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EVALUATION

Evaluation of the European Union Agency for Railways (ERA)

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Glossary

Term or acronym	*Meaning or definition*
AsBo	Assessment Body
ATO	Automatic Train Operation
CER	Community of European Railway and Infrastructure Companies
CSM	Common Safety Method
CSM ASLP	Common Safety Method on Assessment of Safety Levels and Safety Performance
CST	Common Safety Target
CTT	Authorisations in conformity to type
ECVVR	European Centralised Virtual Vehicle Register
EIM	European Rail Infrastructure Managers (Association)
ERA	European Union Agency for Railways
ERADIS	European Railway Agency Database of Interoperability and Safety
ERATV	European Register of Authorised Types of Vehicles
ERSAD	European Railway Station Accessibility Database
ERTMS	European Rail Traffic Management System
ETCS	European Train Control System
EVR	European Vehicle Register
FRMCS	Future Railway Mobile Communication System
GSM-R	Global System for Mobile Communications-Railway
Interoperability	The ability of a rail system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance for these lines.
NIB	National Investigation Body

NoBos	Notified conformity assessment bodies
NSA	National Safety Authority
OPC	Open Public Consultation
OSS	One-Stop-shop
PCP	Priority Country Programme
RDD	Reference Document Database
RINF	Register of Infrastructure
SMS	Safety Management System
SMSS	Smart and Sustainable Mobility Strategy
SPD	Single Programming Document
SRD	Single Rules Database
SSC	Single Safety Certificate
UNIFE	Union of European Railway Industries
VA	Vehicle Authorisation
TSI	Technical Specifications for Interoperability
CCS TSI	TSI relating to the Control Command and Signalling Subsystems
Energy TSI	TSI relating to the energy subsystem of the rail system
Infrastructure TSI	TSI relating to the infrastructure subsystem of the rail system
LOC&PAS TSI	TSI relating to Locomotives and Passenger Rolling Stock
Noise TSI	TSI relating to the subsystem Rolling stock – noise
OPE TSI	TSI for Interoperability on Operation and Traffic Management

PRM TSI	TSI relating to accessibility for persons with disabilities and persons with reduced mobility
SRT TSI	TSI relating to safety in railway tunnels
TAF TSI	TSI relating to telematics applications for freight
TAP TSI	TSI relating to telematics applications for passengers
WAG TSI	TSI relating to the subsystem Rolling stock — Freight Wagons

1. INTRODUCTION

This report presents the findings of the evaluation pursuant to Article 82(1) and (2) of the Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (hereafter "the ERA Regulation"). Pursuant to Article 82(1), the Commission is required to evaluate the impact, effectiveness and efficiency of the Agency and its working practices and address any potential need to modify its mandate. Furthermore, Article 82(2) requires the Commission to assess the functioning of the dual system for vehicle authorisation and safety certification, the one-stop shop facilitating respective applications to ERA and the NSAs, and the harmonised implementation of European Railway Traffic Management System (hereafter ERTMS) in the Union. While this evaluation formally constitutes the first evaluation of the Agency, it also fulfils the obligation set out under Article 82(4) to assess the results achieved by ERA in relation to its mandate, objectives, and tasks.

1.1 CONTEXT

The creation of an integrated European railway area called for harmonised safety rules and improved technical compatibility of infrastructure, rolling stock, signalling, as well as simpler procedures for approving rolling stock for use across the EU. The Agency, based in Valenciennes, France, was set up in 2004 as part of the 2nd Railway Package, by means of Regulation (EC) No 881/2004 of 29 April 2004[1]. The objective of ERA was to contribute, on technical matters, to the implementation of the Union legislation aimed at improving the competitive position of the railway sector by enhancing the level of interoperability of railway systems and at developing a common approach to safety on the European railway system, to contribute to creating a European railway area without frontiers and guaranteeing a high level of safety. ERA was initially responsible for:

- developing, promoting and monitoring a common EU approach to safety management and governance across stakeholders,
- developing the common technical specifications for interoperability (TSIs) and common safety methods and targets (CSMs and CSTs), working closely with stakeholders from the rail sector, national authorities, the EU institutions and other interested parties,
- organising and facilitating the exchange of information within the railway sector by networking with national bodies, providing registers and databases, issuing reports, and giving guidance on the implementation of the regulatory framework.

On 11 May 2016 the co-legislators agreed on a substantial extension of the role of ERA in a new basic act as part of the Technical Pillar of the 4th Railway Package[2]: Regulation (EU)

[1] OJ L 164, 30.4.2004, p.1.

[2] Regulation (EU) 2016/796 on the European Union Agency for Railways and repealing Regulation (EC) n° 881/2004

2016/796 on the European Union Agency for Railways repealing Regulation (EC) No 881/2004.

As of 16 June 2019, three years after the entry into force of the 4th Railway Package, ERA took over several responsibilities of National Safety Authorities (NSAs). It became the EU authority responsible for issuing authorisations for railway rolling stock (locomotives, coaches and wagons) for national or EU-wide use, for issuing single safety certificates (SSCs) for railway undertakings operating in one or more Member States and for approving trackside projects of the ERTMS. According to the 4th Railway Package, the NSAs remain responsible for safety authorisations of infrastructure managers and the authorisation for placing in service of fixed installations relating to rail infrastructure and power supply. Applicants seeking to obtain SSCs or vehicle authorisations limited to the territory of one Member State, may address the request to the NSA of that Member State.

In addition, the Agency is responsible for rail digitalisation, and it is the system authority for ERTMS (in practice train protection, radio communication and part of signalling) and separately, system authority for telematics applications (management of the functional exchanges between the actors of the EU rail sector). Moreover, the Agency is the system authority for important rail registers, which it manages, such as the register of the EU rail infrastructure (RINF), the EU vehicle register (EVR), the register for vehicle types (ERATV), and the register of rail safety-related entities and certificates (ERADIS).

ERA's administrative and management structure comprises an Executive Director, a Management Board and an Executive Board[3].

The Agency is managed by its Executive Director[4], which is accountable to the Management Board for his or her activities (see Section 4.1 for more information). The Executive Director is responsible for:

- day-to-day administration.
- implementing decisions adopted by the Management Board.
- preparing and implementing programming documents.
- preparing consolidated annual activity reports.

According to the ERA Regulation, the main role of the Management Board is to streamline the decision-making process in the Agency and contribute to enhancing its efficiency and effectiveness. It should give general orientations for the Agency's activities and be more closely involved in the monitoring of the Agency's activities, with a view to reinforcing supervision on administrative and budgetary matters. The Management Board has a supervisory role with general responsibility for budgetary and planning matters; the appointment of the Executive Director, the members of the Executive Board, the members of the Board(s) of Appeal and the reporting of the Agency's activities to EU institutions.

Directive (EU) 2016/797 on the interoperability of the rail system within the European Union (Recast of Directive 2008/57/EC)

Directive (EU) 2016/798 on railway safety (Recast of Directive 2004/49/EC)

[3] https://www.era.europa.eu/agency-you/management-executive-boards_en#oe-content-paragraph-462

[4] https://www.era.europa.eu/agency-you/agency/executive-director_en

The Management Board is composed of one representative of each Member State and two representatives of the Commission, all with the right to vote, each one with an alternate in case of absence. Norway participates as a Board member without a right to vote as it is one of the Member States of the European Economic Area (EEA). It also includes six representatives, without a right to vote, of the railway sector at European level (i.e. Railway undertakings, Infrastructure managers, railway industry (i.e. railway equipment manufacturers)), trade-union organisations, passengers and freight customers, appointed by the Commission. All the Management Board members are appointed for a term of office of four years, which may be renewed. They are appointed as well as their alternates in the light of their knowledge of the Agency's core business, taking into account relevant managerial, administrative and budgetary skills.

At the practical level, the Management Board adopts the programming document containing annual and multi-annual programmes by 30 November each year, taking into account the opinion of the Commission. This is forwarded to the European Parliament, the Council and the Commission.

An Executive Board has also been set up to assist the Management Board by preparing the decisions to be adopted, ensure an adequate follow-up to the findings and recommendations after investigations and the various internal or external audits. It also supports and advises the Executive Director in the implementation of the Management Board decisions, with a view to reinforcing supervision of administrative and budgetary management.

It is composed by the following Management Board members: the chairperson of the Management Board (acting as the chairperson of the Executive Board), four representatives of Member States, and one representative of the Commission in the Management Board. The four representatives of the Member States are appointed by the Management Board on the basis of their relevant competence and experience.

The Executive Board meets at least every three months and, where possible, not less than two weeks prior to the meeting of the Management Board.

The 4th Railway Package Steering Group is a subgroup with an advisory character that developed proposals for improvements following the implementation of the 4th Railway Package. The six recommendations are:

1) Recommendation addressed to the Agency to establish two Advisory Groups for vehicle authorisation (VA) and Operations/single safety certification (SSC) and test their functioning
2) Recommendation addressed to the Agency on a short-list of subjects for testing the Advisory Groups
3) Recommendation addressed to the Agency a list of other subjects for discussing in the Advisory Groups
4) Recommendation addressed to the European Commission regarding cross-border agreements
5) Recommendation addressed to the Agency on the cooperation between ERA and NSAs in the PoE mandatory part 6) Recommendation addressed to the VA Advisory Group for short and mid-term solutions for reducing standstill for Conformity to type (CTT) authorisations in case of upgrading (e.g., of ERTMS)

These recommendations were endorsed by the Management Board of ERA under Decision n° 285, in January 2022[5].

1.2 PURPOSE AND SCOPE OF THE EVALUATION

Pursuant to Article 82(1) of the ERA Regulation, the Commission is required to evaluate the impact, effectiveness and efficiency of the Agency and its working practices and address any potential need to modify its mandate. The period under assessment is 2016–2024, i.e. from the adoption of the technical pillar of the 4th Railway Package including ERA Regulation to mid-2024. A particular focus is on 2019–2024, the years when ERA's new mandate was operational, even though the technical pillar of the 4th Railway Package was transposed in three phases: 16 June 2019, 16 June 2020, and 31 October 2020. Further details on timing of activities and limitations are set out in Annex II. Moreover, Article 82(2) requires the Commission to assess the functioning of the dual system for vehicle authorisation and safety certification, the one-stop shop facilitating respective applications to ERA and the NSAs, and the harmonised implementation of ERTMS in the Union. While this evaluation formally constitutes the first evaluation of the Agency, it also fulfils the obligation set out under Article 82(4) to assess the results achieved by ERA in relation to its mandate, objectives, and tasks.

More specifically, and in line with the Better Regulation Guidelines, this evaluation analyses:

- under effectiveness, the extent to which ERA achieved its objectives,
- under efficiency, the use of actual resources relative to the results obtained,
- under internal coherence the compliance with the 4th railway package or other relevant legislation,
- for the EU added value, the impact beyond what reasonably could have been achieved by Member States and NSAs alone, and
- for relevance, whether the overall problem analysis and related objectives are still adequate.

The methodology used to carry out the evaluation was developed with the support of an external study and in line with the Better Regulation Guidelines and Toolbox[6]. It is detailed in Annex II of this report. An evaluation matrix (provided in Annex III of this report) was elaborated to answer the evaluation questions. It identified relevant operational questions, indicators, research tools and data sources.

The following sources of information were used for this evaluation:

- Information from the stakeholder consultation activities. These included an open public consultation (OPC), surveys, interviews, and targeted data requests.

[5] Microsoft Word - DECISION nÂ° 285 of the MB endorsing the recommendations of the 4RP SG following the implementation of the 4RP.docx

[6] https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en

- A review of existing literature including relevant ERA documents such as Annual Activity Reports and Single Programming Documents (SPD), and
- Analysis of relevant ERA datasets.

The limitations inherent to the methodology are:

- The study supporting this evaluation took place in a period when the implementation of certain key aspects of the 4th Railway Package was still incomplete, due to the transposition in three phases: 16 June 2019, 16 June 2020, and 31 October 2020.
- This means that not all key aspects of the 4th Railway Package have been reflected; therefore, additional information had been gathered from ERA tools and documents.
- The learning curve of stakeholders to adjust to the changes and use all opportunities offered under the 4th Railway package has not reached its peak at the time of the evaluation support study, meaning that cost and time saving effects might not have materialised before the finalisation of the support study.
- Insufficient quantitative data on costs of authorisation and certification for applicants, beyond the mere intervention of ERA and NSAs.
- Limited detailed data on time and costs incurred to NSAs for processing applications.

Nevertheless, despite the limitations, this evaluation gives a comprehensive snapshot of the existing information and provides a consistent analysis of the implementation of ERA Regulation and how ERA fulfils its role.

2. WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTION[7]?

2.1 DESCRIPTION OF THE INTERVENTION AND ITS OBJECTIVES

2.1.1 Problem definition

To understand the rationale and objectives of the ERA Regulation, it must be considered within the broader context of the 4th Railway Package. The Regulation forms part of the technical pillar adopted in April 2016, alongside Directive (EU) 2016/797 on the interoperability of the rail system within the European Union (Interoperability Directive) (Recast of Directive 2008/57/EC) and Directive (EU) 2016/798 on railway safety (Safety Directive) (Recast of Directive 2004/49/EC). Both Directives introduce changes to the tasks and the internal organisation of the Agency, justifying the adoption of a new legal act providing for the establishment and tasks of the Agency as well as the tasks of the Member States. One Impact Assessment was conducted in 2013, which accompanied all three legislative proposals[8].

The purpose and general objective of ERA Regulation[9] was to contribute to the further development and effective functioning of a single European railway area without frontiers, by guaranteeing a high level of railway safety and interoperability, while improving the competitive position of the railway sector.

[7] "Intervention" in the context of an Evaluation SWD means the Regulation being evaluated.

[8] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0008:FIN:EN:PDF

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013PC0027&qid=1733599037146

The focus of the ERA Regulation[10], as set out in the Explanatory Memorandum of the Commission proposal, was the removal of the remaining administrative and technical barriers. This was to be done in particular by: (i) establishing a common approach to safety and interoperability rules to increase economies of scale for railway undertakings active across the EU; (ii) decreasing administrative costs and accelerating administrative procedures, and (iii) avoiding disguised discrimination, through the establishment of a European Union Agency for Railways. It was intended to replace the original founding Regulation and to add new important tasks to the Agency, making it a truly European Railway Authority in the field of interoperability and safety.

According to the 2013 Impact Assessment accompanying the proposals for the ERA Regulation, Interoperability Directive and Safety Directive[11], the system of railway authorities in place at that time, while intended to cater for the remaining technical differences between national railway systems, introduced barriers of different natures that contributed, among other factors, to a low degree of efficiency and competitiveness of the rail sector[12]. While in some Member States the national authorities functioned in general efficiently, in others the procedures which they managed were long and costly; this was partly linked to their inadequate resources. At the same time, the interoperability and safety requirements, which in principle should have been aligned by common EU rules, still diverged significantly at the national level. The latter obstacles hampered in particular the processes leading to the delivery by NSAs of the safety certificates and the vehicle authorisations. Therefore, the existing system worked in a sub-optimal manner, and there was room for improvement, especially regarding the operating conditions and administrative costs for railway undertakings.

Based on the above, the key needs and problems identified at the time of the adoption of the 4th Railway Package are:

- **Long and costly authorisation and certification procedures** hindering the development of the common EU railway market and its efficient functioning. This particularly affected new companies wishing to enter the market, thus contributing to a low level of competition and lasting market distortions. As far as the vehicle authorisations issued by the NSAs are concerned, in a large majority of cases national legislation required additional authorisations. The additional authorisation costs amounted to around EUR 1.6 million per vehicle[13]. The high costs and long duration of authorisation and certification contributed also to the slow uptake of innovation and modernisation of railway sector.
- **Insufficient interoperability**: Various national rail networks had grown and evolved heterogeneously over time and relevant national technical and safety rules were put in

[10] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013PC0027&qid=1733599037146

[11] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0008:FIN:EN:PDF

[12] To be noted that safety levels, as such, were not addressed in the 2013 Impact Assessment because, following the introduction of the respective railway packages, the level of railway safety (measured by indicators like number of accidents and fatalities) has had gradually increased. Moreover, the rail safety levels under each option assessed appeared to either remain the same given that the principal responsibilities of each main actor in the safety chain (predominantly Railway Undertakings and Infrastructure Managers) were not changed or could improve slightly as a result of more harmonised national legislation.

[13] ERA (2011), "Report on Railway Vehicle Authorisation", quoted by the 2013 Impact Assessment.

place when no relevant EU rules existed. Even though Directive 2008/57/EC aimed among others at taking steps to avoid situations where Member States adopted new national rules or undertook projects increasing the diversity of the existing system, the experience demonstrated that national rules still represented an obstacle to interoperability within the Single European Rail Area (SERA), as well as a complication for new entrants, especially from other Member States. At the time of the 2013 Impact Assessment, there were still more than 11 000 national rules in the EU.

- **Access barriers for companies wishing to enter the railway market**, in the form of diverging and untransparent processes, were unable to prevent arbitrary and discriminative decisions by NSAs. The approach to safety certification and vehicle authorisation should have in principle allowed the free circulation of trains across the EU. It was based on the principle of mutual acceptance of the Part A certificate[14] regarding the Safety Management System (SMS) and required that NSAs work at similar level of performance. The reluctance of NSAs to accept Part A certificates granted by other NSAs led to additional checks and increased time and cost burdens for rail operators. The new entrants were relatively more vulnerable to complexity and delay in procedures, since their human and financial resources were often limited.

