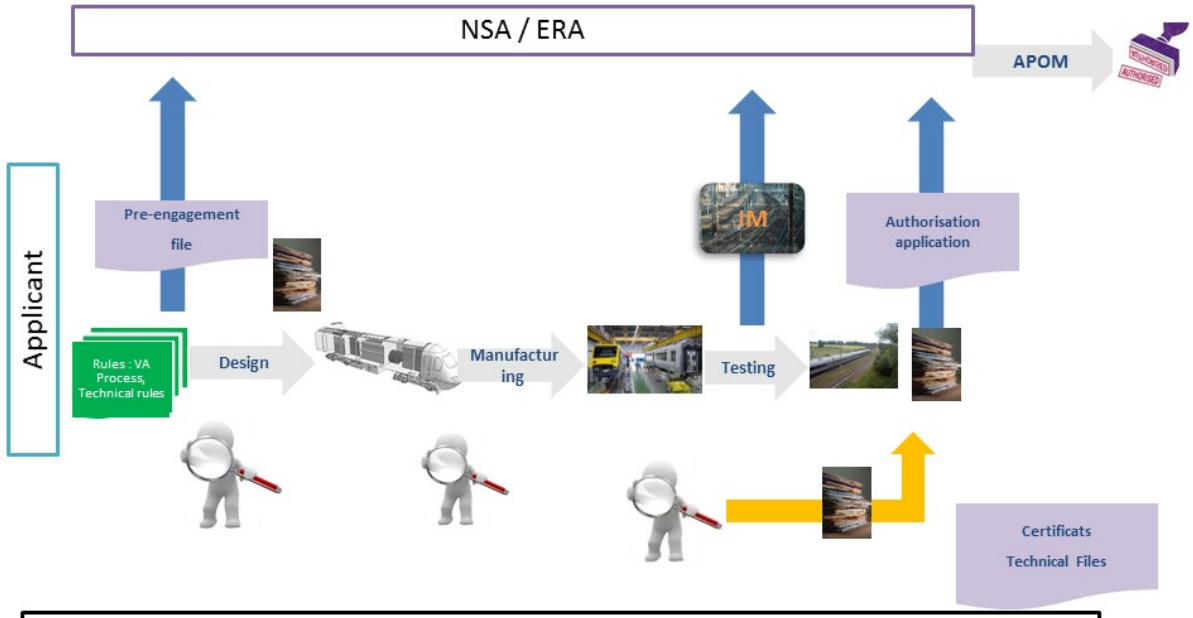
(d) Conditions for use of the vehicle and other restrictions:

- Maximum train current
- Braking performance
- Maximum Speed
- Weather conditions
- ...

Authorisation cases



Vehicle Authorisation phases



Conformity Assessment Bodies involved in all Project phases

Pre-engagement

- **Pre-engagement**
  - Voluntary for the applicant, mandatory for authorising entity / NSAs for the area of use if requested
  - Content of the application: article 23 Regulation (EU) 2018/545
  - Baseline:
    - Opinion of the authorising entity and the NSAs for the area of use on the approach (strategy) proposed by the applicant
    - The approach (strategy) is described in the documents referred to in art 23 of Regulation (EU) 2018/545
    - Has a legal value, but cannot overcome other EU law (e.g. rules)
    - Validity of 84 months
    - Gives certainty to the applicant
  - Pre-engagement is not:
    - A consultancy/training service to be provided to applicants
    - A way to perform a continuous assessment

Case of First authorisation

First authorisation is:

- For **a new vehicle type including its variants and/or versions if any covering an Area of Use,**
- Issued by an authorizing entity to a vehicle type and/or Vehicle(s)

Vehicle Type, Variant & Version

Vehicle Type

Defines the basic design characteristics of vehicle(s) [as covered by a type or design examination certificate]

Vehicle Type Variant

Option for the configuration of a vehicle type that requires an authorisation

Vehicle Type Version

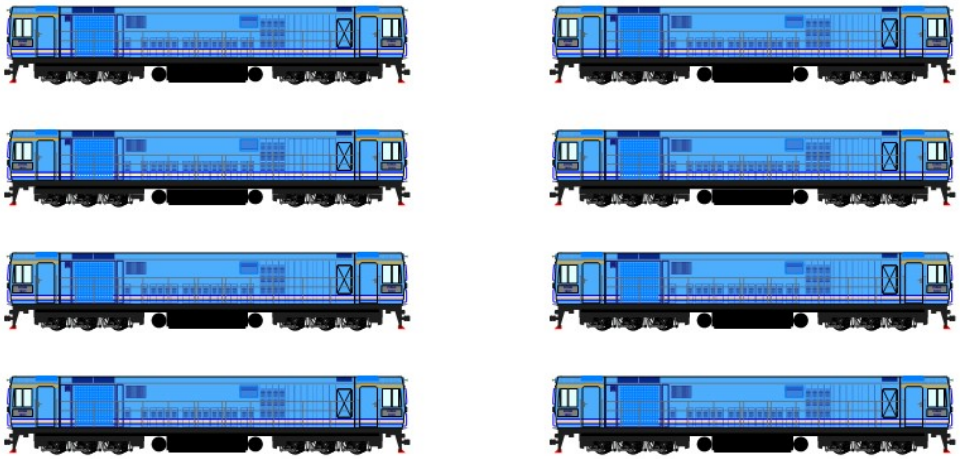
Option for the configuration of a vehicle type or vehicle type variant that does not require an authorisation

Vehicle

Railway vehicle suitable for circulation on wheels on railway lines, with or without traction; a vehicle is composed of one or more structural or functional subsystems

Type, Variant & Version

Vehicle type = concept identified in ERATV



All the vehicles conform to the same type

Type, Variant & Version

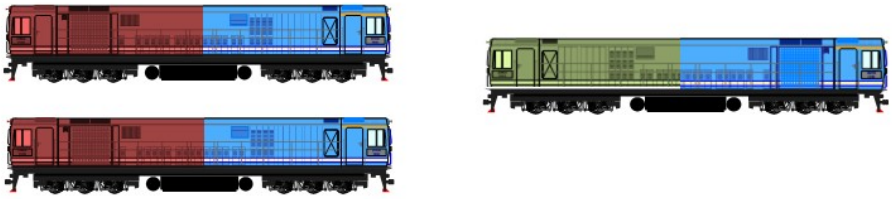
Vehicle type = concept identified in ERATV



Shall be authorised

Vehicle variant A

Vehicle variant B



Do not require a authorisation

Vehicle variant A version 1

Vehicle variant A version 2



Case of New authorisation

When is a new authorisation required?

In case of a change to an authorised vehicle/vehicle type

Article 21(12) of Directive (EU) 2016/797

At least one of the following criteria shall be triggered:

- **Art 21(12)(a)**: changes beyond the thresholds defined in the TSIs (basic design characteristics)
- **Art 21(12)(b):** change has the potential to impact safety adversely (even if in the real implementation it does not)
- **Art 21(1)(c)**: it is required by the relevant TSIs (specific changes always require a new authorisation)

A change that does not require authorisation on the grounds of rules compliance, namely 21(12)(a) or (c), may still affect adversely safety, and may require a new authorisation.

Case of New authorisation Categories of changes

The Regulation 2018/545 defines 4 categories of changes:

- Art 15(1)(a): the change does not introduce a deviation in the technical files accompanying the EC declaration(s) of verification — *no changes in the design*
- Art 15(1)(b): change that introduces a deviation in the technical files but does not impact basic design characteristics nor triggers article 21(12) of Directive (EU) 2016/797: — *change in the design that does not require a new authorisation*
- Art 15(1)(c): change that impacts basic design characteristics but does not trigger article 21(12) of Directive (EU) 2016/797 and does not require a new authorisation — *change that needs to be reflected in ERATV, no need for a new authorisation*
- Art 15(1)(d): change that triggers article 21(12) and requires a new authorisation — *change in the design that requires a new authorisation*

Case of New authorisation

1. The entity managing the change does not have to be the holder of the vehicle type authorisation:
2. If the entity managing the change **is the holder** of the vehicle type authorisation:
   - Change according to **15(1)(a) or (b)** -> *no new authorisation*
   - Change according to **15(1)(c)** -> *no new authorisation (version)*
   - Change according to **15(1)(d)** -> *new authorisation (variant or type)*
3. If the entity managing the change **it is not the holder** of the vehicle type authorisation :
   - Changes according to **15(1)(b),(c) or (d)** -> *new authorisation (type)*
4. Only the elements of the design that are changed and their interfaces with the unmodified parts need to be assessed

Case of Extension of the area of use

Authorisation case defined in Article 14(1)(c) of Regulation (EU) 2016/797

1. Change of the area of use of an authorised type without changes in the design (**without modifications**)
2. The checks to be performed shall be limited to the technical compatibility between the vehicle and the extended network
3. Checks already carried out af the first authorisation shall not be repeated
4. If the extension of the area of use covers networks in another MS, the Agency shall be the authorising entity.
5. Extension of the area of use also applies within 1 MS. The applicant can choose the NSA or the Agency as Authorising Entity

Case of Extension of the area of use

1. The case of authorisation including **stations in neighbouring MSs** is not considered an extension of the area of use nor a case with an area of use covering more than 1 MS
2. In most cases, there is a need to **change the design** before extending the area of use
   - Combination of 2 authorisation cases in article 14(1) of Regulation (EU) 2018/545:

     New authorisation + extended area of use
   - Vehicles and/or vehicle types need to be authorised after the change in the MSs of the original area of use
   - Then the changed vehicles and/or vehicle types authorisation is extended to new network(s)
   - 1 single application combining both cases through OSS
   - 1 common 1+4 month timeframe for to both cases

New/amended roles



Vehicle type holder

1. The applicant for the vehicle type takes the responsibility for the vehicle type as a whole

2. '**Holder of the vehicle type authorisation**' means the natural or legal person that has applied for and received the vehicle type authorisation

3. For a vehicle type, there can only be one holder (clear allocation of responsibilities).

4. The holder is responsible for the configuration management of the vehicle type. This to ensure that the vehicle type always meets the essential requirements after authorisation

5. The role of the holder cannot be transferred / sold, unless if a company ceases to exist (to be treated as another asset)

Vehicle type holder

1. In case of a change of an authorised vehicle type where the new applicant becomes the holder:
   - The new holder is primarily responsible for the new design and the new vehicle type as a whole (e.g.first contact point)
   - New holder is also fully responsible and liable for the changes and the interfaces with the unchanged parts
   - Initial (previous) holder remains responsible and liable for the unchanged parts (no transfer of responsibility/liability to the holder)

2. In case of existing vehicles, the holder will be established:
   - According to ERATV registration (holder is already registered)
   - Only in case of changes, following article 15

Entry into force

OSS is accessible for applicants since 16th February 2019

1. Applicants build applications for vehicle authorisation to put on the market and vehicle type authoristions from that moment onwards
2. Submission of applications possible since 16th June 2019
3. Assessment of applications under the 4THRP started on 16th June 2019
4. Where the date for authorisation falls "shortly" after the relevant date, the applicant should contact the Agency sufficiently in advance of the entry into force of the Regulation (EU) 2018/545
   - Engage with the Agency in the Learning Cases activity (informal pre-engagement)

Entry into force

1. Pre-engagement (baseline) is a concept introduced by 2018/545 => cannot start before the relevant date
2. Case of Wagons compliant to 7.1.2 of WAG TSI 321/2013 :
   - de facto, area of Use covering more than 1 MS
   - Authorising entity = the Agency
   - vehicle authorisation issued by the Agency shall be treated as a vehicule authorisation for placing into service (2008/57) by MS(s) that will transpose the Directive (EU) 2016/797 on 16/06/2020 without additional authorisation

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Questions?



The vehicle (type) authorisation process under 4th RP

Vehicle authorisation technical aspects (Rules & EC Verification)

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Requirements capture

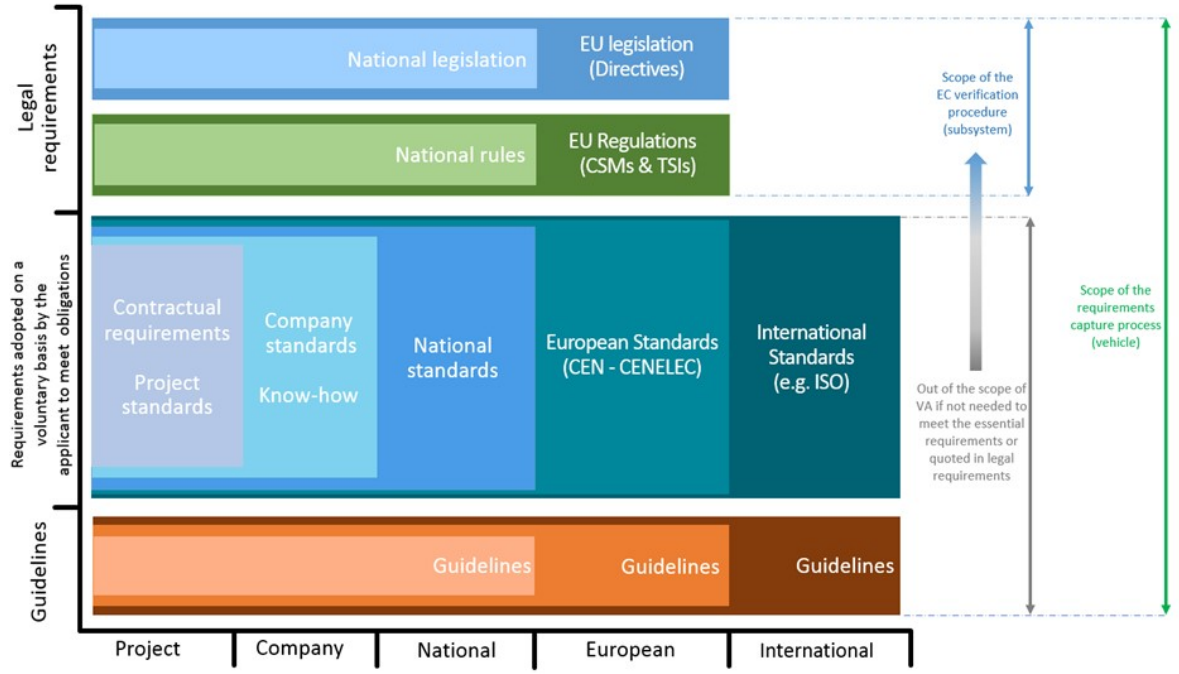
- Requirements capture is performed to ensure that relevant requirements are:
  - Identified
  - Assigned to functions/subsystems
  - Implemented; Validated and
  - Addressed through conditions for use or other restrictions

  with the objective of managing and mitigating the identified risks to an acceptable level

Requirements capture

- Requirements capture covers:
  - Essential requirements for subsystems
  - Technical compatibility of the subsystems within the vehicle
  - Safe integration of the subsystems within the vehicle
  - Technical compatibility of the vehicle with the network in the area of use

Requirements capture scope



Requirements capture roles

- Applicant :
  - Responsible for performing the requirements capture process
  - Use the Risk management process (Annex I of Regulation (EU) 402/2013) as the methodology for safety related aspects
  - Can use the risk management process as the methodology for requirements capture for other essential requirements

Requirements capture roles

- Assessment body (CSM RA):
  - Gives assurance that the processes are systematic and are able to capture, understand, analyze and mitigate hazards
  - Provides a judgement of the correct application of the risk assessment process and suitability of the results
  - Focus on the process. Not an exhaustive check of all the evidence supporting the requirements capture
  - Some detailed assessments (sampling) may be needed (vertical slice assessment of key aspects)

Requirements capture roles

- Authorising entity :
  - Checks completeness, relevance and consistency of evidences (Risk declaration, safety assessment report) when regulation (EU) 402/2013 is used
  - May challenge the assessment report if it demonstrates existence of serious safety risk (burden of proof allocated to authorities)
  - Performs further checks if another methodology is used (when allowed) :
    - Assess the details of the methodology
    - Assess the details of the evidences of the application of the methodology

TSIs Amendment

Art 4.3 (h) of IOD 2016 – New authorisation, upgrading and renewal

- **Basic design characteristics**
  - TSIs LOC & PAS, WAG and CCS : Chap 7

Art 4.3 (i)of IOD 2016 - Compatibility vehicles /routes

- **Route compatibility check**
  - TSIs LOC & PAS, WAG and CCS : Chap 4.9
  - TSI OPE : Chap 4.2.2.5 and Appendix D1

Other amendments

- **Close Open points** : TSIs LOC & PAS, WAG, CCS (TDS)
- **Standards and improve the clarity of the text** : TSIs LOC & PAS, WAG and CCS

TSIs : Basic design characteristics

- Basic Design characteristics is a subset of the vehicle design describing the important/significant elements relevant for technical compatibility or operation of the vehicle (restrictions, conditions of use)

- A change having an impact to a basic design characteristic can generate either :
  - A new vehicle type version or
  - A vehicle type variant or new vehicle type

TSIs upgrading, renewal and new authorisation

- **Principles** to be applied by the applicants and the authorising entities
- **List** the basic design characteristics of a vehicle type
- **Changes** triggering a new vehicle type version or variant
- **Particular** rules for existing RST not covered by an EC declaration of verification

TSI clause	basic design characteristic(s)	Changes generating vehicle type version	Changes generating vehicle type variant
4.2.2.2.3 End coupling	Type of end coupling	Change of end coupler type	N/A
4.2.3.1 Gauging	Reference profile	N/A	Change of reference profile the vehicle is conform to

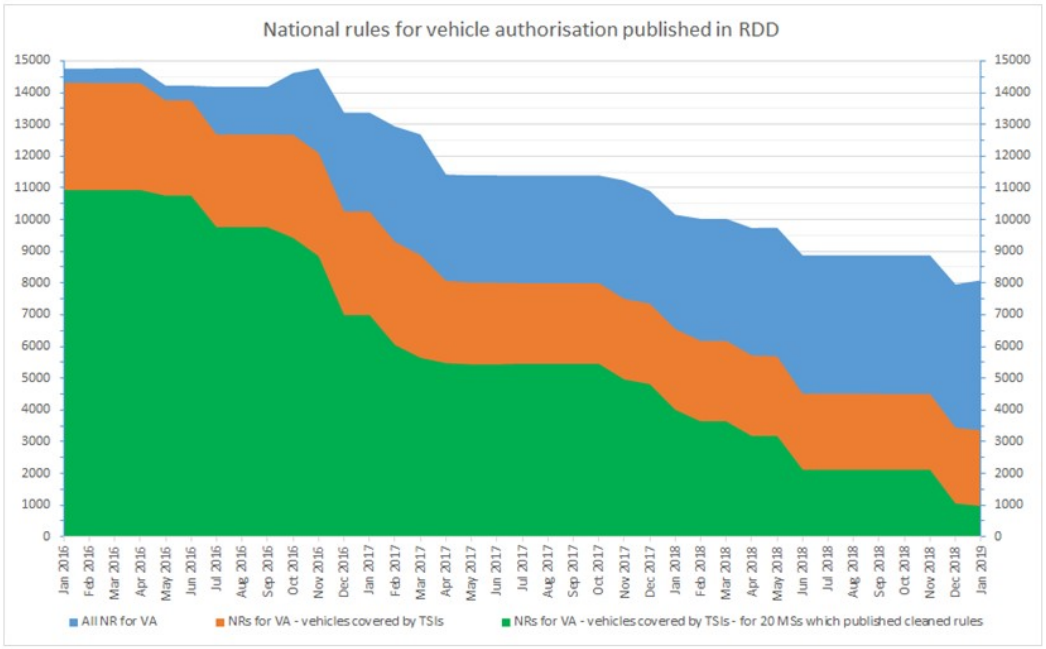
National rules

- New national rules may only be adopted in of the following cases (article 14(4)), :
  - when a TSI does not fully meet the essential requirements;
  - as an urgent preventive measure, in particular following an accident.
- Existing national rules (article 13(2)) are limited to :
  - where the TSIs do not cover, or do not fully cover, certain aspects corresponding to the essential requirements, including **open points** as referred to in Article 4(6)Case where non-application of one or more TSIs or parts of them has been notified under article 7 of directive(EU) 2016/797,
  - Specific cases listed but not described in TSIs,
  - Ensure technical compatibility with existing network not yet in compliance with TSI,
  - Vehicles excluded from the scope of TSIs,
  - Urgent temporary preventive measure, in particular following an accident.

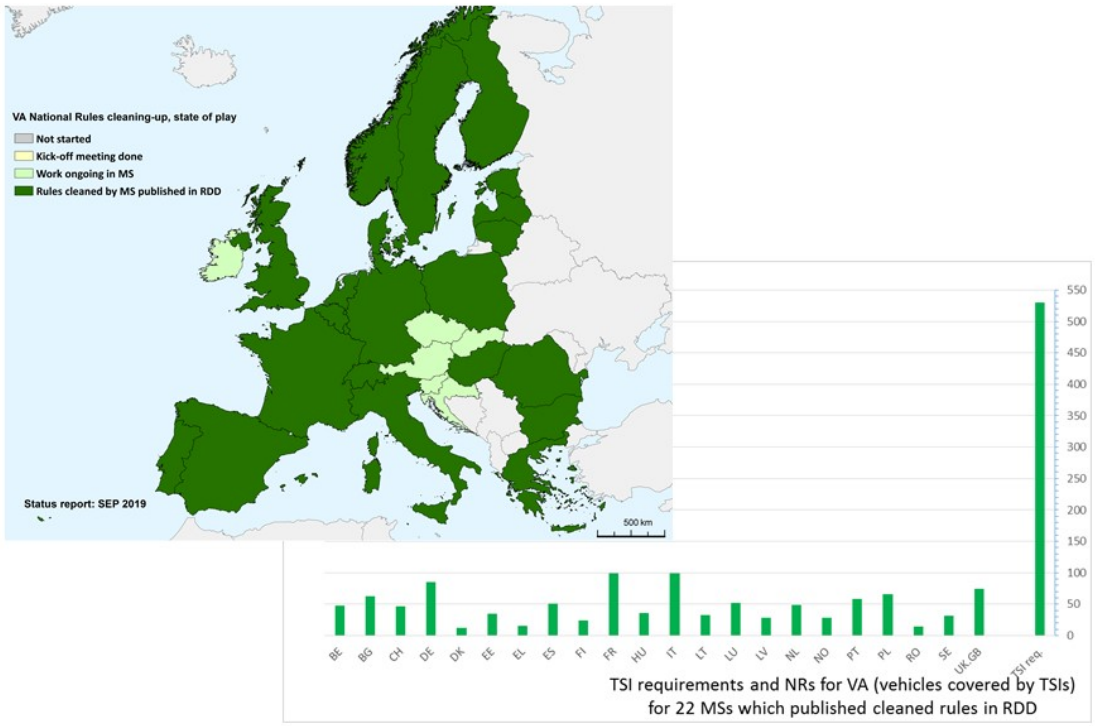
National rule Cleaning up Status

- The Agency made available in ERA website an assessment report covering the evaluation of NRs in addition to latest TSIs for all MSs,
- The Agency addressed to the relevant MSs, a technical opinion, when the evaluation of leads to a negative assessment.
- From 16 June 2019 and pending the SRD, RDD is the reference for applicants, NSAs and the Agency in terms of applicable NRs for VA.

