#ERAwebinars

Réglementation ferroviaire UE: Pourquoi? Pour qui?

10 October 2024 - 14.00 [CEST]

Webinar in French. The English subtitled version will be available after the broadcast.

EUROPEAN UNION AGENCY FOR RAILWAYS

Intervenants

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Main EU institutions

European Council

(27 heads of State and government)

Gives high-level strategic directions to the EU

European Commission

(27 commissioners)

Proposes the EU budget and EU « laws » (Regulations, Directives, Decisions…)

Decentralised Agencies

Council of the EU

(27 ministers)

Adopt the EU budget and most of EU « laws »

European Parliament

(705 deputies)

4

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Two pillars of EU law

Subsidiarity

=> the EU does not take action, unless it is more effective than action taken at the national, regional or local level.

- *decisions are taken at the closest possible level to the citizen.*
- *constant checks to verify that action at the EU level is justified, considering the available possibilities at national, regional or local level.*

Proportionality

=> any action taken by the EU does not go beyond what is necessary to achieve the aims of the treaties.

These two principles are defined in Article 5 of the Treaty on European Union.

The EU Railway System

A shared system, managed by many actors and intended to be operated as an open market for products and services:

A Single European Railway Area

This requires harmonised and transparent rules and processes – like roads and aviation – to define the optimal level of technical harmonisation and maintain/improve the overall safety levels.

A Time-line of EU Railway legislation

2001
European Commission's White paper
A strategy for revitalising the Community's railways

2001
Rail infrastructure package
- levying of charges for the use of railway infrastructure
- licensing of railway undertakings

2004
Second railway package
- Interoperability and Safety Directives
- Establishment of ERA

2007
Third railway package
- Access rights rail freight service from 2007
- Opening of the international passenger transport service market from 2010

2008
- Interoperability Directive **extended to the whole EU Network**
- Directive 2008/110/EC amending Safety Directive: duties for entity in charge of maintenance (ECM)

2016
Fourth Railway Package
- Recast of all major railway Directives
- Single EU wide vehicle authorisation and certification

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ERA Mandate

Recommendations to the European Commission

(TSIs, CSMs, Registers)

Technical development in Railway Safety

Assistance to Member States and the European Commission

Vehicle Authorisation

4RP

Safety Certification of Railway Undertakings

4RP

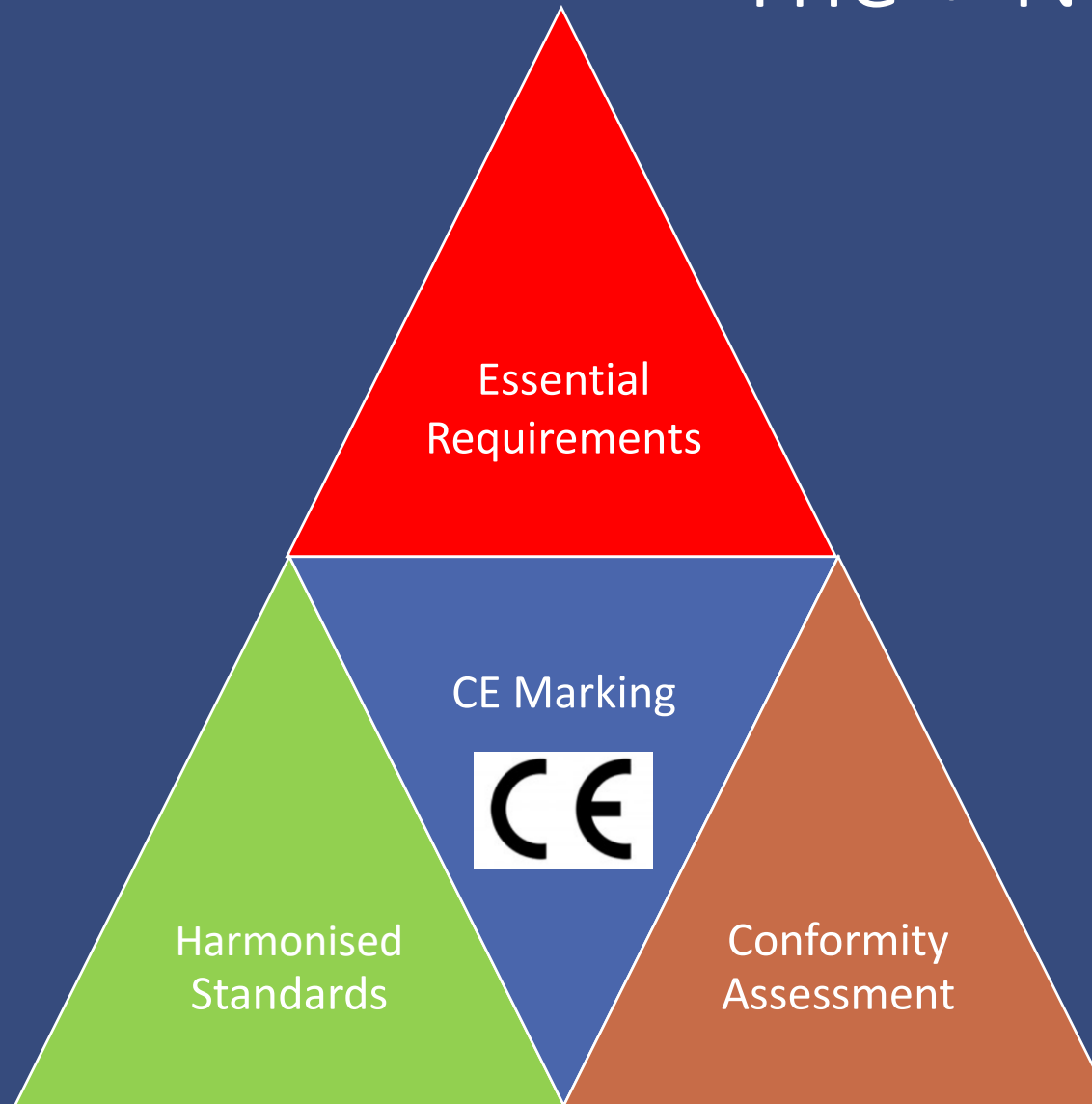ERTMS Trackside approval

4RP

NSA/NoBo Monitoring

4RP

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The goal of harmonisation in the EU legislation