2.1.2 Objectives of intervention

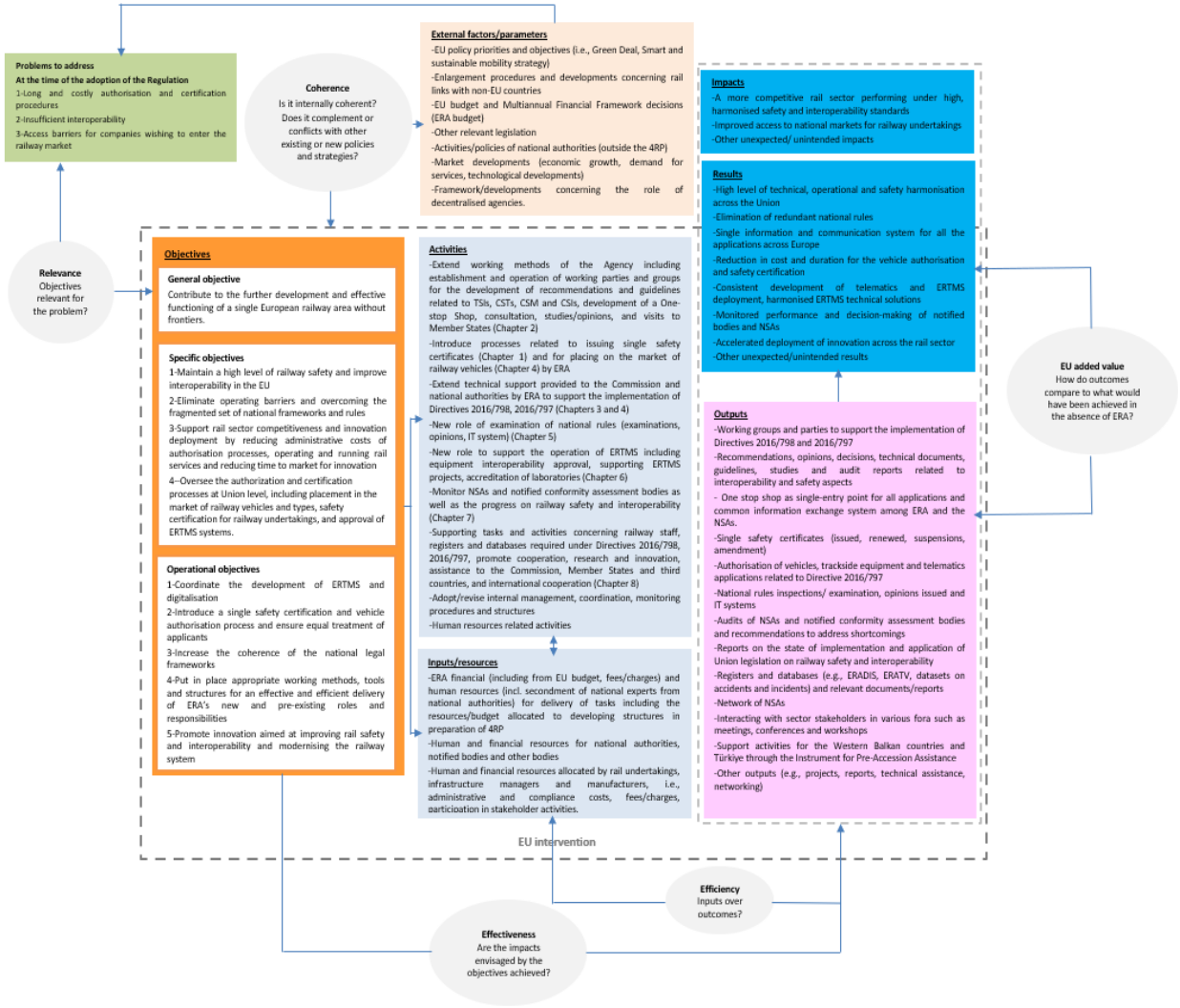
The general objective of the Agency, as expressed in Article 2 of the ERA Regulation, is *to contribute to the further development and effective functioning of a **single European railway area without frontiers**, by guaranteeing a high level of rail **safety** and **interoperability**, while improving the **competitive position** of the railway sector".* The specific objectives of the intervention are the following:

- Maintain a high level of railway safety and improve interoperability in the EU,
- Eliminate operating barriers and overcoming the fragmented set of national frameworks and rules,
- Support rail sector competitiveness and innovation deployment by reducing administrative costs of authorisation processes, operating and running rail services and reducing time to market for innovation,
- Oversee the authorization and certification processes at Union level, including placement in the market of railway vehicles and types, safety certification for railway undertakings, and approval of trackside equipment of ERTMS.

The objectives of the intervention are in line with Sustainable Development Goal (SDG) 9 which covers building resilient infrastructure, promoting inclusive and sustainable industrialisation and foster innovation as well as SDG 11 on making cities and human settlements inclusive, safe, resilient and sustainable. Further, they contribute towards SDG 13 ("Take urgent action to combat climate change and its impacts"). The intervention logic is presented in Figure 1.

[14] The Part A certificate demonstrates that the National Safety Authority has accepted the SMS of the railway undertaking.

Figure 1. Intervention Logic



2.1.3 Activities, inputs and outcomes

The key activities associated with the implementation of the 4th Railway Package and related to the roles of the Agency as defined in chapters 2-8 of the ERA Regulation include both the process of development of the necessary new tools/mechanisms as well as their subsequent operation that is expected to lead to the results. They also cover the management, organisation, human resourcing, monitoring/reporting and other support mechanisms, procedures and structures – as defined in chapters 9-11 of the ERA Regulation – that are intended to ensure that ERA achieves its objectives in an effective and efficient manner.

The intervention logic diagram also points to the role of inputs, in terms of human and financial resources allocated to the Agency and the authorities and by the railway industry. For the Agency, these include the resources coming from the EU budget but also the fees/charges for the approval processes and other chargeable activities that support the implementation. Similarly, national authorities (NSAs and ministries) rely on national budgets and fees charged to industry or to ERA for the support required in delivering specific activities. For the railway industry, they refer to the relevant costs for obtaining

the necessary approvals using the new structures (through the fees paid but also time and other costs associated) and for the participation in other activities (e.g., working groups), where relevant. Capturing these is relevant when it comes to answering the questions on efficiency.

The diagram then captures the expected immediate outputs of these activities, which in turn are expected to lead to results and impacts. The expected results can be defined as follows:

(1) Achieve high level of technical, operational and safety harmonisation in the railway sector,

(2) Eliminate redundant national rules,

(3) Deliver a single information and communication system for all the applications across Europe,

(4) Reduce the cost and duration of the vehicle authorisation and safety certification,

(5) Ensure consistent development of telematics and ERTMS deployment and harmonised ERTMS technical solutions,

(6) Monitor performance and decision-making of notified bodies (NoBos) and NSAs, and

(7) Promote rapid deployment of innovation across the rail sector.

In the longer term, the Agency activities were expected to lead to the following impacts:

(1) A more competitive rail sector performing under high, harmonised safety and interoperability standards, and

(2) Improved access to national markets for railway undertakings.

External factors

A series of external factors were expected to play a role and hence were considered during the evaluation:

- The EU policy context and priorities, including the Market Pillar of the 4th Railway Package but also broader EU policy priorities (e.g. those set by the European Green Deal, and the Smart and Sustainable Mobility Strategy (SSMS)), are to be considered when assessing whether the Agency objectives and activities remain relevant in this context.
- Both market and technological developments in the sector affect the demand for Agency services (such as vehicle authorisations and safety certificates) and the need for adequate resources to respond on time and reduce the time to market of railway innovation. They also need to be reflected in the technical support activities of the Agency – including its own role and contribution to innovation related activities (such as Europe's Rail Joint Undertaking (hereafter "EU-RAIL")).
- Developments at Member States' level including relevant national policies, NSAs' activities, and relevant bilateral or multilateral agreements, as they can influence the effectiveness and EU added value of the ERA activities.

- The EU Multiannual Financial Framework sets the context within which the EU contribution to ERA is determined and hence, the resources available to the Agency to perform its tasks. In addition, the Common Approach on EU decentralised agencies[15] sets certain rules concerning the operation of the Agencies, particularly in organisational and monitoring terms.

2.2 POINT OF COMPARISON

The main point of comparison for this evaluation corresponds to the expected impacts identified in the 2013 Impact Assessment[16] under the preferred policy option as compared to the baseline. The preferred option combines option 4 and the horizontal elements of option 6, while the baseline assumes the continuation of sector developments in the absence of the 4th Railway Package. More details are provided in Annex II.

Table 1 below presents the key aspects of the main point of comparison and identifies relevant targets and benchmarks that have been used in the 2013 Impact Assessment to assess the performance of the Agency in the implementation of the 4th Railway Package.

Table 1. Key aspects of the main point of comparison

Key aspects of the main point of comparison	Expected performance/target compared to the 2013 Impact Assessment baseline
Authorisation and certification timescales and costs for applicants	Authorisation: • Expected 24% reduction of average cost and 22% reduction of average time – from 12 to 9 months. • In addition: 25% reduction in time to market. • Estimated authorisation cost savings for railway undertakings of EUR 235 million expressed as present value over 2015-2025 relative to the baseline. • Additional opportunity costs savings of EUR 265 million for railway undertakings expressed as present value over 2015-2025 relative to the baseline. Safety certification: • Expected 19% reduction of average cost and 33% reduction of average time. ERTMS trackside approval • No defined target as this is a new role. • ERA to check that calls for tenders published in the case of individual deployment projects are in line with the ERTMS specifications.
Impact on resources/costs for certification/ authorisation under new system	ERA 55 additional full-time equivalents (FTEs) per year for authorisation/certification by 2020 (when all staff changes have been phased in) EUR 6.6 million annual increase in ERA budget by 2020 (when all staff changes have been phased in) covering staff and overheads. Expressed as present value over 2015-2025, the additional budget for ERA is estimated at EUR 44 million relative to the baseline.

[15] https://european-union.europa.eu/document/download/d4199ff4-1e3d-45e6-af7e-90cf1a7b10bc_en?filename=joint_statement_on_decentralised_agencies_en.pdf&prefLang=el

[16] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0008:FIN:EN:PDF
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013PC0027&qid=1732820854649

Key aspects of the main point of comparison	Expected performance/target compared to the 2013 Impact Assessment baseline
	NSAs 5 FTE per NSA average annual reduction for authorisation/certification, equivalent to EUR 0.55 million annual staff cost saving per NSA by 2020 (when all staff changes have been phased in). Expressed as present value over 2015-2025 relative to the baseline, the total costs savings (for staff and overhead) for all NSAs are estimated at EUR 68 million.
Evolution of national rules on safety and interoperability	Expected reduction in the number of rules in cooperation with Member States but no set target for level of reduction to be achieved. Member States to be limited in the adoption of new rules to strictly defined cases.
Monitoring of NSAs	No specific performance target set in the Impact Assessment. ERA expected to monitor the performance and decision making of the NSAs, including the capacities (staffing, financial resources) of NSAs to execute tasks related with railway safety and interoperability, and effectiveness of their operations as regards monitoring of SMSs of railway.
Monitoring of NoBos	No specific performance target set in the impact assessment but positive impact from the supervision of NoBos by ERA giving greater confidence in NoBos outputs. Possible increase in costs for NoBos from audits.
Technical support/ recommendations on railway safety and interoperability/ TSI development	No specific target or level of performance set. It can be derived that Agency role and capacity will be strengthened, that work on TSI development will continue and that TSIs will be adopted more broadly in a harmonised way and in the place of applicable national rules.
Datasets/registers	No specific targets set but expectation/requirement that appropriate information tools/registers are in place to support delivery authorisation/certification activities and screening/elimination of national rules.
ERA internal capacity/ resources/ management structures and procedures	Strengthened capacity of the Agency assumed (in terms of resources/expertise) to be able to deliver on the new roles and responsibilities.
Impacts on safety and interoperability	Enhanced level of interoperability of the basis of the adoption of the elimination of national rules incompatible with TSIs and CSMs. Rail safety levels under each option to remain the same or improve slightly as a result of more harmonised national legislation.
Impacts on rail freight market, prices, service levels and rail investments	Expected increased number of market entrants due to the reduction of costs and removal/reduction of restrictions linked to national rules (effect to be greater in countries with higher level of restrictions). Indirect positive impact on rail freight prices, service levels and rail investments triggered by the changes in rail market structure (increased market entry) and reduced authorisation/opportunity costs.

The expected cost impacts of the 2013 Impact Assessment were based on several

assumptions regarding the level of authorisation or certification activity which have proven to underestimate the actual level of activity. Moreover, the cost assumptions concerning the authorisation or certification procedures are not comparable with the actual processes and approach adopted. First, the volume of work performed by ERA is higher than anticipated in the 2013 Impact Assessment. Second, the work NSAs have to do for ERA authorisations is more extensive and thus, more costly than originally expected. Nevertheless, the 2013 Impact Assessment estimations remain useful for comparison purposes.

The 2013 Impact Assessment had also some limitations. It lacked quantitative benchmarks for other parts of the implementation of the 4th Railway Package and provided a relatively brief qualitative description of the expected impacts. In some areas there was no explicit mention of the expected performance, but it is possible to derive the expected impacts based on the Impact Assessment and ERA Regulation. The 2013 Impact Assessment also included a description of the implementation scenario for the preferred policy option and identified several risk parameters and factors that could be detrimental to the successful delivery of the intervention and achievement of the objectives set. The risk factors identified in the 2013 Impact Assessment remain relevant when considering the parameters that actually have affected the performance of the Agency and provide explanation for possible deviations.

3. HOW HAS THE SITUATION EVOLVED OVER THE EVALUATION PERIOD?

3.1 LEGAL FRAMEWORK

The adoption of the technical pillar of the 4th Railway Package in 2016 brought significant changes to the roles and responsibilities of the Agency. However, before the new legislative framework became fully effective and ERA could take up its new tasks, preparatory work was needed to adopt the necessary secondary legislation and establish new tools and working procedures.

The Rail Safety and Interoperability Directives of the 4th Railway Package provided Member States with a choice of two transposition deadlines – 16 June 2019, or, upon notification to the Commission and ERA, 16 June 2020. Further, as part of the emergency measures adopted by the Commission in reaction to the COVID-19 outbreak and in response to Member States' requests, an additional transposition deadline of 31 October 2020 was introduced. As a result, the technical pillar of the 4th Railway Package was transposed by the Member States in three phases[17].

Eight Member States started applying the 4th Railway Package on 16 July 2019, therefore ERA had to finish all preparatory work before that date, to be able to receive and process first applications already on that date. This included developing a plan with all necessary deliverables clustered into projects and setting up an internal structure to manage the project portfolio. The overall progress was monitored by the Agency's management as

[17] Transposition Interoperability Directive:
https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=CELEX:32016L0797
Transposition Safety Directive: https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=CELEX:32016L0798

well as by the 4th Railway Package Steering Group that was established at the level of ERA Management Board and composed of representatives of different stakeholders[18].

Based on formal recommendations as well as on various inputs provided by ERA, between 2017 and 2019 the Commission adopted 14 legislative acts which laid the ground for a smooth implementation of the new roles of the Agency, in particular the roll-out of the dual system[19] of vehicle authorisation and safety certification (Table 2). In parallel, ERA prepared and adopted its internal procedures and deployed first versions of necessary IT tools.

Table 2. List of secondary legislation adopted from 2017 to 2019 in preparation for the application of the technical pillar of the 4th Railway Package

Year	Legislation
2017	– Commission Delegated Decision (EU) **2017/1474** of 8 June 2017 supplementing Directive (EU) 2016/797 of the European Parliament and of the Council with regard to specific objectives for the drafting, adoption and review of technical specifications for interoperability
2018	– Commission Implementing Regulation (EU) **2018/545** of 4 April 2018 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council – Commission Delegated Regulation (EU) **2018/761** of 16 February 2018 establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 1077/2012 – Commission Delegated Regulation (EU) **2018/762** of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010 – Commission Implementing Regulation (EU) **2018/763** of 9 April 2018 establishing practical arrangements for issuing single safety certificates to railway undertakings pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council, and repealing Commission Regulation (EC) No 653/2007 – 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 – 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
2019	– Commission Implementing Regulation (EU) **2019/250** of 12 February 2019 on the templates for EC declarations and certificates for railway interoperability constituents and subsystems, on the model of declaration of conformity to an authorised railway vehicle type and on the EC verification procedures for subsystems in accordance with Directive (EU) 2016/797 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 201/2011 – Commission Implementing Regulation (EU) **2019/772** of 16 May 2019 amending Regulation (EU) No 1300/2014 as regards inventory of assets with a view to identifying barriers to accessibility, providing information to users and monitoring and evaluating progress on accessibility – Commission Implementing Regulation (EU) **2019/775** of 16 May 2019 amending Regulation (EU) No 454/2011 as regards Change Control Management

[18] 4th Railway Package Readiness Assurance Terms of Reference, adopted by ERA Management Board at the meeting on 26 September 2017.

[19] In the case of operations in more than one Member State, the Agency is the authorising entity. Otherwise, the applicant can choose whether to apply to the Agency or to the relevant NSA.

Year	Legislation
	– Commission Implementing Regulation (EU) **2019/776** of 16 May 2019 amending Commission Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1303/2014 and (EU) 2016/919 and Commission Implementing Decision 2011/665/EU as regards the alignment with Directive (EU) 2016/797 of the European Parliament and of the Council and the implementation of specific objectives set out in Commission Delegated Decision (EU) 2017/1474 – Commission Implementing Regulation (EU) **2019/777** of 16 May 2019 on the common specifications for the register of railway infrastructure and repealing Implementing Decision 2014/880/EU – Commission Implementing Regulation (EU) **2019/778** of 16 May 2019 amending Regulation (EU) No 1305/2014 as regards Change Control Management – Commission Implementing Regulation (EU) **2019/779** of 16 May 2019 laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 445/2011

Source: Ricardo (2023) Evaluation support study

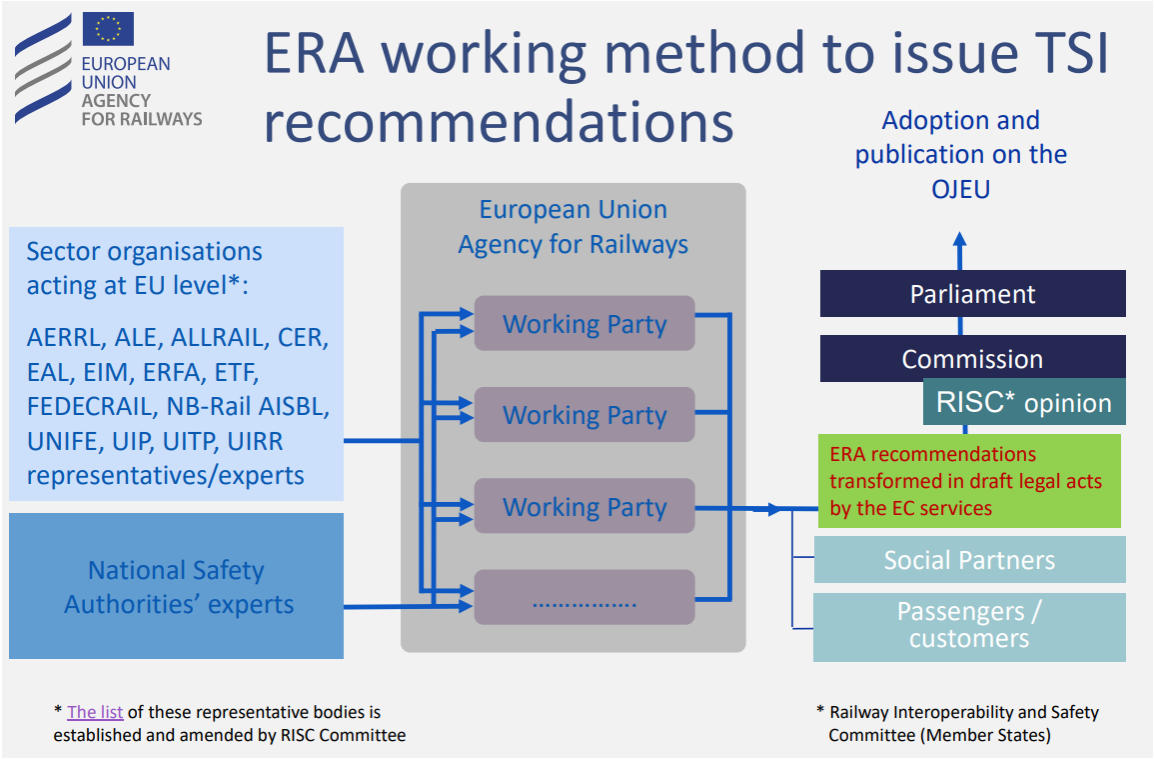
3.2 PROVISION OF TECHNICAL ASSISTANCE

Compared to its previous mandate, the 4th Railway Package brought limited changes to ERA's role in supporting the Commission and the Member States with technical assistance to improve the interoperability of the European railway systems and its safety.