National Rules Overview at EU level



National Rules Overview at EU level



TSI requirements and NRs for VA (vehicles covered by TSIs) for 22 MSs which published cleaned rules in RDD

Classification of National rules Cross acceptance

- Task force provided to EC a proposal for IA on classification of NRs with the aim of facilitating cross-acceptance in different MSs and the placing on the market of vehicles
- The act should be adopted in RISC of **January 2020**
- New / amended :
  - Group of classification
  - New role of NSAs and Agency :
    - NSAs : Provide proposal for classification to Agency
    - Agency: classify NRs on basis of NSAs proposals
  - Cross acceptance certificate "replaced" by Statement of evaluation (shared between NSAs) for NRs that are mutually recognised

EC verification procedure

- EC verification covers the compliance of the subsystem(s) to all essential requirements:
  - TSIs, National rules, Safety assessment report
  - Other requirements needed
- Applicant :
  - Performs the EC verification procedure for the subsystem(s)
  - Responsible for ensuring the subsystem(s) compliance with other applicable legal acts of the Union and any verifications by the assessment bodies required by the other rules
  - Establish the EC Declaration of Verification
  - EC Declarations of Verification incl accompanying technical files are part of the application (Annex I 18.5 of 2018/545)
  - No need for national declaration

EC verification procedure
New templates

- **Interoperable Constituents:**
  - NoBo issues certificate of conformity/suitability for use of ICs
  - Manufacturer issues EC Declaration of conformity or suitability for use of ICs
- **Subsystem :**
  - Applicant issues EC Declaration of verification of subsystem
  - NoBo/DeBo issue:
    - Intermediate Statement of Verification
    - Certificate of verification of subsystem
- **Vehicle:**
  - Applicant issues Declaration of conformity to an authorised vehicle type

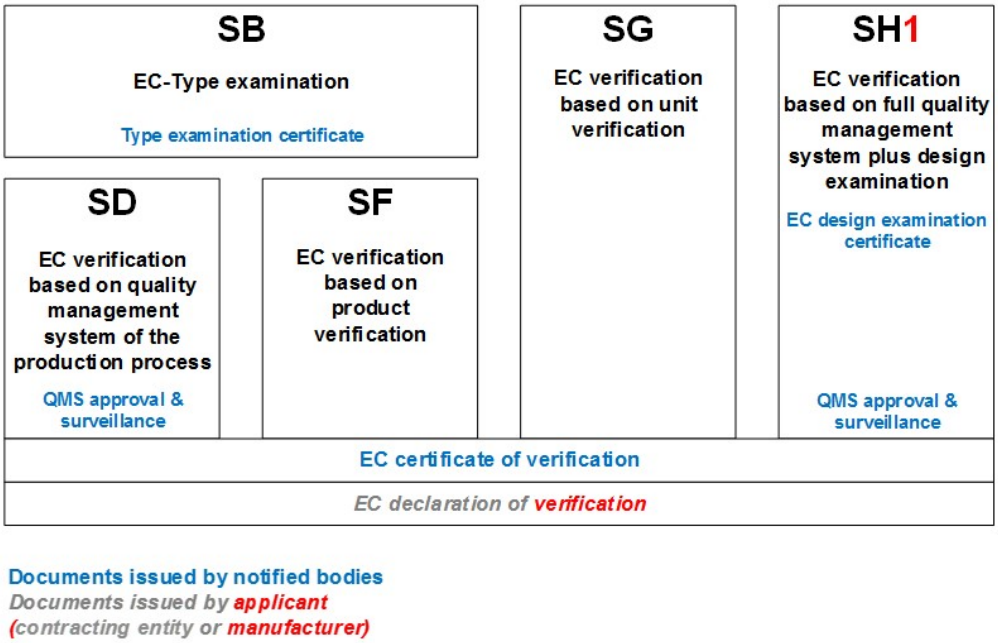
EC verification procedure Assessment Modules

EC Verification procedure is based on application of assessment Modules.

- **Modules :**
  - Are described in decision 2010/713/EC*
  - Cover procedures for conformity assessment (ICs) and EC verification (subsystems)
  - Define responsibilities of participants in the procedures : Manufacturer, applicant, notified body etc.
  - Specify documents necessary to attest conformity

**Decision 2010/713/EC would be amended to apply to DeBo*

EC verification procedure Modules for subsystems



Documents issued by notified bodies
Documents issued by applicant (contracting entity or manufacturer)

EC verification procedure Assessment Modules

- TSIs specify the application of modules in chapter 6 .
- Some modules can be used only in combination with others.
- Modules may involve third party assessment (NoBo) or self-assessment (modules CA, CC).

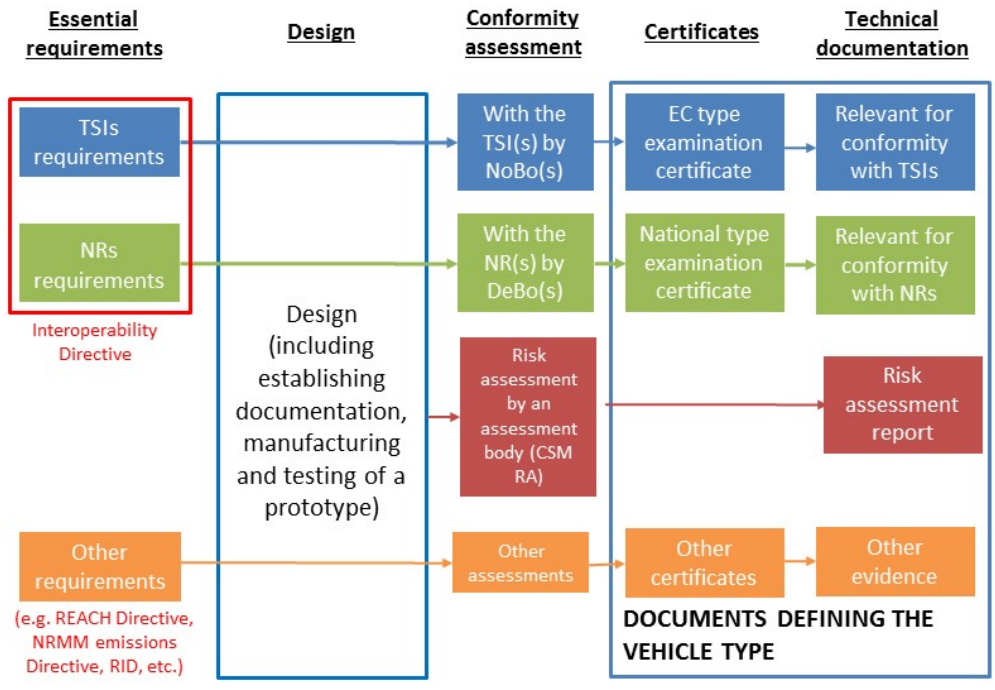
TSI Loc&Pas 1302/2014 for ICs (Eg. For coupler) :

Point	Constituents to be assessed	Module CA	Module CA1 or CA2	Module CB + CC	Module CB + CD	Module CB + CF	Module CH	Module CH1
5.3.1	Automatic centre buffer coupler		X (*)		X	X	X (*)	X
5.3.2	Manual end coupling		X (*)		X	X	X (*)	X

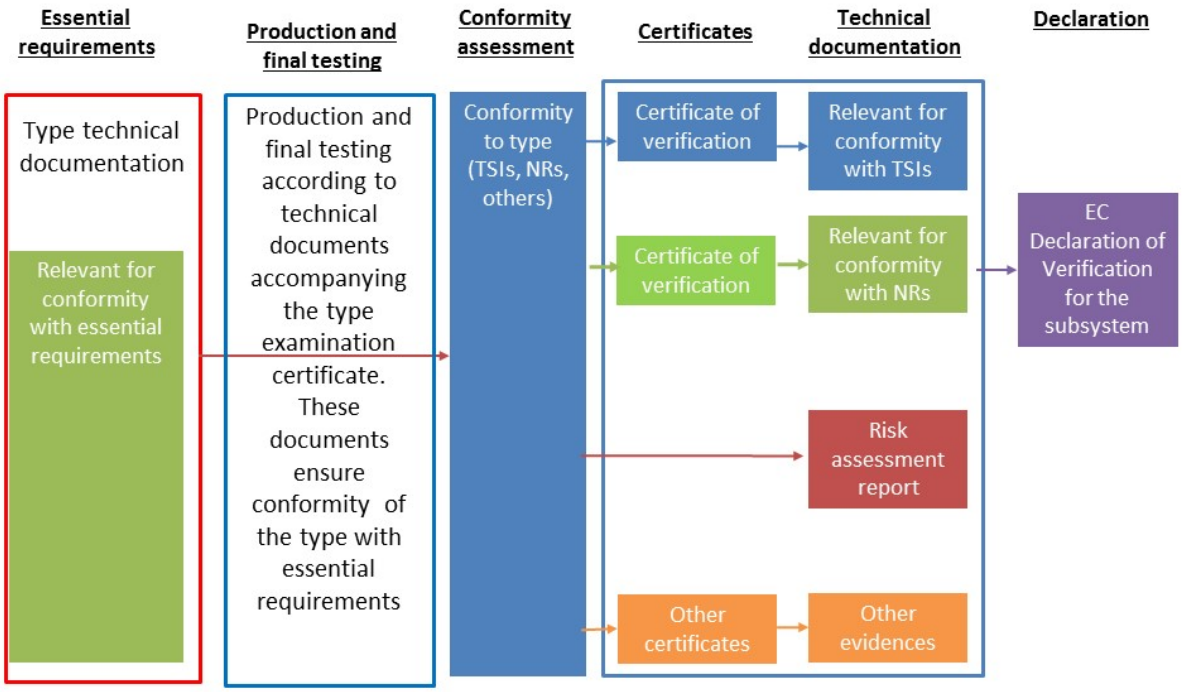
TSI Loc&Pas 1302/2014 for RST:

Applicant chooses one combinations of modules : (SB+SD) or (SB+SF) or (SH1). The assessment is done according to the combination of modules chosen.

EC verification procedure



EC verification procedure



Questions?



Vehicle authorisation and route compatibility checks

Article 21 Directive (EU) 2016/797

Article 23 Directive (EU) 2016/797

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Vehicle Authorisation & Checks before use of vehicles

Applicant defines and demonstrates:

- ❑ **Area of use** (e.g France, Belgium)
- ❑ **Vehicle Technical compatibility with the Network(s) of the area of use** (e.g 3kV, 25kV, KVB, TBL1+, D4 etc.)
- ❑ **Conditions for use and other restrictions** (e.g max speed 140km/h)

Railway Undertaking checks using its SMS process :

- ❑ Vehicle(s) is authorised and Registered
- ❑ Compatibility between Vehicle(s) and indented Route(s)
- ❑ Proper integration in the train composition

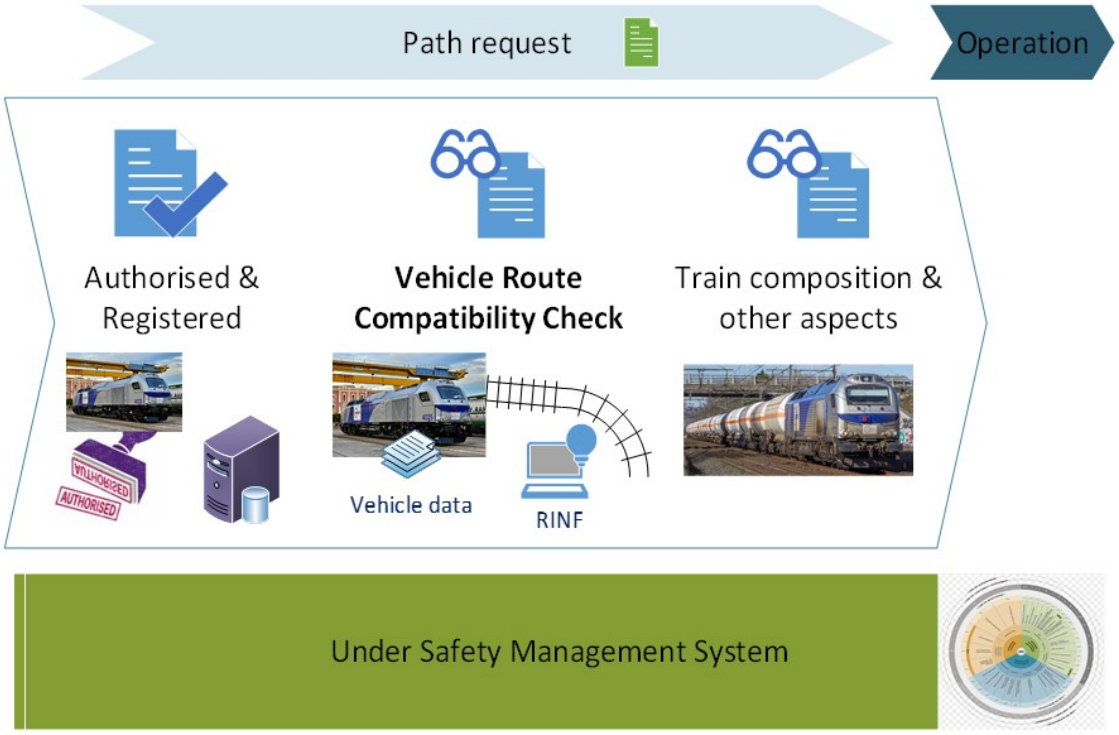
Vehicle authorisation for placing on the Market (art 21)



Checks before the use of authorised vehicles (art 23)



Checks before use of vehicles



Compatibility check between Vehicle and Route

RU task

Most of the Route compatibility items require a simple comparison

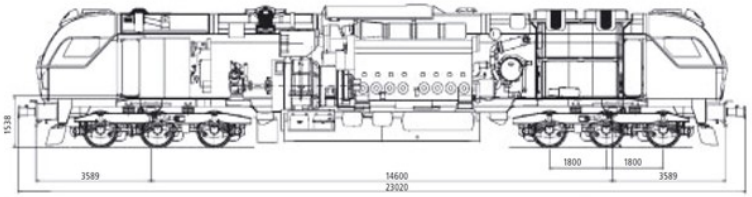
Interface	Vehicle data in ERATV and technical file		Route information available in RINF or provided by IM		Results
	ERATV	Value	RINF ref	Value	
Gauge	4.2.1	G1	1.1.1.1.3.1.1 1.2.1.0.3.4	G1	☺
Train detection systems	4.14.1	track circuits axle counters loops	1.1.1.3.7.1	track circuits axle counters	☺
Wheel set gauge	4.1.3	1435 mm	1.1.1.1.4.1 1.2.1.0.4.1	1435 mm	☺
Minimum in-service wheel diameter	4.8.2	991 mm	1.1.1.1.5.2	330 mm	☺

Compatibility check between Vehicle and Route

RU task

Some items to be checked need specific competencies
(e.g Traffic loads and load carrying capacity of infrastructure)

RU performs static and dynamic compatibility checks with the IM procedures

Interface	Vehicle data in ERATV and technical file		Route information available in RINF or provided by IM		Results
	ERATV	Value	RINF ref	Value	
• Design mass (working order, normal and exceptional payload), 4.5.2 : 121000 kg • Static axle load (working order, normal and exceptional payload), 4.5.3: 20160 kg • Maximum design speed , 4.1.2.1 : 120km/h • Vehicle length, 4.8.1 : 23,02m • Position of the axles along the unit (axle spacing): 					Compatible with lines classified D4

Questions?



The vehicle (type) authorisation process under 4th RP

Registers

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Reference Document Database RDD

- Contains national rules and acceptable national means of compliance
- RDD also holds the classifications of rules agreed between MSs to facilitate cross acceptance.
- Management and **publication** of the content in RDD is the responsibility of the MSs.
- Publicly available: https://rdd.era.europa.eu/rdd/

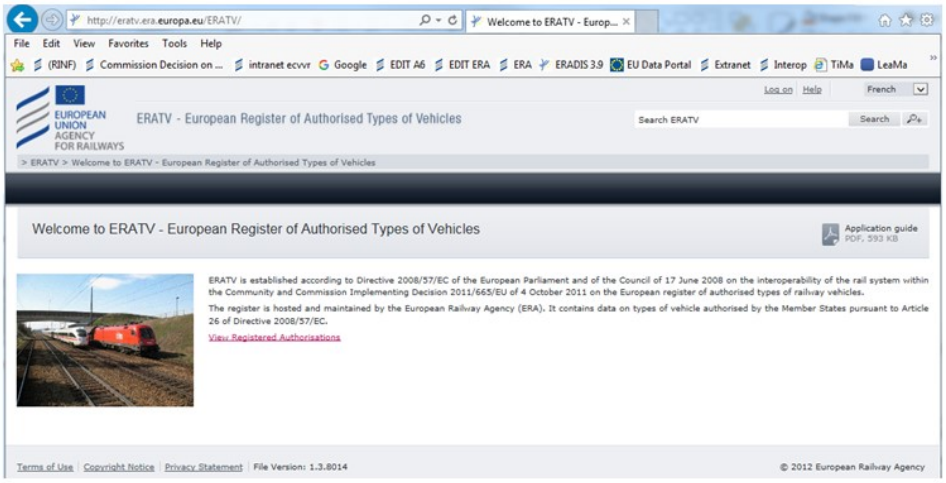


Single Rules Database SRD



European Register of Authorised Types of Vehicles ERATV

- Contains authorised vehicle type
- In operation since beginning of 2013
- 840 type authorisations in ERATV as of today.
- Publicly available: https://eratv.era.europa.eu/eratv



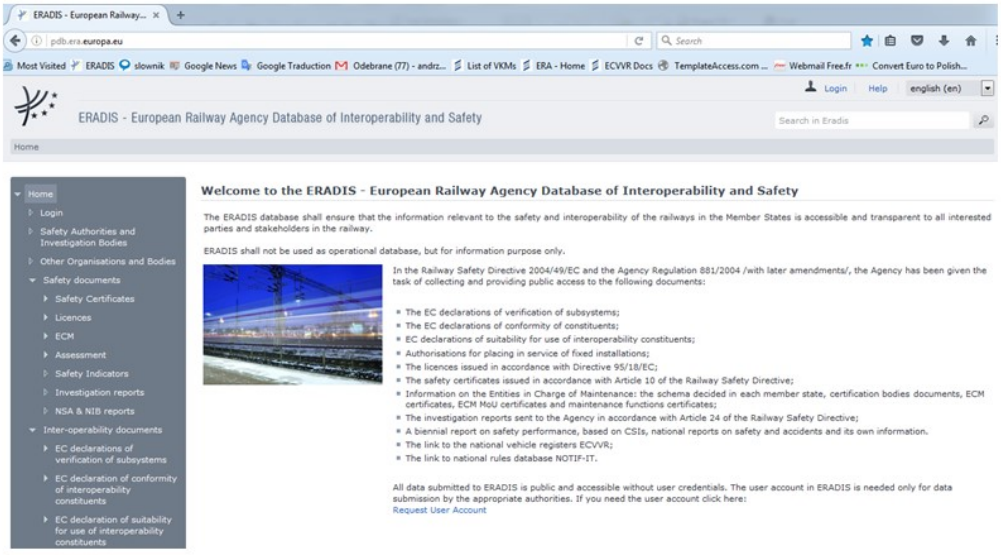
ERATV

- Applicant:
  - Responsible for the integrity of the data provided to the authorising entity.
  - Can fill-in part of the required data (technical data) on behalf of the authorising entity.

- Authorising entity:
  - Always issues a vehicle type authorisation even if the applicant has requested to have only a vehicle authorisation for placing on the market.
  - Responsibility for the data recorded in ERATV

ERA Database on Interoperability and Safety
ERADIS

- Contains certificates, declarations
- Publicly available: http://eradis.era.europa.eu



ERADIS

- Applicant of subsystem, Manufacturer of ICs:
  - Submits EC declarations
- NoBo:
  - Submits EC certificates
- DeBo:
  - No obligation however, the principle of ''mutatis mutandis'' could be applied
- Authorising entity:
  - Ensures that ERADIS is updated before issuing authorisation

Register of Infrastructure RINF

- Provides main features of the European Railway infrastructure.
- Publicly available: http://rinf.era.europa.eu/RINF
- In particular, provides the value of the parameters to be used to check the compatibility between vehicle and route
- May be used for vehicle authorisation when RINF is referenced by TSIs (e.g TSI Loc&Pas 4.2.8.2.9.4.2 on contact strip) or NRs

RINF current state



National Vehicle Register NVR

- Not part of vehicle authorisation
- National Vehicle Register: NVR Decision amended by by Decision (EU) 2018/1614
- Register of all vehicles in service:
  - Kept by each MS
  - Contains information on authorisation and associated Keeper, Owner, ECM
  - NVRs and search engine 'Virtual Vehicle Register' in ERA constitute European Centralized Virtual Vehicle Register.
  - All the information on every vehicle is available via the ECVVR.
- ECVVR in operation since 2009: https://vvr.era.europa.eu/VVR
- Over 1 million vehicles available in ECVVR

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NVR

- Vehicle Keeper :
  - Requests vehicle registration
  - Ensures that data submitted is up-to-date and accurate
- Registration Entity (MSs):
  - Grants EVN and Registers vehicles
  - MSs ensures quality and integrity of data registered by the designated registration entity
- When the area of use of the vehicle :
  - Is limited to one MS: vehicle is registered in the NVR of that MS.
  - Covers more than one MSs: the keeper decides in which MS to register the vehicle, the registration is done in one NVR.
- When the area of use of the vehicle is extended :
  - vehicle is registered only in the NVR of the MS where the vehicle was authorised. In any case the registration is done in just one NVR.

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Questions?



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Authorisation of vehicles from third countries

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Authorisation of vehicles from third countries

Vehicles from third countries are covered by a different regime:

- Article 21(16) of Directive (EU) 2016/797 - Freight wagons and passenger coaches in shared use with third countries, the track gauge of which is different from that of the main rail network within the Union
  - Different VA procedure (rules of this procedure to be notified to the European Commission)
  - Conformity of vehicles with the ERs ensured by the railway undertaking
- Article 21(17) of Directive (EU) 2016/797 - Locomotives and self-propelling trains arriving from third countries until a station that is situated close to the border
  - Vehicle authorisation for placing on the market not mandatory
  - Conformity of vehicles with the essential requirements ensured by the railway undertaking

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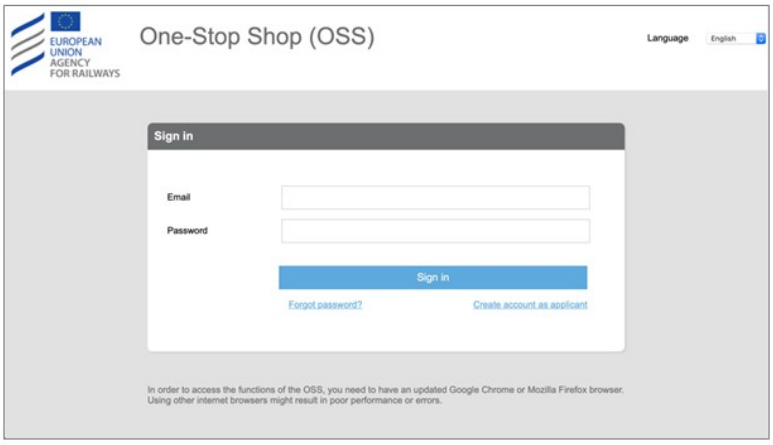
Introduction to the One Stop Shop

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The One-Stop Shop

The one-stop-shop (OSS) is the IT system designed, developed and managed by the Agency through which all applications for single safety certificates, vehicle authorisations and vehicle type authorisations shall be submitted either to the relevant National Safety Authority or to the Agency.



Purpose of the One-Stop Shop

The one-stop shop shall be used by the applicants irrespective of the intended area of operation or area of use (one or more Member States).

The One-Stop Shop will enable efficient and effective communication between all the organisations involved in the process:

- all issues identified by the respective authority during the assessment,
- the replies of the applicant, and
- the final decision

will be communicated with the use of the one-stop-shop.