- Elimination of barriers
- Free movement of goods in the single market
- Protection of EU consumers
- Level playing field
- Competitive EU single market

*Policies and legislative techniques have evolved over the last 40 years of European integration*

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The « New Approach » (1985)

Essential Requirements

CE Marking

Harmonised Standards

Conformity Assessment

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The « New Approach » (1985)

— Legislative harmonisation limited to **essential requirements**

— The technical specifications laid down in **harmonised standards**

— Products compliant with harmonised standards benefit from a **presumption of conformity** with the corresponding essential requirements

— Harmonised or other **standards remains voluntary**

— Manufacturers can apply other technical specifications to meet the requirements (with burden of proof)

Hierarchy of rail interoperability norms

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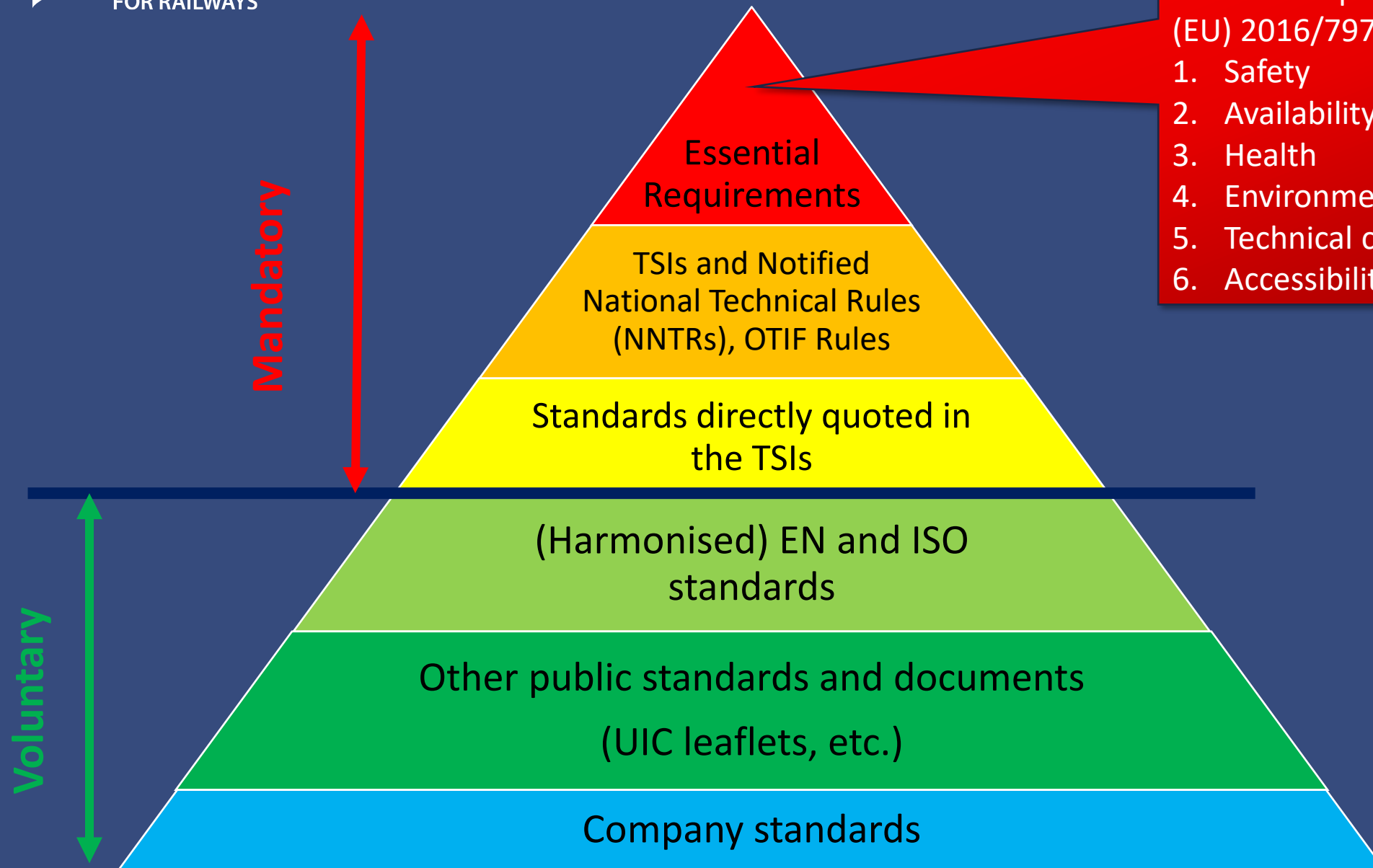
From Interoperability Directive (EU) 2016/797:
1. Safety
2. Availability and Reliability
3. Health
4. Environmental protection
5. Technical compatibility
6. Accessibility

Mandatory

Essential Requirements

TSIs and Notified National Technical Rules (NNTRs), OTIF Rules

Standards directly quoted in the TSIs

Voluntary

(Harmonised) EN and ISO standards

Other public standards and documents

(UIC leaflets, etc.)