The Technical Specifications for Interoperability (TSIs) define the technical and operational standards which must be met by each subsystem[20] or part of subsystem in order to meet the essential requirements and ensure the interoperability of the railway system of the European Union. The essential requirements can be summarised as safety, reliability and availability, health, environmental protection, technical compatibility and accessibility. Article 5(2) of the Interoperability Directive provides for the Commission requesting the Agency to draft TSIs and amendments thereto and make the relevant recommendations to the Commission. The ERA working method to issue TSI recommendations is presented in Figure 2.

[20] Directive (EU) 2016/797 defines the subsystems, either structural or functional, forming part of the railway system of the European Union.

Figure 2. ERA Working method for issuing TSIs recommendations



Since June 2016, two major TSI revisions cycles took place. In addition, and following extensive stakeholder consultations, the request to the Agency for recommendations for future TSI revisions was made in August 2024, outlining a multiannual plan for the upcoming TSI revision cycles until 2030 to prepare TSIs for new technologies, to close open points where national rules may still be possible or add areas inadequately covered in previous versions of TSI.

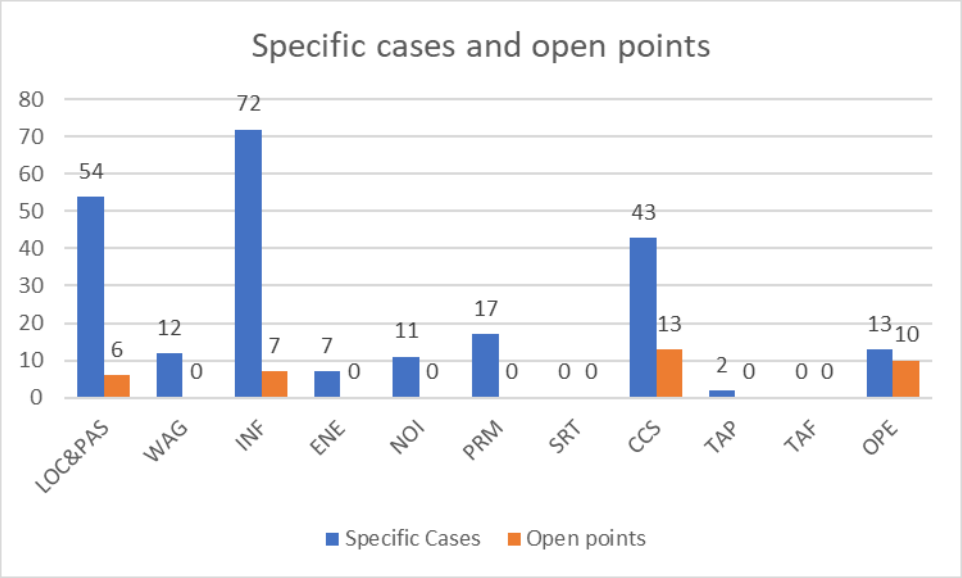
In 2019 all TSIs were revised[21] and brought in line with the 4th Railway Package, only OPE TSI underwent a deeper revision at this stage.

In 2023 eight TSIs[22] were revised with a view of achieving higher levels of interoperability: CCS TSI was recast, while TSIs LOC&PAS, WAG, OPE, INF, ENE and PRM were amended. Figure 3 summarises the specific cases and open points remaining after these revisions. One of the open points concerns TSI Noise (Noise of parked trains), which should be part of the new TSI request to be included in the TSI Revision following a respective recommendation by the Agency in 2028.

[21] A chronology table for all TSIs can be found at https://www.era.europa.eu/system/files/2022-10/TSIs%20chronology%20table.pdf?t=1718972267. It includes details on the Commission Implementing Regulation that updated one or multiple TSIs.

[22] TSI relating to the Control Command and Signalling Subsystems (CCS TSI), TSI relating to Locomotives and Passenger Rolling Stock (LOC&PAS TSI), TSI relating to the infrastructure subsystem of the rail system (INF TSI), TSI relating to the energy subsystem of the rail system (ENE TSI), TSI relating to accessibility for persons with disabilities and persons with reduced mobility (PRM TSI); TSI relating to the subsystem Rolling stock — Freight Wagons (WAG TSI), TSI for Interoperability on Operation and Traffic Management (TSI OPE).

Figure 3. Specific cases and open points per TSI as of 30 June 2024



Source: ERA

Further, under Article 6(2) of the ERA Regulation, the Agency is tasked to issue recommendations to the Commission concerning the CSMs[23]. These methods describe how the safety levels, the achievement of safety targets and compliance with other safety requirements should be fulfilled. Currently, there are five CSMs which cover requirements for SMSs, monitoring, supervision, risk assessment and assessment of safety targets. Further, two CSMs on conformity assessment remain temporarily in force until 30 October 2025 when last certificates issued based on these requirements will expire.

In January 2019 ERA received a mandate from the Commission to draft a recommendation for a new CSM concerning the Assessment of Safety Levels and Safety Performance of railway operators at national and Union level (CSM ASLP), building on results of earlier work of the Agency performed under Article 18 of the ERA Regulation on exchange of information on safety-related accidents. On that basis, ERA analysed the possibility of introducing a system for reporting occurrences, which would facilitate the exchange of information on accidents and their causes between relevant actors. The recommendation for the CSM ASLP was presented by the Agency to the Commission in 2021 and it was accompanied by an impact assessment[24]. The Commission Delegated Regulation on CSM ASLP has not yet been adopted. Its adoption (estimated for 2026) aims to support railway safety by providing a preventive framework for addressing accidents and their causes.

In addition to recommendations, the Agency has also developed opinions, which are non-binding acts providing specialised expertise on railway issues to decision-makers, including the European Commission, National Regulatory Bodies or Member States. A total of 78 opinions[25] have been provided by the Agency since the adoption of the 4th Railway Package.

[23] The current structure of CSMs was introduced in 2018, following their latest partial revision. Based on a mandate from 2014 (updated in 2016 to reflect the new legal basis), the Agency has issued in 2017 a recommendation covering two CSMs: on safety management systems and supervision.
[24] Impact Assessment (2).pdf
[25] https://www.era.europa.eu/library/documents-regulations/opinions-and-technical-advices?f%5B0%5D=lp_opitecha_title%3AOpinion

ERA is also required to provide technical advice on matters requiring specific knowledge and collecting information through networks. Technical advice mainly regarding interoperability was provided on 24 occasions[26] since the adoption of the 4th Railway Package. Finally, ERA Regulation also introduced the requirement for an impact assessment of recommendations and opinions. Depending on the nature of the change, the Agency may sometimes conduct a light impact assessment instead of a full impact assessment.

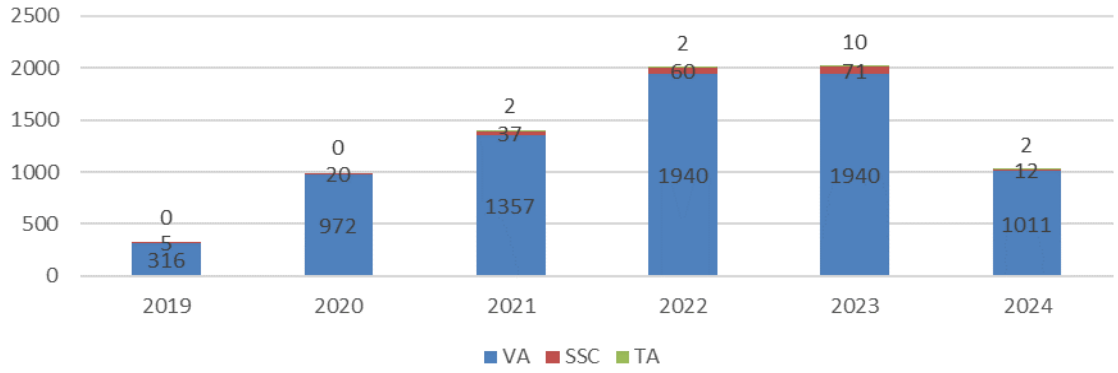
3.3 AUTHORITY[27] TASKS

Authority tasks of the Agency are related to safety certification for railway undertakings, vehicle authorisation and ERTMS trackside approval.

The Agency started delivering authority tasks on 16 July 2019, and ERA's new role became fully applicable in all Member States at the end of October 2020 when the last deadline for transposition of the technical pillar of the 4th Railway Package passed. The volume of work related to the new authority tasks increased over time and especially since October 2020. Figure 4 presents the total number of application decisions issued by ERA since 2019 and the respective vehicles authorised; the steady uptake of the workload of ERA until it fully took up the relevant roles is apparent. The figure shows the gradual increase in ERA's workload after 2021, which was the first full year when the Agency authority role was applicable in all Member States.

Despite the increasing workload, all decisions have been taken within the deadline set in the legal framework taking into account any time freeze agreed with the applicants[28].

Figure 4. Number of decisions issued by the Agency for authority tasks (June 2019 - June 2024)



Source: ERA – One-Stop Shop. Note: VA stands for Vehicle Authorisation; SSC stands for Single Safety Certificate and TA stands for ERTMS trackside approval

[26] https://www.era.europa.eu/library/documents-regulations/opinions-and-technical-advices?f%5B0%5D=lp_opitecha_title%3Aadvice

[27] Where provided for by the Safety and the Interoperability Directives, the Agency shall perform the role of Union authority responsible for issuing authorisations for the placing on the market of railway vehicles and vehicle types and for issuing single safety certificates for railway undertakings. Further, ERA shall act as the system authority to ensure the coordinated development of telematics applications, system authority for ERTMS, as well as for all registers and databases referred to in the Safety Directive and Interoperability Directive.

[28] Annual Activity Reports of the Agency, 2019-2023.

3.3.1 Vehicle authorisation

Any new or significantly modified railway vehicle must be authorised before operating on the EU railway network. An authorisation is valid for a defined area of use, i.e. a network or networks within one or more Member States. If the area of use is limited to a network or networks within one Member State, the applicant can submit the application for vehicle authorisation either to the NSA or to ERA. In case of vehicles having an area of use in more than one Member State, ERA is always the issuing authority.

Two main categories of vehicle authorisations can be distinguished:

- authorisations pertaining to a new vehicle design – normally the first in class, which are complex and require the complete assessment of the vehicle's design against the applicable requirements,
- authorisations in conformity to type (CTT), provided to individual vehicles conforming to an already authorised type. The process involves simple administrative checks and can be finalised in a couple of days.

These two processes also apply to significant changes to existing vehicles and types - in practice the source of much of the work of ERA. Until end of June 2024, the Agency has delivered decisions in 7 536 applications for vehicle authorisation which included 710 applications for type authorisations and 6 826 applications for CTT (Table 3). In the same period, the NSAs processed over 4 900 applications, i.e. around 2 500 applications less than ERA.

Table 3. Number of vehicle authorisations delivered by ERA and NSAs between June 2019 and June 2024

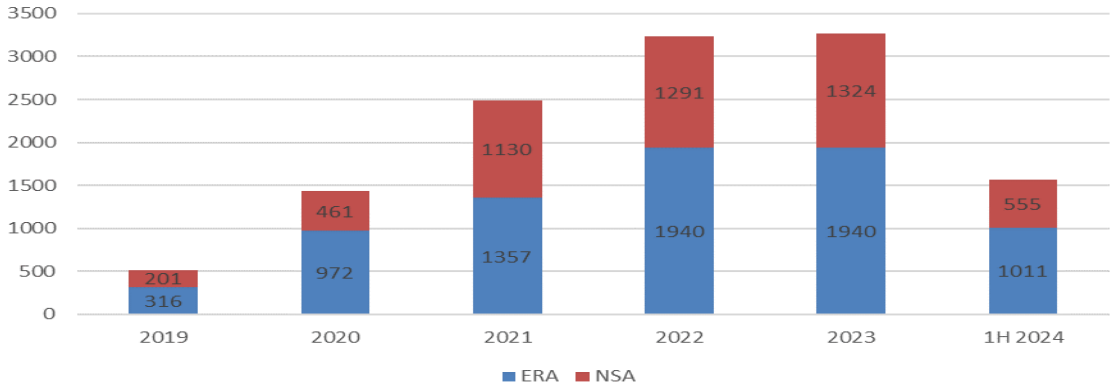
	ERA	**NSAs**
Authorisation in conformity to type	6 826	3 952
Type authorisations	710	1 010
Total	**7 536**	**4 962**

Source: ERA - One-Stop Shop

The number of applications received every year by ERA and NSAs was rising sharply until 2022 and stabilised in 2023 at a level of around 3 200 decisions (Figure 5). A similar or slightly higher number can be expected in 2024 assuming the tendency from the first half of 2024 is kept.

Overall, after five years of operation as an authorisation entity, the Agency processed 60.3% of all vehicle authorisation applications registered in the One-Stop Shop (OSS). This share remains relatively stable throughout the years with a maximum of 67.8% in 2020, when however not all Member States were yet included in the new authorisation system.

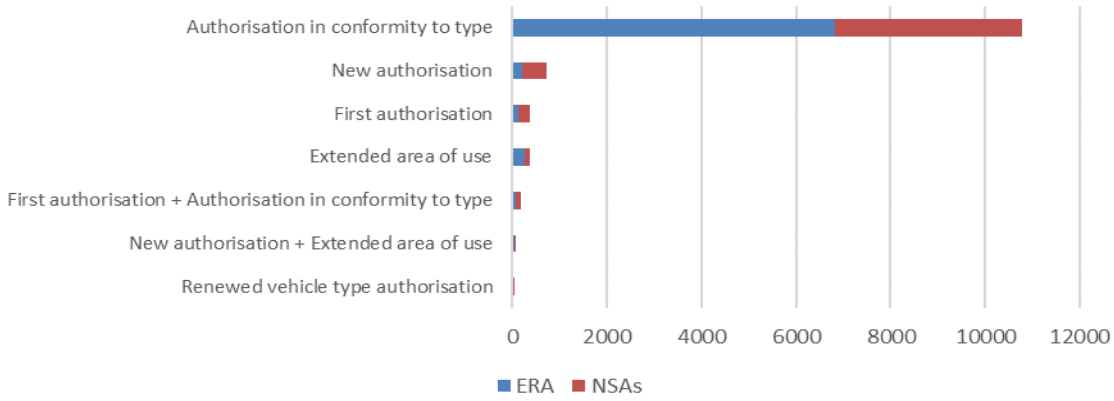
Figure 5. Number of vehicle authorisation decisions issued by ERA and NSAs (June 2019 - June 2024)



Source: ERA – One-Stop Shop

Vehicle authorisations (VA) are categorised according to cases which are listed in Article 14 of Implementing Regulation (EU) 2018/545[29]. Authorisations in conformity to type constitute the largest group which dominates the work of both ERA and the NSAs; they account for 90.6% of VA workload of the Agency and 79.7% of VA workload of NSAs. For other types of applications, the differences between ERA and NSAs become more visible. The Agency processes 71% of all applications linked to an extension of area of use of railway vehicles and 52.5% of cases when a new authorisation is combined with an extension of area of use. On the other hand, NSAs process 71.2% of applications for new and first authorisations and ERA 64.4% (Figure 6).

Figure 6. Structure of all vehicle authorisation applications by authorisation case (June 2019 – June 2024)



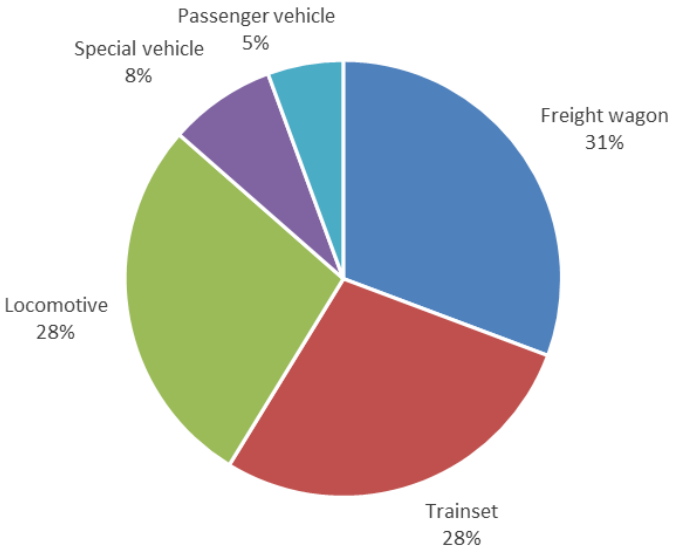
Source: One-Stop Shop data

This distribution of work between ERA and NSAs is driven by two important factors: the expected area of use of a vehicle and its type (locomotive, trainset, special vehicle, wagon or coach).

[29] When a first vehicle of a certain design is authorised, a vehicle type authorisation is granted at the same time ('first authorisation'). Throughout its life cycle, changes can be introduced to the vehicle which when meet certain thresholds trigger a need for a 'new authorisation'. It is also possible to receive an authorisation extending area of use of an existing vehicle not subject to any changes to another network or networks, also in a different Member State ('extension of area of use'). When TSIs or national rules provide so, type authorisation might also require a renewal to verify its compliance with revised requirements contained in these acts ('renewed type authorisation').

In general, regardless of the authorising entity, most applications for vehicle authorisation cover freight wagons (Figure 7). They account for 31% of all applications. Trainsets and locomotives have the same share of 28% each. Special vehicles account for 8% of applications and the remaining 5% belong to passenger coaches.

Figure 7. Structure of decisions for vehicle authorisation by vehicle type (June 2019 - June 2024)



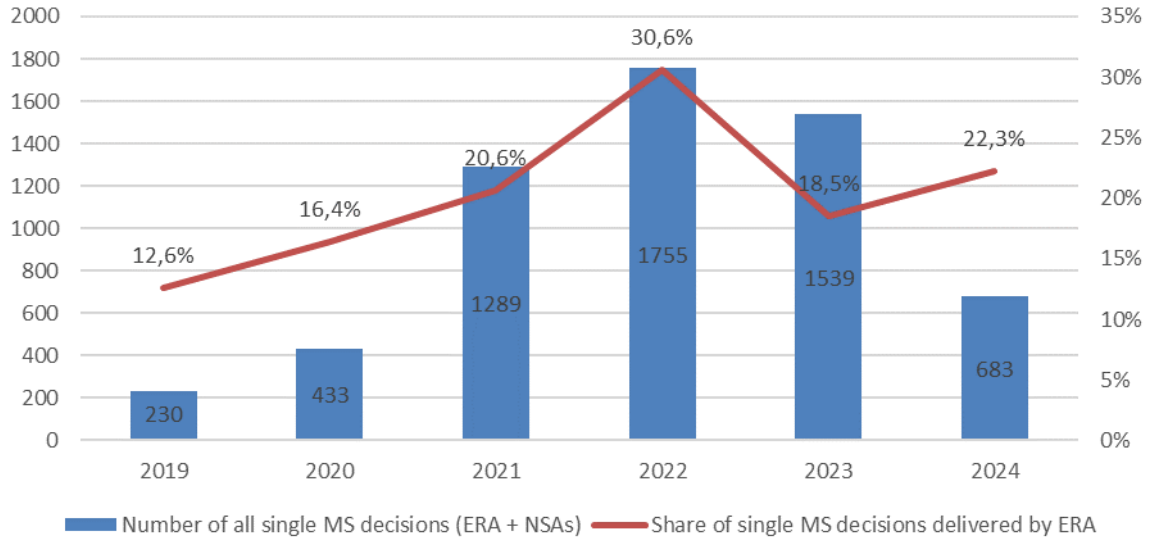
Source: One-Stop Shop data.