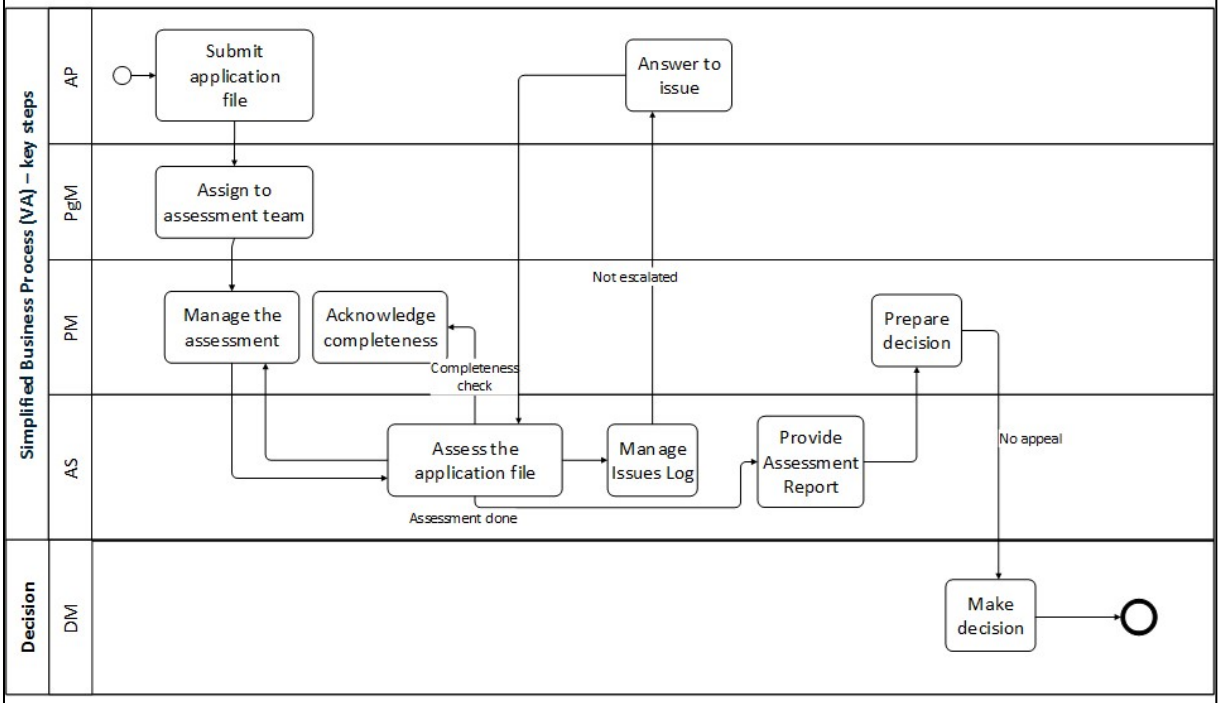
Users management in the One-Stop Shop

All users representing the Agency and the NSAs shall be registered in advance in the one-stop-shop by their own organizations.



An applicant, before submitting its application, shall go through the registration process.

OSS Simulation



Questions?



Cooperation agreements

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Cooperation Agreements – State of play

- The Management Board of the Agency has adopted, in June 2018, guidelines and the list of main elements
- The NSA sub-group has reached an agreement on draft cooperation agreements clauses
- The Agency is currently engaged in bilateral meetings with NSAs to conclude with each of them the relevant cooperation agreement
- Cooperation is needed over the results from Supervision and Assessment

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Questions?



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3. **Antoine Defosses, Nordine Bousouff**: The vehicle (type) authorisation process under 4th RP

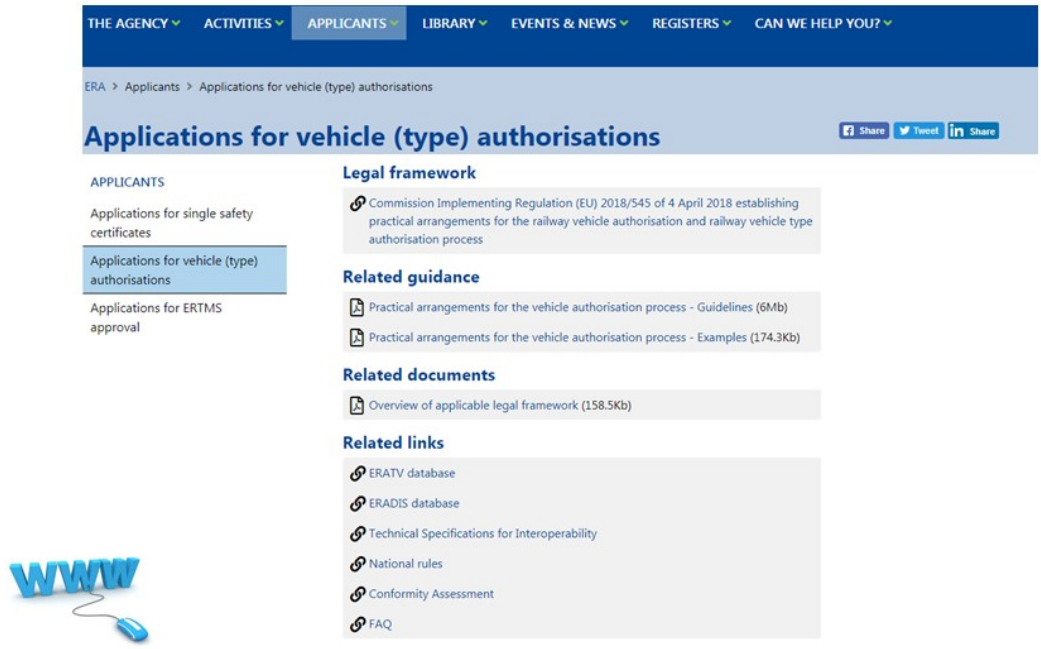
The vehicle (type) authorisation process under 4th RP

EU legal framework for Vehicle Authorisation

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VA documents in ERA website



EU legal framework

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

2007
- **3rd 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
- **4th 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

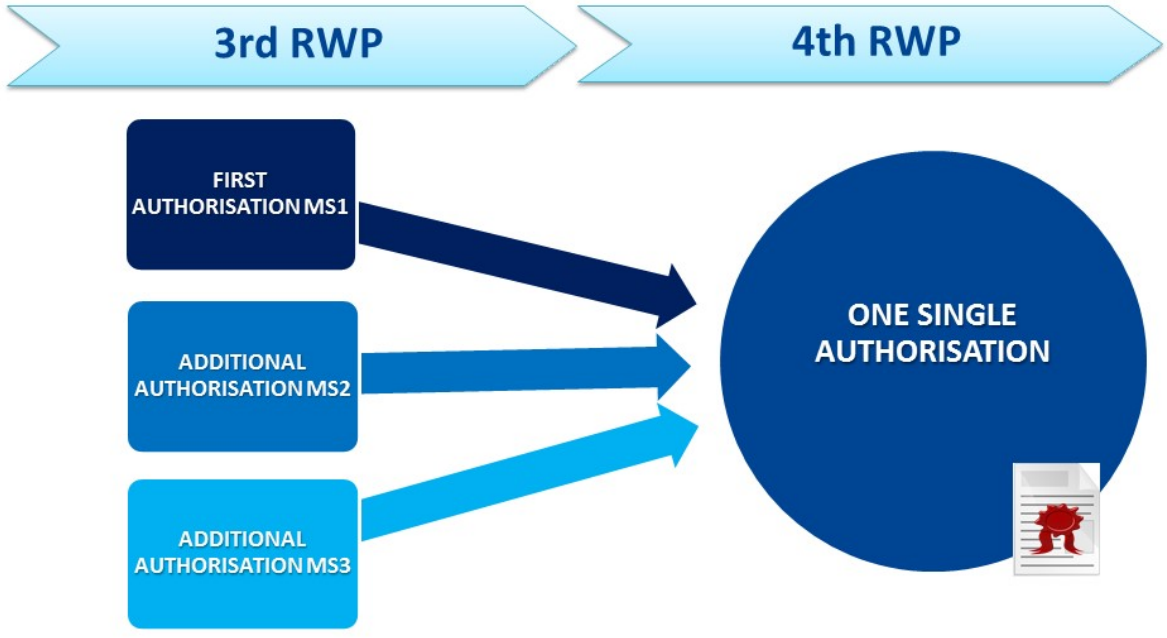
Technical pillar of the 4RP (1/2)

Directives & Regulations	• Regulation (EU) 2016/796 The Agency regulation • Directive (EU) 2016/797 Interoperability • Directive (EU) 2016/798 Safety
Commission Implementing Regulations	• (EU) 2018/545 Practical arrangements for VA • EC declaration of verification (voted RISC 83) • Cross-acceptance (draft) • Other (Fees & Charges, Board of Appeal)
Guidance	• ERA-PRG-005/02_361 Guidelines for the practical arrangements for the vehicle authorisation process • ERA-PRG-005/02_374 Catalogue of examples • Guidance to the IA EC declaration of verification (draft)
Agreements	• Cooperation agreements between Agency and NSAs • Multilateral agreements

Technical pillar of the 4RP (2/2)

Revised TSIs	• Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 amending LOC&PAS, WAG, SRT, CCS, INF, ENE TSIs and ERATV specification • Commission Implementing Regulation (EU) 2019/773 of 16 May 2019 (OPE TSI, voted RISC 85)
Other legal texts	• Regulation (EU) 402/2013 CSM RA • Decision 2010/713/EU conformity assessment modules • Regulation (EU) 1300/2014 PRM
Other	• Decision (EU) 2018/1614 EVR specification • Commission Implementing Regulation (EU) 2019/777 of 16 May 2019 (Revised RINF specification) • RDD: decision 2011/155/EU on the reference document • RDD: ERA/GUI/XA v3.0 Part 1 reference document • Guidance to TSIs and Registers

Key aspects of the 4RP: single authorisation



Key aspects of the 4RP: APOM

3rd RWP → 4th RWP

APIS → **APOM**

Authorisation for placing **in service**

Authorisation for placing **on the market** for an area of use

Key aspects of the 4RP: Authorising entity

The authorising entity depends on the area of use

Area of use = more than one Member State
ERA authorising entity, collaboration with NSAs

Area of use = one Member State
The applicant can choose the Agency or the NSA

All requests addressed via the OSS

Key aspects of the 4RP: main steps







Applicant submits request for VA to the One-Stop-Shop

- Specifying the area of use
- Including relevant documentation

ERA/NSA issues APOM (or communicate negative decision)

- Within 4 months from reception of complete documentation
- Following detailed rules established in Reg. **(EU) 2018/545**

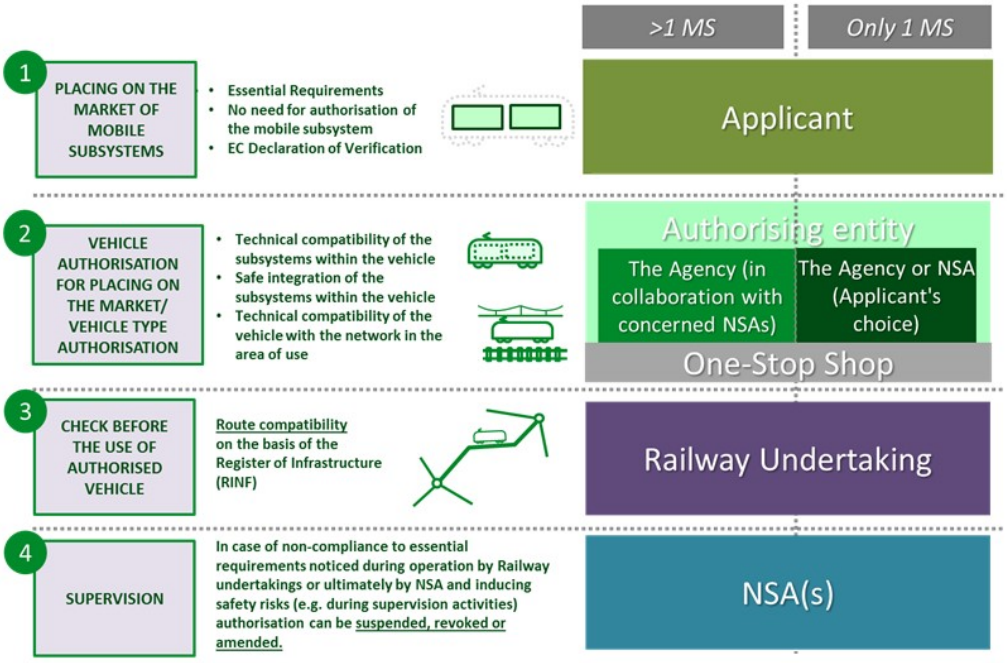
Vehicle registration

RU checks, including:

- Route compatibility
- Proper integration in the train composition

⇒ No need of „additional authorisations“ if vehicle stays within area of use, conditions for use and restrictions

EU legal framework for VA



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Questions?



The vehicle (type) authorisation process under 4th RP

Regulation (EU) 2018/545

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Overview of the Process




Stage 1 Preparation of the application


Stage 2 Pre-engagement


Stage 3 Conformity assessment


Stage 4 Submitting the application


Stage 5 Processing the application


Stage 6 Final documentation


Suspension, revocation or amendment

EU HARMONISED PROCESS

What is authorisation?

Reasonable assurance: Authorising entity has reached the confidence that actors have fulfilled their responsibilities

1. Not necessary to have an absolute certainty
2. Level of engagement should be proportional and take into account:
   - Complexity and risk associated with the vehicle/type being authorised
   - Quality of the evidence provided by the applicant
   - Return of experience
   - Confidence gained in the applicant
3. Detailed assessments are to be performed by applicant & assessment bodies; avoid duplication of assessments

Area of use (AoU)

- Area of Use of a Vehicle = MSs & list of networks
- An issued authorisation contains:
  - Area of use (MSs & Network(s))
  - Values of the parameters checked for technical compatibility
  - Conditions for use of the vehicle and other restrictions
- This means that **the actual lines on which a vehicle can operate can be smaller than the Area of use.**

Area of use (AoU)

(a) Area of Use: Networks of Belgium, France, UK, CT

(b) Values of parameters checked for technical compatibility btw Vehicle and the Networks of the AoU:

Parameter*	Value(s)*
INF	
• Nominal track gauge	• 1435 m
• Axle load	• 22,5 T
• Gauge	• GB, GC
• Minimum radius of horizontal curve	• 100 m
• Rail inclination	• 1/20, 1/30
ENE	
• Voltage and frequency	• 1,5kV,3kV, 25kV-50Hz
• Pantograph gauge	• 1950 mm
CCS	
• ETCS baseline	B3R2
• Class B	TBL1+, KVB
• Radio System	GSM-R BL 1

** Illustrating purpose : list of parameters/values non exhaustive*

Area of use (AoU)

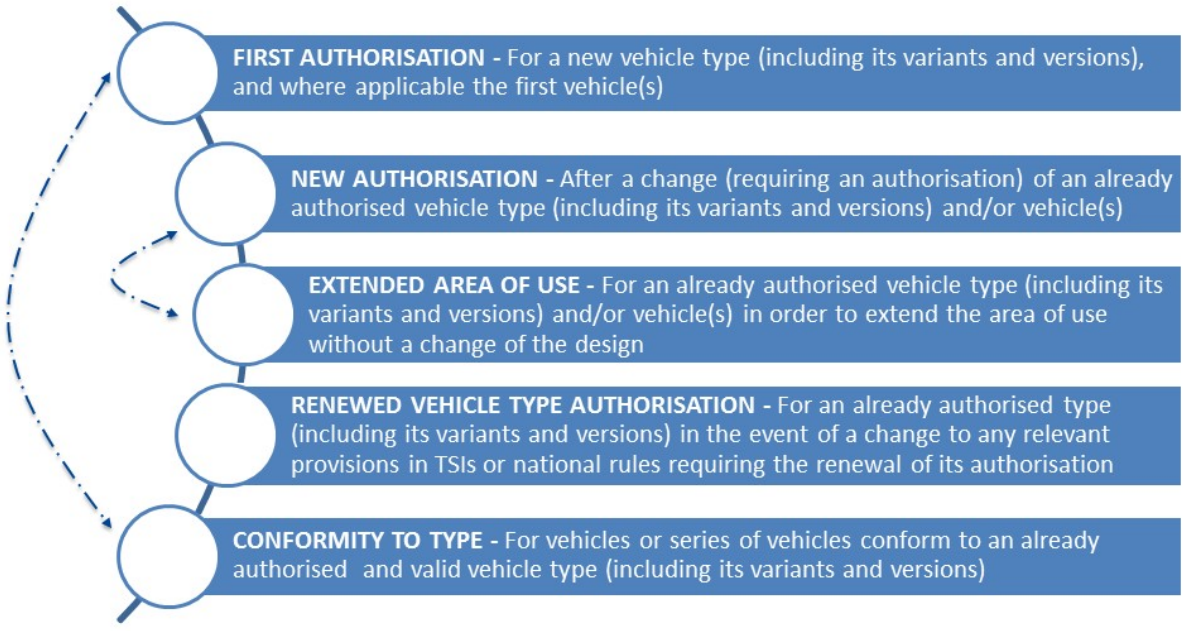
(c) Vehicle's compliance with the relevant TSIs and sets of national rules

- TSIs: 1302/2014 Loc&Pas TSI, 1300/2014 PRM TSI, 1304/2014 NOI TSI, 2016/919 CCS TSI
- National Rules: France, Belgium, UK, Channel Tunnel

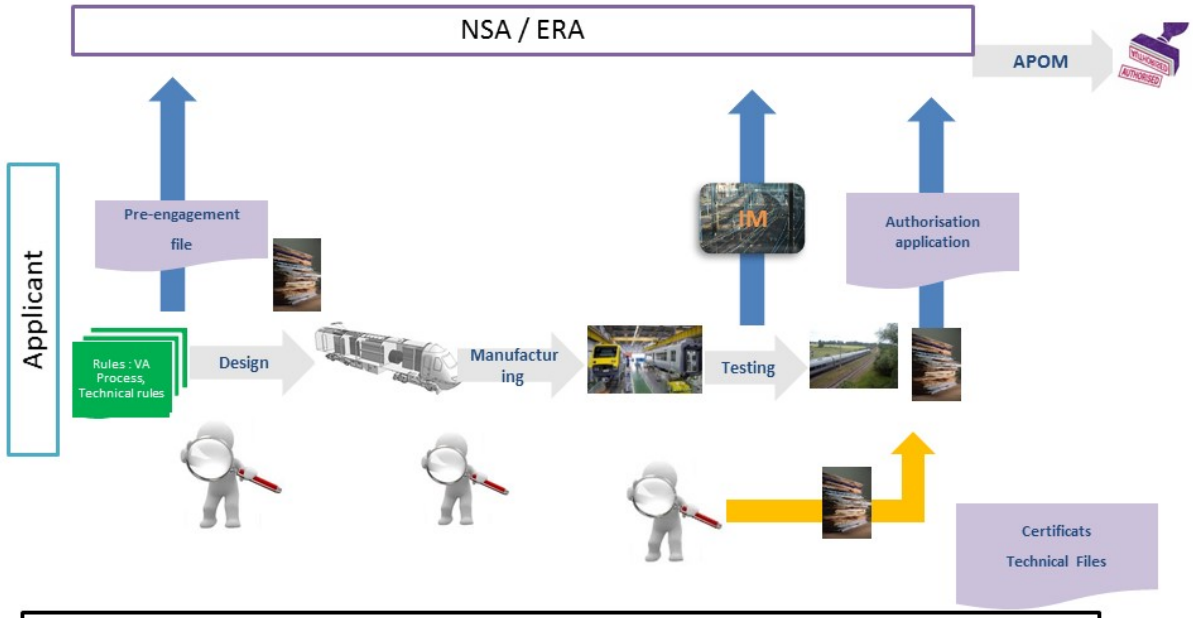
(d) Conditions for use of the vehicle and other restrictions:

- Maximum train current
- Braking performance
- Maximum Speed
- Weather conditions
- ...

Authorisation cases



Vehicle Authorisation phases



Conformity Assessment Bodies involved in all Project phases

Pre-engagement

- **Pre-engagement**
  - Voluntary for the applicant, mandatory for authorising entity / NSAs for the area of use if requested
  - Content of the application: article 23 Regulation (EU) 2018/545
  - Baseline:
    - Opinion of the authorising entity and the NSAs for the area of use on the approach (strategy) proposed by the applicant
    - The approach (strategy) is described in the documents referred to in art 23 of Regulation (EU) 2018/545
    - Has a legal value, but cannot overcome other EU law (e.g. rules)
    - Validity of 84 months
    - Gives certainty to the applicant
  - Pre-engagement is not:
    - A consultancy/training service to be provided to applicants
    - A way to perform a continuous assessment

Case of First authorisation

First authorisation is:

- For **a new vehicle type including its variants and/or versions if any covering an Area of Use,**
- Issued by an authorizing entity to a vehicle type and/or Vehicle(s)

Vehicle Type, Variant & Version

Vehicle Type

Defines the basic design characteristics of vehicle(s) [as covered by a type or design examination certificate]

Vehicle Type Variant

Option for the configuration of a vehicle type that requires an authorisation

Vehicle Type Version

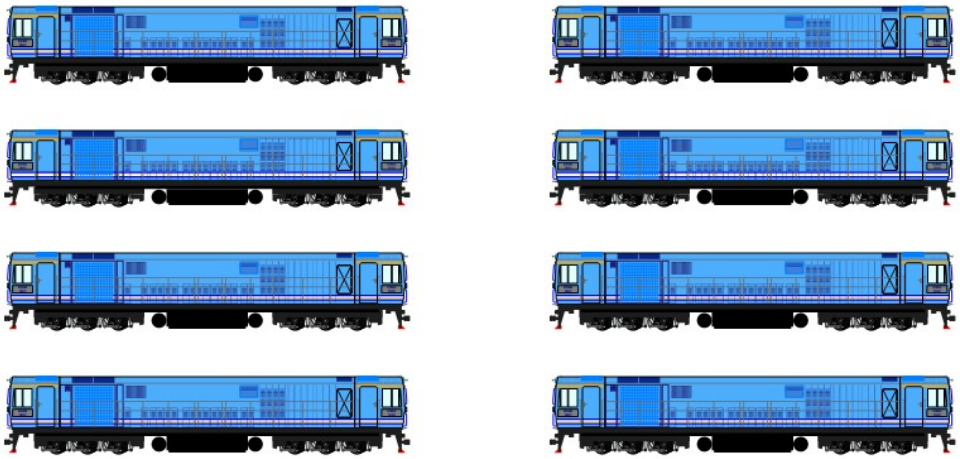
Option for the configuration of a vehicle type or vehicle type variant that does not require an authorisation

Vehicle

Railway vehicle suitable for circulation on wheels on railway lines, with or without traction; a vehicle is composed of one or more structural or functional subsystems

Type, Variant & Version

Vehicle type = concept identified in ERATV



All the vehicles conform to the same type

Type, Variant & Version

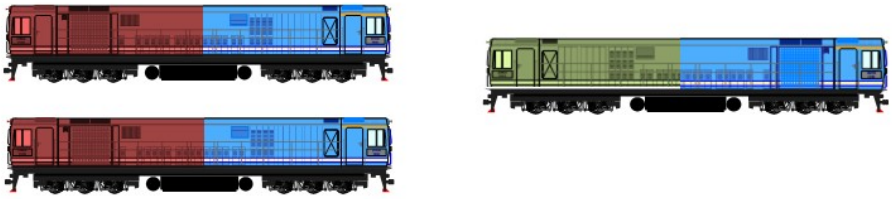
Vehicle type = concept identified in ERATV



Shall be authorised

Vehicle variant A

Vehicle variant B



Do not require a authorisation

Vehicle variant A version 1

Vehicle variant A version 2



Case of New authorisation

When is a new authorisation required?

In case of a change to an authorised vehicle/vehicle type

Article 21(12) of Directive (EU) 2016/797

At least one of the following criteria shall be triggered:

- **Art 21(12)(a)**: changes beyond the thresholds defined in the TSIs (basic design characteristics)
- **Art 21(12)(b):** change has the potential to impact safety adversely (even if in the real implementation it does not)
- **Art 21(1)(c)**: it is required by the relevant TSIs (specific changes always require a new authorisation)

A change that does not require authorisation on the grounds of rules compliance, namely 21(12)(a) or (c), may still affect adversely safety, and may require a new authorisation.

