4th Railway Package – Single safety certificates

Copenhagen, 16 January 2020

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What is new?

What is new?

ERA as new authority

June 2019

One-stop shop

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

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OR

NSA

Single safety certificate

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

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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

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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
	2019/773 – 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

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.)

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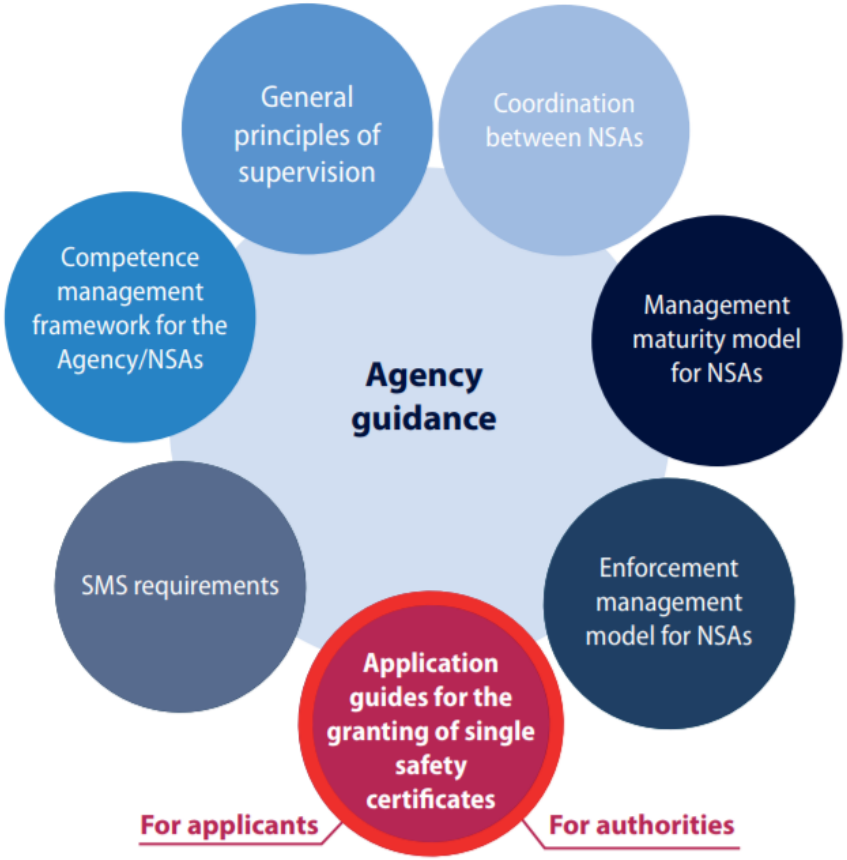
Compendium of Agency guidance

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



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

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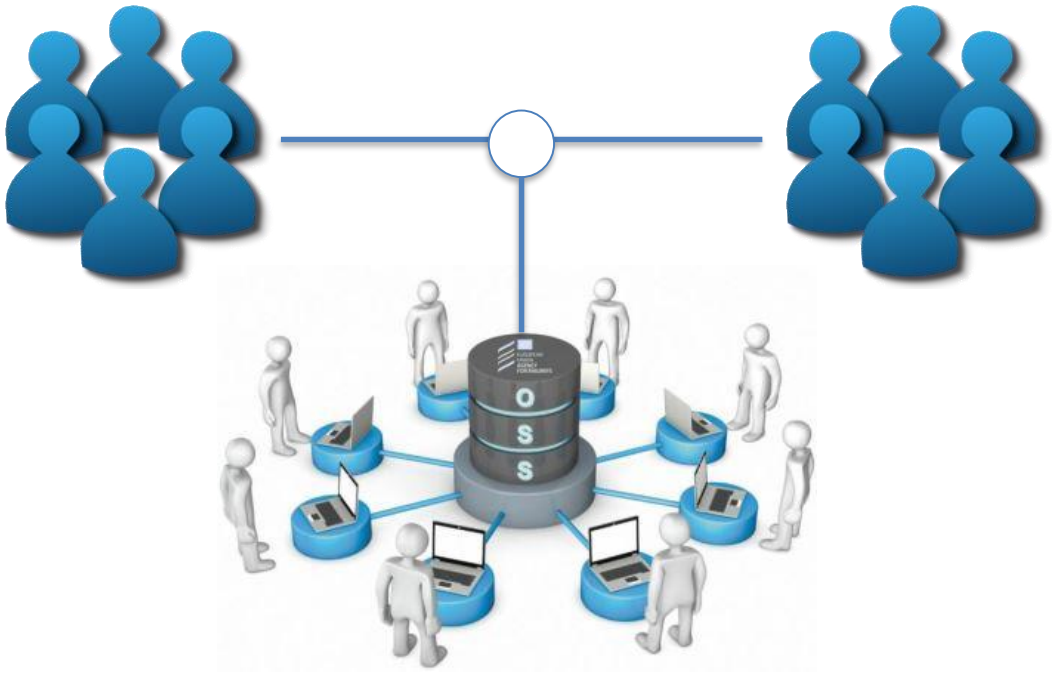
One-Stop Shop