Freight wagons are the only type of rolling stock where multi-country applications for vehicle authorisation prevail over single-country applications, i.e., 95.8% of all authorisation applications for freight wagons cover multiple Member States and must be addressed to the Agency. On the contrary, for locomotives the share of multiple Member States applications is 48.4% and further decreases for passenger vehicles (15.2%), trainsets (13.2%) and special vehicles (7.9%).

This specific situation of freight wagons is linked to the fact that freight wagons are largely designed to be and often are operated in the whole EU, and the existing legal framework facilitates obtaining an EU-wide authorisation for this type of vehicles.

The Agency's workload is further increased by single-country applications which are addressed to ERA by applicants on a voluntary basis. ERA is particularly often chosen as authorisation entity in case of locomotives – 33.6% single-country applications for that type of vehicles are addressed to ERA. For trainsets this share is 22.4%, for special vehicles 11.2% and for passenger coaches 10%. Overall, on average every fifth application (22.6%), which covered only one Member State, was sent to the Agency (Figure 8).

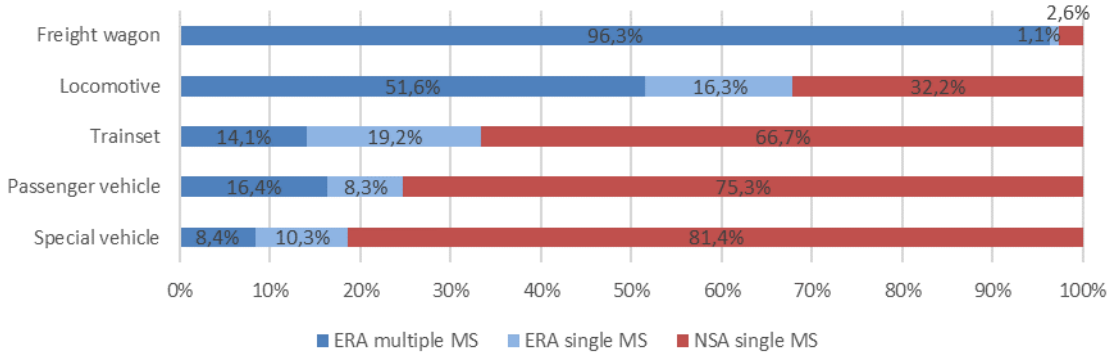
Figure 8. Evolution in the number of vehicle authorisation decisions covering single Member States delivered by ERA+NSAs and share of decisions issued by ERA (June 2019 - June 2024)



Source: One-Stop Shop data.

The crucial role played by the Agency in authorising freight wagons in the EU is illustrated in Figure 9. ERA issued 97.4% of all authorisation decisions relating to this type of vehicles (both for single and multiple Member States). The Agency's role is also very important in terms of authorising locomotives, where it is responsible for issuing 67.9% of all decisions. In both these cases the leading role of ERA as authorising entity is largely a result of the international character of these rolling stock manufacturing segments, as these types of vehicles are largely produced to be operated on a wider, EU market. This is less the case for trainsets, passenger vehicles and special vehicles which remain a national domain, with leading role of NSAs as authorising entities. ERA issues respectively only 33.3%, 24.7% and 18.7% of the decisions for these groups of vehicles.

Figure 9. Structure of decisions for vehicle authorisation by vehicle type, authorising entity, and area of use (June 2019 - June 2024)

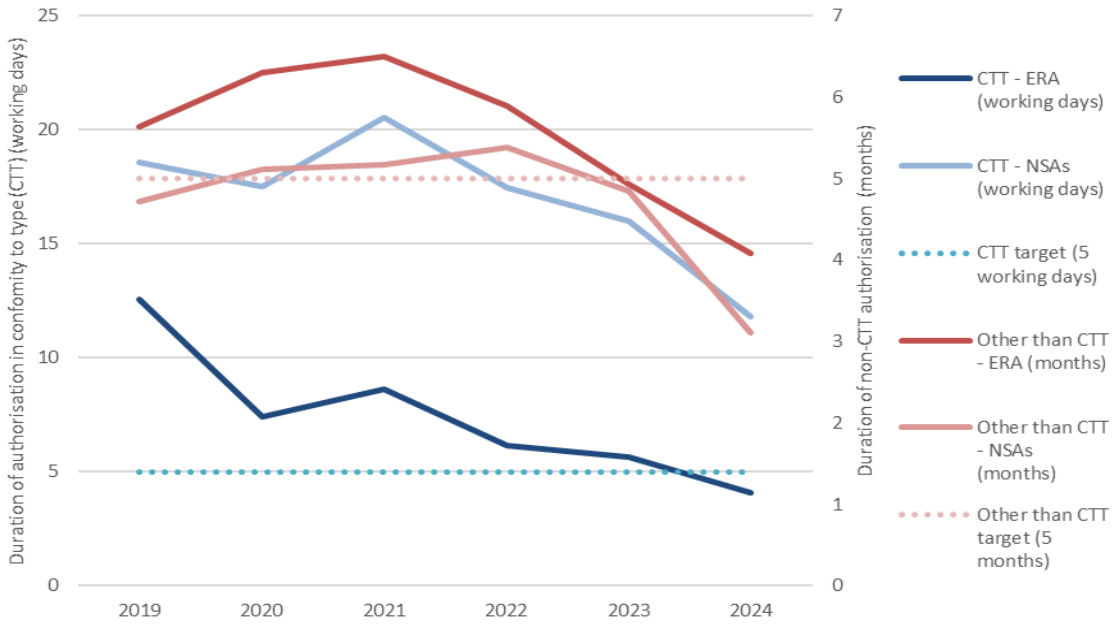


Source: One-Stop Shop data.

Processing of applications for vehicle authorisation, both by the Agency and by the NSAs, is subject to deadlines imposed by Article 34 of Implementing Regulation 2018/545[30], i.e., one month for CTT authorisations, and five months for other types of authorisation cases (non-CTT). However, the period when the clock is on hold to allow the applicant to collect additional necessary documents (time freeze) is not counted. The Agency monitors its performance against the legal deadlines and reports the results in its annual activity reports. From 2019 until 2023 the Agency reported 100% compliance with legal deadlines, taking into account the time freeze agreed with the applicants. On average, processing an application for vehicle authorisation took 5.3 months over the period June 2019 - June 2024. When the authorising entity is the Agency, a decision is issued on average after 5.7 months, while in the case of NSAs, a decision is issued after 5 months.

It is worth, however, noting that the performance of both ERA and NSAs is gradually improving (Figure 10). In 2020 and 2021 the Agency needed respectively 6.3 and 6.5 months to deliver a decision in non-CTT vehicle authorisation cases. The same types of applications were processed in 5.1 and 5.2 months by NSAs. In 2022 the gap between both types of authorities started to close and was almost closed in 2023, when ERA processed a non-CTT application in 4.9 months and NSAs in 4.8 months. This significant improvement in the application processing times was largely possible thanks to increasing level of knowledge about the process and associated requirements among applicants which led to an increasing quality of applications.

Figure 10. Average duration for processing vehicle authorisations (in working days for CTT and in months for the others) by ERA and NSAs (June 2019 - June 2024)



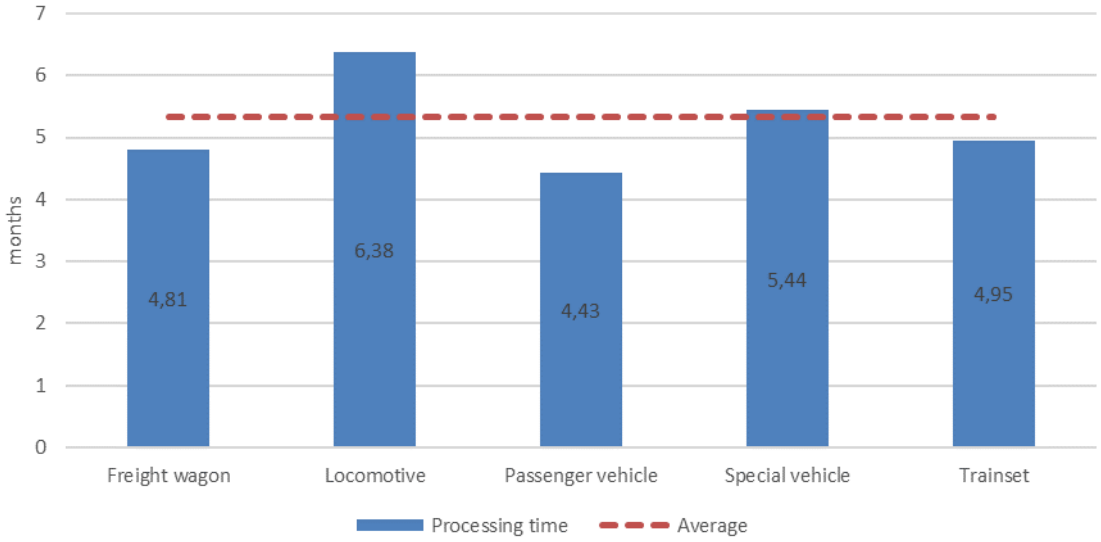
Source: One-Stop Shop data.

The average time for delivering an authorisation depends on the vehicle type concerned (Figure 11). The best performance is recorded for passenger vehicles and freight wagons, where for all authorities, processing an application takes on average respectively 17% and 10% less time than the average for all types of vehicles. The performance is also better

[30] OJ L 90, 6.4.2018, p. 66–104

than the average in case of trainsets. On the other hand, authorisation of locomotives requires almost 20% more time than the average. In case of special vehicles, the time required to receive an authority's decision almost equals the average.

Figure 11. Difference in average time to obtain a decision for non-CTT vehicle authorisations, per vehicle type (June 2019 - June 2024)

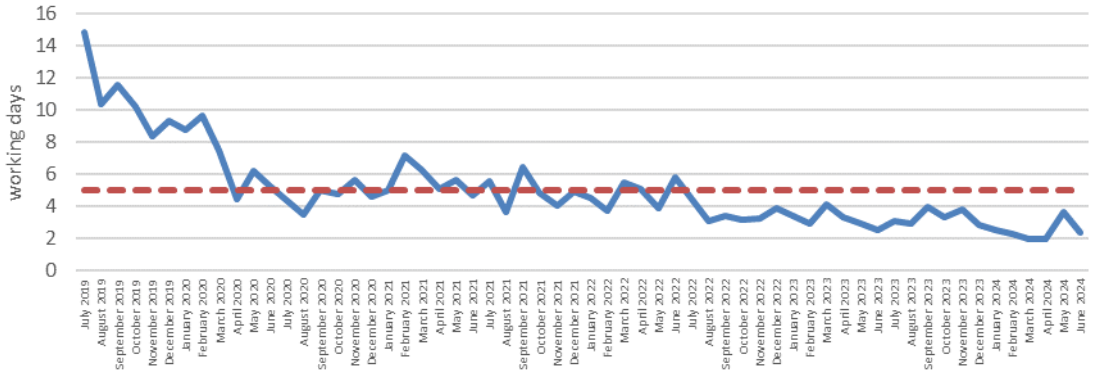


Source: One-Stop Shop data

For all vehicle types except freight wagons the average time to deliver an authorisation has improved when compared to the targets indicated in the 2013 Impact Assessment (22% reduction from 24 months baseline of authorisation time to 18.7 months). For freight wagons the target was not met since the baseline authorisation time prior to 4th Railway Package was set to 2 months which is much shorter than the legal deadline currently applicable.

In case of CTT authorisations, the legal deadline for issuing a decision is one month; however, ERA imposed on itself a more ambitious target of five working days. Since April 2020 the Agency's performance fluctuated around that target to stabilise below it in August 2022 (Figure 12). From that moment, it takes ERA between 2.5 and 4 working days to deliver a CTT decision. In case of NSAs, on average a period of 17.3 working days is required before a decision is issued; however, a positive trend of decreasing the necessary time can be observed since 2021. Data for first half of 2024 show that NSAs issued their decisions in less than 12 working days.

Figure 12. Average time needed by ERA to reach a decision on applications for vehicle authorisation for CTT (June 2019 - June 2024)



Source: ERA

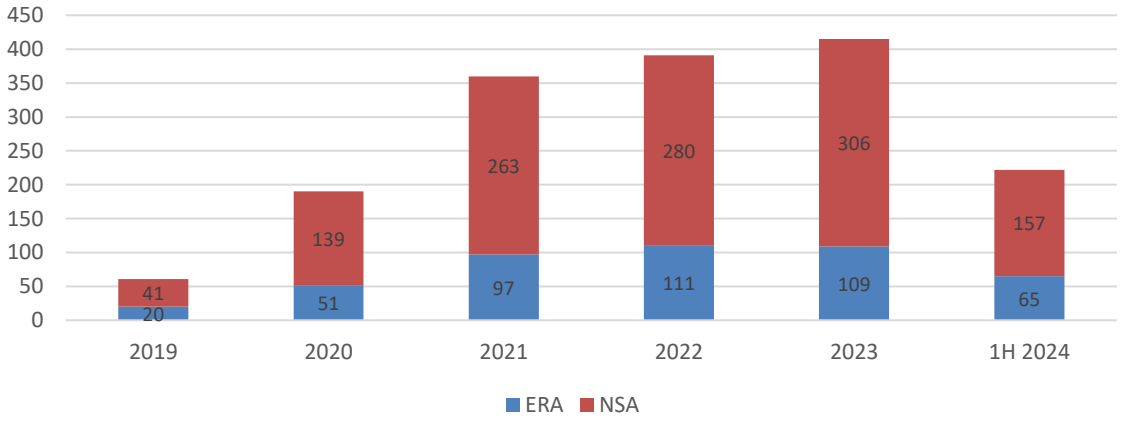
3.3.2 Safety certification

Access to the railway infrastructure is granted only to railway undertakings that hold a valid safety certificate confirming that the railway undertaking has established its SMS and is able to comply with its legal obligations. The SSC, introduced by the 4th Railway Package, has replaced the previous scheme[31].

A SSC is valid for a given area of operation, i.e. a network or networks within one or more Member States where the railway undertaking intends to operate. If the area of operation covers more than one Member State, the application must be submitted to ERA. For single-country applications, applicants can decide to apply either to ERA or to NSA.

Between June 2019 and June 2024, the Agency received in total 453 applications for SSC. Contrary to vehicle authorisation, in case of safety certification most of applications are processed by the NSAs. In total, between June 2019 and June 2024 the NSAs delivered more than 2 times more applications than ERA, i.e., 1186 (Figure 13).

Figure 13. Number of SSC applications received by ERA and NSAs (June 2019 - June 2024)



[31] Prior to the entry into force of the 4th Railway Package, the safety certificate comprised a valid Part A safety certificate (certification confirming acceptance of the railway's undertaking safety management system) and at least one Part B safety certificate (certification confirming acceptance of the provisions adopted by the railway undertaking to meet specific requirements necessary for the safe supply of its services on the relevant network).

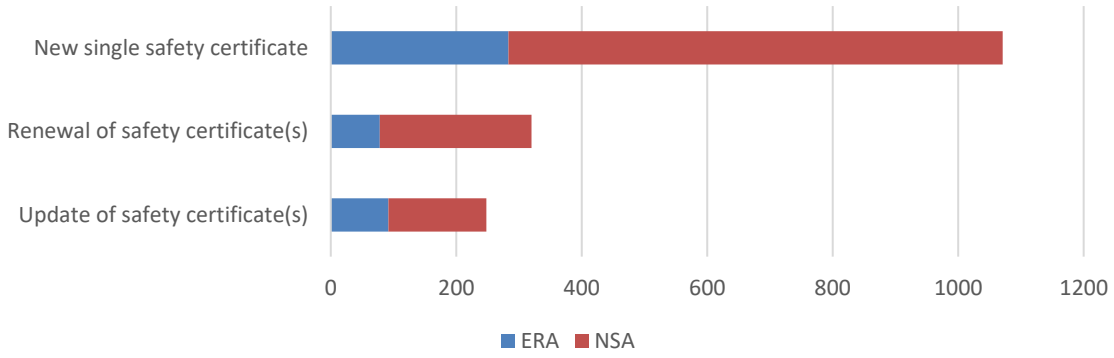
Source: One-Stop Shop data

The number of issued SSC decisions increased constantly since 2019, both for ERA and the NSAs. Every year the Agency is responsible for between 26% and 33% of all SSC decisions.

There are three main types of applications for SSC. When a company did not yet have an SSC in the past, it needs to apply for one. Since SSCs are issued for a fixed period of time, not exceeding five years, when a certificate is about to expire, the concerned railway undertaking needs to apply for its renewal. Finally, if during the period of validity of certificate, information included therein needs to be updated, an application for an update of SSC should be filed. This case also includes situations when a railway undertaking extends its area of operation (either inside or outside a Member State).

Most of the applications processed since 2019 by ERA and NSAs concern a new SSC (Figure 14). They account for 65.3% of all applications received. This high share is linked with the transition period from a model based on part A and B safety certificates towards a new model based on only one SSC.

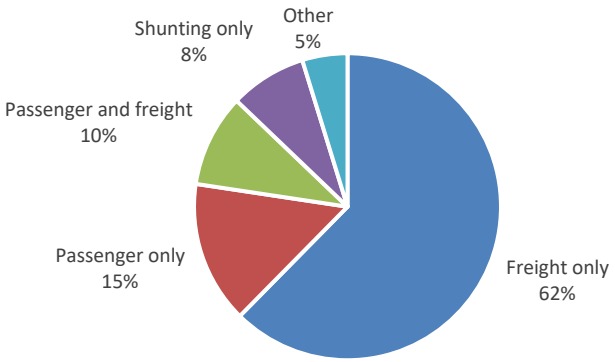
Figure 14. Number of SSC applications per type received by ERA and NSAs (June 2019 - June 2024)



Source: One Stop Shop data

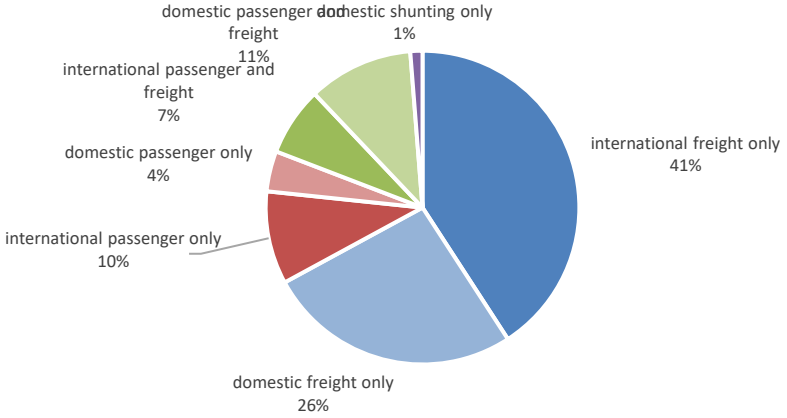
SSCs are valid for types of operation indicated on the document: passenger traffic, freight traffic or shunting only, where the first two types can be combined. It is also possible to declare other type of operation, which needs to be further specified in the certificate.