Case of New authorisation Categories of changes

The Regulation 2018/545 defines 4 categories of changes:

- Art 15(1)(a): the change does not introduce a deviation in the technical files accompanying the EC declaration(s) of verification — *no changes in the design*
- Art 15(1)(b): change that introduces a deviation in the technical files but does not impact basic design characteristics nor triggers article 21(12) of Directive (EU) 2016/797: — *change in the design that does not require a new authorisation*
- Art 15(1)(c): change that impacts basic design characteristics but does not trigger article 21(12) of Directive (EU) 2016/797 and does not require a new authorisation — *change that needs to be reflected in ERATV, no need for a new authorisation*
- Art 15(1)(d): change that triggers article 21(12) and requires a new authorisation — *change in the design that requires a new authorisation*

Case of New authorisation

1. The entity managing the change does not have to be the holder of the vehicle type authorisation:
2. If the entity managing the change **is the holder** of the vehicle type authorisation:
   - Change according to **15(1)(a) or (b)** -> *no new authorisation*
   - Change according to **15(1)(c)** -> *no new authorisation (version)*
   - Change according to **15(1)(d)** -> *new authorisation (variant or type)*
3. If the entity managing the change **it is not the holder** of the vehicle type authorisation :
   - Changes according to **15(1)(b),(c) or (d)** -> *new authorisation (type)*
4. Only the elements of the design that are changed and their interfaces with the unmodified parts need to be assessed

Case of Extension of the area of use

Authorisation case defined in Article 14(1)(c) of Regulation (EU) 2016/797

1. Change of the area of use of an authorised type without changes in the design (**without modifications**)
2. The checks to be performed shall be limited to the technical compatibility between the vehicle and the extended network
3. Checks already carried out af the first authorisation shall not be repeated
4. If the extension of the area of use covers networks in another MS, the Agency shall be the authorising entity.
5. Extension of the area of use also applies within 1 MS. The applicant can choose the NSA or the Agency as Authorising Entity

Case of Extension of the area of use

1. The case of authorisation including **stations in neighbouring MSs** is not considered an extension of the area of use nor a case with an area of use covering more than 1 MS
2. In most cases, there is a need to **change the design** before extending the area of use
   - Combination of 2 authorisation cases in article 14(1) of Regulation (EU) 2018/545:

     New authorisation + extended area of use
   - Vehicles and/or vehicle types need to be authorised after the change in the MSs of the original area of use
   - Then the changed vehicles and/or vehicle types authorisation is extended to new network(s)
   - 1 single application combining both cases through OSS
   - 1 common 1+4 month timeframe for to both cases

New/amended roles



Vehicle type holder

1. The applicant for the vehicle type takes the responsibility for the vehicle type as a whole

2. '**Holder of the vehicle type authorisation**' means the natural or legal person that has applied for and received the vehicle type authorisation

3. For a vehicle type, there can only be one holder (clear allocation of responsibilities).

4. The holder is responsible for the configuration management of the vehicle type. This to ensure that the vehicle type always meets the essential requirements after authorisation

5. The role of the holder cannot be transferred / sold, unless if a company ceases to exist (to be treated as another asset)

Vehicle type holder

1. In case of a change of an authorised vehicle type where the new applicant becomes the holder:
   - The new holder is primarily responsible for the new design and the new vehicle type as a whole (e.g.first contact point)
   - New holder is also fully responsible and liable for the changes and the interfaces with the unchanged parts
   - Initial (previous) holder remains responsible and liable for the unchanged parts (no transfer of responsibility/liability to the holder)

2. In case of existing vehicles, the holder will be established:
   - According to ERATV registration (holder is already registered)
   - Only in case of changes, following article 15

Entry into force

OSS is accessible for applicants since 16th February 2019

1. Applicants build applications for vehicle authorisation to put on the market and vehicle type authoristions from that moment onwards
2. Submission of applications possible since 16th June 2019
3. Assessment of applications under the 4THRP started on 16th June 2019
4. Where the date for authorisation falls "shortly" after the relevant date, the applicant should contact the Agency sufficiently in advance of the entry into force of the Regulation (EU) 2018/545
   - Engage with the Agency in the Learning Cases activity (informal pre-engagement)

Entry into force

1. Pre-engagement (baseline) is a concept introduced by 2018/545 => cannot start before the relevant date
2. Case of Wagons compliant to 7.1.2 of WAG TSI 321/2013 :
   - de facto, area of Use covering more than 1 MS
   - Authorising entity = the Agency
   - vehicle authorisation issued by the Agency shall be treated as a vehicule authorisation for placing into service (2008/57) by MS(s) that will transpose the Directive (EU) 2016/797 on 16/06/2020 without additional authorisation

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Questions?



The vehicle (type) authorisation process under 4th RP

Vehicle authorisation technical aspects (Rules & EC Verification)

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Requirements capture

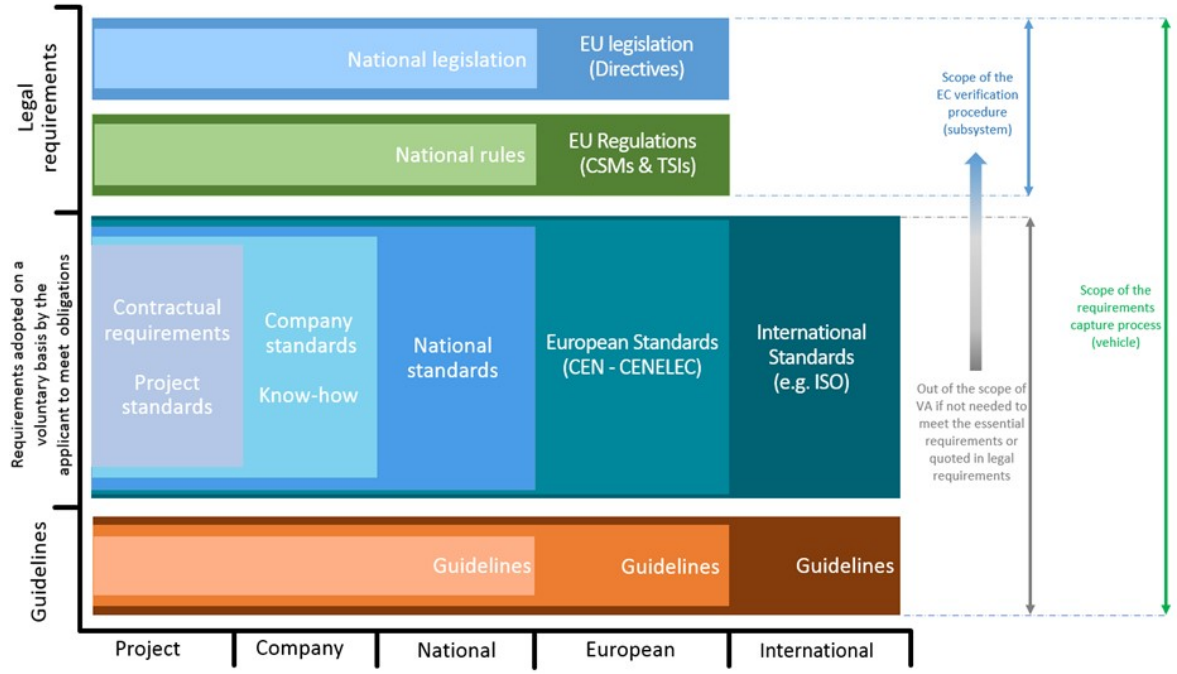
- Requirements capture is performed to ensure that relevant requirements are:
  - Identified
  - Assigned to functions/subsystems
  - Implemented; Validated and
  - Addressed through conditions for use or other restrictions

  with the objective of managing and mitigating the identified risks to an acceptable level

Requirements capture

- Requirements capture covers:
  - Essential requirements for subsystems
  - Technical compatibility of the subsystems within the vehicle
  - Safe integration of the subsystems within the vehicle
  - Technical compatibility of the vehicle with the network in the area of use

Requirements capture scope



Requirements capture roles

- Applicant :
  - Responsible for performing the requirements capture process
  - Use the Risk management process (Annex I of Regulation (EU) 402/2013) as the methodology for safety related aspects
  - Can use the risk management process as the methodology for requirements capture for other essential requirements

Requirements capture roles

- Assessment body (CSM RA):
  - Gives assurance that the processes are systematic and are able to capture, understand, analyze and mitigate hazards
  - Provides a judgement of the correct application of the risk assessment process and suitability of the results
  - Focus on the process. Not an exhaustive check of all the evidence supporting the requirements capture
  - Some detailed assessments (sampling) may be needed (vertical slice assessment of key aspects)

Requirements capture roles

- Authorising entity :
  - Checks completeness, relevance and consistency of evidences (Risk declaration, safety assessment report) when regulation (EU) 402/2013 is used
  - May challenge the assessment report if it demonstrates existence of serious safety risk (burden of proof allocated to authorities)
  - Performs further checks if another methodology is used (when allowed) :
    - Assess the details of the methodology
    - Assess the details of the evidences of the application of the methodology

TSIs Amendment

Art 4.3 (h) of IOD 2016 – New authorisation, upgrading and renewal

- **Basic design characteristics**
  - TSIs LOC & PAS, WAG and CCS : Chap 7

Art 4.3 (i)of IOD 2016 - Compatibility vehicles /routes

- **Route compatibility check**
  - TSIs LOC & PAS, WAG and CCS : Chap 4.9
  - TSI OPE : Chap 4.2.2.5 and Appendix D1

Other amendments

- **Close Open points** : TSIs LOC & PAS, WAG, CCS (TDS)
- **Standards and improve the clarity of the text** : TSIs LOC & PAS, WAG and CCS

TSIs : Basic design characteristics

- Basic Design characteristics is a subset of the vehicle design describing the important/significant elements relevant for technical compatibility or operation of the vehicle (restrictions, conditions of use)

- A change having an impact to a basic design characteristic can generate either :
  - A new vehicle type version or
  - A vehicle type variant or new vehicle type

TSIs upgrading, renewal and new authorisation

- **Principles** to be applied by the applicants and the authorising entities
- **List** the basic design characteristics of a vehicle type
- **Changes** triggering a new vehicle type version or variant
- **Particular** rules for existing RST not covered by an EC declaration of verification

TSI clause	basic design characteristic(s)	Changes generating vehicle type version	Changes generating vehicle type variant
4.2.2.2.3 End coupling	Type of end coupling	Change of end coupler type	N/A
4.2.3.1 Gauging	Reference profile	N/A	Change of reference profile the vehicle is conform to

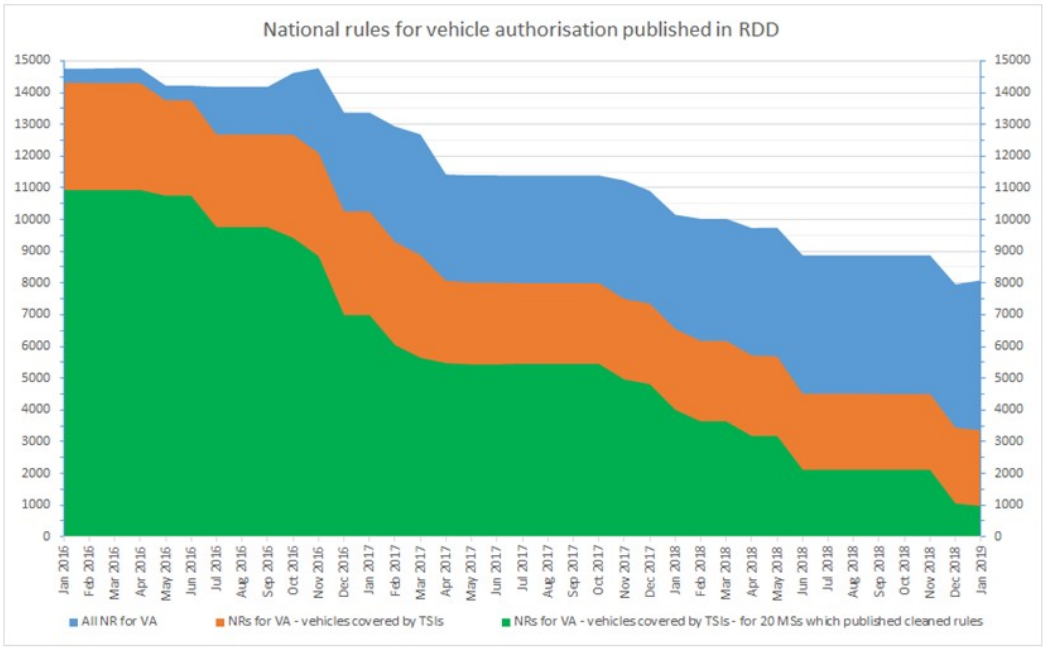
National rules

- New national rules may only be adopted in of the following cases (article 14(4)), :
  - when a TSI does not fully meet the essential requirements;
  - as an urgent preventive measure, in particular following an accident.
- Existing national rules (article 13(2)) are limited to :
  - where the TSIs do not cover, or do not fully cover, certain aspects corresponding to the essential requirements, including **open points** as referred to in Article 4(6)Case where non-application of one or more TSIs or parts of them has been notified under article 7 of directive(EU) 2016/797,
  - Specific cases listed but not described in TSIs,
  - Ensure technical compatibility with existing network not yet in compliance with TSI,
  - Vehicles excluded from the scope of TSIs,
  - Urgent temporary preventive measure, in particular following an accident.

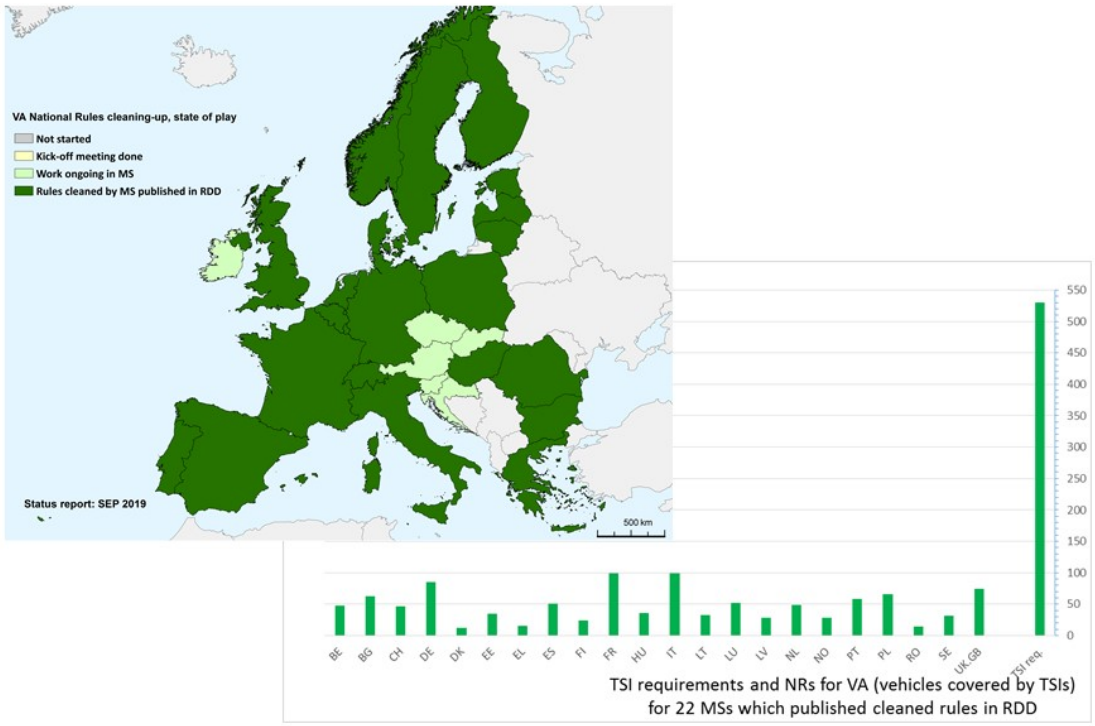
National rule Cleaning up Status

- The Agency made available in ERA website an assessment report covering the evaluation of NRs in addition to latest TSIs for all MSs,
- The Agency addressed to the relevant MSs, a technical opinion, when the evaluation of leads to a negative assessment.
- From 16 June 2019 and pending the SRD, RDD is the reference for applicants, NSAs and the Agency in terms of applicable NRs for VA.

National Rules Overview at EU level



National Rules Overview at EU level



TSI requirements and NRs for VA (vehicles covered by TSIs) for 22 MSs which published cleaned rules in RDD

Classification of National rules Cross acceptance

- Task force provided to EC a proposal for IA on classification of NRs with the aim of facilitating cross-acceptance in different MSs and the placing on the market of vehicles
- The act should be adopted in RISC of **January 2020**
- New / amended :
  - Group of classification
  - New role of NSAs and Agency :
    - NSAs : Provide proposal for classification to Agency
    - Agency: classify NRs on basis of NSAs proposals
  - Cross acceptance certificate "replaced" by Statement of evaluation (shared between NSAs) for NRs that are mutually recognised

EC verification procedure

- EC verification covers the compliance of the subsystem(s) to all essential requirements:
  - TSIs, National rules, Safety assessment report
  - Other requirements needed
- Applicant :
  - Performs the EC verification procedure for the subsystem(s)
  - Responsible for ensuring the subsystem(s) compliance with other applicable legal acts of the Union and any verifications by the assessment bodies required by the other rules
  - Establish the EC Declaration of Verification
  - EC Declarations of Verification incl accompanying technical files are part of the application (Annex I 18.5 of 2018/545)
  - No need for national declaration

EC verification procedure
New templates

- **Interoperable Constituents:**
  - NoBo issues certificate of conformity/suitability for use of ICs
  - Manufacturer issues EC Declaration of conformity or suitability for use of ICs
- **Subsystem :**
  - Applicant issues EC Declaration of verification of subsystem
  - NoBo/DeBo issue:
    - Intermediate Statement of Verification
    - Certificate of verification of subsystem
- **Vehicle:**
  - Applicant issues Declaration of conformity to an authorised vehicle type

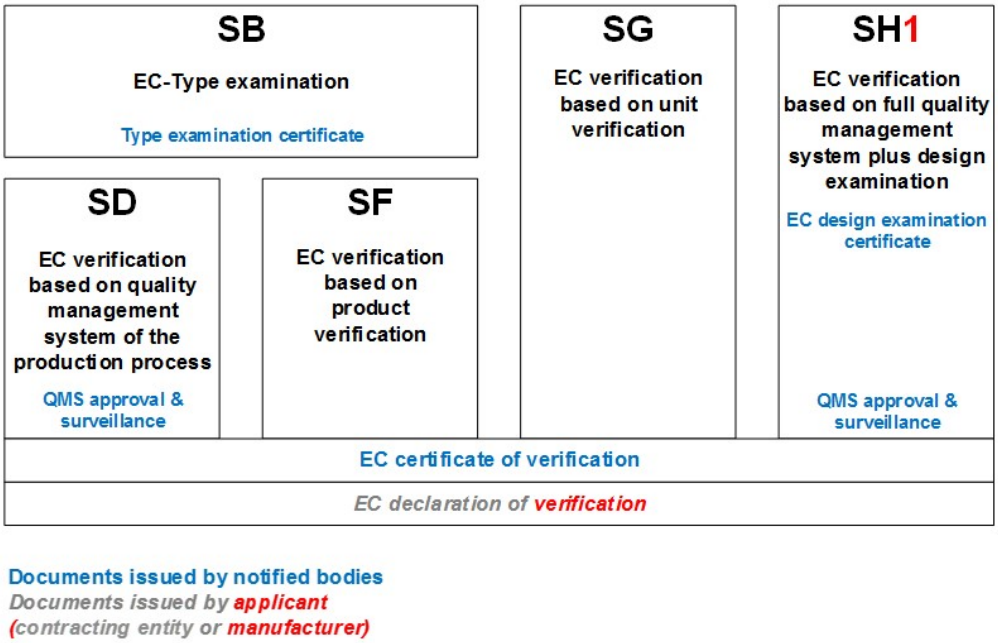
EC verification procedure Assessment Modules

EC Verification procedure is based on application of assessment Modules.

- **Modules :**
  - Are described in decision 2010/713/EC*
  - Cover procedures for conformity assessment (ICs) and EC verification (subsystems)
  - Define responsibilities of participants in the procedures : Manufacturer, applicant, notified body etc.
  - Specify documents necessary to attest conformity

**Decision 2010/713/EC would be amended to apply to DeBo*

EC verification procedure Modules for subsystems



Documents issued by notified bodies
Documents issued by applicant
(contracting entity or manufacturer)

EC verification procedure Assessment Modules

- TSIs specify the application of modules in chapter 6 .
- Some modules can be used only in combination with others.
- Modules may involve third party assessment (NoBo) or self-assessment (modules CA, CC).

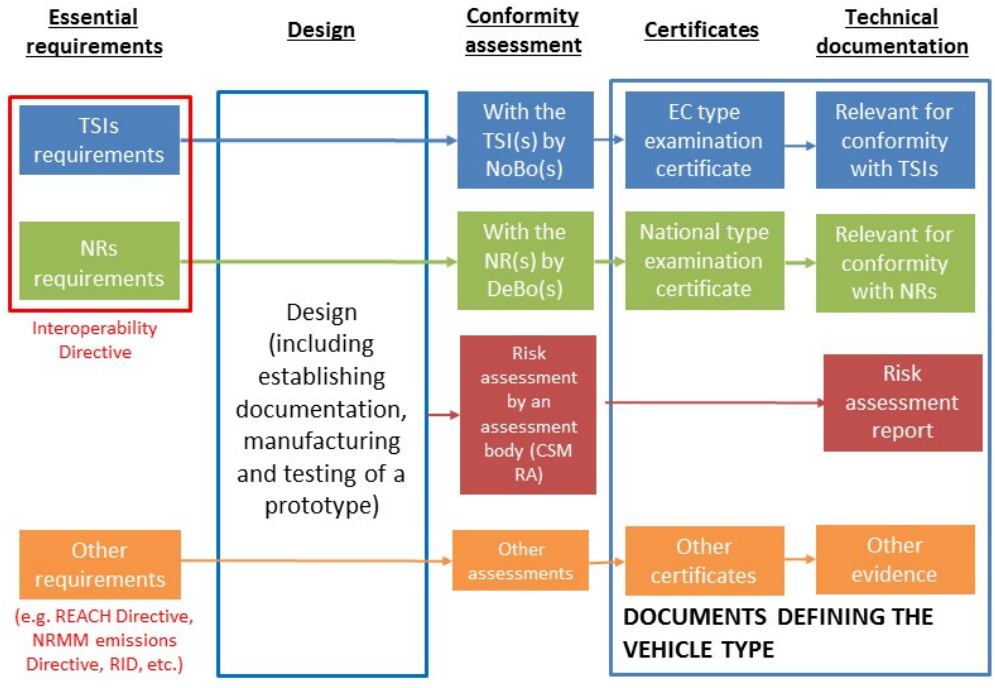
TSI Loc&Pas 1302/2014 for ICs (Eg. For coupler) :

Point	Constituents to be assessed	Module CA	Module CA1 or CA2	Module CB + CC	Module CB + CD	Module CB + CF	Module CH	Module CH1
5.3.1	Automatic centre buffer coupler		X (*)		X	X	X (*)	X
5.3.2	Manual end coupling		X (*)		X	X	X (*)	X

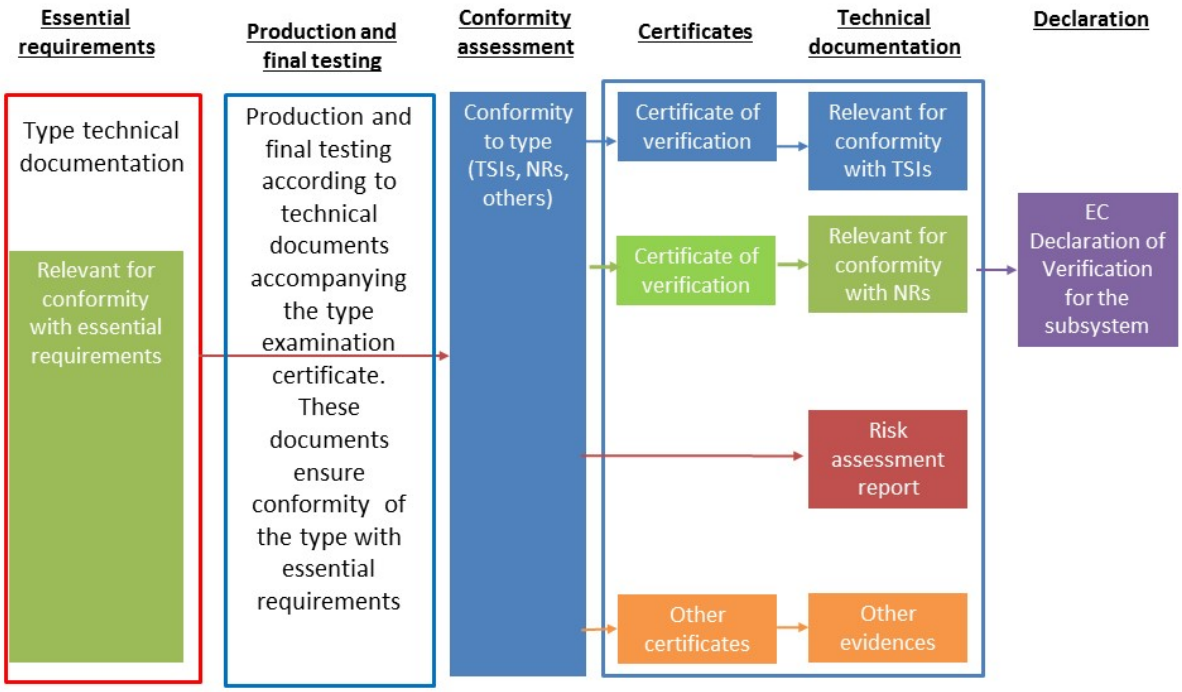
TSI Loc&Pas 1302/2014 for RST:

Applicant chooses one combinations of modules : (SB+SD) or (SB+SF) or (SH1). The assessment is done according to the combination of modules chosen.