One Stop Shop

Users management in the One-Stop Shop



https://oss.era.europa.eu/

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Training

- 47 **training sessions** (in addition to the PoE trainings) for both applicants and assessment teams delivered since December 2018. More than 500 users trained

- Further training sessions are planned for the coming months. More info here: OSS training guidelines

- All future users encouraged to take part to the training sessions

- For any training related request and registration send email to oss.training@era.europa.eu

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ERA organisation

ERA organisation

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/VA/ERTMS.TA projects and **programme manager** for the planning and monitoring of SSC/VA/ERTMS.TA projects

- Close coordination with other Units for the assignment of staff to SSC/VA/ERTMS.TA projects

- Decision taken by the Executive Director (or one of his delegates)

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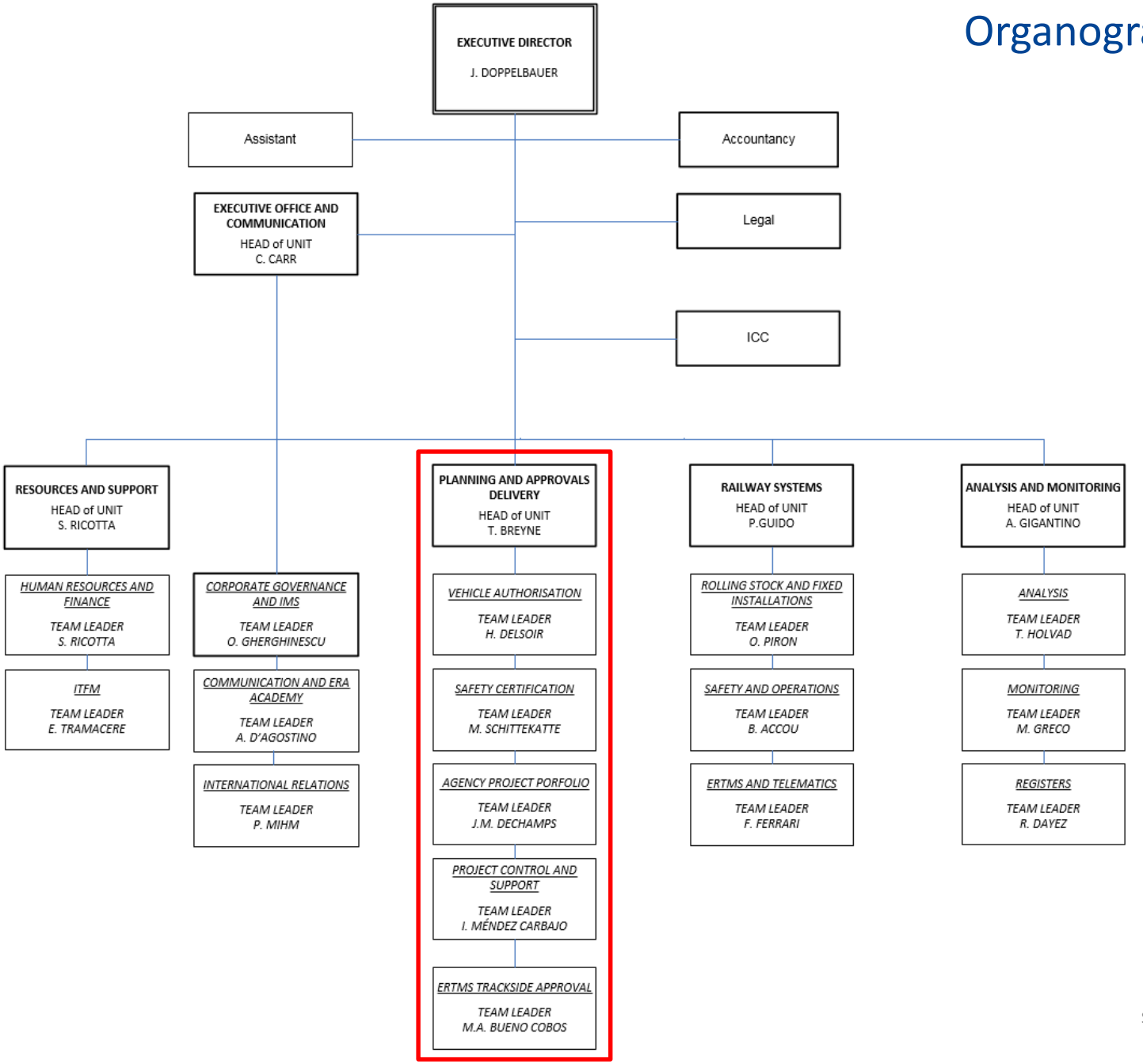
Organogram