Figure 15. SSC issued by NSAs per type (June 2019 - June 2024)



Source: ERADIS data

Figure 16. SSC issued by ERA per type and area of operation (June 2019 - June 2024)

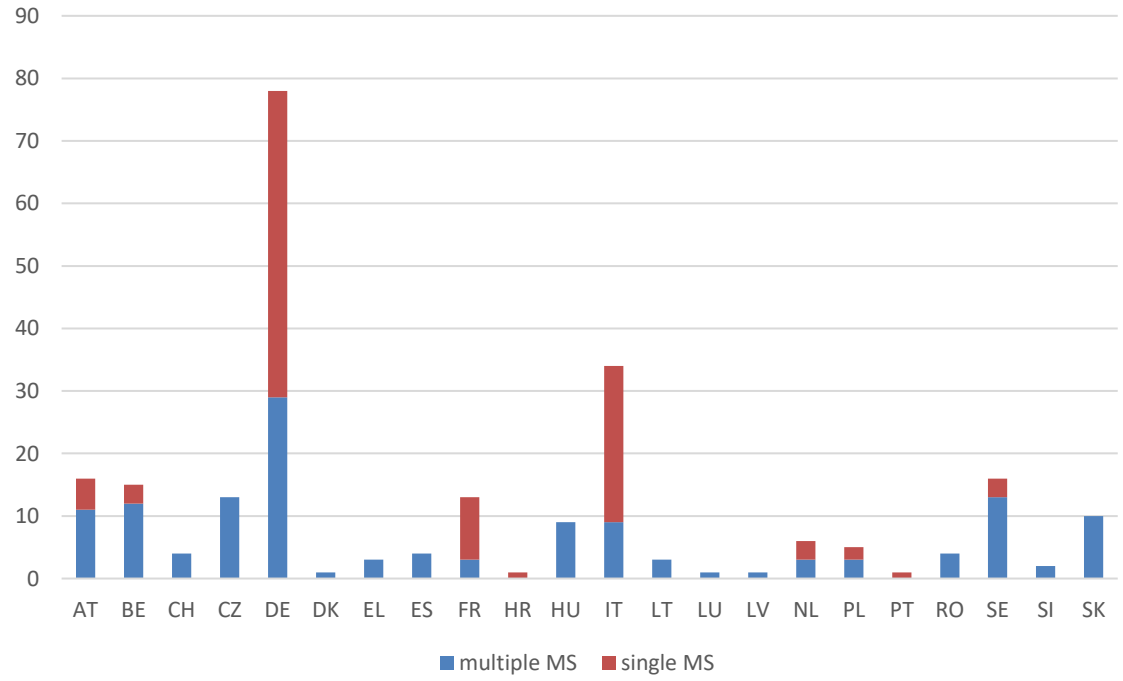


Source: ERADIS data

It can be seen in Figures 15 and 16 that the structure of issued SSCs by type of operation does not differ significantly between ERA and the NSAs. Around two thirds of SSC issued by both authorities cover only freight operations. Certificates valid for only passenger operations are the second most popular with an approximately five times lower share. In total, 58% of certificates issued by ERA cover international operations and 42% domestic. Therefore, ERA's workload is driven more by voluntary applications covering single Member States than in case of VA, where the average share of single Member States applications is 19.3%.

Most certificates covering operations only in one Member State were issued by ERA for railway undertakings from Germany (Figure 17). This was linked to a change of the German national legislation requiring also domestic railway undertakings to apply for an SSC from ERA.

Figure 17. Origin of railway undertakings receiving SSC from ERA per area of operation (June 2019 - June 2024)



Source: ERADIS data

Overall, the share of multi-country certificates in all issued documents is estimated at 14.6%.

According to most recent data from the Agency's annual activity reports[32], all the applications received until end of 2023 were processed according to legal deadlines, i.e., 150 days (five months), without counting the additional time the applicant needed to collect missing information.

3.3.3 ERTMS Trackside Approvals

The ERTMS trackside approval is issued by ERA and is required for the NSA to deliver an authorisation for the placing into service of trackside control-command and signalling subsystems. The approval process aims at confirming that the envisaged technical solutions are fully compliant with the relevant TSIs and are therefore fully interoperable.

By June 2024, ERA has issued 19 decisions concerning ERTMS trackside approval and was processing further 125 applications, with 65% of the applications covering the roll-out of European Train Control System (ETCS)[33], further 26% applications pertaining to Global System for Mobile Communications-Railway (GSM-R) and 9% concerning the deployment of ERTMS (ETCS and GSM-R). Most applications come from Spain, Italy and Germany.

The ERTMS trackside approval process begins before the call for tenders relating to ERTMS trackside equipment is issued. The Agency is obliged to issue a decision within two months from reception of all required information. However, since the application is shared with ERA at an early stage of the project, not all the necessary details will be known at the time of applying. The availability of necessary information depends largely on the tender preparation process, which is out of control of ERA. Experience from completed applications show that it can take up to 43 months to collect the necessary data which allows the Agency to issue its decision. On average, it takes 19 months before all the required information become available and the Agency can issue its decision.

3.4 REMOVAL OF OBSOLETE NATIONAL RULES

National rules[34] refer to all binding rules adopted in a Member State, irrespective of the body issuing them, which contain railway safety or technical requirements, other than those laid down by Union or international rules, and which are applicable within that Member State to railway undertakings, infrastructure managers or third parties.

National rules may be applied in addition to European rules only under certain conditions, as defined in the Interoperability and Safety Directives, e.g. when they relate to the placing on the market or placing in service of structural subsystems, the operation of the Union rail system, the role of the actors, the safety certification, the safety authorisation and the

[32] ERA Work Programmes and Activity Reports | European Union Agency for Railways

[33] ETCS is installed on lineside, using balises only for location and radio for continuous communication with the on-board units.

[34] National rules often include requirements which are partly relevant for both interoperability and safety purposes. This explains why the terms 'national safety rules' and 'national technical rules', as defined in former Directive 2004/49/EC and Directive 2008/57/EC respectively, are now replaced by the concept of 'national rules'.

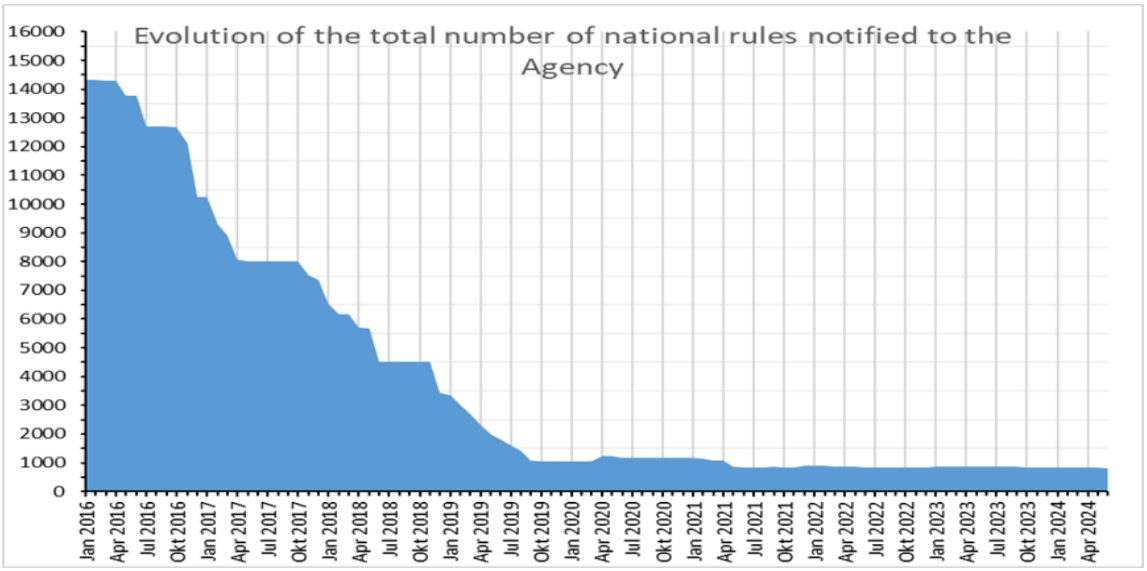
accident investigation. National rules, which are often based on national technical standards, are being gradually replaced by rules based on common standards, established by CSMs and TSIs.

The volume of national rules, including operating rules, is expected to be reduced as a consequence of extending the scope of the TSIs to the whole of the Union rail system and of closing open points in the TSIs. For that purpose, Member States should keep their system of national rules updated, remove obsolete rules and inform the European Commission and the Agency thereof without delay. ERA examines the existing national rules in the Member States to ensure that only those national rules that are allowed under the relevant Union legislation remain applicable. The procedure for examination of draft national rules and of existing national rules is described in Article 25 and Article 26, respectively, of ERA Regulation. Further, ERA is developing the Single Rules Database (SRD)[35] that will be the unique tool for the notification of all draft national rules and all existing national rules. The process is very burdensome and binds significant ERA resources; for example, 2 400 working hours were used in 2024 for the management of the national rules.

In 2016, ERA developed a national rules cleaning-up programme[36], which presents the methodology and the concrete actions to remove obsolete national rules as well as a series of deadlines for achieving significant milestones, including e.g., the analysis and validation of national technical rules for vehicle authorisation by end of 2016, the analysis and validation of national technical rules for fixed installations by end of 2018, and the removal types 4 and 5 national safety rules (made redundant by the entry into force of the revised OPE TSI) by December 2018. However, the Agency has only partially achieved these goals and delays emerged in all areas. In 2019 there were still 1026 national rules applicable in addition to the TSIs in force, down from 13 459 in January 2016 (Figure 18). In June 2024, 796 national rules relevant for vehicle authorisation and fixed installations (formerly referred to collectively as technical national rules) remained in EU Member States. The progress in removing these national rules since 2020 is shown in more detail in Figure 19.

Figure 18. Progress in the removal of national rules relating to vehicle authorisation and fixed installations since 2016 (including the United Kingdom until the end of 2019)

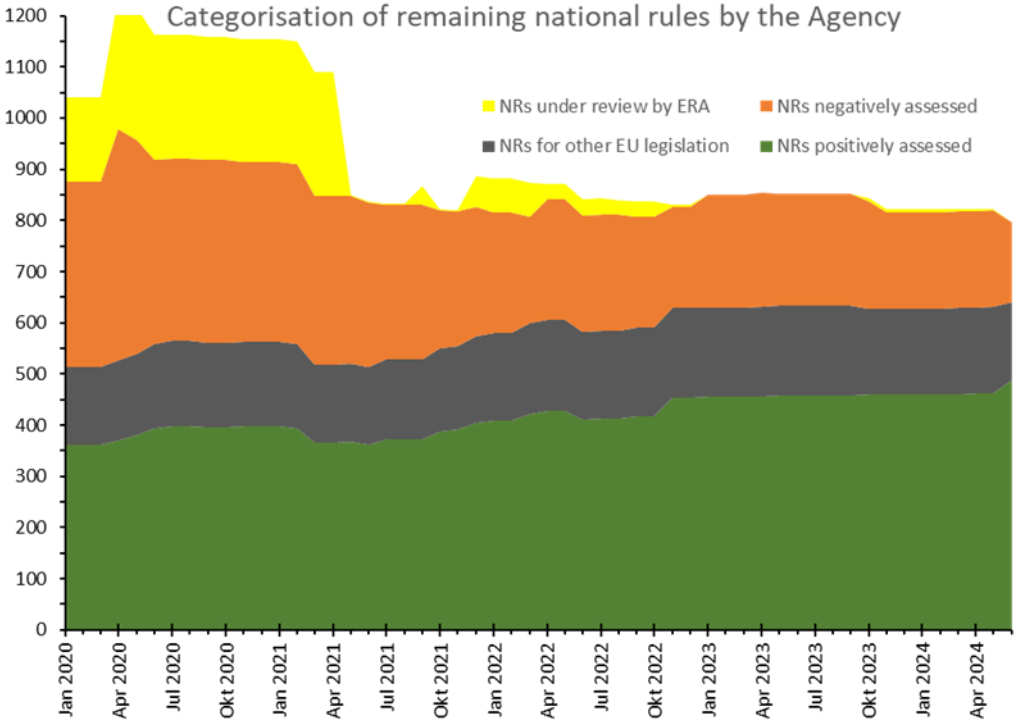
[35] https://www.era.europa.eu/domains/registers/srd_en
[36] https://www.era.europa.eu/system/files/2022-11/era_rules_plan_overview_20160323_en.pdf



Source: ERA Report on Railway Safety and Interoperability in the EU 2024[37]

For all rules categories (vehicle authorisation, fixed installations and safety), the clean-up progress is still in its first round. This means that for some countries the Agency is still assessing the first set of rules notified according to Article 14(1)(a) of Directive (EU) 2016/797.

Figure 19. Evolution of national rules for vehicle authorisation and fixed installations since January 2020 (EU27)



Source: ERA Report on Railway Safety and Interoperability in the EU 2024

[37] ERA Report on Railway Safety and Interoperability in the EU - 2024

3.5 COOPERATION WITH NATIONAL SAFETY AUTHORITIES

With the implementation of the technical pillar of the 4th Railway Package, the Agency has taken over some responsibilities from the NSAs, however, their important role in operation of the railway system is maintained. The applicants have the choice between applying to the NSAs or to ERA for VA and SSC covering a single Member State. The NSAs also ensure oversight of the railway actors and safe performance of the national railway system. Furthermore, NSAs maintain a significant level of technical expertise necessary to perform their functions, which can be also used to support ERA in performing its own tasks.

This dual system, with responsibilities shared between NSAs and the Agency, relies on effective cooperation between them. In the context of ERA's authority tasks, there are two main areas of cooperation. The first area relates to the obligatory participation of NSAs' experts in assessment of those parts of applications that are addressed to ERA, which are linked to national specificities or national rules of a Member State. To this end, Article 76 of the ERA Regulation requires the Agency to sign a cooperation agreement with each NSA, which lays down the tasks and conditions for deliverables as well as the time limits applying for their delivery, and how the fees payable by applicants should be shared between ERA and the NSAs, to compensate the latter for their work[38].

The Agency signed cooperation agreements with all NSAs before the target date of 31 October 2020[39], which was the transposition date of the technical pillar of the 4th Railway Package applicable to the last group of Member States.

The second area of cooperation between ERA and NSAs is voluntary and relates to the possibility of participation of NSAs' experts in assessment of the Agency's part of applications, under Agency's responsibility and upon its request. This arrangement is often referred to as 'Pool of Experts' and is based on voluntary cooperation agreements between ERA and the NSAs. The aim of establishing a Pool of Experts is to cover gaps in ERA's resources to perform authority tasks, more specifically the shortage in some specific language skills in the Agency since applicants are entitled to submit their application in any one of the official EU languages. The insufficient coverage of the necessary language skills is considered to be the main barrier for ERA to fully cover the issuance of vehicle authorisation and SSCs with its own resources.

NSAs are financially compensated for the expert support provided to ERA according to the terms defined in cooperation agreements.

As of September 2024, 18 Member States[40] plus Norway and Northern Ireland have signed the voluntary cooperation agreements with ERA. The 6 remaining Member States seem not interested in similar agreements mostly due to the resource constraints they face to

[38] These agreements draw upon guidelines developed by ERA and NSAs that set out the main elements that could be used for the drafting of cooperation agreements between ERA and NSAs. Most NSAs have taken these guidelines as basis for their agreement with ERA, without major changes. Source: NSA Network Information Bulletin, October 2020, European Union Agency for Railways

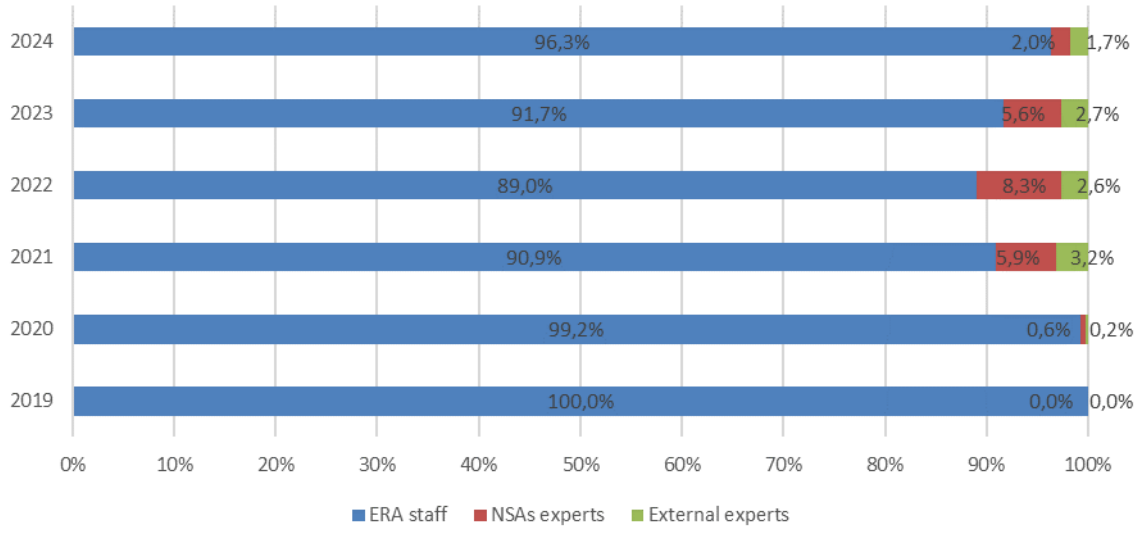
[39] Source: Consolidated Agency Activity Report 2020

[40] Belgium, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Latvia, Luxembourg, Hungary, Netherlands, Poland, Portugal, Romania, Slovakia, Finland, Sweden

ensure processing of their own applications[41]. The Agency strives to increase the involvement of the pool of experts; however, this remains a challenge[42]. For the same reason, the Agency has difficulties in fully benefiting from the work of experts from NSAs which signed the voluntary cooperation agreements. Participation of an NSA expert in a specific project always requires a prior approval of the NSA which might not be granted if at the same time the NSA struggles to ensure adequate resources for processing of its own applications.

Since 2019, experts from 8 NSAs have participated in processing of applications concerning VA. In case of SSCs, 13 NSAs provided their experts. Nevertheless, the share of work performed by NSAs' experts is limited and amounts at only 5.3% of all the work hours performed on Agency's applications since 2019 (Figure 20). The highest level of participation of NSAs' experts was recorded in 2022 when it reached 8.3%. This was also the first year when the Agency issued almost 2000 decisions therefore the NSAs involvement was an important factor which helped to limit the pressure on Agency's internal resources. However, in 2023 the share of workload provided by NSAs' experts decreased to 5.6%. The share for 2024 is even lower, however data in this respect might not be entirely representative as the NSAs report their workload with a delay.

Figure 20. Distribution of workload related to the assessment of ERA's part of applications (June 2019 - June 2024)



Source: European Union Agency for Railways

To compensate for the limited capacity of NSAs, the Agency uses services of external experts and private companies. A call for independent experts in the field of safety is permanently open on the Agency's website with the aim of supporting the tasks concerning issuing of SSCs. Currently, 32 experts are pre-qualified with different areas of expertise. Additionally, a cascade of private companies has been selected in a Framework Contract to ensure support for all Agency's authority tasks. However, since 2019, both external experts and private companies covered only 2.4% of the overall workload required to

[41] Voluntary cooperation agreements (PoE). State-of-play, ERA presentation for the 61st meeting of the ERA Management Board, 16 November 2022

[42] Source: Consolidated Annual Activity Report of the European Union Agency for Railways, 2022

process applications received by the Agency. Main challenges related to the use of external experts and private companies concern the difficulty in ensuring necessary independence and lack of availability in critical moments in time.