EC verification procedure



EC verification procedure



Questions?



The vehicle (type) authorisation process under 4th RP

Registers

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Reference Document Database RDD

- Contains national rules and acceptable national means of compliance
- RDD also holds the classifications of rules agreed between MSs to facilitate cross acceptance.
- Management and **publication** of the content in RDD is the responsibility of the MSs.
- Publicly available: https://rdd.era.europa.eu/rdd/



Single Rules Database SRD

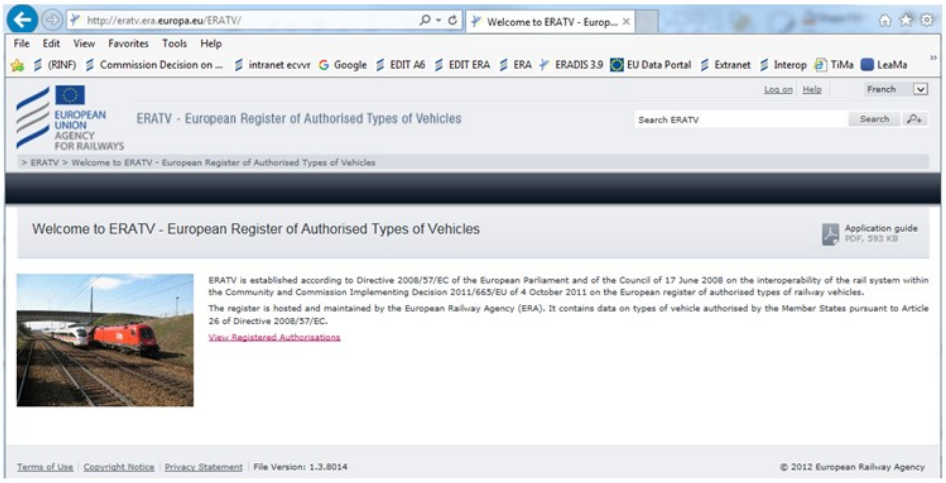
SRD



- Existing Rules
- Draft Rules
- Acceptable National Means of Compliance
- Classifications (VA NRs)
- Record of rule notifications and evaluation

European Register of Authorised Types of Vehicles ERATV

- Contains authorised vehicle type
- In operation since beginning of 2013
- 840 type authorisations in ERATV as of today.
- Publicly available: https://eratv.era.europa.eu/eratv



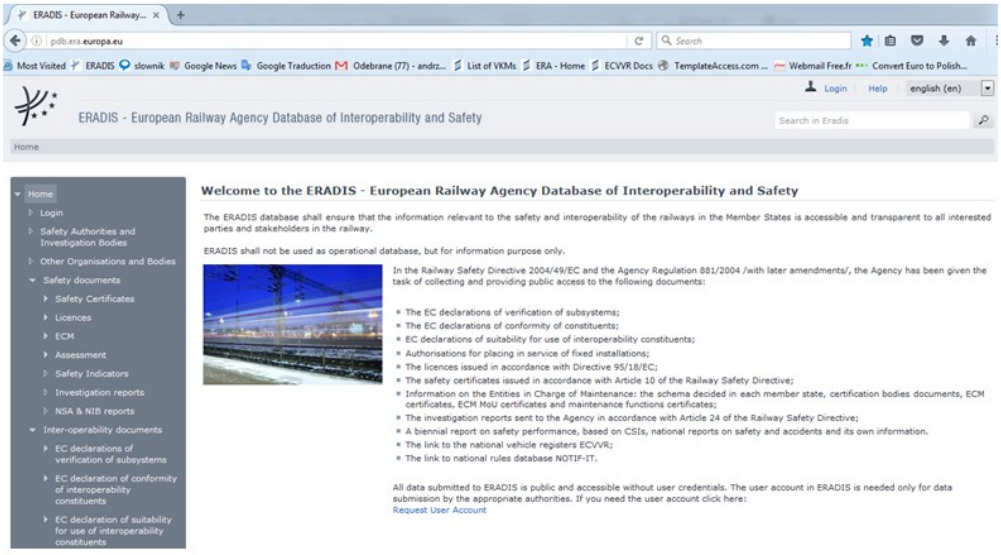
ERATV

- Applicant:
  - Responsible for the integrity of the data provided to the authorising entity.
  - Can fill-in part of the required data (technical data) on behalf of the authorising entity.

- Authorising entity:
  - Always issues a vehicle type authorisation even if the applicant has requested to have only a vehicle authorisation for placing on the market.
  - Responsibility for the data recorded in ERATV

ERA Database on Interoperability and Safety ERADIS

- Contains certificates, declarations
- Publicly available: http://eradis.era.europa.eu



ERADIS

- Applicant of subsystem, Manufacturer of ICs:
  - Submits EC declarations
- NoBo:
  - Submits EC certificates
- DeBo:
  - No obligation however, the principle of ''mutatis mutandis'' could be applied
- Authorising entity:
  - Ensures that ERADIS is updated before issuing authorisation

Register of Infrastructure RINF

- Provides main features of the European Railway infrastructure.
- Publicly available: http://rinf.era.europa.eu/RINF
- In particular, provides the value of the parameters to be used to check the compatibility between vehicle and route
- May be used for vehicle authorisation when RINF is referenced by TSIs (e.g TSI Loc&Pas 4.2.8.2.9.4.2 on contact strip) or NRs

RINF current state


North Sea
Baltic Sea
Bay of Biscay
NORWAY
SWEDEN
FINLAND
Stockholm
Helsinki
Tallinn
ESTONIA
Riga
LATVIA
LITHUANIA
Minsk
BELARUS
Gdańsk
Kaliningrad
Vilnius
Warszawa
Białystok
Brest
Lviv
Ternopil'
Khmel'nits'kyy
Vinnitsa
Kyiv
Luts'k
UKRAINE
Rovaniemi
Oulu
Tampere
Turku
Mikkeli
Pskov
Saint Petersburg
Gothenburg
Oslo
Trondheim
Bergen
Copenhagen
Malmö
Aarhus
Esbjerg
Hamburg
Bremen
Hannover
Berlin
Dresden
Leipzig
Frankfurt
Köln
Düsseldorf
Dortmund
Essen
Amsterdam
Rotterdam
Utrecht
Eindhoven
Groningen
Arnhem
Nijmegen
Antwerpen
Gent
Brussels
Liège
Charleroi
Luxembourg
Metz
Nancy
Strasbourg
Mulhouse
Basel
Zürich
Bern
Lausanne
Geneva
Milan
Turin
Genoa
Monaco
Marseille
Nice
Lyon
Grenoble
Montpellier
Nîmes
Toulouse
Bordeaux
Tours
Orléans
Paris
Le Havre
Caen
Rouen
Lille
Calais
Dunkerque
Reims
Metz
Nancy
Dijon
Besançon
Belfast
Douglas
Newcastle
Liverpool
Manchester
Birmingham
Cardiff
Swansea
Dublin
Cork
Limerick
Galway
Rosslare
Waterford
Le Mans
Angers
Nantes
Rennes
Brest
Quimper
Lorient
Vannes
Saint-Nazaire
La Rochelle
Poitiers
Limoges
Clermont-Ferrand
Saint-Étienne
Valence
Avignon
Arles
Nîmes
Montpellier
Perpignan
Narbonne
Carcassonne
Toulouse
Pau
Bayonne
Hendaye
Irún
San Sebastián
Bilbao
Santander
Oviedo
Gijón
A Coruña
Vigo
Pontevedra
Santiago de Compostela
Lugo
Ourense
Zamora
Salamanca
Valladolid
Palencia
León
Burgos
Vitoria-Gasteiz
Logroño
Pamplona
Huesca
Lleida
Tarragona
Barcelona
Girona
Figueres
Zaragoza
Teruel
Castellón de la Plana
Valencia
Alicante
Murcia
Cartagena
Albacete
Cuenca
Guadalajara
Madrid
Toledo
Ciudad Real
Puertollano
Córdoba
Sevilla
Huelva
Cádiz
Jerez de la Frontera
Algeciras
Málaga
Granada
Almería
Jaén
Linares-Baeza
Badajoz
Mérida
Cáceres
Plasencia
Salamanca
Zamora
Porto
Aveiro
Coimbra
Figueira da Foz
Leiria
Lisboa
Setúbal
Évora
Beja
Faro
Portimão
Lagos
Sagres
Tavira
Vila Real de Santo António
Ayamonte
Huelva
Sevilla
Córdoba
Jaén
Linares-Baeza
Albacete
Cuenca
Guadalajara
Madrid
Toledo
Ciudad Real
Puertollano

NVR

- Vehicle Keeper :
  - Requests vehicle registration
  - Ensures that data submitted is up-to-date and accurate
- Registration Entity (MSs):
  - Grants EVN and Registers vehicles
  - MSs ensures quality and integrity of data registered by the designated registration entity
- When the area of use of the vehicle :
  - Is limited to one MS: vehicle is registered in the NVR of that MS.
  - Covers more than one MSs: the keeper decides in which MS to register the vehicle, the registration is done in one NVR.
- When the area of use of the vehicle is extended :
  - vehicle is registered only in the NVR of the MS where the vehicle was authorised. In any case the registration is done in just one NVR.

Questions?



Vehicle authorisation and route compatibility checks

Article 21 Directive (EU) 2016/797

Article 23 Directive (EU) 2016/797

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Vehicle Authorisation & Checks before use of vehicles

Applicant defines and demonstrates:

- ❑ **Area of use** (e.g France, Belgium)
- ❑ **Vehicle Technical compatibility with the Network(s) of the area of use** (e.g 3kV, 25kV, KVB, TBL1+, D4 etc.)
- ❑ **Conditions for use and other restrictions** (e.g max speed 140km/h)

Railway Undertaking checks using its SMS process :

- ❑ Vehicle(s) is authorised and Registered
- ❑ Compatibility between Vehicle(s) and indented Route(s)
- ❑ Proper integration in the train composition

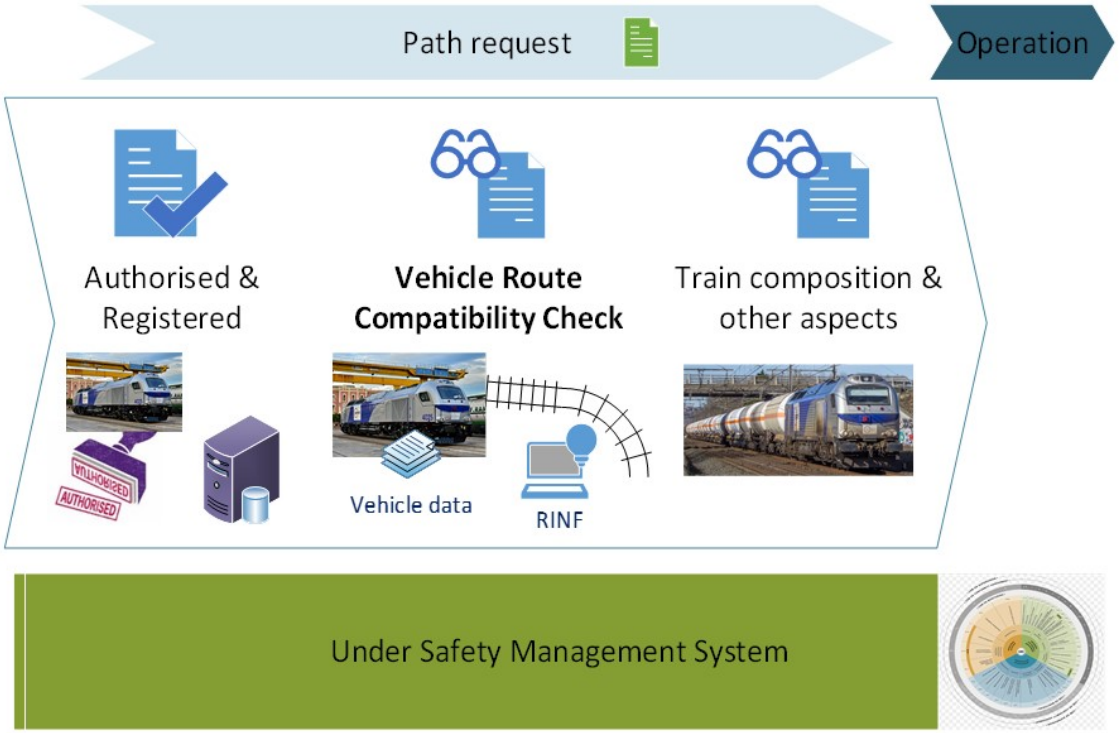
Vehicle authorisation for placing on the Market (art 21)



Checks before the use of authorised vehicles (art 23)



Checks before use of vehicles



Compatibility check between Vehicle and Route

RU task

Most of the Route compatibility items require a simple comparison

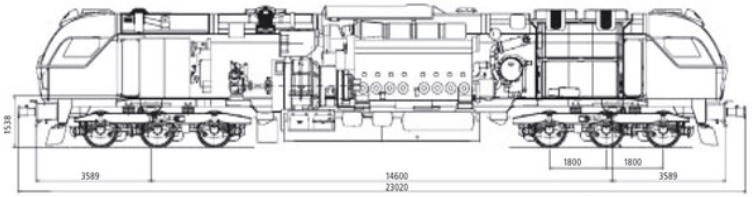
Interface	Vehicle data in ERATV and technical file		Route information available in RINF or provided by IM		Results
	ERATV	Value	RINF ref	Value	
Gauge	4.2.1	G1	1.1.1.1.3.1.1 1.2.1.0.3.4	G1	☺
Train detection systems	4.14.1	track circuits axle counters loops	1.1.1.3.7.1	track circuits axle counters	☺
Wheel set gauge	4.1.3	1435 mm	1.1.1.1.4.1 1.2.1.0.4.1	1435 mm	☺
Minimum in-service wheel diameter	4.8.2	991 mm	1.1.1.1.5.2	330 mm	☺

Compatibility check between Vehicle and Route

RU task

Some items to be checked need specific competencies
(e.g Traffic loads and load carrying capacity of infrastructure)

RU performs static and dynamic compatibility checks with the IM procedures

Interface	Vehicle data in ERATV and technical file		Route information available in RINF or provided by IM		Results
	ERATV	Value	RINF ref	Value	
• Design mass (working order, normal and exceptional payload), 4.5.2 : 121000 kg • Static axle load (working order, normal and exceptional payload), 4.5.3: 20160 kg • Maximum design speed , 4.1.2.1 : 120km/h • Vehicle length, 4.8.1 : 23,02m • Position of the axles along the unit (axle spacing): 					Compatible with lines classified D4

Questions?



Authorisation of vehicles from third countries

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Authorisation of vehicles from third countries

Vehicles from third countries are covered by a different regime:

- Article 21(16) of Directive (EU) 2016/797 - Freight wagons and passenger coaches in shared use with third countries, the track gauge of which is different from that of the main rail network within the Union
  - Different VA procedure (rules of this procedure to be notified to the European Commission)
  - Conformity of vehicles with the ERs ensured by the railway undertaking
- Article 21(17) of Directive (EU) 2016/797 - Locomotives and self-propelling trains arriving from third countries until a station that is situated close to the border
  - Vehicle authorisation for placing on the market not mandatory
  - Conformity of vehicles with the essential requirements ensured by the railway undertaking

Slide 78

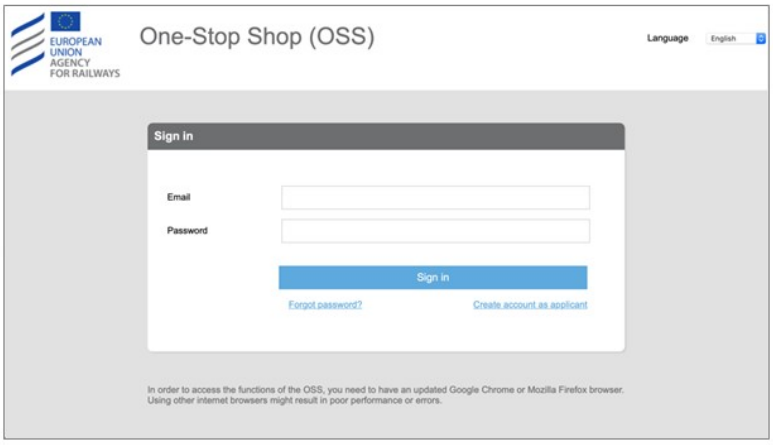
Introduction to the One Stop Shop

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EUROPEAN UNION AGENCY FOR RAILWAYS

The One-Stop Shop

The one-stop-shop (OSS) is the IT system designed, developed and managed by the Agency through which all applications for single safety certificates, vehicle authorisations and vehicle type authorisations shall be submitted either to the relevant National Safety Authority or to the Agency.



Purpose of the One-Stop Shop

The one-stop shop shall be used by the applicants irrespective of the intended area of operation or area of use (one or more Member States).

The One-Stop Shop will enable efficient and effective communication between all the organisations involved in the process:

- all issues identified by the respective authority during the assessment,
- the replies of the applicant, and
- the final decision

will be communicated with the use of the one-stop-shop.

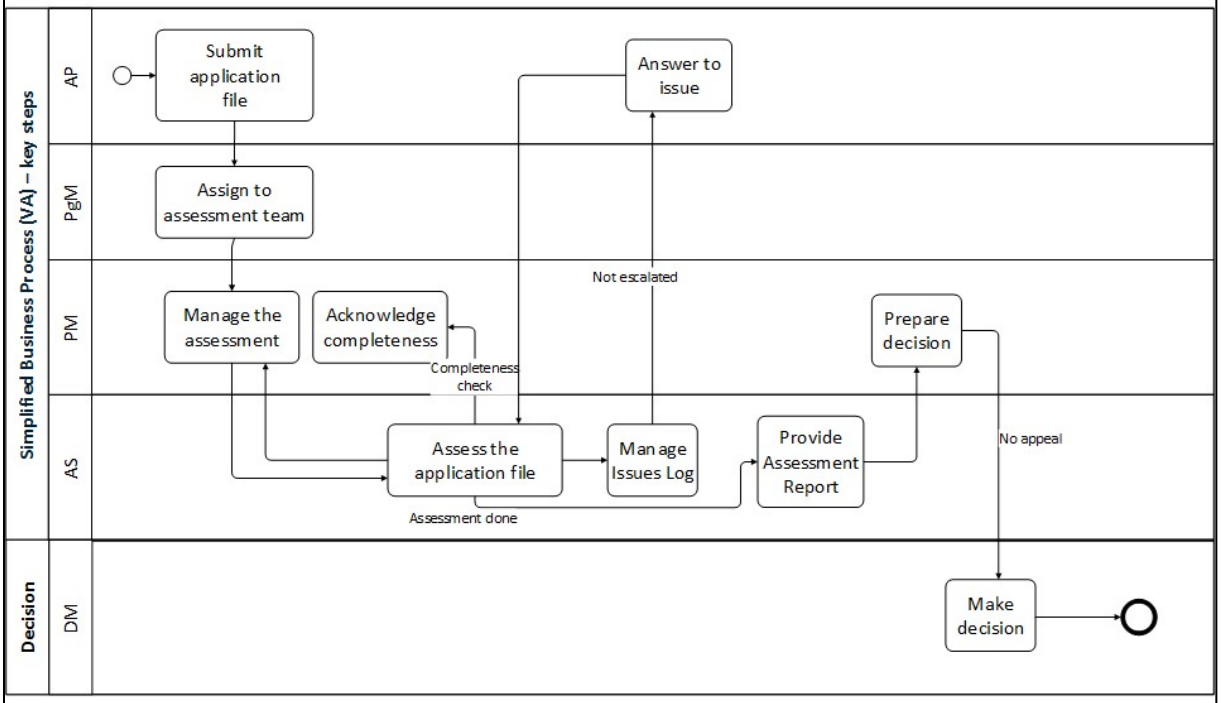
Users management in the One-Stop Shop

All users representing the Agency and the NSAs shall be registered in advance in the one-stop-shop by their own organizations.



An applicant, before submitting its application, shall go through the registration process.

OSS Simulation



Questions?



Cooperation agreements

EUROPEAN UNION AGENCY FOR RAILWAYS

Cooperation Agreements – State of play

- The Management Board of the Agency has adopted, in June 2018, guidelines and the list of main elements
- The NSA sub-group has reached an agreement on draft cooperation agreements clauses
- The Agency is currently engaged in bilateral meetings with NSAs to conclude with each of them the relevant cooperation agreement
- Cooperation is needed over the results from Supervision and Assessment

Slide 86

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Questions?



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Discover our job opportunities on **era.europa.eu**

ISO 9001:2015 BUREAU VERITAS Certification

4. Antoine Defosses, Nordine Bousouff: Vehicle authorisation in the framework under 4th Railway Package

Vehicle authorisation in the framework of the 4th Railway Package

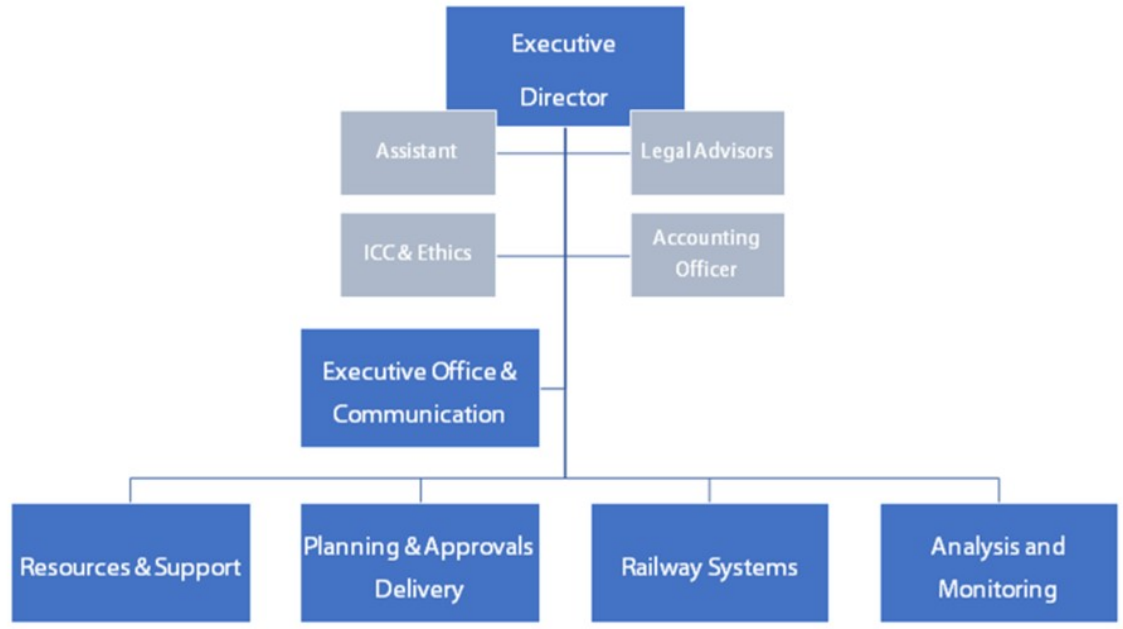
Antoine DEFOSSEZ, Nordine BOUSSOUF

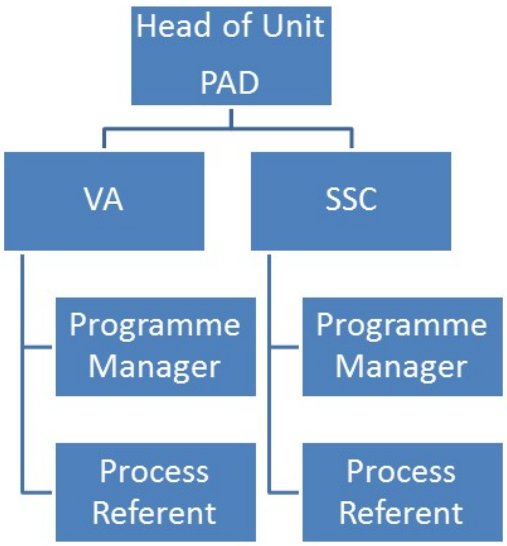
Zagreb, 2 October 2019

EUROPEAN UNION AGENCY FOR RAILWAYS

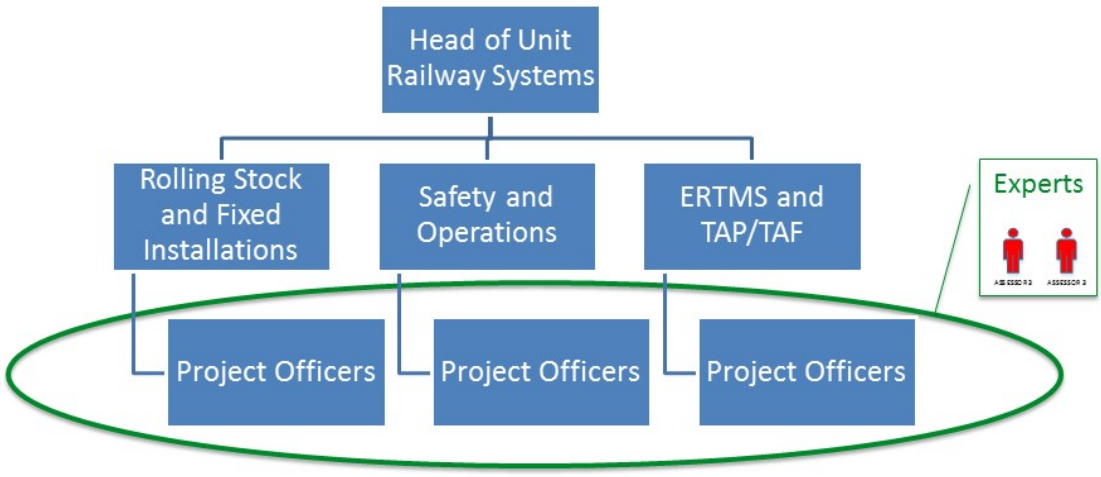
ERA organisation

- **Matrix based organisation** in place since July 2018
- **Planning and Approvals Delivery Unit** in charge of the portfolio of programme, projects and services at ERA and management of certification/authorisation/approval activities
- **Technical coordinator** for the technical coordination of VA/SSC projects and **programme manager** for the planning and monitoring of VA/SSC projects
- Close coordination with other Units for the assignment of staff to VA/SSC projects
- Decision taken by the Executive Director (or one of his delegates)





Note: not all functions represented



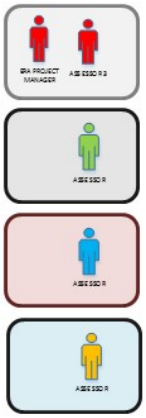
Note: not all functions represented

ERA organisation

- **All applications** for single safety certificates or vehicles authorisations are **projects**.
- ERA appoints a **project team** for the part of the assessment it is responsible for
- The **project manager** is responsible for the coordination of the assessment. S/he is the **contact point** for the applicant and the NSA(s) concerned.