Company standards

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Technical Specifications for Interoperability
The Agency prepares TSIs under a Mandate from the European Commission
TSIs are then adopted as delegated act (EC Regulations)

A **TSI** is a common specification defining
the elements that need to be harmonized to achieve interoperability
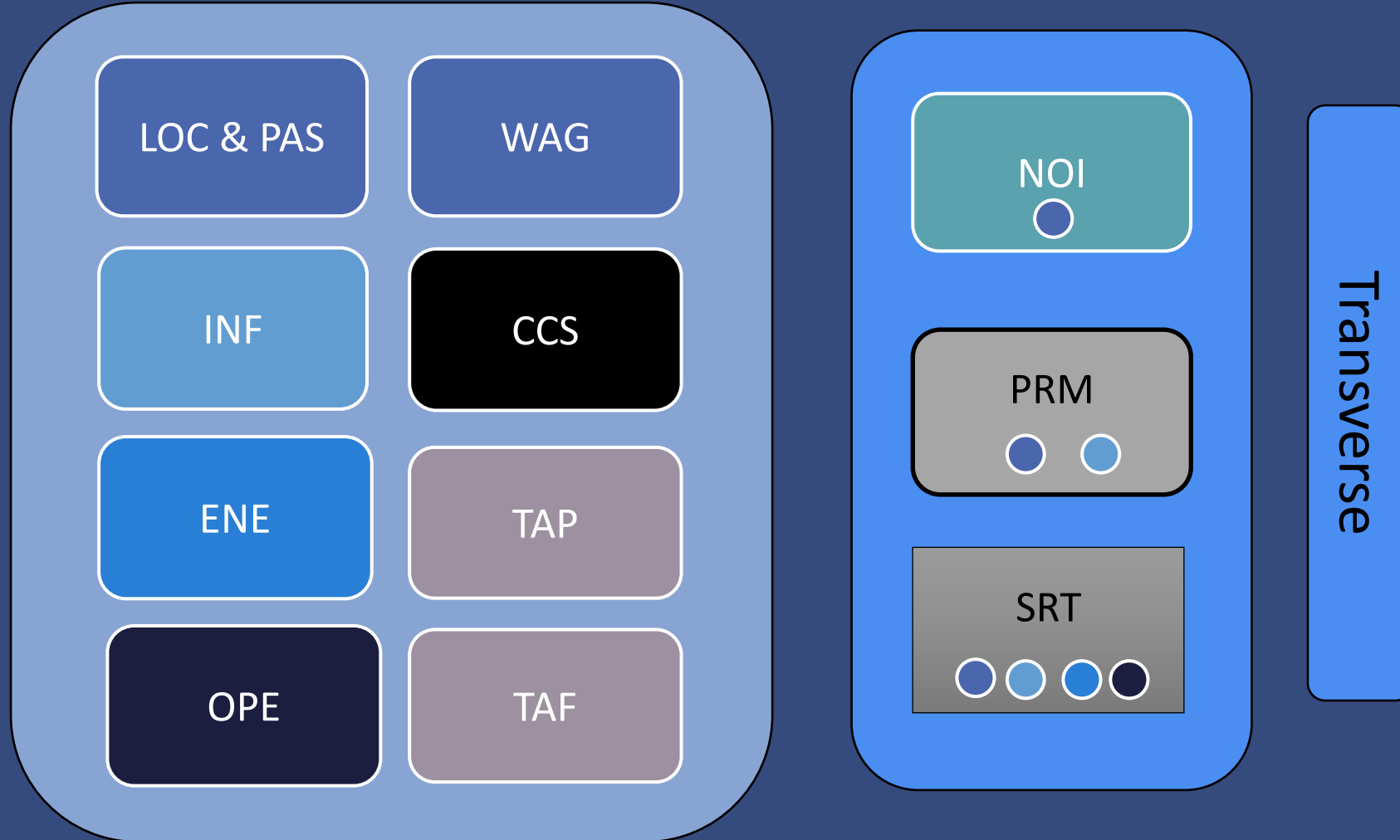
TSIs relate to
- structural subsystems (infrastructure, rolling stock, energy, CCS), or
- functional subsystems (maintenance, traffic operation and management, telematics applications for passengers and freight services)

The TSI framework is supplemented by notified national
technical rules (NNTRs)
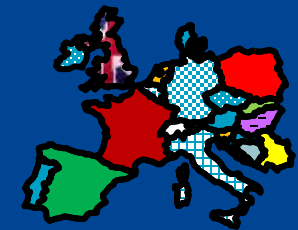
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Technical Specifications for Interoperability

Transverse

LOC & PAS

WAG

INF

CCS

ENE

TAP

OPE

TAF

NOI

PRM

SRT

Transverse

THANK YOU

Moving Europe towards a sustainable and safe railway system without frontiers.

Follow us:

Railway Industries Association (AIF – Association des industries ferroviaires)

Who are we ?

Association des Industries Ferroviaires
Hauts-de-France

Key Figures

AIF

1995
CREATION
OF AIF

1st
FRENCH
RAILWAY
CLUSTER
The oldest

100% **RAILWAY**
ACTORS REPRESENTED
Infrastructures, control-command, rolling stock (freight), maintenance, services and training.

A STRONG AND LEGITIMATE NETWORK :

- ➢ **Anchored in a territory**
- ➢ **Unites a hundred companies specialized in the railway sector**
- ➢ **Skills integrator**
- ➢ **Advocates for the interests of the sector**
- ➢ **Offers companies actions tailored to their needs**

OUR GOAL ?