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**.

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Return of Experience since June 2019

Return of Experience

Figures (2019)

26

SSC APPLICATIONS (ERA 11, NSA 15)

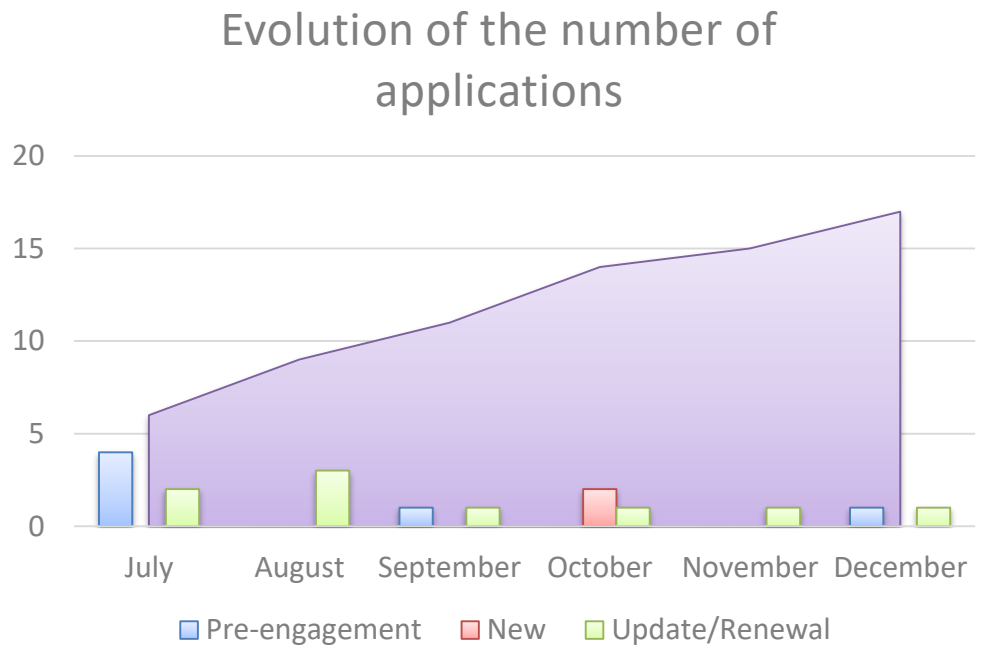
11 SSC issued (ERA 5, NSA 6)