Example of organisation

- Applicant request: EMUs to be authorised for an AoU in AT, DE, IT



ERA

NSA AT

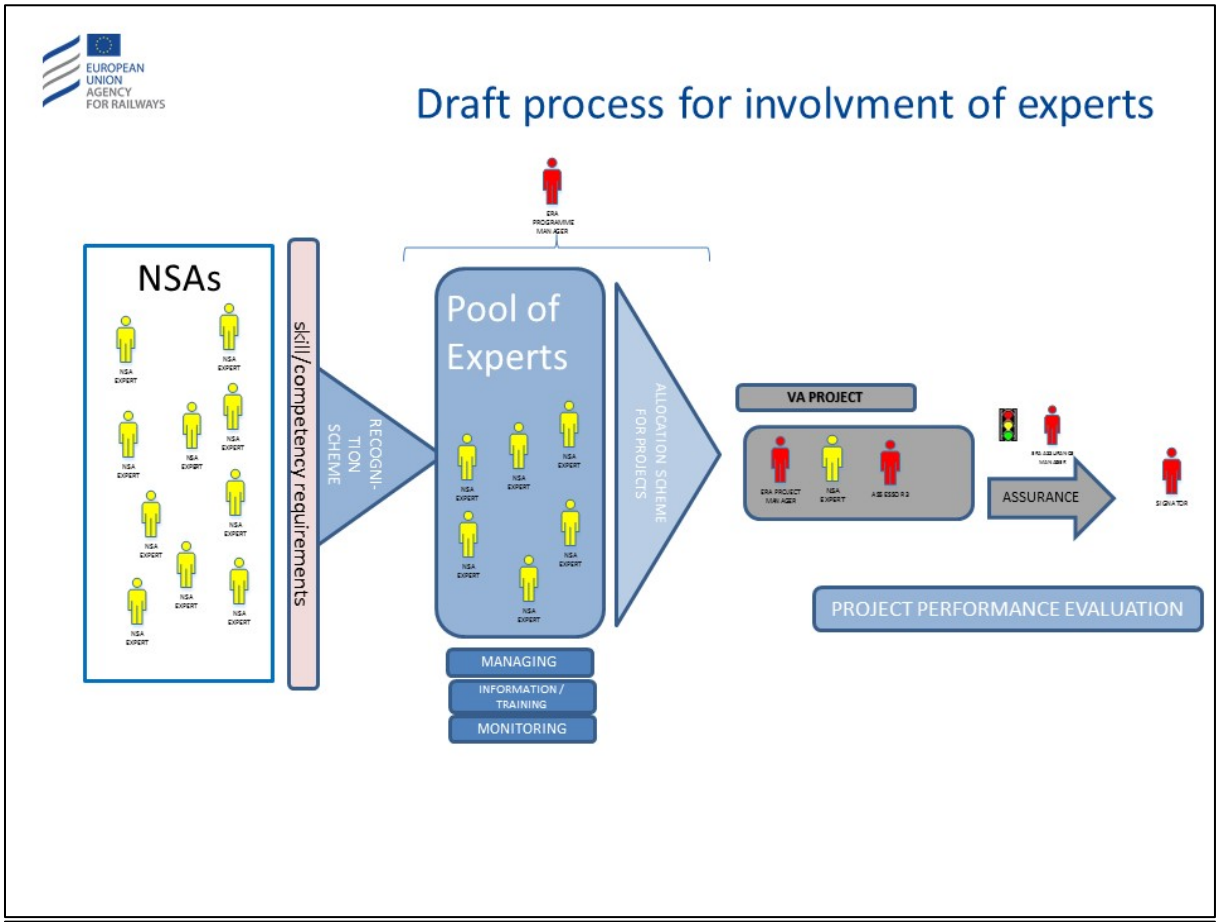
NSA DE

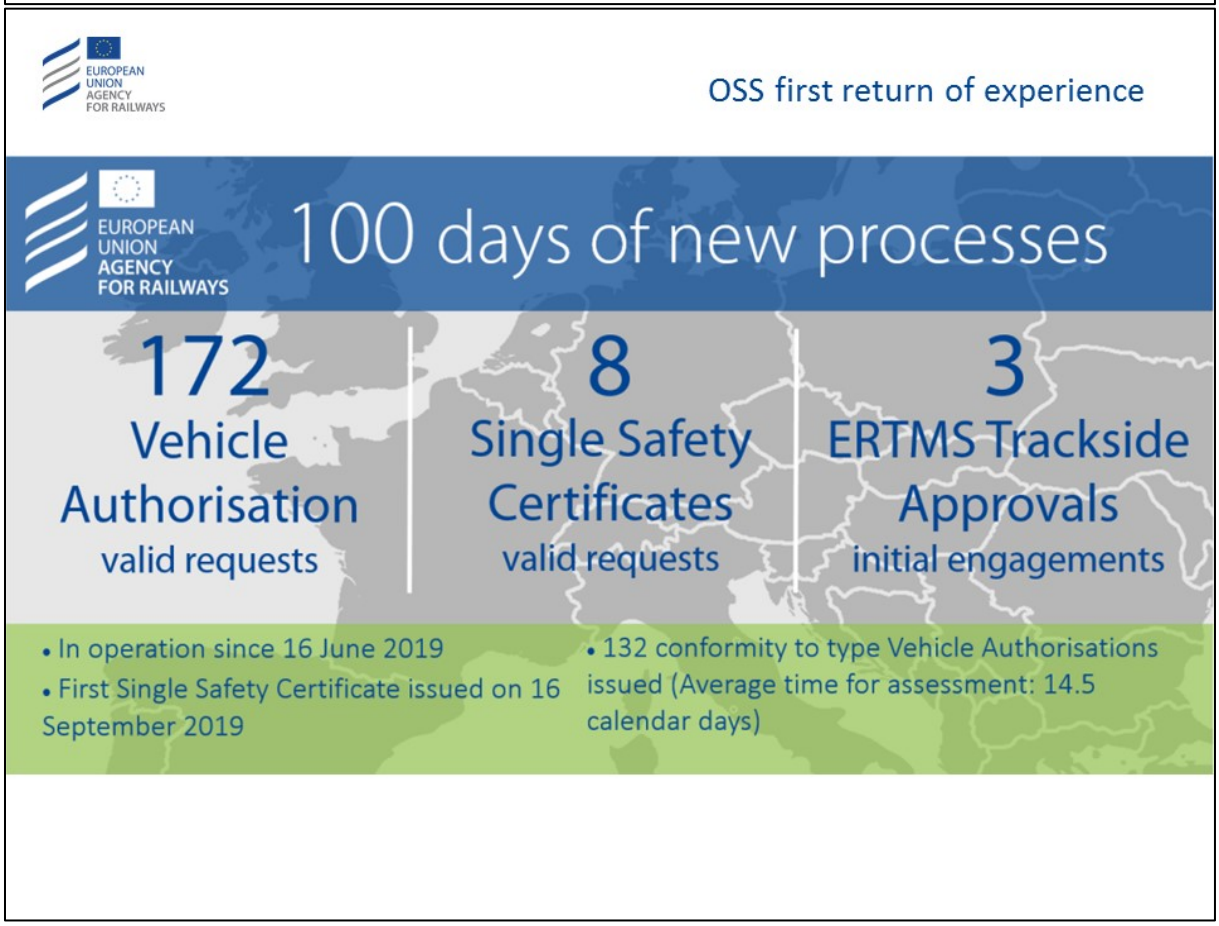
NSA IT

Who will be the Authorising entity ?

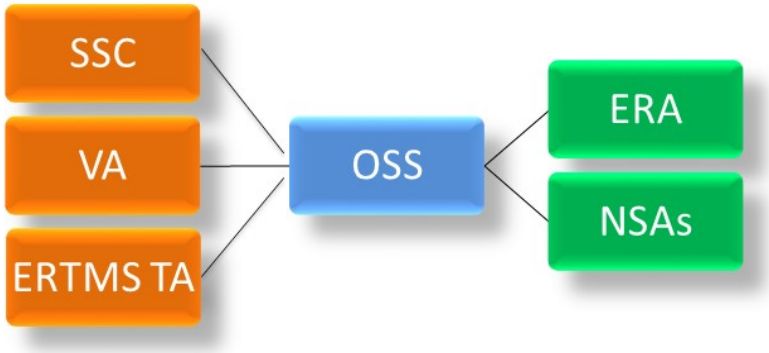
Assistance of ERA: the Pool of Experts

- The Pool of Experts (PoE) refers to a group of experts who will assist the Agency in the performance of its tasks (SSC, VA, ERTMS Tks), by providing advice the Agency
- All the experts who are nominated to the Pool of Experts by their NSA have to meet the "Skill/competency requirements" as defined in the "Role descriptions"
- Before being allocated to an application/assessment team, experts must have followed the dedicated training week.


EUROPEAN UNION AGENCY FOR RAILWAYS
Draft process for involvment of experts
NSAs
skill/competency requirements
RECOGNI-TION SCHEME
Pool of Experts
ALLOCATION SCHEME FOR PROJECTS
VA PROJECT
ASSURANCE
PROJECT PERFORMANCE EVALUATION
MANAGING
INFORMATION / TRAINING
MONITORING


EUROPEAN UNION AGENCY FOR RAILWAYS
OSS first return of experience
EUROPEAN UNION AGENCY FOR RAILWAYS
100 days of new processes
172
Vehicle Authorisation
valid requests
8
Single Safety Certificates
valid requests
3
ERTMS Trackside Approvals
initial engagements
• In operation since 16 June 2019
• First Single Safety Certificate issued on 16 September 2019
• 132 conformity to type Vehicle Authorisations issued (Average time for assessment: 14.5 calendar days)

One-Stop Shop (OSS)



- OSS in partial service since 16 February 2019
- Full operation since 16 June 2019
- **Availability 98,7%**
  - 7 hours unavailability due problems with SRM licenses, IT infrastructure problem, planned IT maintenance, new release put in production)
  - Target 99%
- 172 valid requests for Vehicle Authorisation
- **132 Decisions** already made (Conformity to Type)
- ERA issued the first SSC to CFL (**Luxembourg**) in mid-September



Cooperation Agreements – State of play

- The Management Board of the Agency has adopted, in June 2018, guidelines and the list of main elements
- The NSA sub-group has reached an agreement on draft cooperation agreements clauses
- The Agency is currently engaged in bilateral meetings with NSAs to conclude with each of them the relevant cooperation agreement
- Cooperation is needed over the results from Supervision and Assessment

EUROPEAN UNION AGENCY FOR RAILWAYS

Questions?



5. Vili Milković: Usporedbe (razlike) s postojećim nacionalnim postupkom u autorizaciji vozila – promjene u pravnom obliku

ASŽ Agencija za sigurnost željezničkog prometa

USPOREDBE (RAZLIKE) S POSTOJEĆIM NACIONALNIM POSTUPKOM U AUTORIZACIJI VOZILA. PROMJENE U PRAVNOM OBLIKU

mr.sc.Vili Milković,dipl.ing.stroj.

ASŽ Agencija za sigurnost željezničkog prometa

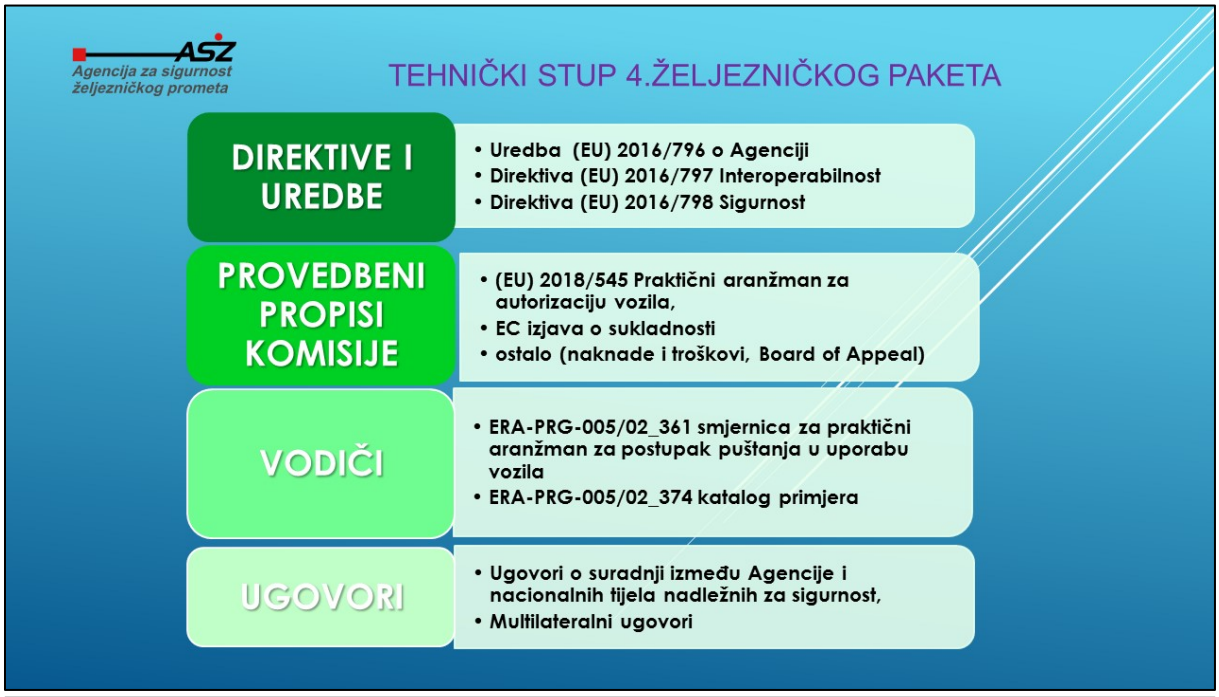
POVIJEST PRAVNOG OKVIRA EUROPSKE UNIJE ZA ŽELJEZNICU

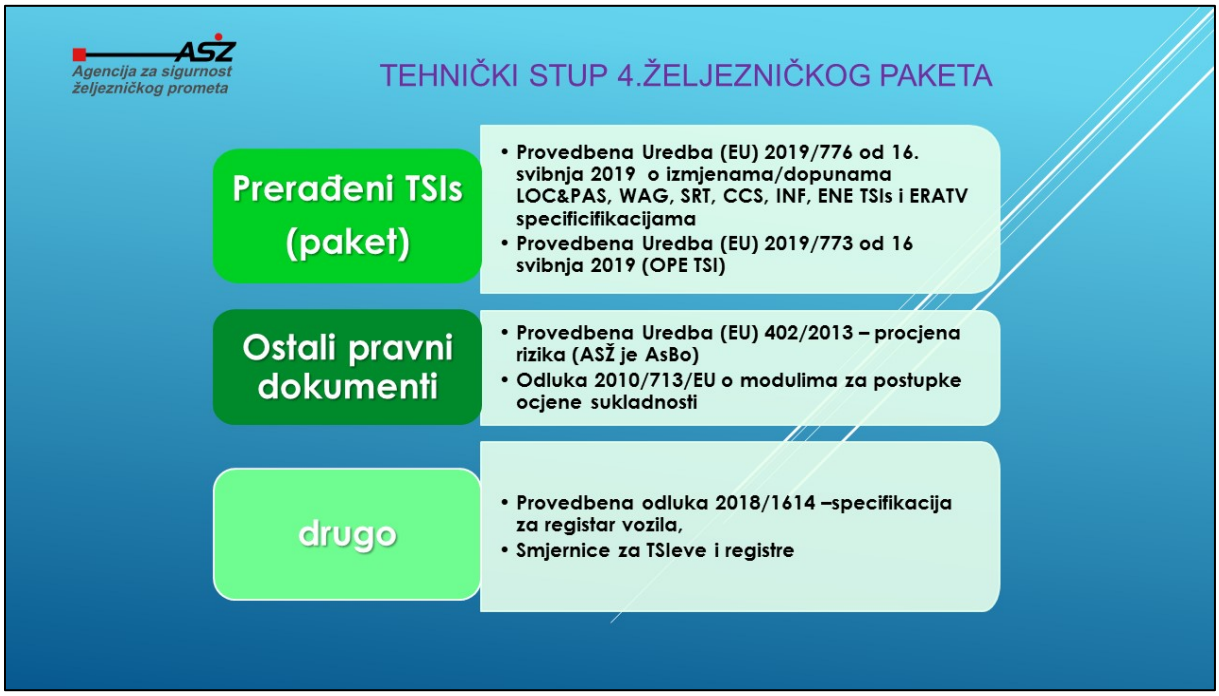
2004 • **Drugi željeznički paket:** izmijenjena direktiva operabilnosti (pokrivanje TEN mreže), Direktiva sigurnosti 2004/49/CE i Uredba 881/2004 (osnivanje Europske Agencije za željeznicu)

2007 • **Treći željeznički paket :** osigurana bolja prava putnika, otvaranje tržišta za međunarodne usluge željeznice (od siječnja 2010), Europska dozvola za strojovođe

2008 • Direktiva interoperabilnosti 2008/57/EC pokrivenost svih željezničkih mreža Direktiva 2008/110/EC – izmjena Direktive za sigurnost (ECM uveden)

2016 • **Četvrti željeznički paket (technical pillar):** velika revizija propisa ERA, direktive za sigurnost i interoperabilnost, nove uloge i odgovornosti za ERA ERA, jedinstveni certifikati za sigurnost i poboljšanje procesa autorizacije željezničkih vozila


ASŽ Agencija za sigurnost željezničkog prometa
TEHNIČKI STUP 4.ŽELJEZNIČKOG PAKETA
DIREKTIVE I UREDBE
• Uredba (EU) 2016/796 o Agenciji
• Direktiva (EU) 2016/797 Interoperabilnost
• Direktiva (EU) 2016/798 Sigurnost
PROVEDBENI PROPISI KOMISIJE
• (EU) 2018/545 Praktični aranžman za autorizaciju vozila,
• EC izjava o sukladnosti
• ostalo (naknade i troškovi, Board of Appeal)
VODIČI
• ERA-PRG-005/02_361 smjernica za praktični aranžman za postupak puštanja u uporabu vozila
• ERA-PRG-005/02_374 katalog primjera
UGOVORI
• Ugovori o suradnji između Agencije i nacionalnih tijela nadležnih za sigurnost,
• Multilateralni ugovori


ASŽ Agencija za sigurnost željezničkog prometa
TEHNIČKI STUP 4.ŽELJEZNIČKOG PAKETA
Prerađeni TSIs (paket)
• Provedbena Uredba (EU) 2019/776 od 16. svibnja 2019 o izmjenama/dopunama LOC&PAS, WAG, SRT, CCS, INF, ENE TSIs i ERATV specificifikacijama
• Provedbena Uredba (EU) 2019/773 od 16 svibnja 2019 (OPE TSI)
Ostali pravni dokumenti
• Provedbena Uredba (EU) 402/2013 – procjena rizika (ASŽ je AsBo)
• Odluka 2010/713/EU o modulima za postupke ocjene sukladnosti
drugo
• Provedbena odluka 2018/1614 –specifikacija za registar vozila,
• Smjernice za TSIeve i registre

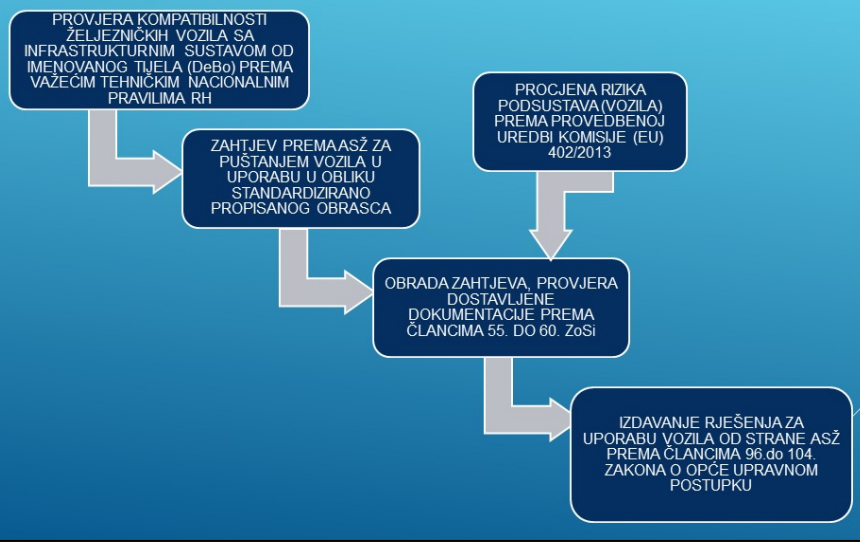
AUTORIZACIJA VOZILA – VAŽEĆE ZAKONODAVSTVO U RH

- Zakon o sigurnosti i interoperabilnosti željezničkog sustava (NN 82/13; 18/15; 110/15 i 70/17) – implementirane odredbe 2. i 3. željezničkog paketa za autorizaciju vozila od strane ASŽ, **Direktiva 2004/49/EZ Europskog parlamenta**
- Nadležnosti ASŽ – članak 9. stavak 3.c) Zakon o sigurnosti i interoperabilnosti željezničkog sustava - **izdavanje odobrenja za puštanje u uporabu strukturnih podsustava (infrastrukturni podsustavi i vozila);**
- Postupak odobravanja željezničkih vozila za promet definiran je člancima 55. do 61. (Prvo i dodatno odobrenje za sukladnost i nesukladnost važećim TSI-jevima),

AUTORIZACIJA VOZILA–VAŽEĆE ZAKONODAVSTVO U RH

- Željezničko vozilo prije odobrenja za uporabu prolazi provjeru imenovanog tijela (DEsignated BOdy-DEBO- ustanova ovlaštena i definirana Zakonom od MMPI),
- Imenovano tijelo provjeru provodi prema važećim nacionalnim tehničkim pravilima (propisima) – Pravilnik o željezničkim vozilima (NN 121/15), Pravilnik o tehničkim uvjetima za PU i SS željeznički infrastrukturni podsustav (NN 97/15) itd.
- Izdavanje Rješenja od strane ASŽ za uporabu željezničkog vozila prema člancima 96. do 104. Zakona o opće upravnom postupku (NN 47/09).