Network of stakeholders in the railway sector to strengthen and enhance activity, attractiveness and employment in our région

Key Figures

HAINAUT

1st **FRENCH RAILWAY NETWORK**
Promoting the growth of the industry

1964
CREATION OF THE UNIVERSITY
And training programs tailored to the Valenciennes industrial fabric

> Creation of a centre of expertise

THE "UNGLORIOUS" THIRTY YEARS in the 70's

DECLINE OF THE COAL AND STEEL INDUSTRY

Valenciennes retains its tube **factories**, railway construction **workshops**, and **mechanical engineering facilities**

2 MANUFACTURERS
For several years : **an unprecedented situation**

> 1983 : Alstom obtains CIMT

> 1989 : Canadian manufacturer **BOMBARDIER** buys ANF industries, a manufacturer located in CRESPIN since **1882**

Philippe SUBRA, « L'université contre la crise ? Le cas de l'université de Valenciennes et du Hainaut Cambrésis », Les annales de la recherche Urbaine, 1994.

Valuval, années 90.

01

OUR MEMBERS

Valenciennes, European Capital of Railways

OUR CHALLENGES

CYBER
➢ Support our members in complying with the NIS2 directive

CERTIFICATION
➢ IRIS ISO 22163 – Certification of Management Systems

INDUSTRY 4.0
➢ Digitalization / Big Data / Cloud Compunting / Cyberindustry

PROCESS / NORMS
➢ Meet customer and railway rules qualification requirements

TRAINING
➢ Train the people for answering the challenges of the railway industry

LOCAL STAKEHOLDERS
BY OUR SIDE

OUR SUPPORTERS

OUR PARTNERS

04

"Build a safer world and encourage innovation and progress in the field of mobility and special equipment."

OUR LOCATIONS

25+
Locations

25+
Years of experience

500+
experts supported
by regional
experts' network

500+
Ongoing projects

10 000+
Completed projects

OUR BUSINESS UNITS

CERTIFER

Your 3rd party independent assessment under accreditation

CERTIFER SOLUTIONS

Tailor-made solutions for the successful delivery of your projects

OUR MARKETS

Systems, Infrastructure & Energy

Signalling (track-side & on-board)

Metro & Tramway

Hoisting, Piling & Lifting

Rolling Stock

OTM & Road Rail Machines

Workshop & Maintenance

Innovation Services

OUR TIC SERVICES

- Notified Body (NoBo)
- Independent Cybersecurity Assessment (ICA)
- Test Organisation & Testing activities
- Onboard ETCS Laboratory & Certification (Try&Cert)
- ECM certification Combined with VPI
- Designated Body (DeBo)
- Audit & Certification of Management Systems
- Assessment Body (AsBo)
- Technical Control I.C.
- Fire Behaviour
- Hoisting, Piling & Shipping Inspections
- Independent Safety Assessment (ISA)
- Non-destructive testing
- CERTIFER Academy
- Urban Insertion assessment

Independent Assessment

✓ A service undertaken by a third party to check that a railway product or system meets legal and regulatory standards.

✓ It can encompass the assessment and audit of all design, manufacture, installation, testing, and extend to all operation and maintenance procedures, in place before putting into service a system or placing a product on the market.

✓ The assessment body will perform INSPECTION and/or CERTIFICATION missions

Inspection & Certification

- ✓ **30 recognitions**

- ✓ **6 notified bodies**

- ✓ **4 international accreditations**

- ✓ **17020A: inspection**

- ✓ **17065: certification**

- ✓ **17021: management systems**

- ✓ **17025: testing and calibration laboratories**

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DE PRODUITS
ET SERVICES

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Inspection & Certification

✓ Planning and execution of the assessment activities in accordance with customer's milestones

✓ Independent Document/Procedure Review
(proof of conformity to regulations/standards)

✓ In-house audits when necessary

✓ Installation & test witnessing

✓ Give an independent opinion on the compliancy of the system assessed according to the regulations/standards

✓ Issue reports and certificates
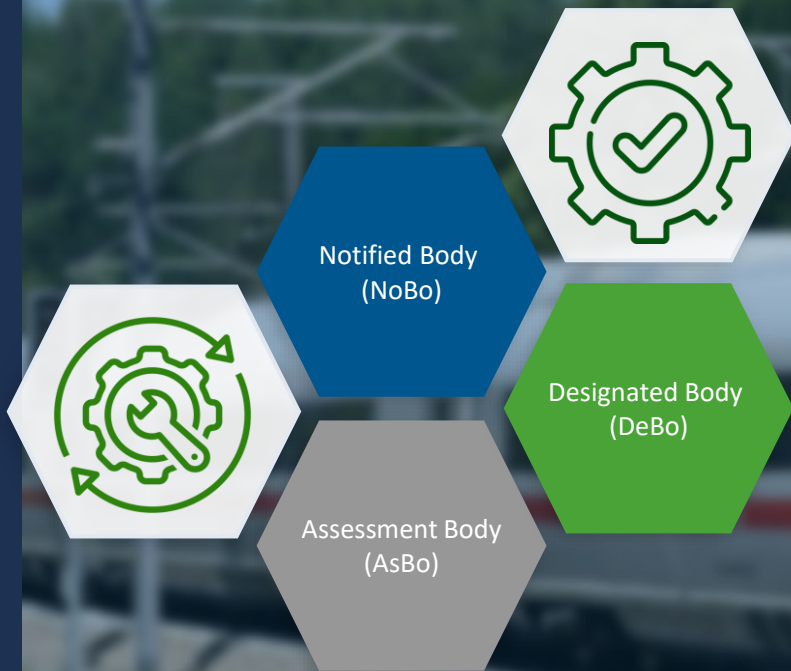
Inspection & Certification

A team made of:

✓ **A project manager**

✓ **A technical leader**

✓ **A lead inspector and Inspectors (technical experts)**

✓ **A quality auditor (if needed)**

Inspection & Certification Services

Notified Body
(NoBo)

Designated Body
(DeBo)

Assessment Body
(AsBo)

NoBo services: independent assessment of products and systems for conformance to interoperability standards (TSI = Technical Specification of Interoperability).