Although assessment of border stations is strictly not an area of cooperation between NSAs and ERA, it is also worth mentioning as it poses specific challenges for the operation of the dual system and impacts processing of applications both by the Agency and the NSAs. The Safety and Interoperability Directives introduced a specific simplified solution to include border stations from neighbouring Member States in the area of operation of railway undertakings and the area of use of authorised vehicles. This solution allowed in particular that application for SSC or VA could still be addressed to the NSA if it covered one Member State plus only border stations in neighbouring Member States. Requirements applicable to include border stations in certificate or authorisation should be limited to facilitate cross-border traffic between Member States. Details of the applicable requirements and necessary assessment were to be established between NSAs in written agreements or on an ad-hoc basis.

In practice, implementation of this mechanism proved to be difficult. Historically, NSAs had little or no role in identification of border stations and definition of applicable requirements as this was managed by the infrastructure managers themselves or set out in international agreements at Member State level. For this reason, since the entry into force of the 4th Railway Package[43], the NSAs have signed only 12 border agreements to date.

As a result, applicants are often faced with legal uncertainties and differing approaches between NSAs. This remains a problem, with impact on cross-border traffic, in particular for vehicle authorisation where applicants seeking to access with their vehicles only short cross-border sections to border stations are required to meet the same requirements as when seeking authorisation covering the whole network of a neighbouring Member State.

To address some of these issues, the network of NSAs has created a subgroup dedicated to discussion concerning border agreements.

3.6 ONE-STOP-SHOP (OSS)

OSS is an IT system supporting the applicants, ERA and the NSAs in performing their tasks related to safety certification, vehicle authorisation and ERTMS trackside approval. It enables the exchange of documentation between all involved actors and allows ERA and the NSAs to share their comments and questions requiring a reply from the applicant. It aims to streamline and manage applications in a fair and transparent way that allows users to track progress and interact with both ERA and NSAs from the pre-engagement stage through to an authorisation or certification being issued.

Due to the different deadlines for the transposition of the 4th Railway Package, initially only 8 Member States used the OSS in June 2019, with the remaining Member States joining by October 2020.

[43] Informative lists of border stations in accordance with Article 10(8) of Directive (EU) 2016/798, 22 May 2024, European Union Agency for Railways, available at: https://www.era.europa.eu/system/files/2022-11/informative-list-border-stations_en.pdf?t=1734431347

According to ERA, more than EUR 7 million have been allocated to the development of the OSS and registers between 2015 and 2024, most of which was spent during the 2017-2019 period. This includes effort and resources allocated in the period from 2020 to 2024 to develop an interface between the OSS and the (ERADIS[44] and ERATV[45] supporting the safety certification and vehicle authorisation process. Further, the annual maintenance costs for the OSS were estimated at around EUR 0.5 million in 2024 (Table 4) and the human resources required at around 1.5 FTE (equivalent to approximately additional EUR 190 000).

Table 4. Financial resources allocated to the development and maintenance of OSS and interfaces with ERADIS and ERATV

Year	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024 (est.)
Amount (million EUR)	0.05	0.85	1.55	1.00	1.20	1.00	0.50	0.50	0.20	0.55

Source: ERA estimates

To support applicants in using the OSS and to help them understand ERA's new responsibilities and activities, the Agency developed guidelines, templates, and checklists, organised training activities for NSA staff[46], and performed other dissemination activities. Furthermore, ERA maintains an OSS Helpdesk to resolve issues flagged by NSAs or applicants.

ERA monitors the operation and performance of the OSS and has set a KPI target that for at least 95% of significant problems detected during operation, solutions should be available in a next release[47]. According to the annual activity reports this target was met each year from 2019 to 2023.

3.7 Monitoring of National Safety Authorities

Article 33 of the ERA Regulation granted to the Agency a new task concerning the monitoring of performance and decision-making of the NSAs on behalf of the European Commission. These audit activities are focused on the capacity of NSAs to perform their tasks as well as on the effectiveness of their monitoring of SMSs of railway undertakings and infrastructure managers.

The NSAs play a pivotal role in ensuring safety of the railway system. Through its certification and supervision activities they monitor the performance of individual actors, enforce the existing rules and drive the system towards continuous improvement.

[44] The ERADIS database shall ensure that the information relevant to the safety and interoperability of the railways in the Member States is accessible and transparent to all interested parties and stakeholders in the railway, in accordance with the Directive (EU) 2016/798, the Directive (EU) 2016/797 and the Regulation (EU) 2016/796. https://www.era.europa.eu/domains/registers/eradis_en

[45] https://www.era.europa.eu/domains/registers/eratv_en

[46] For example, from March to April 2025, the Agency is offering training sessions on the One-Stop Shop (OSS) system for both Applicant Representatives and ERA/NSA officers, https://www.era.europa.eu/content/oss-training-2025.

[47] Release v1.9.1 of the OSS was released in February 2023.

Additionally, they support the actors in understanding and correctly applying the existing legislative framework.

ERA's Management Board was not able to reach a consensus on a method to be applied by the Agency during the audits. As a result, two methods were allowed: compliance model and monitoring matrix model[48]. The choice of the method to be applied in a given audit was left to the audited NSA[49]. The system of dual models creates some difficulties for all stakeholders; however, ERA made a considerable effort to ensure that both produce comparable results.

The audits are structured in three-year cycles during which all EU NSAs (and, upon agreement, the NSAs of Norway and Switzerland) are to be audited. Potentially, the scope of ERA's NSA monitoring activities could cover all the tasks allocated to NSAs in relation to railway safety and interoperability. However, for the first three-year audit cycle 2019-2021, it was decided to focus on priority aspects considered essential to get assurance on the safety level achieved by Member States. The decision taken by the Management Board for a targeted scope of audits was justified by the Agency with reference to the significant resource constraints for the financial years 2019-2021. Therefore, the scope of the first audit cycle 2019-2021 was restricted to two specific areas: staff competence management within NSA and supervision activities. The Agency identified 82 deficiencies and 135 observations[50]. On average, there were 3.15 deficiencies and 5.19 observations per audit. For 9 audited NSAs no deficiency was identified and only observations were recorded.

Out of the two audited topics, supervision was raising the most concerns – it accounted for 57 deficiencies. All NSAs with deficiencies had at least one related to this area. The main identified issues covered the lack of prioritisation of the supervision activities and risk-based plan, the lack of evidence of decision-making criteria on how NSAs evaluate the correct application and the effectiveness of SMSs by rail companies, as well as the lack of fully effective enforcement powers.

In the area of competence management 25 deficiencies were recorded, which covered 13 NSAs. The issues identified concerned the lack of proper competence management system for NSA staff, lack of independence in the recruitment process, staff turnover and difficulties in recruiting and retaining staff with the necessary level of experience, and staff shortage.

The second cycle 2022-2024 was extended to cover all tasks allocated to NSAs according to the EU acquis, including when an NSA is designated to perform a task by a Member

[48] The Compliance Model is based on the concept of compliance or non-compliance with a set of criteria and is aimed at evaluating the extent to which deviations from these criteria constitute minor or major deficiencies. The Monitoring Matrix Model is based on the concept of PDCA (Plan- Do-Check-Act) cycle and focuses on evaluating the willingness and capability of the NSA to perform and monitor its tasks, identify gaps and implement changes when problems are identified.

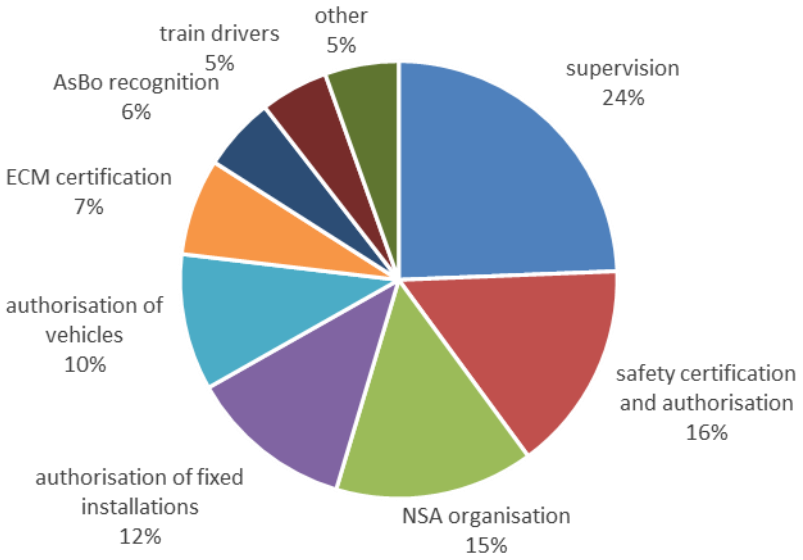
[49] Out of 43 finalised audits, only in 7 cases the NSAs decided to apply the matrix model.

[50] An observation is a finding that does not prevent the NSA concerned from effectively carrying out its duties in relation to railway safety and/or interoperability, while a deficiency is a finding or combination of findings that prevents the NSA concerned from effectively carrying out its tasks in relation to railway safety and/or interoperability. For deficiencies, the Agency requests NSAs to take appropriate remedy actions and NSAs are requested to produce action plans to address them (source: "Annex II: Evaluation Procedure" of Management Board Decision 161 of 29/11/2017).

State provided that this task is linked with the application of EU law. As of February 2025, results were available for 20 NSAs. The extended scope of audits resulted in a higher number of findings: 238 deficiencies and 291 observations. This gives an average of 11.9 deficiencies and 14.6 observations per audit[51].

As in the case of the first audit cycle, supervision remains the biggest concern followed by safety certification and authorisation processes, organisation of the NSA (which covers the topic of competence from the first audit cycle) and authorisation of fixed installations (Figure 21).

Figure 21. Share of deficiencies identified by the Agency in the second NSA monitoring cycle, per topic



Source: ERA audit reports

NSAs are required to produce an action plan to address all identified deficiencies. The assessment performed by the Agency during the second audit cycle showed that the NSAs made limited progress to address the identified deficiencies from the first cycle. Only 18% of deficiencies were fully addressed; a further 51% were addressed only partially. The remaining 31% deficiencies were not addressed at all. In a limited number of cases only, lack of reaction is linked to the fact that the identified issue is beyond the control of NSA (it requires an intervention at Member State level, e.g. change of legislation or allocation of additional resources).

Deficiencies from the first cycle that were confirmed as open were incorporated into the findings from the second audit cycle and will be followed up during the third audit cycle.

In case of four NSAs audited in the second cycle, the Agency identified more than 20 deficiencies (Table 5). For a further two, more than 15 deficiencies were registered. Among these six NSAs deficiencies were identified for at least 2/3 of all audited processes,

[51] A degree of caution should be applied when drawing conclusions from these numbers. In the second audit cycle, the Agency prioritised NSAs which had poor results in the first cycle. As a result, NSAs with better performance were planned to be audited closer to the end of the cycle. Therefore, current interim results are likely biased towards poorer performance.

with one NSA having deficiencies in all audited processes. Out of all audited NSAs, 12 of them had deficiencies in at least half of the audited areas.

Table 5. Summary of findings in the second cycle of NSAs audits

	Number of deficiencies	Number of observations	Share of processes with deficiencies
NSA 1	27	14	88.9%
NSA 2	25	20	70.0%
NSA 3	24	19	90.0%
NSA 4	24	11	100.0%
NSA 5	17	17	66.7%
NSA 6	17	10	81.8%
NSA 7	13	21	80.0%
NSA 8	13	16	63.6%
NSA 9	13	15	60.0%
NSA 10	12	11	71.4%
NSA 11	11	11	44.4%
NSA 12	10	15	75.0%
NSA 13	7	14	30.0%
NSA 14	6	13	50.0%
NSA 15	5	13	30.0%
NSA 16	4	30	30.0%
NSA 17	4	8	25.0%
NSA 18	3	11	20.0%
NSA 19	2	13	11.1%
NSA 20	1	9	9.1%

Source: ERA audit reports

3.8 MONITORING OF NOTIFIED BODIES

NoBos provide independent third-party conformity assessment to demonstrate whether specific requirements related to a product have been met, both in terms of design and manufacturing. They typically intervene in the process before ERA and the NSAs conduct their assessments of the applications received and their positive assessment is a prerequisite for obtaining an authorization for the placing on the market of vehicles and authorization for placing into service of fixed installations. NoBos must meet the requirements laid down in Article 30 of Interoperability Directive[52]; this is verified either by a designated authority of a Member State (recognised NoBo), or by a national accreditation body (accredited NoBo).

Both types of NoBos are subject to the monitoring activities of the Agency. Pursuant to Article 33(6) of ERA Regulation, the Agency is empowered to perform inspections of all NoBos in order to verify specific areas of their activities and operation, and in particular to review documents, certificates and records relating to performed conformity assessment

[52] Such as being established under national law and having legal personality, being capable of carrying out all the conformity assessment tasks assigned to it by the relevant TSI and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

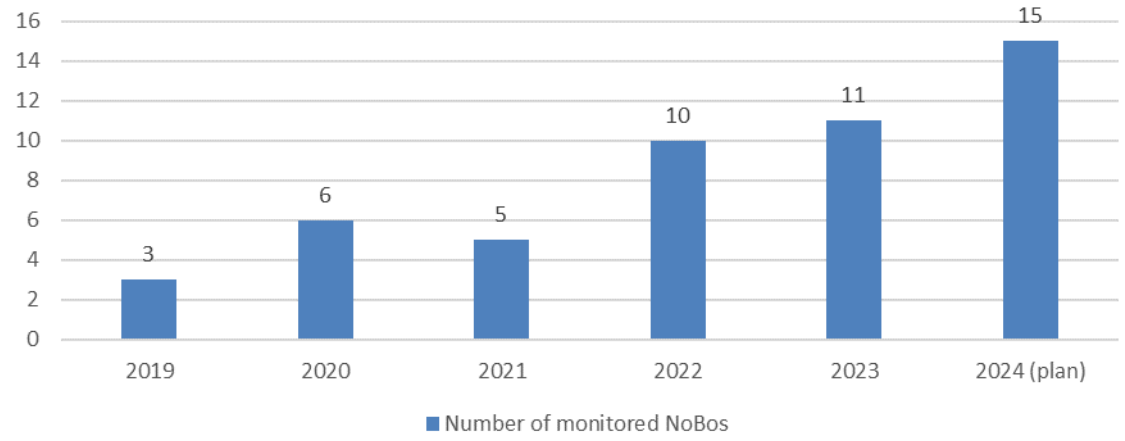
procedures. Additionally, in case of recognised NoBos, pursuant to Article 33(3) of ERA Regulation, the Agency can audit them to verify their capacity to meet the requirements of the Interoperability Directive. Therefore, the requirements checked by audits cover a wider scope of requirements than inspections.

The procedure for auditing NoBos has been established by ERA Management Board in 2017[53]. ERA and the national notifying authority (or its delegate) jointly define the scope of any audit and carry out the audit as a joint activity. Unlike the case of NSA monitoring, ERA's Management Board did not indicate any multi-annual target to be achieved about the number of NoBos to be monitored each year.

Inspections are performed according to a Work Instruction being part of the internal quality management system of the Agency. The process of preparing and performing an inspection largely mirrors the procedure for audits.

There are 68 NoBos for the purposes of the Interoperability Directive, out of which 14 are recognised and 54 accredited. Until November 2024, a total of 49 NoBos were audited or inspected (Figure 22) that represents 72% of all NoBos under the Interoperability Directive. The number of audits and inspections increased from 2022 onwards.

Figure 22. Number of NoBos monitored by ERA per year, 2019 - 2024



Source: ERA presentation at the NSA Network meeting of 13 November 2024

ERA has completed the first three-year full monitoring cycle for NoBos (2019-2021) over the course of which it issued in total 14 audit/inspection reports. Therefore, in this first cycle, ERA audited only 23% of the total number of NoBos under its mandate. For the cycle 2022-2024 ERA issued 10 audit/inspection reports in 2022 and another 11 in 2023. Therefore, auditing all 68 NoBos in the period 2022-2024 will likely not be achieved, which reflected the difficulties in securing adequate resources for this task.

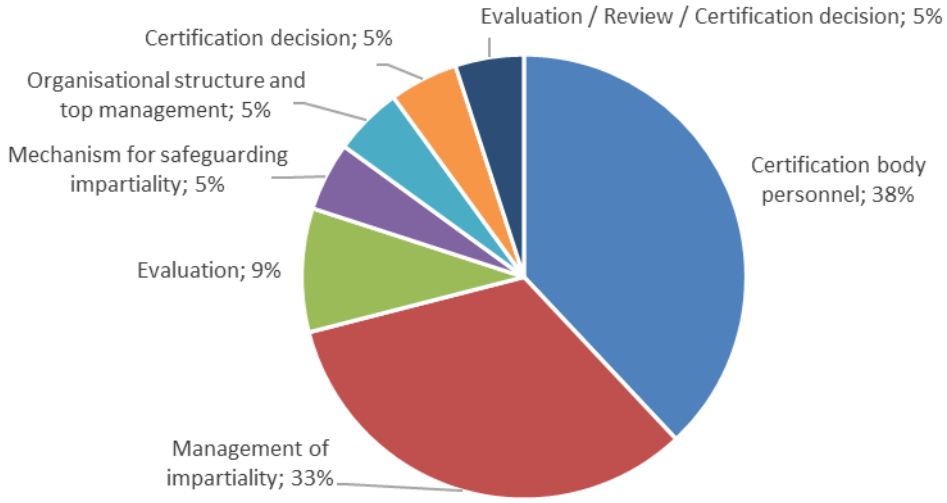
The allocation of additional resources under the Strengthening Action Plan increased the FTEs assigned to NoBo monitoring. On top of regular 4 FTEs assigned to this task, in 2023, the work of 1 additional FTE was added. In 2024 the overall resource envelope was further increased to 6.1 FTEs, with 2.1 FTEs assigned from the Strengthening Action

[53] Decision n°156 of the Management Board of the European Union Agency for Railways adopting the provisions on auditing notified conformity assessment bodies in the framework of Article 34 § 3 of Regulation (EU) 2016/796, 27 June 2017

Plan[54]. This allowed to gradually increase the number of audits and inspections performed per year, up to 15 in 2024. The Agency plans to monitor 18 NoBos in 2025, which would allow to close the first cycle of monitoring of NoBos after 7 years.

The Agency has identified 190 deficiencies[55], out of which 21 were classified as major deficiencies which impacted NoBos from 9 Member States (Figure 23). To follow them up, the Agency acting in accordance with Article 34(4) of ERA Regulation, has issued a recommendation asking the Member State where the NoBo is established to take the appropriate measures to address the major deficiencies within a mutually agreed deadline. Two thirds of all major deficiencies (14 cases) have been positively closed within 6 months; the remaining 7 deficiencies are open and will be followed up during the next monitoring cycle.

Figure 23. Distribution of major deficiencies per criteria, 2019 - 2024



Source: ERA presentation on NSA Network of 13 November 2024

Over 70% of major deficiencies identified by the Agency were linked to two areas: certification body personnel and management of impartiality. The most recurring major deficiencies concerned ability of certification body to ensure continuity of the necessary competence (4 cases) and impartiality towards actors linked with assessed products, processes or services and providing consultancy to them (3 cases).