AUTORIZACIJA VOZILA–VAŽEĆE ZAKONODAVSTVO U RH



AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA

DIREKTIVA (EU) 2016/797 EUROPSKOG PARLAMENTA I VIJEĆA OD 11. SVIBNJA 2016. O INTEROPERABILNOSTI ŽELJEZNIČKOG SUSTAVA EUROPSKOJ UNIJI

- Kako bi se doprinijelo dovršetku jedinstvenog europskog željezničkog prostora, smanjili troškovi i trajanje postupaka izdavanja odobrenja te poboljšala sigurnost željeznica, prikladno je racionalizirati i uskladiti postupke izdavanja odobrenja na razini Unije.
- Kako bi se olakšalo stavljanje vozila na tržište i smanjila administrativna opterećenja, trebalo bi uvesti koncept odobrenja za stavljanje vozila na tržište koje će vrijediti u cijeloj Uniji. Iako odobrenja za stavljanje na tržište omogućuju trgovanje vozilima na cijelom tržištu Unije, vozilo se može koristiti samo na području uporabe koje je obuhvaćeno njegovim odobrenjem.
- U tom kontekstu, svako proširenje područja uporabe trebalo bi podlijegati ažuriranom odobrenju za vozilo.
- Potrebno je da vozila za koja su već izdana odobrenja na temelju prijašnjih direktiva također dobiju odobrenje za stavljanje na tržište ako su namijenjena korištenju na mrežama koje nisu obuhvaćene njihovim odobrenjem.

AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA

DIREKTIVA (EU) 2016/797 EUROPSKOG PARLAMENTA I VIJEĆA OD 11. SVIBNJA 2016. O INTEROPERABILNOSTI ŽELJEZNIČKOG SUSTAVA EUROPSKOJ UNIJI

- Ako je područje uporabe ograničeno na mrežu ili mreže u jednoj državi članici, podnositelj zahtjeva trebao bi moći odabrati hoće li zahtjev za izdavanje odobrenja za vozilo putem jedinstvene kontaktne točke iz Uredbe (EU) 2016/796 podnijeti nacionalnom tijelu nadležnom za sigurnost te države članice ili Agenciji.
- Odabir podnositelja zahtjeva trebao bi biti obvezujući do trenutka u kojem je postupak podnošenja zahtjeva završen ili prekinut.

Agencija za sigurnost željezničkog prometa

AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA

PROVEDBENA UREDBA KOMISIJE (EU) 2018/545 – za postupak odobravanja željezničkih vozila i postupak odobavanja tipa željezničkih vozila u skladu s direktivom 2016/797 EU

- Praktični aranžmani za postupak odobravanja vozila iz Direktive (EU) 2016/797 trebali bi smanjiti složenost, trajanje i trošak postupka odobravanja vozila, osigurati jedinstvene uvjete za usklađivanje odobrenja za tip vozila i/ili odobrenja za stavljanje vozila na tržište u Uniji i promicati suradnju među svim stranama uključenima u postupak odobrenja vozila. Kako bi se smanjili trajanje i trošak postupka odobravanja vozila, rokovi bi u stvarnosti trebali biti što kraći.

AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA

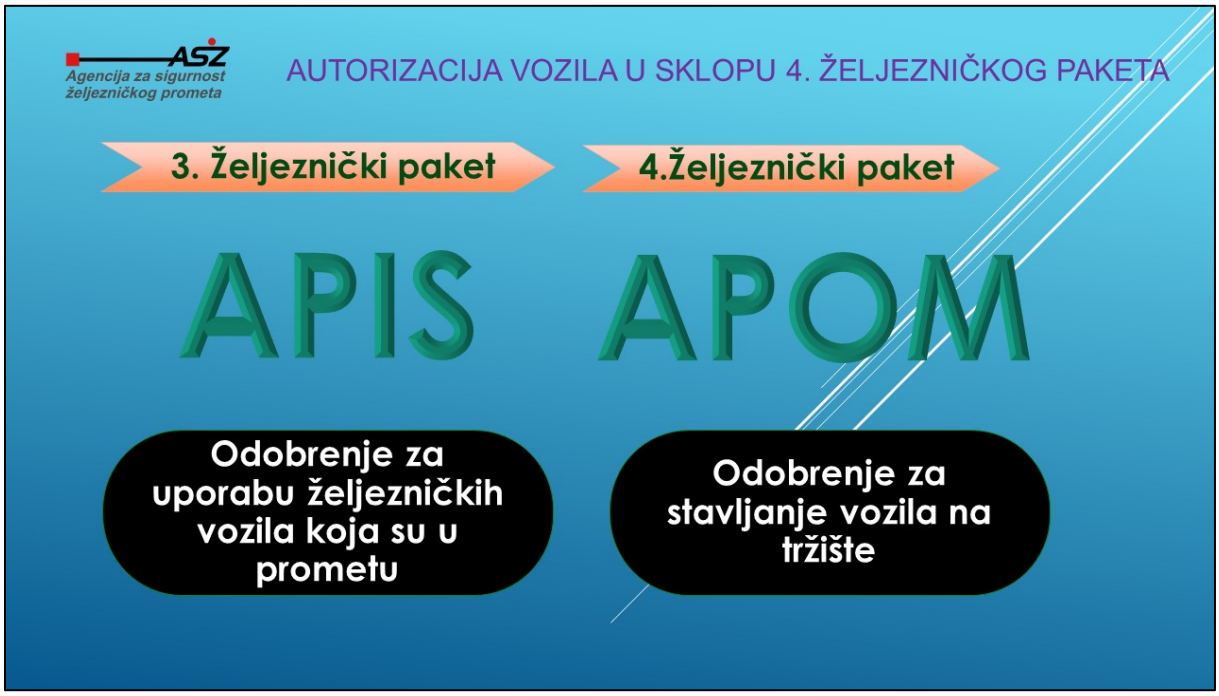
Preliminarni postupak

- Dobrovoljno za podnositelja, obavezan za subjekta koji ovlašćuje / NSAi za područje uporabe ukoliko se traži,
- Sadržaj podnošenja zahtjeva : prema članku 23 provedbene Uredbe(EU) 2018/545
- Osnovno:
  - -Mišljenje subjekta za ovlašćivanje i nacionalnih tijela za sigurnost za područje uporabe za pristup (strategiju) predloženu od strane podnositelja zahtjeva.
  - -Pristup (strategija) je propisana u dokumentima koji su navedeni u članku 23 Provedbene Uredbe (EU) 2018/545
  - -Rok ne duži od 84 mjeseca,
  - -Davanje uvjerenja podnositelju zahtjeva

Agencija za sigurnost željezničkog prometa
AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA
Preliminarni postupak

- Preliminarni postupak nije:
  - Konzultantski / trening servis namijenjen podnositelju zahtjeva,
  - Put određivanja kontinuirane procjene.


ASZ Agencija za sigurnost željezničkog prometa
AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA
3.ŽELJEZNIČKI PAKET
4.ŽELJEZNIČKI PAKET
PRVA AUTORIZACIJA VOZILA MS1
DODATNA AUTORIZACIJA VOZILA MS2
DODATNA AUTORIZACIJA VOZILA MS3
JEDINSTVENA AUTORIZACIJA VOZILA


ASZ Agencija za sigurnost željezničkog prometa
AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA
3. Željeznički paket
4.Željeznički paket
APIS
APOM
Odobrenje za uporabu željezničkih vozila koja su u prometu
Odobrenje za stavljanje vozila na tržište

AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA – PREGLED POSTUPKA


Korak 1 Priprema zahtjeva


Korak 2 Preliminarni postupak


Korak 3 Provjera sukladnosti


Korak 4 Podnošenje zahtjeva


Korak 5 Procesuiranje zahtjeva


Korak 6 Završetak provjere dokumentacije


Odbijanje, dopuna ili ispravak

AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA

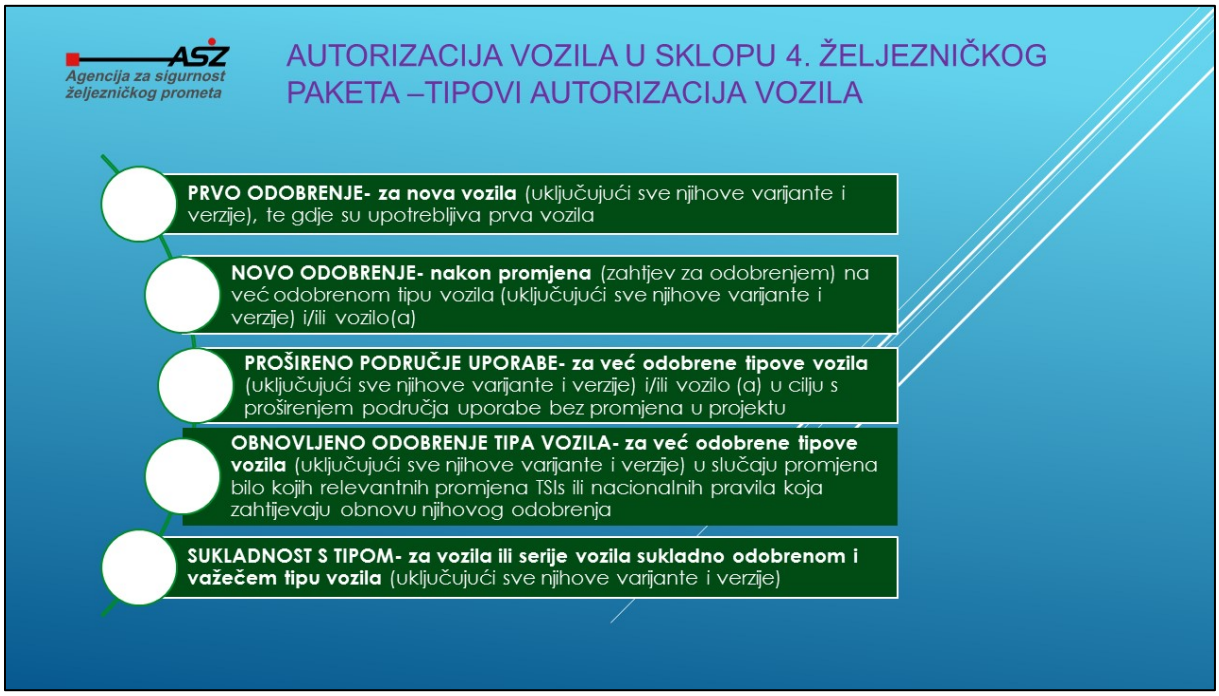
Subjekti ovlašteni za autorizaciju vozila ovise o području uporabe

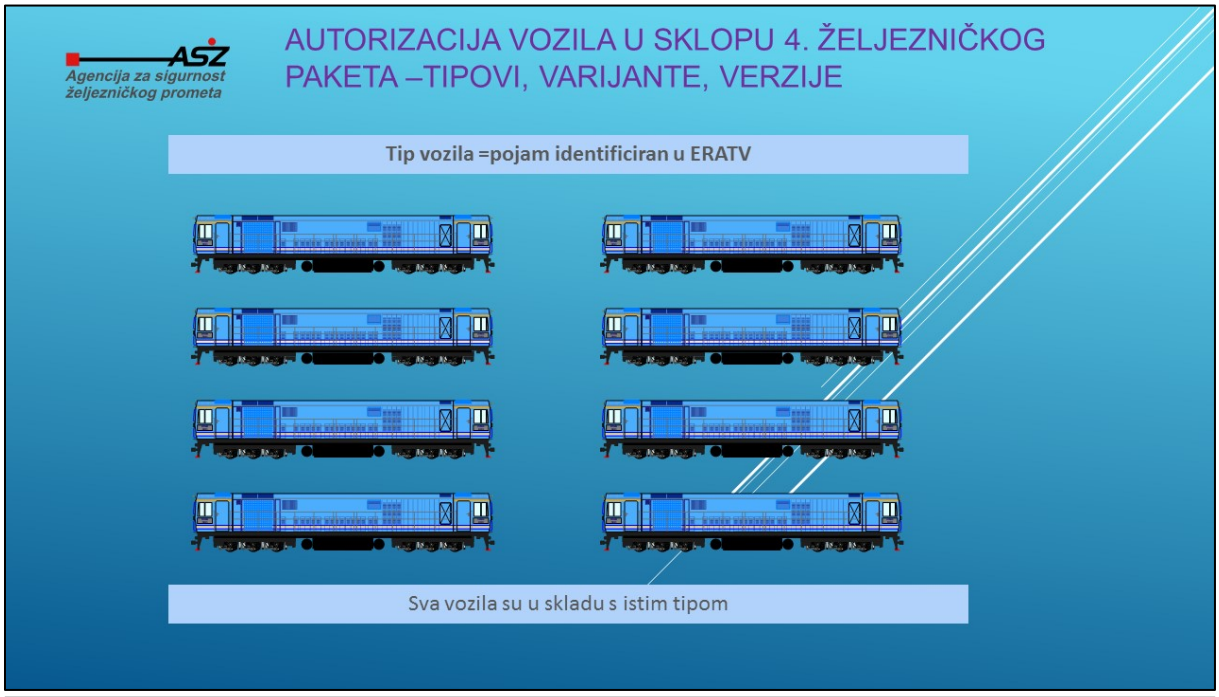
Područje uporabe= više od jedne zemlje članice ERA, u suradnji s nacionalnim tijelima nadlažnim za sigurnost

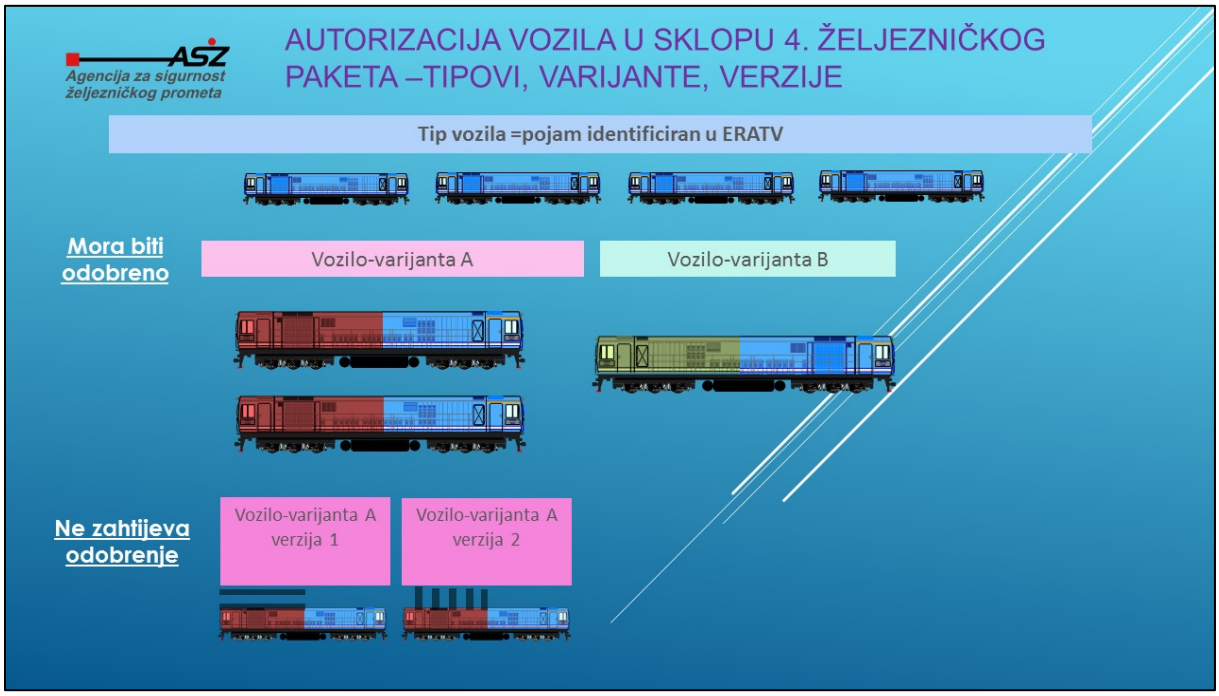
Područje uporabe= jedna zemlja članica,podnositelj zahtjeva može birati Agenciju ili nacionalno tijelo za sigurnost

Svi zahtjevi se adresiraju na jedinstvenu kontaktnu točku


ASŽ Agencija za sigurnost željezničkog prometa
AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA – GLAVNI KORACI U AUTORIZACIJI VOZILA
Podnositelj prilaže zahtjev za autorizaciju vozila preko jedinstvene kontaktne točke (One-Stop- Shop)
• Specifikacija područja uporabe
• Uključujući bitnu dokumentaciju
ERA/NSA izdaju APOM (ili priopćavaju negativnu odluku)
• unutar 4 mjeseca od zaprimanja potpune dokumentacije,slij edeći detaljna pravila iz Reg. (EU) 2018/545
Registracija vozila
Provjera s upraviteljem infrastrukture, uključuje:
• Kompatibilnost s trasom,
• Ispravno uvrštenje u sastav vlaka


ASŽ Agencija za sigurnost željezničkog prometa
AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA –TIPOVI AUTORIZACIJA VOZILA
PRVO ODOBRENJE- za nova vozila (uključujući sve njihove varijante i verzije), te gdje su upotrebljiva prva vozila
NOVO ODOBRENJE- nakon promjena (zahtjev za odobrenjem) na već odobrenom tipu vozila (uključujući sve njihove varijante i verzije) i/ili vozilo(a)
PROŠIRENO PODRUČJE UPORABE- za već odobrene tipove vozila (uključujući sve njihove varijante i verzije) i/ili vozilo (a) u cilju s proširenjem područja uporabe bez promjena u projektu
OBNOVLJENO ODOBRENJE TIPA VOZILA- za već odobrene tipove vozila (uključujući sve njihove varijante i verzije) u slučaju promjena bilo kojih relevantnih promjena TSIs ili nacionalnih pravila koja zahtijevaju obnovu njihovog odobrenja
SUKLADNOST S TIPOM- za vozila ili serije vozila sukladno odobrenom i važečem tipu vozila (uključujući sve njihove varijante i verzije)


Agencija za sigurnost željezničkog prometa
AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA –TIPOVI, VARIJANTE, VERZIJE
Tip vozila =pojam identificiran u ERATV
Sva vozila su u skladu s istim tipom


Agencija za sigurnost željezničkog prometa
AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA –TIPOVI, VARIJANTE, VERZIJE
Tip vozila =pojam identificiran u ERATV
Mora biti odobreno
Vozilo-varijanta A
Vozilo-varijanta B
Ne zahtijeva odobrenje
Vozilo-varijanta A verzija 1
Vozilo-varijanta A verzija 2

AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA –SLUČAJ NOVOG ODOBRENJA (AUTORIZACIJE)

- U kojem slučaju se zahtijeva novo odobrenje (autorizacija)?

Članak 21(12) Direktive (EU) 2016/797

- U slučaju obnove ili modernizacije postojećih vozila koja već imaju odobrenje za stavljanje vozila na tržište, novo odobrenje za stavljanje vozila na tržište potrebno je ako:

(a) se izmijene vrijednosti parametara ikoje su izvan raspona prihvatljivih parametara kako su utvrđeni u TSI-ovima;

(b) bi predviđeni radovi mogli imati negativan učinak na ukupnu razinu sigurnosti dotičnog vozila; ili

(c) to zahtijevaju relevantni TSI-ovi.

AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA – TEHNIČKI ASPEKTI (PRAVILNICI I EC VERIFIKACIJE -ZAHTJEVI

- Zahtjevi pokrivaju:

-osnovne zahtjeve za podsustave,

-Tehničku kompatibilnost podsustava unutar vozila,

-Sigurnu integraciju podsustava unutar vozila,

-Tehničku kompatibilnost vozila s mrežom u području uporabe

- Podnositelj zahtjeva je:

- Odgovoran za izvršavanje postupka zauzeća zahtjeva,
- Uporaba procjene rizika (Aneks I provedbene Uredbe (EU) 402/2013) kao metodologiju za aspekte vezane za sigurnost,
- Može koristiti proces procjene rizika kao metodologiju za druge osnovne zahtjeve.

AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA –TEHNIČKI ASPEKTI (PRAVILNICI I EC VERIFIKACIJE)

- Tijelo za procjenu rizika(CSM RA):

-Daje sigurnost da su procesi sustavni i da se mogu razumjeti, analizirati i umanjiti opasnosti,

-Daje prosudbu ispravne primjene postupka procjene rizika i prikladnosti rezultata,

-Fokus na sam proces. Nije iscrpna provjera svih dokaza koji su potkrijepljeni zahtjevima,

-mogućnost potreba nekih detaljnih procjena (uzorkovanje) (vertikalna procjena ključnih aspekata)

- Tijelo nadležno za odobrenje:

-Provjerava potpunost, relevantnost i dosljednost dokaza (Izjava o riziku, izvješće o sigurnosti) kada se koristi Uredba (EU) 402/2013,

-Može osporiti izvješće o procjeni ako pokazuje postojanje ozbiljnog sigurnosnog rizika,

-Obavlja daljnje provjere upotrebljava li se druga metodologija (kada je dopušteno):

a.) procjena detalja metodologije i
b.) procjena detalja dokaza primjene metodologije

AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA –Tehnički aspekti (pravilnici i EC verifikacije) –TSI poboljšanja,obnova i nova odobrenja, nacionalna pravila

- Načela koja trebaju primijeniti podnositelji zahtjeva i tijela koja daju ovlaštenje,
- Popis (lista) osnovnih konstrukcijskih karakteristika tipa vozila (TSIs LOC & PAS – za vučna vozila –lokomotive i vlakovi, WAG – za teretne vagone..),
- Postojeća nacionalna pravila (članak 13. stavak 2.) ograničena su:

  - ako TSI-i ne obuhvaćaju ili ne pokrivaju u potpunosti neke aspekte koji odgovaraju osnovnim zahtjevima, uključujući otvorene točke kako je navedeno u članku 4. (6) Slučaj u kojem je prijavljeno nepodnošenje jednog ili više TSI-ja ili njihovih dijelova na temelju članka 7. Direktive (EU) 2016/797,

  - ako su specifični slučajevi navedeni, ali nisu opisani u TSI-jevima,

  - ako je osigurana tehnička kompatibilnost s postojećom mrežom koja još nije u skladu s TSI-jem,

AUTORIZACIJA VOZILA U SKLOPU 4. ŽELJEZNIČKOG PAKETA –Tehnički aspekti (pravilnici i EC verifikacije) –TSI poboljšanja,obnova i nova odobrenja, nacionalna pravila

- **Postojeća nacionalna pravila** (članak 13. stavak 2.) ograničena su :

- ako su vozila isključena iz područja TSI-ja i

- U slučaju hitna privremena preventivna mjera, posebno nakon nesreće.

- **Nova nacionalna pravila** mogu se primijeniti samo u sljedećim slučajevima (članak 14. stavak 4.):

- kad TSI ne ispunjava u potpunosti osnovne zahtjeve;

- kao hitna preventivna mjera, posebno nakon nesreće.

PITANJA I NEPOZNANICE U SVEZI ZADAĆA ASŽ U AUTORIZACIJI VOZILA NAKON STUPANJA NA SNAGU 4.ŽELJEZNIČKOG PAKETA

- AGENCIJA ZA SIGURNOST ŽELJEZNIČKOG PROMETA IZDAJE DOZVOLE ZA UPORABU VOZILA U OBLIKU RJEŠENJA PREMA članku 96. ZAKONA O OPĆEM UPRAVNOM POSTUPKU KAO PRAVNA OSOBA S JAVNIM OVLASTIMA – PITANJE – kako će se u budućnosti i na koji način izdavati (Rješenja) certifikati za puštanje vozila na željezničko tržište?,

Agencija za sigurnost željezničkog prometa

IZVORI I LITERATURA

1. **(EU) 2018/545 Praktični aranžman za autorizaciju vozila**
2. **Uredba (EU) 2016/796 o Agenciji**
3. **Direktiva (EU) 2016/797 o Interoperabilnosti**
4. **Direktiva (EU) 2016/798 Sigurnost**
5. Zakon o sigurnosti i interoperabilnosti željezničkog sustava (NN 82/13; 18/15; 110/15 i 70/17)
6. Prezentacije u PowerPointu sa raznih radionica Agencije EU za željeznicu

Agencija za sigurnost željezničkog prometa

HVALA NA PAŽNJI!