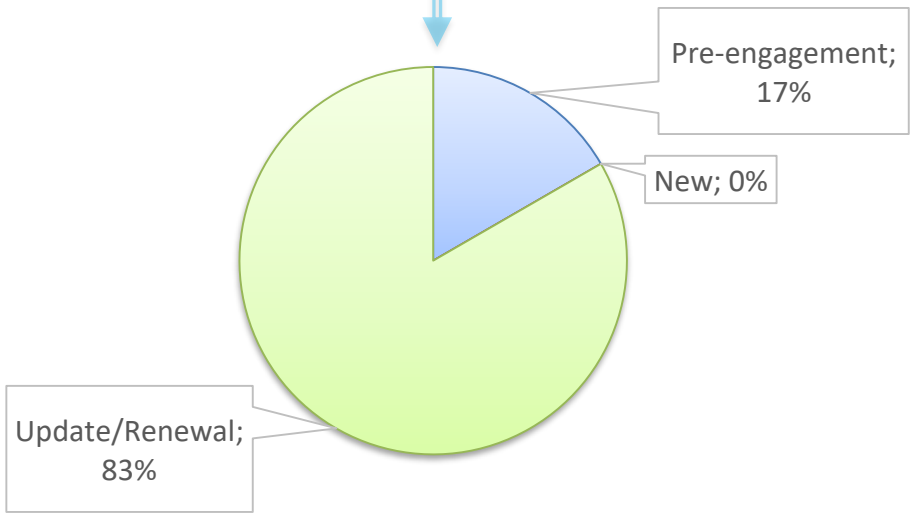
888

ONE-STOP SHOP USERS

681 applicants, 207 ERA+NSA

Figures (2019)





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Sowing the seeds for success

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First steps… and first challenges

Assessment

Trafik-, Bygge- og Boligstyrelsen
Danish Transport, Construction and Housing Authority

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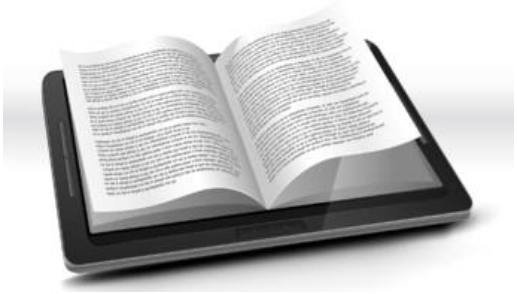
epsf

Service public fédéral Mobilité et Transports

Eisenbahn-Bundesamt

...