DeBo services: assessment of the compliance with NNTR (Notified National Technical Rules) in different countries.

AsBo services: assessment of the correct application of the risk management process and the suitability of its results (CSM = Common Safety Method – Reg (EU)402/2013).

Inspection & Certification Services

Independent Safety Assessment (ISA)

Independent Cybersecutiry Assessment (ICA)

Independent Safety Assessment services: application of a systematic RAMS management process in the railway sector (products, subsystems) - CENELEC standards (EN50126/129/716) and IEC61508

Independent Cybersecurity Assessment services: system wide assessment of cyber threats and risks to provide confidence that vulnerability levels are effectively controlled to ensure safe and reliable services (TS 50701)

Inspection & Certification Services

ECM certification Combined with VPI

Audit & Certification of Management Systems

Entity in Charge of the Maintenance certification: assessment against the European regulation 2019/779 (OTIF ATMF Annex-A for non-EU Countries). It covers wagon, locomotives, high-speed vehicles, passenger carriages, multiple units, OTMs, etc.

Quality management system audits certification: assessment according to ISO 9001 covering the maintenance of rolling stock (EA29), the leasing and renting of rolling stock (EA32) and the engineering, manufacturing and testing of hard and software (EA33).

Tests Services

Test services: Tests performed before placing vehicules into service, in order to validate the vehicule under real conditions and its compatibility with the other subsystems (trackside, ...).

Try&Cert: On-Board ETCS laboratory testing activity and certification. A hub created with SNCF's Rolling Stock Engineering Center (CIM)

Fire Behaviour: Inter-laboratory comparison on railway fire behaviour tests (in accordance with EN 45545-2 and NF F16-101 standards)

NDT services: Assessment of the safety of railway equipment, products and systems without destroying the serviceability of the component

Test Organization & Testing activities

Onboard ETCS Laboratory & Certification (Try&Cert)

Fire Behaviour

Non-destructive testing

THE EUROPEAN NIS2 DIRECTIVE

Marie-Christine MORETTI
CEO
mcmoretti@sesame-expertises.fr
Tel : 06/09/46/13/57

The European NIS2 directive

WHEN ?

NIS2 comes into effect

Member States must adopt and publish measures to comply with the NIS 2 Directive

Member States shall establish a list of essential and important entities

January 16, 2023

July 17, 2024

October 17, 2024

January 17, 2025

April 17, 2025

October 17, 2027

First Cyber Crises Liaison Organisation Network (EU-CyCLONe) report

CSIRTs network shall assess progress made with regard to operational cooperation

Revision of the directive

The European NIS2 directive

WHO ?

Expanded scope NIS 2 Directive

NIS 1 and NIS 2

ENERGY

HEALTH

TRANSPORT

DRINKING WATER

BANKING

DIGITAL INFRASTRUCTURE

FINANCIAL MARKET INFRASTRUCTURE

DIGITAL SERVICE PROVIDERS
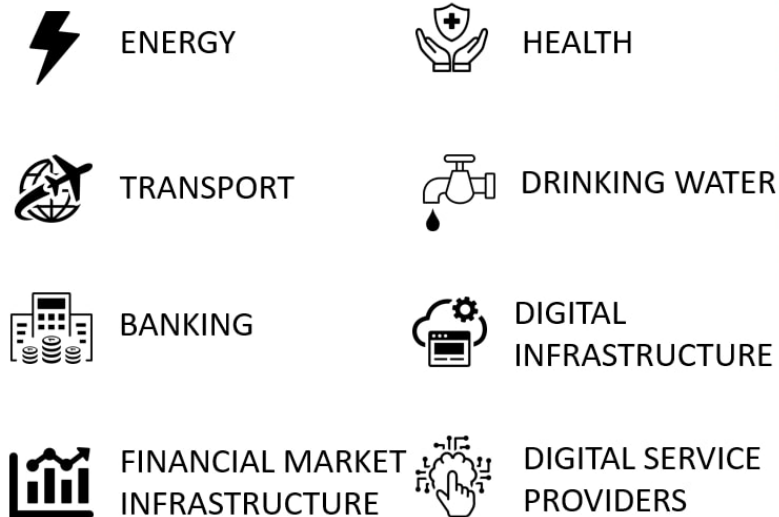
NIS 2 additional sectors