6. David Kupfer: Fourth railway package – the rail manufacturing industry's expectations

Fourth Railway Package
The rail manufacturing industry's expectations

David Kupfer
Technical Affairs Manager
UNIFE

-

Workshop on the technical pillar of the 4RP, 2nd day
Zagreb, 02 October 2019

WWW.UNIFE.ORG

About UNIFE

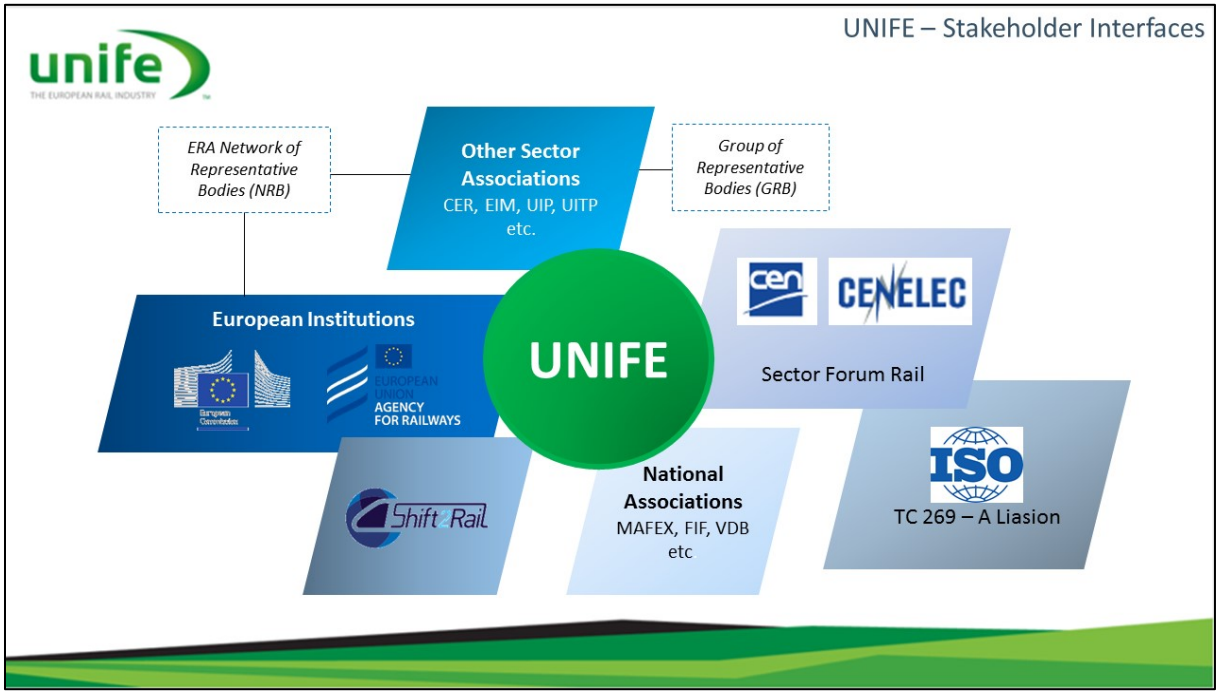
- **UNIFE represents the European Rail Supply Industry (rolling stock, infrastructure, energy, telecommunication and signalling sub-systems)**
- **UNIFE is a trusted partner of European and international institutions in all matters related to rail transport**
- **A unique network of over 100 full members of the largest and small sector and 13 associated members representing almost 1000 suppliers of railway equipment**



World leaders:

UNIFE members have a 84% market share in Europe and supply 46% of the worldwide rail production

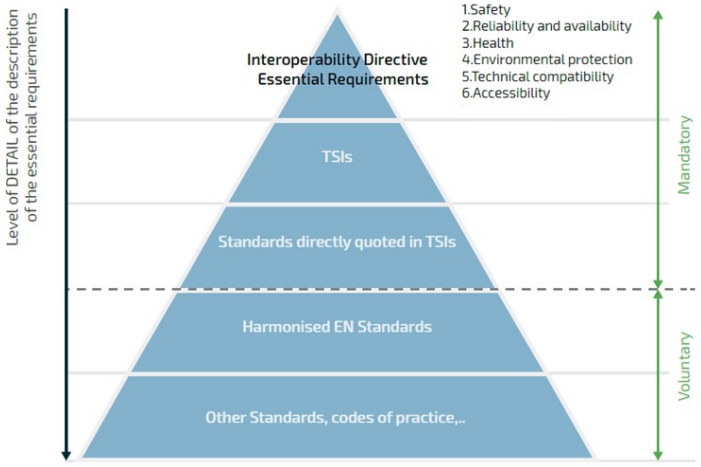

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UNIFE Members
Associate Members


UNIFE – Stakeholder Interfaces
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THE EUROPEAN RAIL INDUSTRY
ERA Network of Representative Bodies (NRB)
Other Sector Associations
CER, EIM, UIP, UITP etc.
Group of Representative Bodies (GRB)
European Institutions
UNIFE
Sector Forum Rail
Shift2Rail
National Associations
MAFEX, FIF, VDB etc
TC 269 – A Liasion

UNIFE Standards and Regulation Group - Scope

UNIFE Standards and Regulation Group:

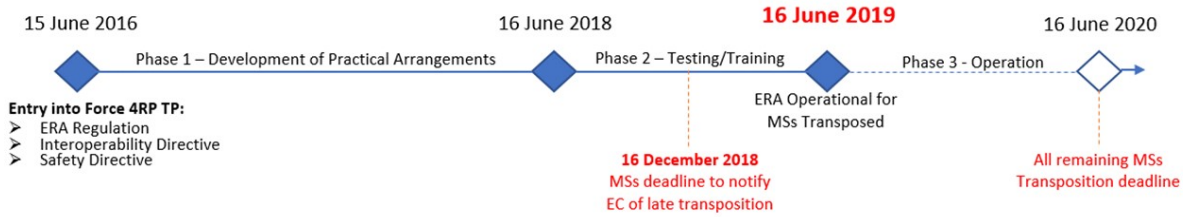
- Coordination of UNIFE positions regarding the **Fourth Railway Package**
- Coordination of **UNIFE working groups** and UNISIG for input related to the **ERA Working Parties** and revision of TSIs
- Coordination the UNIFE input toward **railway standardisation** via SFR/JPC-R, RASCOP etc.



4th Railway Package Technical Pillar

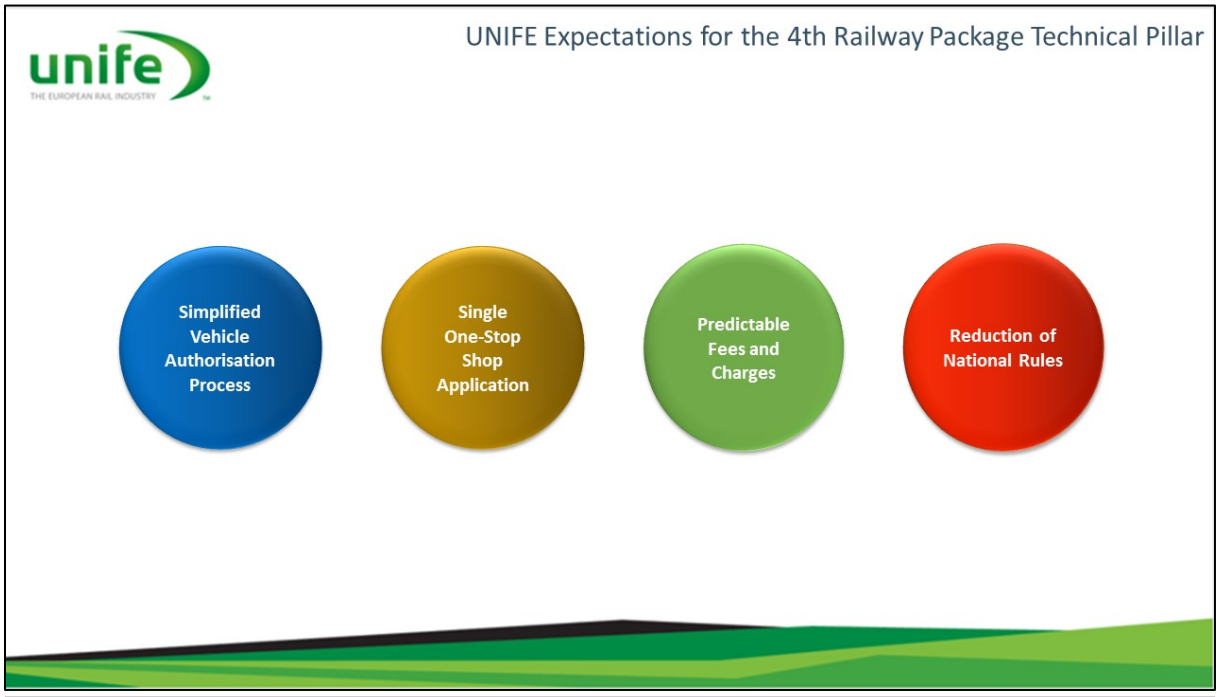
For UNIFE, the priority **Technical Regulation** topic is the **Implementation of the Fourth Railway Package Technical Pillar**

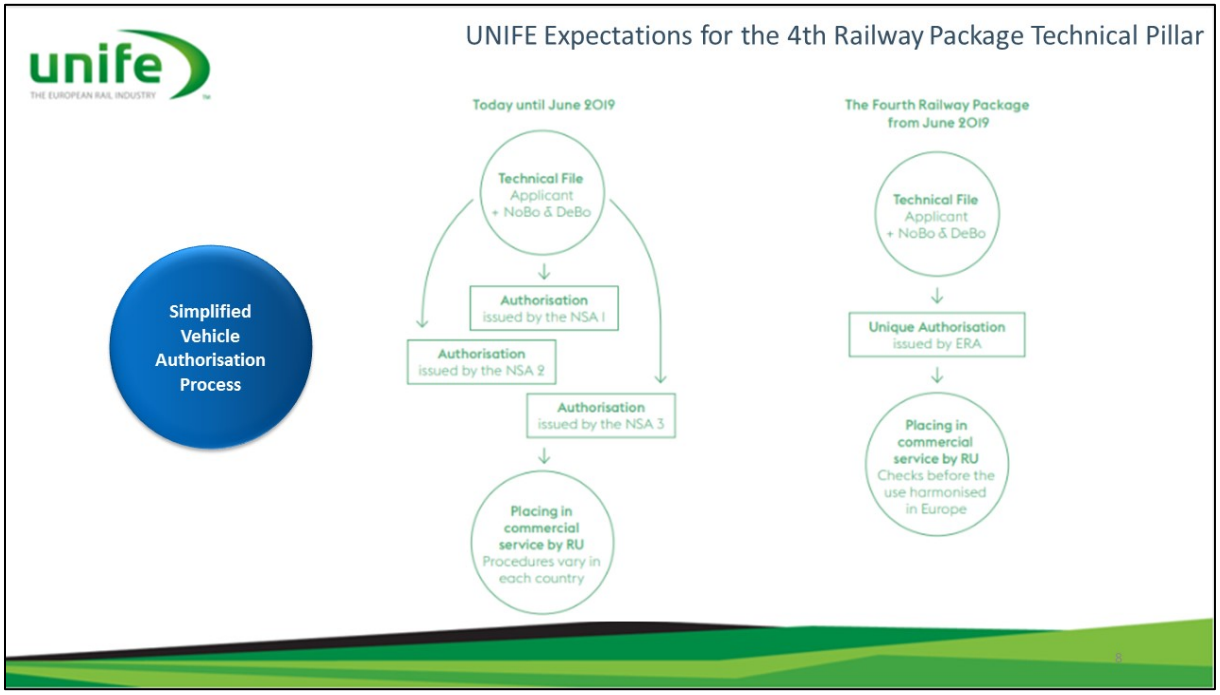
4RP Timeline



16 June 2019 – 4RP Regime Entered into Operation with ERA and 8 Member States

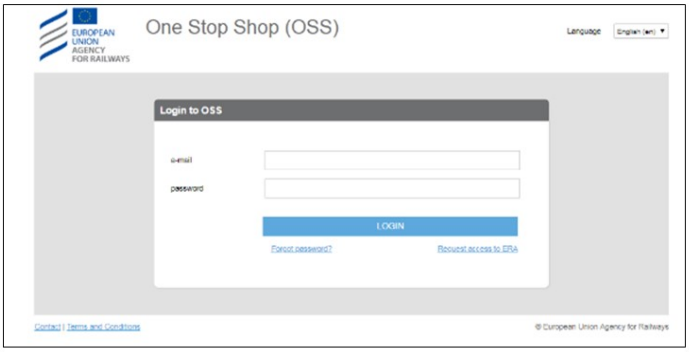
- Goal - Reduce time and cost of vehicle authorisation by 20%
- ERA to grant all multi-country authorisations – **no more duplication of assessment by NSAs**
- Create a Single European process for vehicle authorisation via the OSS, more transparency and certainty for industry


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UNIFE Expectations for the 4th Railway Package Technical Pillar
Simplified Vehicle Authorisation Process
Single One-Stop Shop Application
Predictable Fees and Charges
Reduction of National Rules


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UNIFE Expectations for the 4th Railway Package Technical Pillar
Simplified Vehicle Authorisation Process
Today until June 2019
Technical File
Applicant
+ NoBo & DeBo
Authorisation
issued by the NSA 1
Authorisation
issued by the NSA 2
Authorisation
issued by the NSA 3
Placing in commercial service by RU
Procedures vary in each country
The Fourth Railway Package from June 2019
Technical File
Applicant
+ NoBo & DeBo
Unique Authorisation
issued by ERA
Placing in commercial service by RU
Checks before the use harmonised in Europe

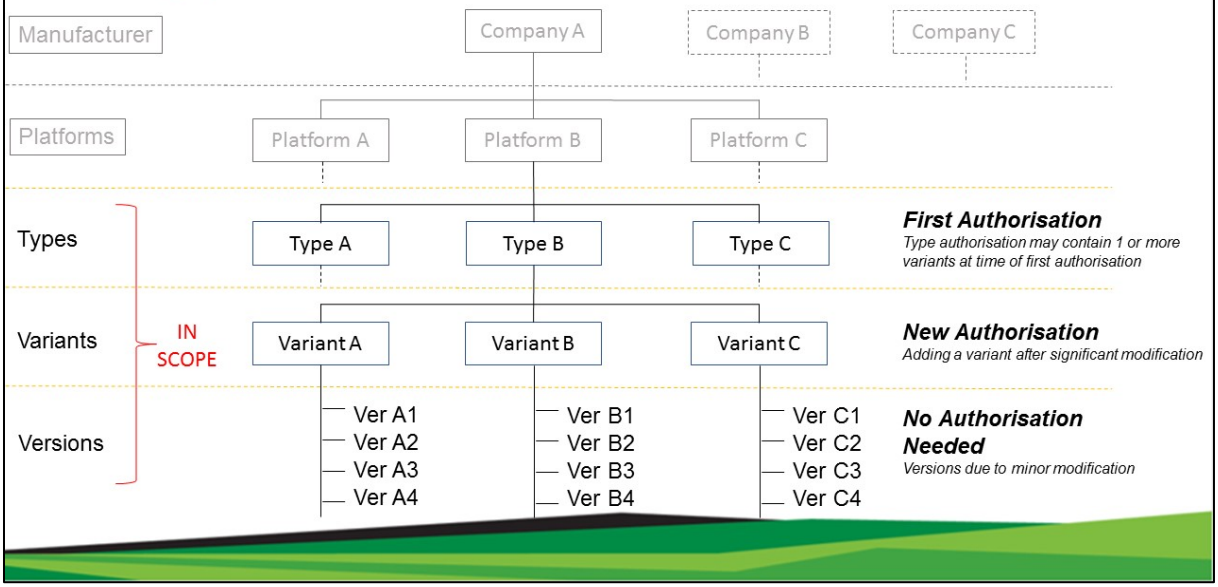
UNIFE Expectations for the 4th Railway Package Technical Pillar

Single One-Stop Shop Application



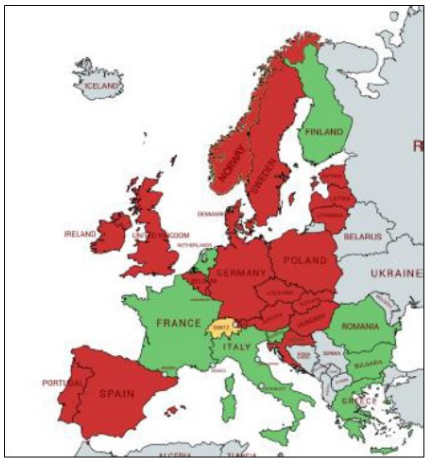
All applications, both to ERA and NSA, sent via OSS

UNIFE Expectations for the 4th Railway Package Technical Pillar



4th Railway Package - Transposition by Member States

When and Where?



- The recast directives give a **three year transposition** period to bring the 4RP into national law, however an **option of 1-year delayed transposition** was possible if a Member State notified the EC by 16 Dec 2018 with justification.
- Notifications were been received by **18 Member States**, extending the transposition period to **16 June 2020**: Austria, Belgium, Croatia, Czech Republic, Estonia, Denmark, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Poland, Portugal, Slovakia, Spain, Sweden, United Kingdom.
- Consequently, the remaining applicable **8 Member States**, as well as Norway and Switzerland, are confirmed as transposing the Fourth Railway Package Technical Pillar for **16 June 2019**: Bulgaria, Finland, France, Greece, Italy, Netherlands, Romania, Slovenia, Norway, Switzerland.

16/06/2019

16/06/2020

4th Railway Package - Key Milestones

15 June 2016 — 16 June 2018 — 16 June 2019 — 16 June 2020

Phase 1 – Development of Practical Arrangements

Phase 2 – Readiness & Test

Phase 3 – Operation and Delivery

4th Railway Package Technical Pillar – entered into force 16 June 2016

- Interoperability Directive (EU) 2016/797
- Safety Directive (EU) 2016/798
- European Union Agency for Railways (ERA) Regulation (EU) 2016/796

Directives

Supporting Regulations Published 2018-2019:

- Commission Implementing Regulation (EU) 2018/545 of 4 April 2018 establishing practical arrangements for the railway **vehicle authorisation and railway vehicle type authorisation** process
- EC Declaration Templates Regulation (EU) 2019/250 of 12 February 2019
- Fees and Charges Regulation (EU) 2018/764 of 2 May 2018
- Board(s) of Appeal Regulation (EU) 2018/867 of 13 June 2018

Key Regulations

4th Railway Package - Key Milestones

15 June 2016 — 16 June 2018 — 16 June 2019 — 16 June 2020

Phase 1 – Development of Practical Arrangements | Phase 2 – Readiness & Test | Phase 3 – Operation and Delivery

- **Guidelines**
  - ERA-PRG-005/02_361 -Practical arrangements -VA process
  - ERA-PRG-005/02_374 -Catalogue of examples

VA Guidelines, further guidelines and FAQ also produced on ERA website

- **2019 TSI Revision – Rail Interoperability Package**
  - (EU) 2019/772 – TSI PRM
  - (EU) 2019/773 – TSI OPE
  - (EU) 2019/774 – TSI NOISE
  - (EU) 2019/775 – TSI TAP
  - (EU) 2019/776 – TSIs LOC&PAS, CCS, WAG, INF, ENE, + ERATV
  - (EU) 2019/777 – Register for Infrastructure (RINF)
  - (EU) 2019/778 – TSI TAF
  - (EU) 2019/779 – ECM Regulation

Key Regulations published 27 May 2019 completing IoD and VA Regulation concepts

- **OSS Users' Group development and User Acceptance Testing**

V0.6 of OSS release in Feb19 for VA input
V1.0 launched Jun19 for submission

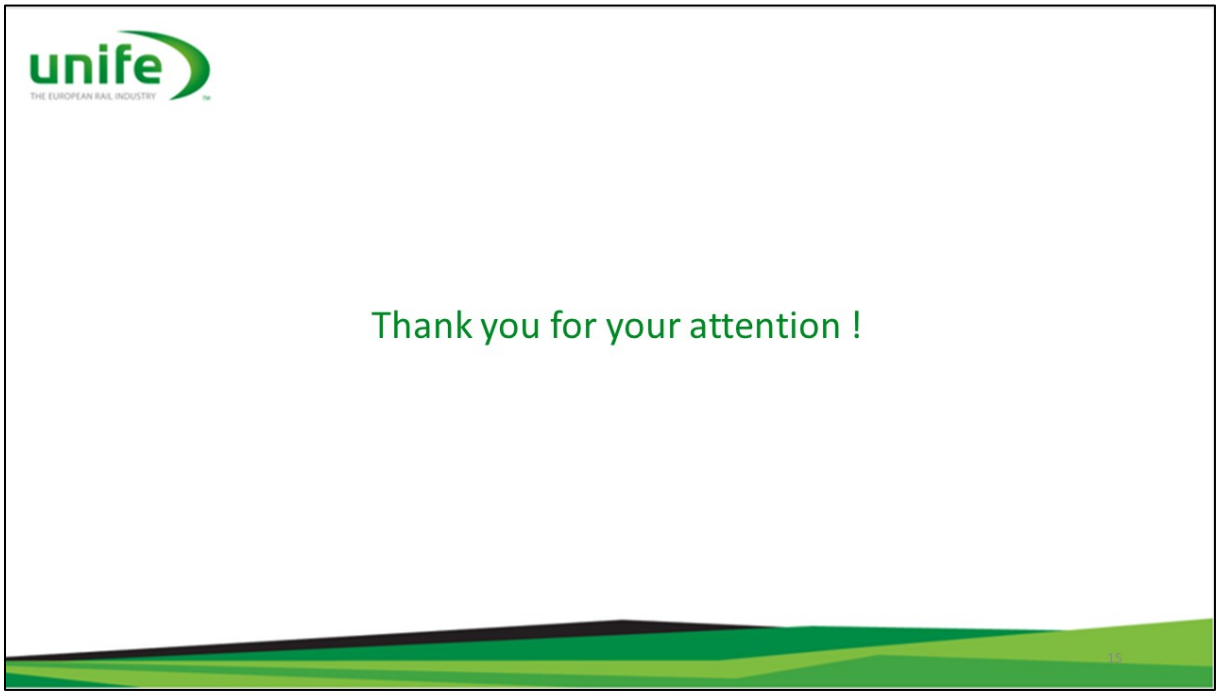
4th Railway Package – Priorities for the Next Year

15 June 2016 — 16 June 2016 — 16 June 2019 — 16 June 2020

Phase 1 – Development of Practical Arrangements | Phase 2 – Readiness & Test | Phase 3 – Operation and Delivery

- **Full transposition by Member States**
- **Monitoring of first implementation of the 4RP – Industry practice and feedback**
  - To improve guidance, tools or process if needed
  - Result of National Rules Cleaning to be reviewed
- **Final Regulations for 4RP scheduled:**
  - Classification of National Rules (2nd half 2019)
  - Derogations to TSIs
- **Define the TSI revision process from 2020 and beyond**
  - Next TSI Package 2022?
  - Balance stability of regulations vs updates of standards/innovation?
  - Improve efficiency and transparency of drafting process
- **Continued ERA IT Development – OSS and Single Rules Database**

Full engagement of UNIFE and our members


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Thank you for your attention !
15

Photographs:

Day 1











Day 2










Directives & Regulations
Commission Implementing Regulations
Guidance
Agreements


Stage 1 Preparation of the application
Stage 2 Pre-engagement
Stage 3 Conformity assessment
Stage 4 Submitting the application
Stage 5 Processing the application
Stage 6 Final documentation
Suspension, revocation or amendment
EU HARMONISED PROCESS




Vehicle Authorisation under the 4th RP
EUROPEAN UNION AGENCY