For other findings (minor deficiencies and observations) NoBos usually present an action plan that is further verified by the corresponding national authority or national accreditation body in their surveillance activity. The Agency is kept informed about the developments.

[54] Single Programming Documents of the Agency for 2023 and 2024.

[55] The Agency classifies findings of its monitoring activities of notified bodies as major deficiencies, minor deficiencies, and observations. Major deficiencies are defined as those that prevent the notified body from effectively carrying out its tasks in relation to railway interoperability. Minor deficiencies do not impact the ability of notified body to perform its tasks in relation to railway interoperability.

4. EVALUATION FINDINGS (ANALYTICAL PART)

4.1 TO WHAT EXTENT WAS THE INTERVENTION SUCCESSFUL AND WHY?

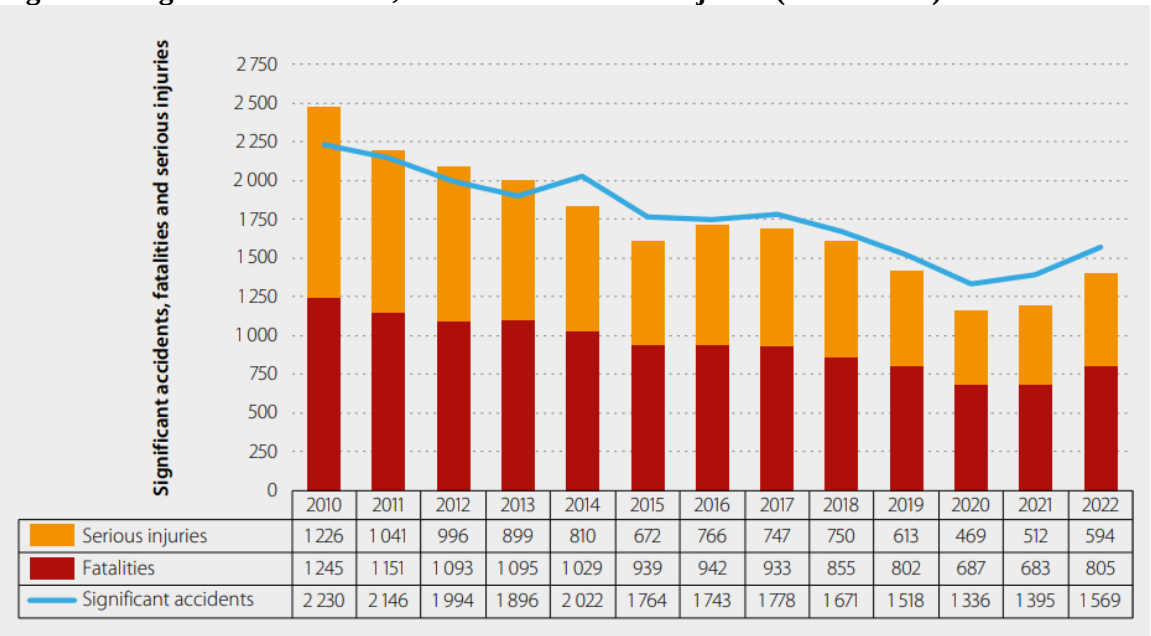
Effectiveness

Agency's achievement of objectives

In relation to its **first objective**, i.e. to maintain a **high level of railway safety and improve interoperability in the EU**, the Agency has delivered relevant outputs - fully or partly - in several areas that contribute to maintaining and further enhancing safety in the railway sector and identifying and addressing existing limitations. Its work on screening national safety rules, developing and updating CSMs, and issuing SSCs contributes towards ensuring a more harmonised approach on safety aspects across the EU. Achieving tangible impacts to improve safety is a process that takes time and depends on several factors, including the capacity, resources available and action taken at national level, by NSAs, infrastructure managers and national authorities.

The **safety level of the EU** railway system remains very high; it is in fact one of the safest railway systems in the world. The number of significant accidents and resulting casualties have decreased steadily since 2010; however, in 2021 and 2022, an increase was recorded, going back to pre-COVID-19 levels[56] (Figure 24).

Figure 24. Significant accidents, fatalities and serious injuries (2010 – 2022)



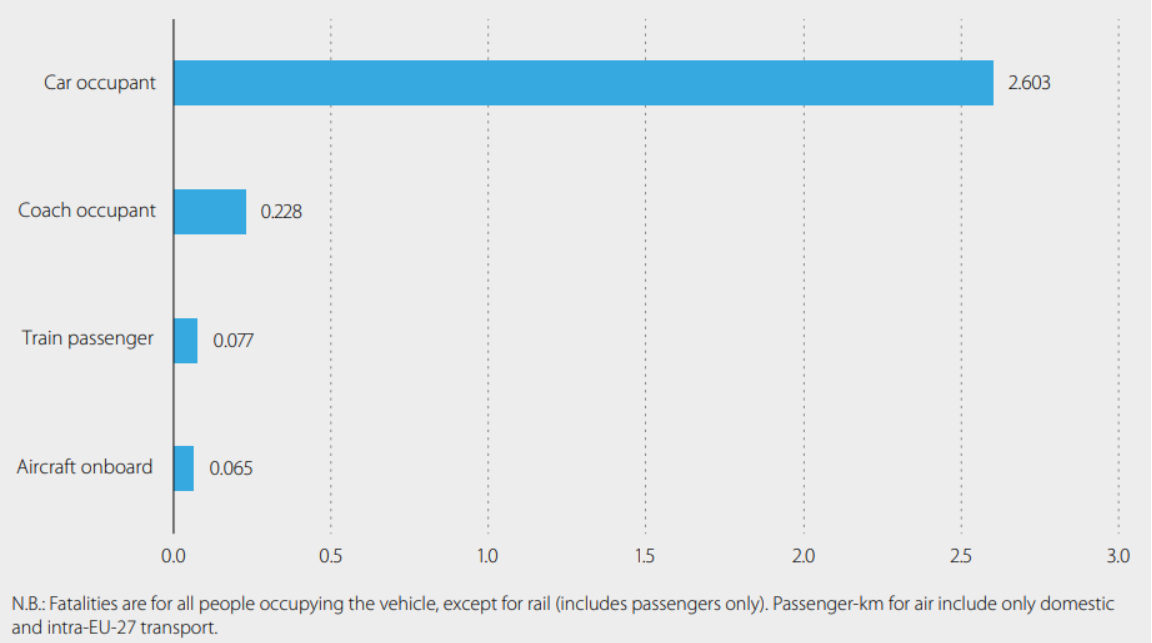
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Serious injuries	1 226	1 041	996	899	810	672	766	747	750	613	469	512	594
Fatalities	1 245	1 151	1 093	1 095	1 029	939	942	933	855	802	687	683	805
Significant accidents	2 230	2 146	1 994	1 896	2 022	1 764	1 743	1 778	1 671	1 518	1 336	1 395	1 569

Source: ERA Report on Railway Safety and Interoperability in the EU – 2024

In a multimodal comparison, rail appears the safest mode of land transport in the EU, with a fatality rate for passengers similar to that for aircraft passengers (Figure 25).

[56] Report on Railway Safety and Interoperability in the EU - 2024

Figure 25. Onboard fatalities per billion passenger-km



Source: ERA Report on Railway Safety and Interoperability in the EU – 2024

The results of the latest assessment of the achievement of safety targets[57] (carried out annually by ERA) indicate that safety performance remains acceptable at the EU level, although possible deterioration in safety performance was identified in four instances. Such a result is in line with the previous assessments, which typically identified possible deterioration in safety performance in a few countries and categories.

Major rail accidents resulting in five or more fatalities have become rare: no such accidents occurred in 2018, 2020 and 2021, but five such accidents occurred in 2022 and 2023 (including the tragic accident in Tempi, Greece, in February 2023, which caused 57 fatalities). The number of fatal train collisions and derailments has decreased continuously since 1990. In recent years (2020–2022), however, a slight increase was registered, with 18 such accidents. The rates of significant accidents, fatalities, and fatalities and weighted serious injuries (FWSIs) per million train-km have decreased substantially since 2010, with the lowest values registered in 2020 and 2021; however, in 2022, the rates returned to pre-COVID-19 levels. Progress has also been uneven across the EU Member States with significant variation in safety levels. Despite the drop in 2021, the passenger fatality rate shows a worrying stagnating (even slightly rising) trend since 2017.

An important role in maintaining a high level of safety should be played by the occurrence reporting that is aimed at helping railway operators assess the risks of their activities and prevent accidents. While it is easy to make a link between accidents and their causes after they occur, it is essential to identify and share the relevant information beforehand, to prevent accidents from happening.

Article 18 of ERA Regulation provides for the obligation of the Agency to encourage the exchange of safety related occurrence information for the purpose of developing best

[57] Report Assessment of achievement of safety targets – 2025 | European Union Agency for Railways

practices. However, it does not provide the means to enable proper data collection and enforcement of obligations on the different actors.

The inability to identify and share relevant information in advance can lead to serious safety issues. On 2 January 2019 a passenger train operating over the Great Belt Bridge in Denmark collided with debris that had come off a freight train, killing 8 passengers and injuring 16. The likely cause of the accident was that one of the lorry trailers carried by the freight train was damaged by high winds while crossing the bridge. Accidents caused by high wind velocity have happened in several Member States, and in the UK (one accident in 2015, two in 2008), Norway (in 2017) and Switzerland (in 2018). However, this information was not shared systematically between Member States. A Joint Network Secretariat (JNS) procedure[58] "Great Belt bridge accident/incident" was initiated in June 2019.

Since May 2017, 10 JNS procedures were launched. This demonstrates the increasing importance of this workstream within the Agency.

The CSMs for occurrence reporting are not matched by an appropriate enabling tool and resources. Nowadays, the Agency is suffering of the historical accumulation of safety-related IT tools based on different technologies, lacking a consistent approach.

Shortly after the Great Belt Bridge rail accident in Denmark, on 7 January 2019 the Commission mandated the Agency to draft common safety methods for assessing the safety level and the safety performance of railway operators at national and Union level (CSM ASLP). Consequently, the Agency addressed a Recommendation for this CSM ASLP[59], largely endorsed by all railway stakeholders, to the Commission on 18 May 2021. The Commission Delegated Regulation on CSM ASLP[60] has not yet been adopted. Once adopted, the CSMs introduced in this Regulation should establish a harmonised assessment of safety levels, a harmonised assessment of safety performance and a well-structured process to help each railway operator, NSAs and ERA to qualitatively and quantitatively learn about the causes of accident and incident occurrences and about their consequences in terms of victims and damages. The successful and smooth implementation of CSM ASLP strongly depends on the availability of an 'Information Sharing System' (ISS), for which adequate resources are needed, supporting in general the 'safety digitalisation' of the railway sector. Such an approach has already been successfully implemented in the aviation sector.

On the monitoring of NSAs, the Agency activities have been partly delivered and contributed to improving the functioning of NSAs and NoBos and harmonising their performance. A large share of NSAs and national authorities responding to a survey

[58] The JNS procedures aim at EU-wide harmonisations of any action taken after accidents or incidents on EU railways: Joint Network Secretariat (JNS) | European Union Agency for Railways

[59] https://www.era.europa.eu/system/files/2022-10/CSM%20Regulation%20recommended%20for%20adoption.pdf?t=1759151061

[60] Adoption foreseen for 2026.

organised in the context of the evaluation support study provided a positive opinion on the contribution of ERA's NSA monitoring towards:

- improving performance and decision-making of NSAs (7 out of 12 NSAs and 7 out of 10 national authorities), and
- its contribution to ensuring that NSAs effectively monitor the SMSs of the rail actors (seven out of 11 NSAs and 6 out of 10 national authorities).

The first audit cycle was completed – albeit with reduced scope – and there is generally positive input on the effectiveness of ERA's monitoring activities. Most NSAs and national authorities contributing to the survey indicated that their experience with NSA monitoring has been positive in terms of the quality of the audit process. On average, concerning all the parameters on which an assessment was requested, 10 out of 12 of NSAs and 8 out of 10 national authorities that responded provided positive feedback on the monitoring, compared, respectively, to two NSAs and one national authority which provided negative feedback.

As presented in detail in Section 3.7, the second cycle 2022-2024 was extended to cover all tasks allocated to NSAs according to the EU acquis, including when an NSA is designated to perform a task by a Member State provided that this task is linked with the application of EU law. The extended scope of audits resulted in a higher number of findings: 238 deficiencies and 291 observations. The assessment performed by the Agency during the second audit cycle showed that the NSAs made limited progress to address the identified deficiencies. In some cases, this is linked to the fact that the identified issue is beyond the control of NSA (it requires an intervention at Member State level, e.g. change of legislation or allocation of additional resources). One of the main difficulties which impact the effectiveness of addressing the deficiencies by NSAs is lack of appropriate knowledge, experience and competences among the NSAs staff.

The findings from the Agency's audits show that there are Member States where the NSAs are unable to effectively perform their role[61], and hence the urgent need for improvement in this respect, given that this poor performance results in weak oversight of the railway system in specific Member States. This creates a potential gap which could result in significant non-conformities being left unnoticed for years.

There is a need to ensure a full cycle for the monitoring activities, in which findings – supplemented and feeding information from other tasks (e.g. SSCs, VAs, safety data, etc.) - are consistently reviewed and acted upon, regularly tracking the progresses.

The NSA monitoring process is not adequate to identify such wider potential issues due to its limited scope which does not cover the performance of other stakeholders having an important safety role like railway undertakings, infrastructure managers, National Investigation Bodies (NIBs) or Member States authorities.

[61] In case of four NSAs audited in the second cycle the Agency identified more than 20 deficiencies. For further two more than 15 deficiencies were registered. Among these six NSAs deficiencies were identified for at least 2/3 of all audited processes, with one NSA having deficiencies in all audited processes. Out of all audited NSAs, 12 of them had deficiencies in at least half of the audited areas (see 3.5 Monitoring of National Safety Authorities).

Although the Agency is empowered under Article 35 of ERA Regulation to perform complex assessments of practical implementation of rail safety and interoperability legislation which could cover all relevant actors, this process was designed as an ad hoc task performed on a specific request of the Commission and not as a regular monitoring process. As a result, the current budgetary envelope of the Agency does not include the necessary resources to perform such complex assessments at Member State level on a regular basis.

This weakness of the existing Union framework was also noticed during the investigation of the tragic accident in Tempi, Greece, which costed the lives of 57 people. In its final investigation report, the Hellenic Air and Rail Safety Investigation Authority included a recommendation (2025-RL01-013) which calls on the European Commission to 'develop and implement a framework where, based on continuous monitoring of the respect and effectiveness of Members State responsibilities under the Safety Directive, necessary corrective actions can be agreed, and their timely implementation followed up and enforced'[62].

Linked to the above considerations and to the difference in safety levels across EU Member States, the Agency proposed in 2023 a Priority Country Programme (PCP) which is a strategic initiative that aims to assess and monitor the state of railway safety and interoperability legislation implementation in Member States providing a comprehensive picture of railway safety and helping the Member States to identify areas for improvement. As of now, the PCP is still awaiting the necessary resources for implementation. Should the required resources become available, the PCP will support selected countries through: (1) a comprehensive assessment of the implementation of rail safety and interoperability legislation, (2) tailored Action Plans at Member State levels and (3) dissemination activities tailored to the needs of each country.

With regard to the NoBo monitoring, the number of responses to the survey questions was low (4 contributors). The NSAs and national authorities were generally positive about the effectiveness of ERA's monitoring activities: all 4 respondents agreed that ERA's monitoring has significantly contributed to a better harmonisation of accreditation/ recognition of NoBos. 2 out of 4 respondents agreed that the Agency's monitoring contributed significantly to ensuring a standard level of performance, organisation, and decision-making of NoBos.

Nonetheless, the stakeholders answering the survey expected that the results of the NoBos monitoring would be more evident in the years to come because ERA was still gaining experience in this area. To be noted that by the time the consultation activities were conducted (April-July 2022), only a small number of NoBos were monitored and little information was available on the results.

As presented in more detail in Section 3.8, ERA has completed the first three-year full monitoring cycle for NoBos (2019-2021). Over this period, it audited only 23% of the total number of NoBos under its mandate and issued in total 14 audit/inspection reports. For the cycle 2022-2024 ERA issued 10 audit/inspection reports in 2022 and another 11 in 2023.

[62] Recommendation 2025-RL01-013 from the rail accident report Head-on collision between a passenger train and a freight train in Tempi, 28 February 2023, document available at https://www.harsia.gr/index.php/2025/02/25/prosechos-to-porisma-gia-ta-tempi-stis-27-2-2025/

Therefore, auditing all 68 NoBos in the period 2022-2024 was not achieved, which reflects the difficulties in securing adequate resources for this task.

The Agency has identified 190 deficiencies[63], out of which 21 were classified as major deficiencies which impacted NoBos from 9 Member States. Two thirds of all major deficiencies (14 cases) have been positively closed within 6 months; the remaining 7 deficiencies are open and will be followed up during the next monitoring cycle.

Over 70% of major deficiencies identified by the Agency were linked to two areas: certification body personnel and management of impartiality. The most recurring major deficiencies concerned the ability of a certification body to ensure continuity of the necessary competence (4 cases) and impartiality towards actors linked with assessed products, processes or services and providing consultancy to them (3 cases). These findings, along with insights from the ERA VA process, indicate a need to strengthen the reliability and performance of certain NoBos.

In terms of **technical support in the field of railway safety and interoperability**, ERA has delivered most of the requested opinions and technical advice within the legal deadlines or with slight delays, and with output that was assessed by most stakeholders to be of high quality.

Six out of 14 NSAs and all industry rail representatives (10 out of 10) participating in the survey provided positive input on the quality of opinions issued concerning safety-related and interoperability-related aspects. Some issues were nevertheless mentioned by the stakeholders such as the non-compliance with the deadlines for publication of opinions - 5 out of a total of 29 opinions were published with over 6 months delay - and the use of light impact assessments accompanying opinions in cases that are considered inappropriate by some stakeholders.

There was mixed input from NSAs or railway sector representatives participating in the survey on the quality of the impact assessments. Only a subset of NSAs (6 out of 14) provided a positive assessment and 6 out of 8 rail industry representatives commented that the quality of these outputs was “poor”. Some railway sector stakeholders considered that important decisions, with a potentially significant financial impact for the sector, were made on the basis of impact assessments which, in their view, were excessively light and superficial in content. However, these issues did not have a significant impact on the effectiveness of ERA’s technical support in the field of railway safety and interoperability.

The available evidence does not allow to quantify the **level of contribution towards the achievement of the objective of maintaining a high level of safety and interoperability** of the EU railway system. The Agency’s contribution in this area was a result of the combination of its work in the development of common requirements for safety management, its activities in monitoring and promoting the implementation of a common EU approach to safety management across the EU, as well as through its new role as the authority issuing SSCs. ERA has delivered relevant outputs in a number of areas

[63] The Agency classifies findings of its monitoring activities of notified bodies as major deficiencies, minor deficiencies, and observations. Major deficiencies are defined as those that prevent the notified body from effectively carrying out its tasks in relation to railway interoperability. Minor deficiencies do not impact the ability of notified body to perform its tasks in relation to railway interoperability.

contributing towards maintaining and further enhancing safety in the railway sector and identifying and addressing existing limitations such as the annual assessment of the performance of Member States on the basis of Common safety indicators, a recommendation for the CSM ASLP in 2021, and the assessment of the SMS of the applicants as part of the safety certification process and the issuing of SSCs.