FOOD

WASTE WATER

MANUFACTURING

WASTE MANAGEMENT

POSTAL & COURIER

PUBLIC ADMINISTRATION

PROVIDERS OF PUBLIC ELECTRONIC COMMUNICATIONS NETWORKS OR SERVICES

SPACE

RESEARCH

ICT SERVICE MANAGEMENT

CHEMICALS
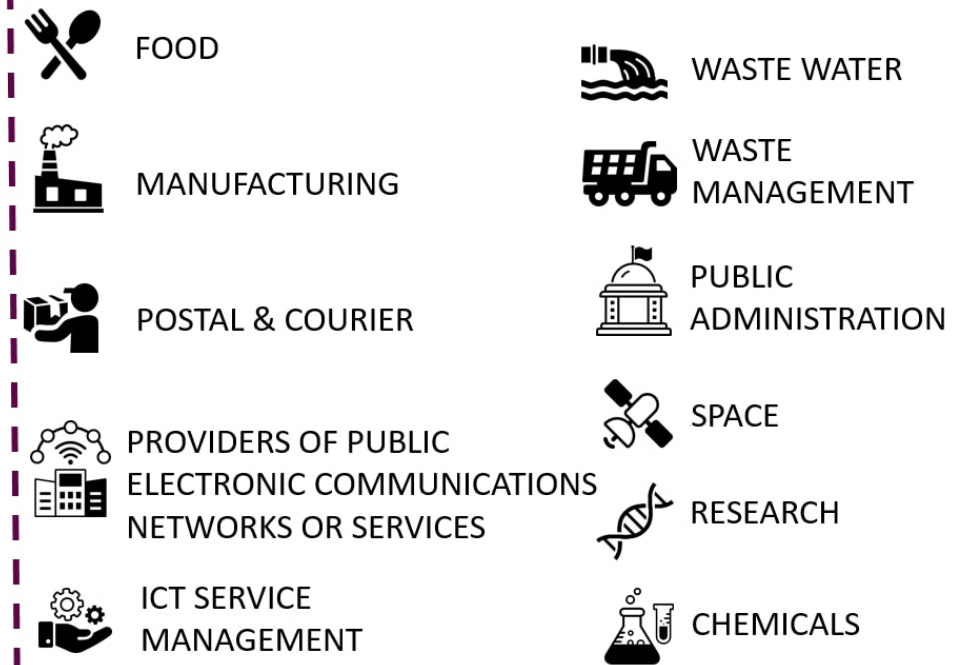
The European NIS2 directive

WHO ?

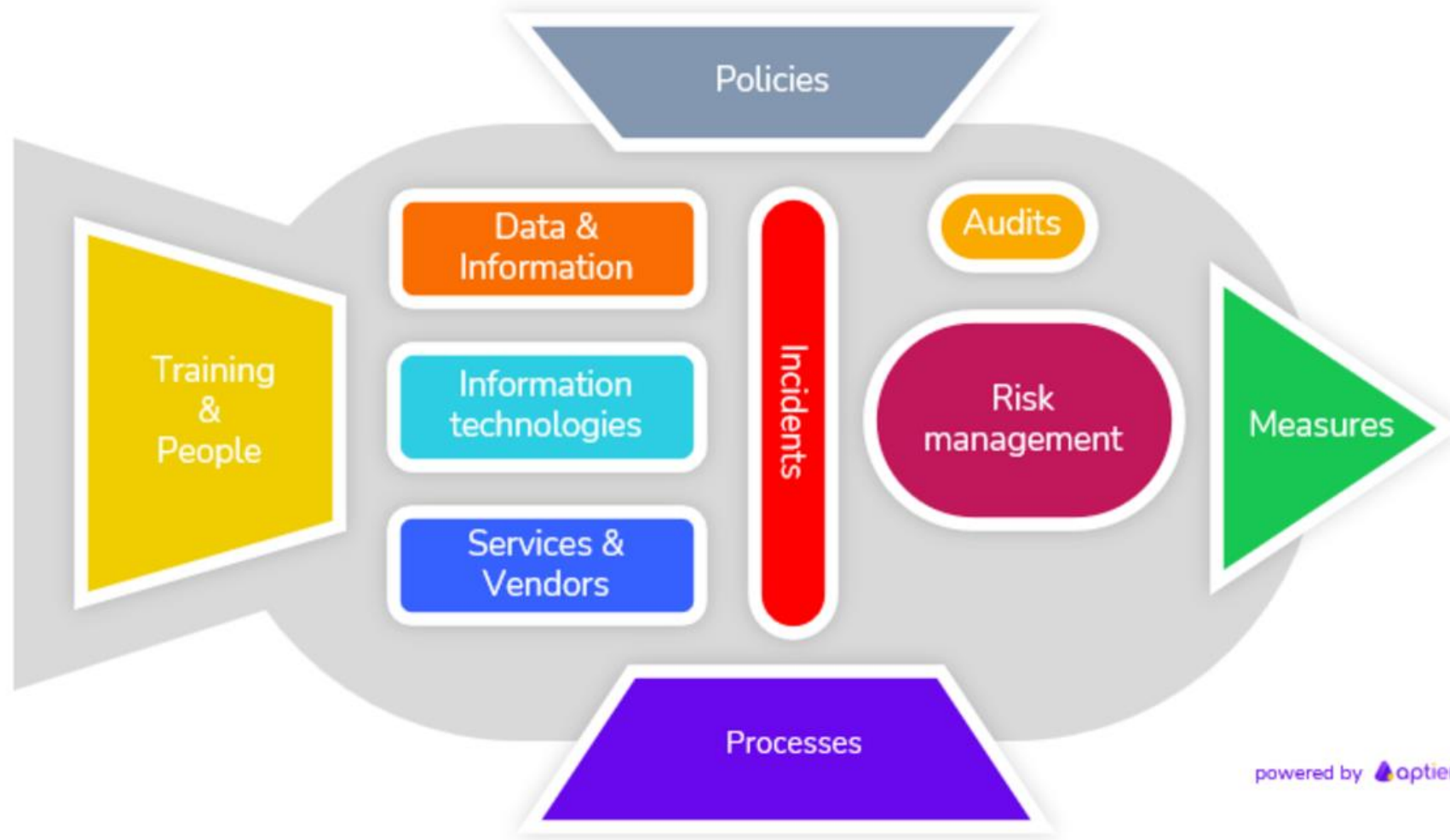| TURNOVER (M€)	EMPLOYEES	ANNUAL REVIEW	ENTITIES
10 M€ - 50M€	50 - 249	10 M€ - 43 M€	IMPORTANT ENTITIES
> 50M€	250 and more	> 43 M€	ESSENTIAL ENTITIES
< 10 M€	1 – 49	< 10 M€	N/A