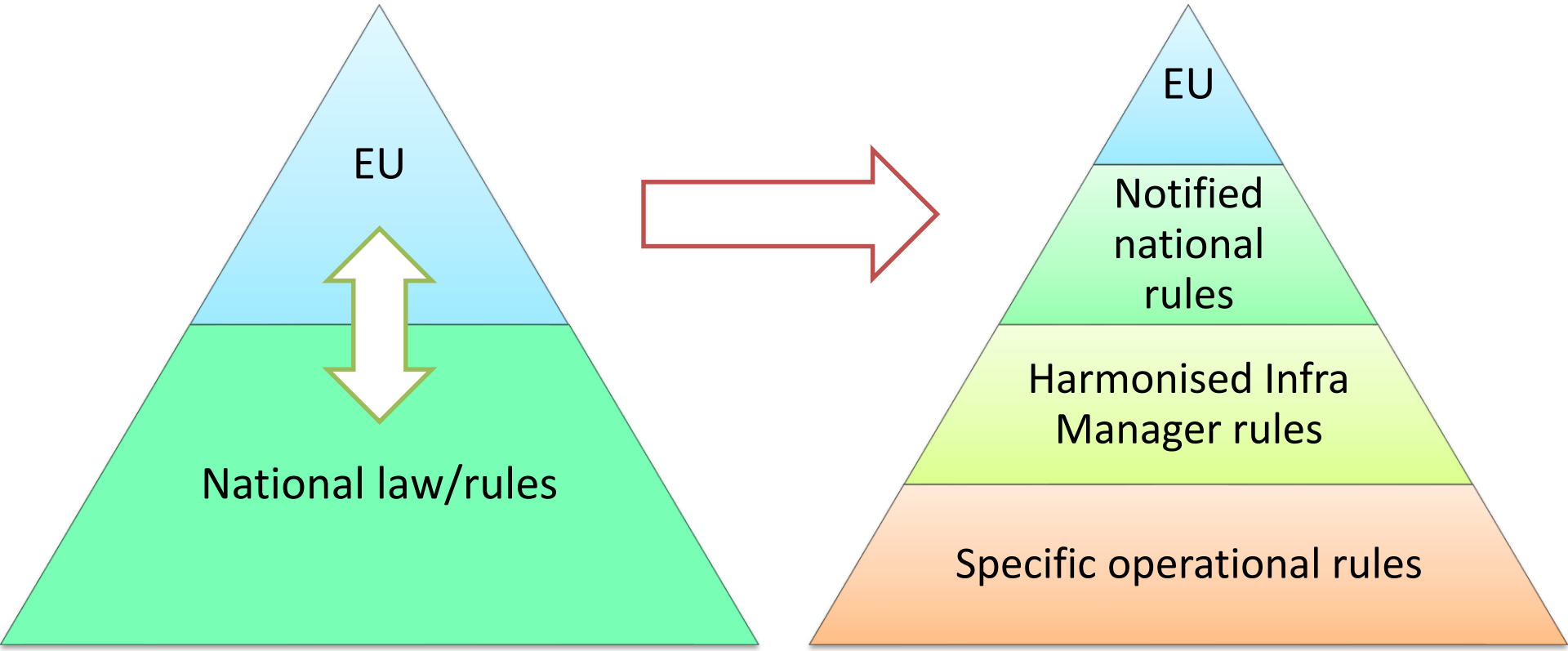


EU Regulations
National rules

National rules

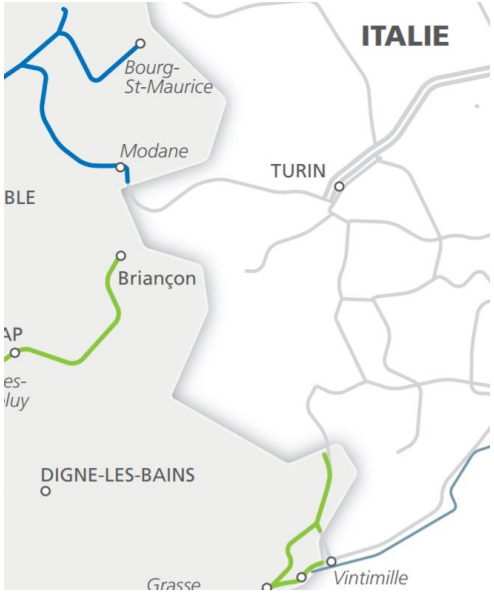
- National law vs. national rules
- National rules redundant by EU law (TSI, CST, CSM etc.)
- National rules notified in NOTIF-IT database

National rules



Border stations

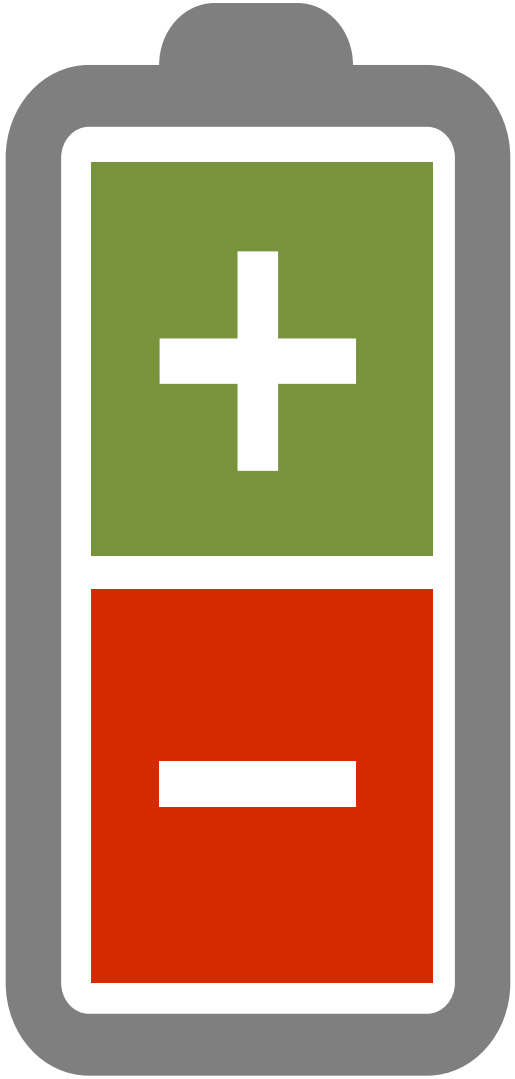
- Concept of border station - A border station is not the same thing as an agreement between member states as to where the real border is (border point)
- Consultation required between NSAs concerned
- NSA to set up specific arrangements, as appropriate, in the cases where the NSA or ERA is safety certification body



Supervision

- Good information on how the safety management system of the applicant is performing is critical in performing an efficient and effective assessment
- Importance to share the supervision results with a level of details (scope, context, findings) sufficient for ERA to understand the impact on the SMS and to have a targeted approach

One-stop shop



- Submission of applications
- Team assignement and user rights management
- Use of web forms
- Publication of certificates

- Ergonomy (complexity)
- Library (export, config. management)
- Notifications
- Dashboard
- Update of the application file via Issue Log

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ISO 9001:2015
BUREAU VERITAS
Certification