The European NIS2 directive

WHAT ?
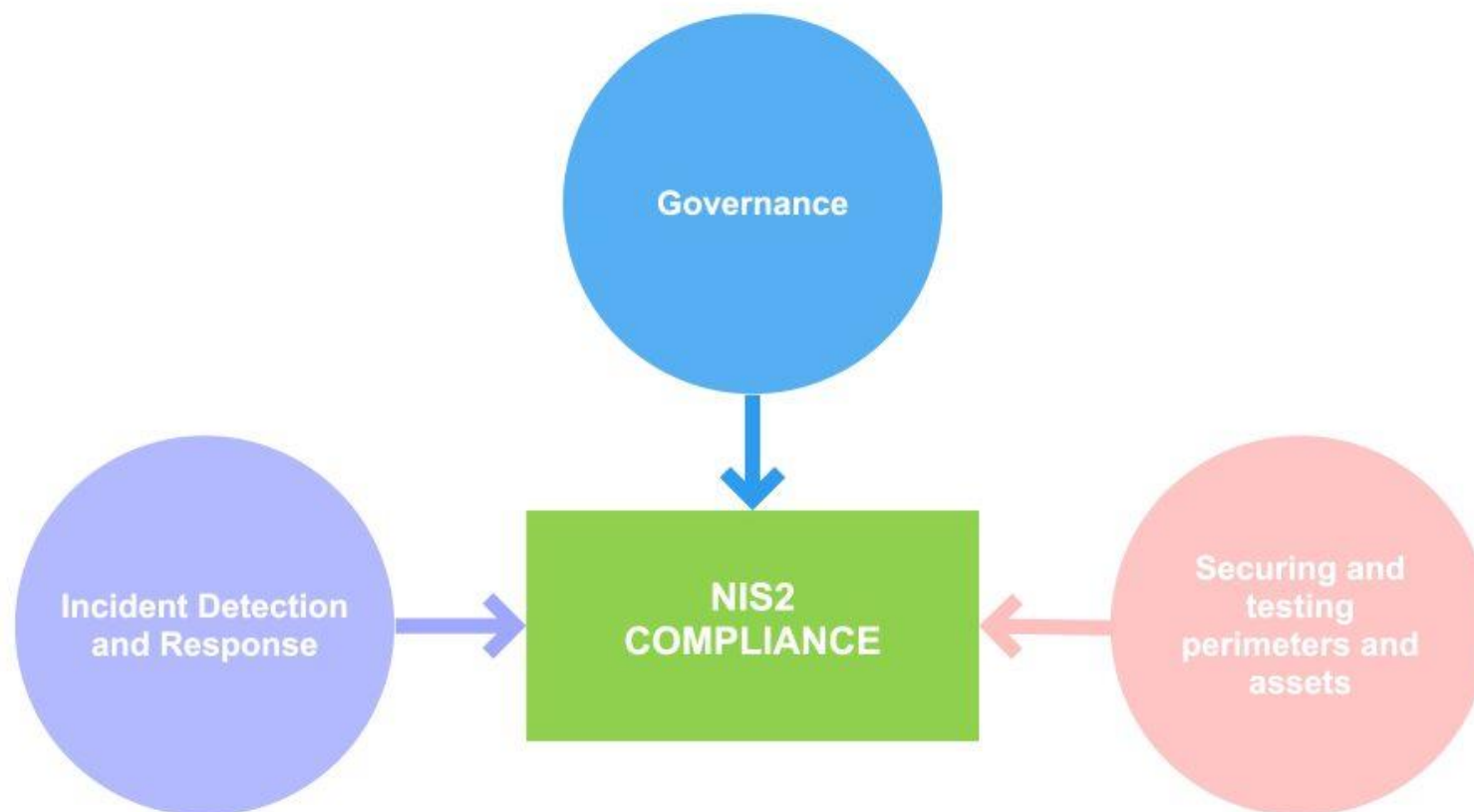
The European NIS2 directive

The European NIS2 directive

NEWS

What's new in NIS 2.0 compared to NIS 1.0

NIS2 aims to strengthen cybersecurity and resilience across the EU by:

- Expanding its scope to include essential and important entities based on services

- Enforcing security audits (subcontractors and certain local authorities) and incident reporting within 72 hours to CSIRTs (GDPR alignment)

- Ensure business continuity in the event of major cyber incidents (BCP/DRP)

- Aligning the Directive with the sector-specific legislation : DORA (Resilience ACT) regulations set uniform requirements for network security and CER Directive on the resilience of critical entities

The European NIS2 directive

REQUIREMENTS

NIS2 strengthens security requirements in the EU with:

- Consideration of supply chain security

- Streamlining reporting obligations

- Stricter execution requirements

- A notion of the responsibility of management bodies within companies

- Harmonisation and toughening of sanctions in all Member States

The European NIS2 directive

REQUIREMENTS

Raise awareness among top management of the sanctions and fines defined by NIS2

The NIS2 directive defines two types of sanctions: :

- Heavy and quantified administrative fines;
- **Accountability of senior managers and C-level executives within organizations.**

It is the CISO's responsibility – but not only – to make the sanctions provided for by the NIS2 directive clear to the management staff.

For your information, all the sanctions and fines described above are explained in Chapter VII, Supervision and Enforcement (Articles 32, 33 and 34).

Fines of "at least" €10M or 2% of annual worldwide turnover

NIS2 clarifies and strengthens the fines defines by law in the event of non-compliance of:
- Reporting obligations under Article 23
- Cybersecurity risk management measures, as provided for in Article 21

For Significant Entities (IE), the NIS2 Directive defines "administrative fines of a maximum amount of at least €7 million or at least 1.4% of the total annual worldwide turnover for the previous financial year of the company to which the significant entity belongs, whichever is greater."

The European NIS2 directive

REQUIREMENTS

A responsibility of the "management bodies" in terms of cybersecurity risk management

The NIS2 directive introduces a notion of the responsibility of top management in terms of safety – and more precisely of the "management bodies" according to the final text. The objective: to induce the appropriation of risk by senior managers and the board of directors to guarantee better governance.

"The CEO and the board of directors can be sentenced to a personal fine defined from 1.4 to 2% for Essential Entities.

NIS2: Sanctions for top management allowed by Member States' authorities to order offending entities:

- **Publish the aspects of non-compliance with the Directive;**
- **Publish a statement that identifies the natural and legal person(s) responsible for the breach, and the nature of the breach;**

In the context of an Essential Entity (EE), these sanctions can go up to:

- **A suspension of certifications and authorizations for services or activities provided by the organization;**
- **A temporary ban from exercising managerial functions within the entity for any person exercising managerial responsibilities at the level of chief executive officer or legal representative.**

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Votre avis

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Evénement
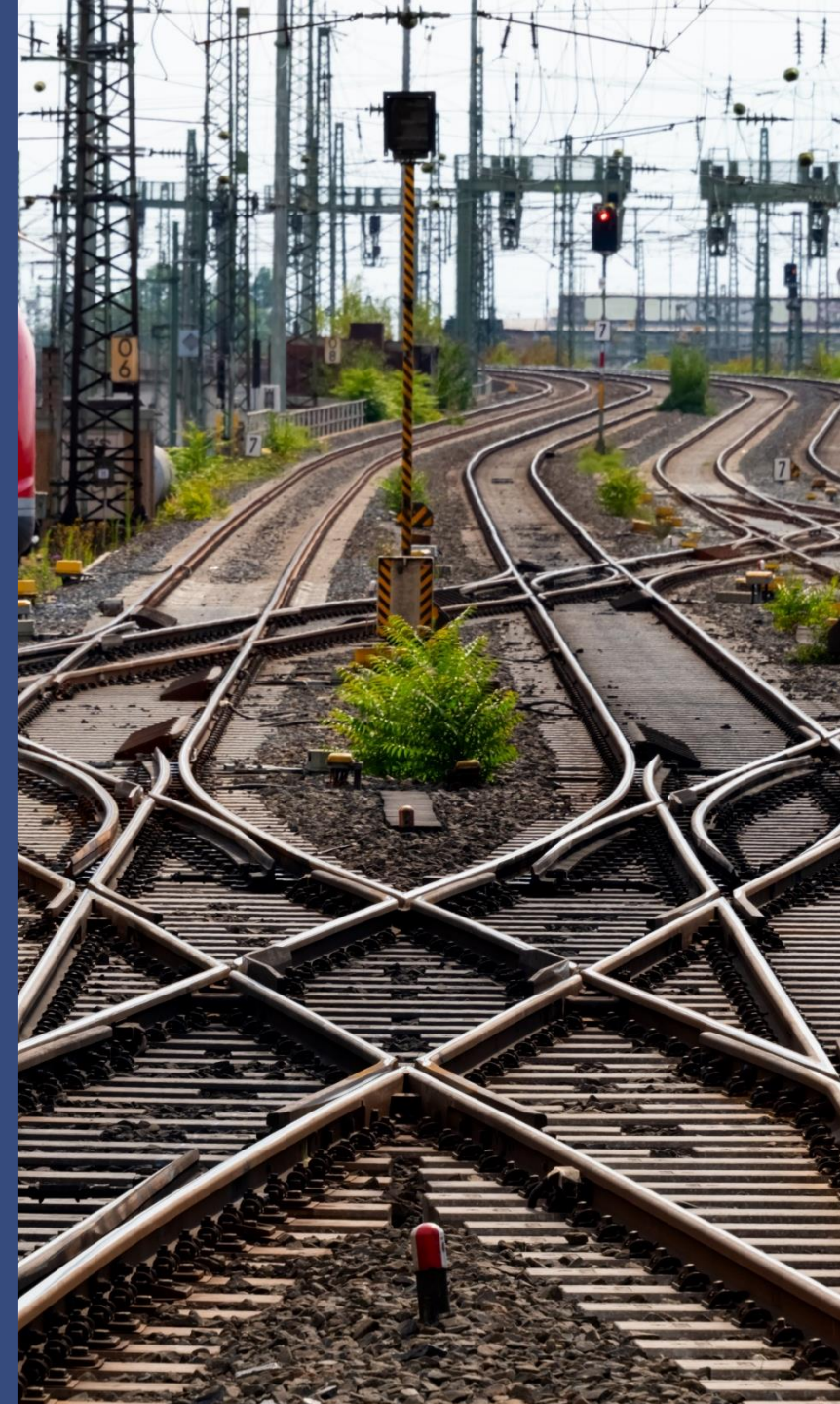
12th Budapest Workshop

Online

16 October

REGISTER NOW

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Evénement

HOF in Risk Management Conference

Valenciennes, France

22-23 October

VOTRE AVIS

Formation
https://academy.era.europa.eu

THANK YOU

Moving Europe towards a sustainable and safe railway system without frontiers.

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