Concerning **its <u>second objective</u>**, i.e. to **contribute to eliminating operating barriers and overcoming the fragmented set of national frameworks and rules**, the Agency's main roles are in the structured and systematic process of screening and removing obsolete national rules and its assistance in the development of TSIs.

ERA assisted in the **development and update of 16 TSIs since 2017** - including the most recent 2023 TSI revision package - integrating technological development in terms of digitalisation and automation. In general, the process of contributing to developing the TSIs - through the support of the working parties - has received positive comments from the stakeholders, including the approach of developing and updating TSIs in packages that can also increase consistency, even though there are still some concerns in terms of ERA's capacity to effectively integrate change requests as well as innovation in the TSIs. The consensus-based approach adopted by the Agency in the development of the TSIs may not always allow to integrate technological development in the TSIs adopted. Further, the additional time and costs that are needed for obtaining authorisations and certification of innovative solutions could also be an inhibiting factor.

Further, the Agency has made progress in the **screening and removal of national technical rules** to ensure an approach that is harmonised across the EU and consistent with the TSIs. However, there have been significant delays in the process in relation to the initial deadline of November 2018. In June 2024, 796 national rules relevant for VA and fixed installations remained in EU Member States, down from 13 459 in January 2016. According to ERA, to achieve a complete removal of all existing national rules, the number of FTEs allocated to this task would need to increase from around 5 FTE in the period 2020-2022 to over 8 FTEs. Screening and removing these additional rules will require considerable effort by personnel with detailed technical and operational knowledge, while there is in parallel significant demand for work on TSIs, CSMs, safety certification and VA.

Stakeholders provided a mixed view on the activities of the Agency related to the review of existing and new national rules:

- NSAs had a mixed opinion on the effectiveness of ERA's assessment of national rules and the identification of redundant ones, while opinions were mostly positive when commenting on the actual reduction of the total number of national rules.
- The opinion of railway sector representatives was instead mostly positive on the effectiveness of ERA's evaluation of national rules and the identification of redundant ones, while a mixed view was provided on the reduction of the national rules. Furthermore, they agreed that reducing national rules has resulted in cost savings and expressed a desire for speeding up the clean-up of the remaining rules.
- National authorities were either neutral or provided a mixed view on the three parameters.

The main strengths of the process of screening and reduction of national rules are considered to be:

- the good level of development and thoroughness of the screening process and the consequent transparency of existing national rules and identification of the potential for further harmonization in TSIs.
- the technical knowledge of the Agency's staff and their willingness to interact with national authorities and provide guidance.
- the availability of guidelines to ensure a homogeneous approach to national rules across the EU.

The main benefits of the process were considered to be the actual reduction in the number of national rules, the stimulus given by the ERA to Member States in terms of questioning the relevance of their national rules, as well as the guidance provided by ERA, which helps to form a common understanding of the remaining areas where national standards remain relevant and how harmonized EU legislation should relate to these remaining standards.

In terms of the main limitations of the process, according to stakeholders these include:

- the perceived slowness of the evaluation of national rules and the frequent delays with respect to regulatory deadlines,
- the limited knowledge of national legal systems by ERA staff,
- the uncertainty about the definition of what constitutes a national rule,
- lack of clarity on the general objectives of the process,
- difficulties in using national rules registers (e.g. the Single Rules Database).

Concerning any adverse effects or unintended consequences of the process, stakeholders mentioned the potential for legal uncertainty and the creation of gaps in legislation (i.e. areas no longer covered by national rules but not adequately covered by EU legislation either); administrative burden for national authorities; and a potential burden on railway undertakings, as rail companies compensate for the elimination of national rules with additional internal procedures. These concerns appear valid and, while they are context specific, if unaddressed, they could limit the processes' ability to achieve its objectives.

On the **establishment and operation of key registers**, the ERA Regulation requires the Agency to set up and maintain the EVR and the ERATV. Further, ERA shall act as a system authority for a series of registers[64] referred to in other pieces of legislation such as the Interoperability and Safety Directives; this includes among others the ERADIS, the European Railway Station Accessibility Database (ERSAD), the SRD, the Reference

[64] The tasks of the Agency include in particular:

(a) developing and maintaining specifications of the registers.

(b) coordinating developments in the Member States in relation to the registers.

(c) providing guidance on the registers to relevant stakeholders.

(d) addressing recommendations to the Commission regarding improvements to the specifications of existing registers, where necessary including simplification and deletion of redundant information, and any need to set up new ones, subject to a cost-benefit analysis.

Document Database (RDD), the European Centralised Virtual Vehicle Register (ECVVR) and the RINF.

Overall, the development of registers has been mostly in line with the expected outcomes of the 4th Railway Package. However, due to the small number of responses received from the consulted stakeholders (i.e., rail sector representatives and NSA), it is not possible to draw strong conclusions.

Rail sector representatives had, in general, a neutral view (neither agree nor disagree) on the easiness of use of the registers. However, for some specific registers they disagreed. This is the case of ERATV (4 out of 6), RDD (4 out of 6), and RINF (3 out of 6). The view of NSAs slightly differs from that of the rail industry. A larger proportion of NSAs disagreed with ERADIS being an easy tool to use (4 out of 13). It is also worth noting the relatively higher proportion of NSA who disagree with this statement for EVR (3 out of 7). Like rail sector businesses, NSAs see RINF as the most difficult to use with half of the respondents disagreeing with this statement (5 out of 10).

Concerning the extent to which the registers are tailored according to the users' needs, the view of NSAs is relatively more negative than that of the rail industry. A majority of NSAs that replied disagreed with registers and IT tools being tailored to user needs for ERADIS (7 out of 12), RDD (8 out of 13), ECVVR (8 out of 10) and EVR (5 out of 8). The level of disagreement was lower for SRD (3 out of 9) and RINF (3 out of 9).

In this context it should be noted that less positive assessments by stakeholders were mostly associated with significant delays in the development of some registers.

There are some major limitations being reported by register users that participated in the survey, in particular for RINF and SRD, indicating that these registers are not fully delivering the expected outcomes in terms of facilitating route compatibility checks[65] and providing clarity on applicable national rules, respectively.

The main criticism concerns the similar data being required by different EU rail registers such as ERADIS, ERATV, and EVR due to a lack of integration. The users have to introduce the same data in the various registers, which leads to complexity, increased cost of sharing data across platforms and potentially higher data errors. While this duplication can create some administrative burden for the users, the evaluation shows that it does not critically affect the overall harmonisation in the rail sector.

Overall, concerning the second objective, ERA has not fully delivered a high level of technical, operational and safety harmonisation in the railway sector, due to not meeting in full its objective of screening and effectively removing obsolete national rules, the limitations concerning the monitoring of NSAs and NoBos as well as the delays in setting up registers and their lack of integration.

In addition to the above, several types of technical, operational, administrative and infrastructural issues pose challenges to interoperability and represent barriers to rail cross-border traffic. The absence of a structured EU-wide mapping of cross-border

[65] The objective is to check if a certain railway vehicle (read as a locomotive unit, passenger car, wagon, etc) of an authorized type of vehicle, can travel the route from operational point A to operational point B. Each route is composed of sections of lines (tracks) with different technical parameters. Each track is between two operations points.

interoperability bottlenecks does not allow targeted action and systematic monitoring of the progress towards seamless rail operations. An example of operational harmonisation challenge is when compliant ERTMS solutions in neighbouring Member States fail to work together effectively, as a result of deploying without the cross-border objective in mind.

Concerning **the third objective** of **supporting rail sector competitiveness and innovation deployment** by reducing administrative costs of authorisation processes, operating and running rail service and reducing time to market for innovation, the Agency has effectively delivered several **activities and outputs intended to promote innovation** (development/update of TSI, active support of Europe's Rail Joint Undertaking (EU-RAIL)) and has put together the new harmonised vehicle authorisation and safety certification process.

The Agency had a positive role through its involvement in EU-RAIL (and before that the Shift2Rail JU) by identifying relevant research and innovation topics/themes to be pursued by EU-RAIL in the context of the development of SERA, providing input to ensure that interoperability and safety considerations and the experience from the TSIs are taken into account in the development of new technologies and, more recently, through its involvement in the preparation of the System Pillar of EU-RAIL. According to the representative of EU-RAIL, ERA has contributed to the higher adoption / market uptake of new technologies and digitalisation (specifically in relation to the introduction of ETCS and specifications related to the TSIs), the higher degree of digitalisation in the sector (in terms of update of the Control Command and Signalling (CCS) and TSI relating to telematics applications for passengers/freight (TAP/TAF) TSIs), as well as to the improved time to market for the deployment of rail innovation and the lower cost of deploying rail sector innovation.

It was mentioned by the representative of EU-RAIL that ERA's support can accelerate the authorisation process as the Agency is already aware of the technical developments and can plan regulation changes accordingly. This improves the competitiveness of the rail sector. However, 20 out of 35 respondents to the survey in the context of the evaluation support study were rather sceptical concerning the contribution of ERA activities towards rail sector competitiveness and innovation deployment. 8 out of 15 authorities provided a negative view and 5 out of 9 railway sector representatives were also sceptical, indicating a contribution to limited extent and 4 more to some extent.

There was also similar scepticism concerning the contribution of ERA activities towards reducing the time to market with only five of 32 respondents indicating 'completely' or 'to a significant extent'. Among NSAs, three out of eight indicated not at all or only to a limited extent and four to some extent. Among national authorities, nine indicated to some extent and four provided a positive assessment. Railway sector representatives were also in general sceptical about ERA activities towards reducing the time to market, with five out of nine indicating that ERA contributed to a limited extent and four to some extent.

The explanations provided for these answers included that any assessment of impact on innovation is rather premature, given the early stages of the implementation of the 4th Railway Package, although important part of the work related to the promotion of innovation took place even before the adoption of the 4th Railway Package. However, for

the majority that provided a negative assessment the main criticism was the alleged higher time and costs for authorisation and certification that is identified as an obstacle in the uptake of new technologies.

These obstacles may in part be explained by some limitations in the operation of the ERA Working Parties that – due to their focus on ensuring the largest possible consensus – have not always been equally effective in integrating change and innovation in the adopted TSIs.

Assistance to Member States, candidate countries and stakeholders: Article 43 of the ERA Regulation stipulates that the Agency "shall engage in training and other appropriate activities concerning the application and explanation of railway safety and interoperability legislation and related products of the Agency such as registers, implementation guides and recommendations" at the request of Commission, Members States, candidate countries, networks of NSAs or representative bodies. This should allow candidate countries to become fully acquainted with the 4th Railway Package, stay in touch with the latest developments regarding the sector in general and promoting a safety culture. In principle, the costs of such assistance to third countries shall be borne by the requesting party (in line with Article 43 of the ERA Regulation). However, this does not translate in an adequate increase in the number of FTEs for ERA who therefore cannot meet these obligations in full. To be noted that these activities were not included in the 2013 Impact Assessment and therefore, there were no estimates concerning the resources needed.

Outside the EU, via the IPA programme, the Agency has delivered **support to the NSAs of the Western Balkans** – mainly in the form of "soft" actions including capacity building and knowledge exchange – to promote convergence with the EU railway safety and interoperability legal framework. Overall, the stakeholders that provided input on this topic (namely from the Serbian Directorate for Railways, the Transport Community (TCT)[66], and DG NEAR) gave a positive assessment of ERA's role and its delivery of its' goals through the Pre-accession Instrument (IPA) project, with focus on bringing the Western Balkans railway system closer to the EU state of play. This has been achieved by allowing the regional railway institutions and experts to become fully acquainted with the 4th Railway Package, stay in touch with the latest developments regarding the sector in general and promoting the safety culture. At the same time, they pointed to some limitations to the delivery of activities by ERA, in particular:

- Budgetary and resource constrains on the side of the Agency meant that not all workshops initially planned were delivered and that, among those delivered, some were reduced in size with a smaller number of beneficiaries – representatives of the NSAs - being able to attend. For example, to implement the IPA Programme the Agency has received, for each period of the contract, between EUR 200 000 and EUR 450 000 with a total of around 1 FTE allocated for the implementation of the IPA programme for both 2020 and 2021. The latter is lower than what was projected in the Agency's programming documents (2 FTEs in 2020 and 3 FTEs in 2021).
- The TCT and the Serbian Directorate for Railways commented that the COVID-19 pandemic caused delays in the implementation of the Rail Action plan and the

[66] Treaty concluded between the Union and South European Parties (i.e., Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Kosovo and Serbia) - https://www.transport-community.org/wp-content/uploads/2022/10/treaty-en.pdf

cancellation of some training activities (i.e. training courses on risk management; SMSs) while others had to be delivered online.

Resourcing issues from the side of the Agency together with the practical implications of the COVID pandemic have posed some limitations to the delivery of the IPA programme, hence impacted on the Agency's ability to deliver assistance to Member States, candidate countries and stakeholders.

In addition, the recent geopolitical developments further show the strategic importance of integrating new accession countries such as Ukraine and Moldova in the EU rail system. There is a pressing need to speed up the cooperation with candidate countries in mirroring the EU processes for VA and safety certification. The under-resourcing directly impacts the Agency's ability to meet its obligations, leading to reduced delivery on planned activities.

When it comes to its **fourth objective**, the Agency has been largely successful in performing its role as the **Union authority responsible for issuing authorisations** for placing in the market railway vehicles and vehicle types, SSCs for railway undertakings, and issuing **ERTMS system approvals**. In that respect, ERA successfully developed the necessary infrastructure and mechanisms to ensure that it was ready to assume its role by June 2019 and has since then rather effectively delivered on this role. There have not been any major disruptions to the development and operation of the OSS; the input from stakeholders is positive concerning most of its features.

Responses from three of the stakeholder groups (NSAs, railway sector representatives and railway businesses) were similar, with over half (7 out of 13 NSAs, 5 out of 9 railways sector representatives and 107 out of 185 railway businesses) agreeing that the operation of the dual system meets the needs of the railway sector. Nonetheless, there was also a sizeable share which appeared more sceptical. National authorities were more supportive of this, with all 17 that replied indicating agreement with this statement. At the same time, 8 out of 185 railway businesses considered the dual system complicated, long and expensive with duplication in documentation required across ERA, NSAs and NoBos adding to the costs for railway businesses and indicating that the process should be shortened and simplified. While this represents a small proportion of respondents, it signals that some businesses experience administrative burden, and that simplification could be beneficial. As an example, redundant national rules which overlap with TSIs are an important factor that increases the processing time of applications. Since national rules have to be reviewed by NSAs even in applications submitted to ERA, the sole existence of redundant national rules increases the complexity of the process and processing time unnecessarily.

The Agency has always met the respective legal deadlines for processing of the respective applications and the granting of authorisations and certification. This should be considered in the context of a high number of applications for authorisation and certification submitted and the fact that a high share of them were approved. In all cases, but particularly in relation to CTT authorisations, the number of applications to ERA has been significantly higher than those initially expected by the Agency for the initial period. Nonetheless, ERA managed to respond by re-allocating resources from the policy related tasks to authorisation tasks despite significant resource constraints.

The increasing share of single country applications for CTT – circa 18% in 2021 – submitted directly to ERA rather than to the NSAs, is seen as an expression of the high confidence towards the Agency performance, as well as an indication of the preference for having a single interlocutor for both single-country and multi-country applications. A significant share of respondents to the surveys (48 out of 78 in the case of vehicle authorisations and 53 out of 78 for safety certifications) indicated preference to use ERA – instead of NSAs – for single-country applications, due to expectation that ERA process would be more structured and predictable concerning the outcome. Most railway businesses that replied (38 out of 71) provided a positive assessment concerning the predictability of the outcome of the process.

Ten out of 17 national authorities that expressed a view indicated that ERA was either quite effective or very effective in its role concerning authorisation and certification. The railway sector representatives considered that ERA was only somehow effective when it comes to VAs, while 6 out of 9 did not have an opinion on safety certification. The explanations provided by the representatives of the railway sector were related to the legal requirements set by the 4th Railway Package as well as on the allegedly strict and demanding interpretation of those requirements by the Agency.

As described in section 3, the Agency cooperates with the NSAs in the processing part of applications, based on cooperation agreements signed with all NSAs before the target date of 31 October 2020. This new model based on cooperation between ERA and NSAs in the processing part of applications enables an effective transfer of knowledge from the Agency to the NSAs and helps harmonising approaches on certain aspects. It supports also the creation of a network of experts working on similar aspects who can reach out to other members of the network where relevant.

However, there are some challenges which require mention/attention. The Agency is often faced with serious difficulties in complying with internal project milestones or even legal deadlines when processing applications as a result of late inputs coming from the NSAs. There have been repeated situations when NSAs communicated issues linked to the assessment of national parts of applications very late in the overall process, when most of time available for assessment has already elapsed. This results in extension of the timeframe and delays for the applicants.

In case of applications for SSCs, some NSAs do not provide the necessary feedback from their supervision activities. The Agency is therefore unable to target its assessment at aspects which cause problems in practical implementation. This limits the ability of the sector to learn from experience and to ensure continuous improvement of its SMSs.

As regards the question whether the working practices of the Agency as set out in the ERA Regulation are sufficiently supporting the Agency's objectives and sector needs, the analysis of the work and operations of the Working Parties suggests that, through their outputs, they had a positive contribution towards achieving the Agency's objectives on the effective implementation of railway safety and interoperability legislation. The development of recommendations for TSIs and CSMs by the Working Parties were generally considered of good quality and in line with the needs of the sector.

All in all, the analysis of the level of participation in the Working Parties suggests that the most directly affected stakeholders – including both from the authorities and the industry

perspective – are directly involved while others are involved on a case-by-case basis. There is no indication of practical barriers to participation set by the design of the Working Parties and of any explicit selection process. Resource constraints and absence of relevant expertise are the most common reasons limiting some stakeholders and national authorities' representation.

Factors affecting the Agency's achievement of its objectives

The two most important factors hindering ERA's performance and achievement of objectives were the resource limitations linked to the Union contribution and the establishment plan, and the higher-than-expected workload for the delivery of authority tasks. The resulting prioritisation of authority tasks impacted the delivery of its policy-related tasks aimed at eliminating operating barriers and addressing the fragmented set of national rules. Beyond that, performance issues of some NSAs and limitation in their cooperation with the Agency have negatively affected ERA's ability to achieve its objectives. Both aspects are considered work in progress. Similarly, the varying level of performance of NoBos across the EU also has an impact on the delivery of the activities and the objective to reduce administrative costs.

The delayed and staged transposition of the 4th Railway Package seemed not to have had a significant impact on the Agency performance and achievement of objectives beyond some initial challenges.

Concerning the role of external factors, the COVID-19 pandemic posed specific challenges to the Agency's ability to deliver its tasks; nonetheless, the evidence suggests that ERA effectively responded to them. There are no indications or input from stakeholders suggesting any important negative impacts of the pandemic specifically on the Agency's delivery of its authority tasks. The OSS had been designed to manage all the exchanges between concerned actors fully electronically ensuring minimum level of disruption. Furthermore, the Agency effectively moved to remote working and the use of virtual meetings to support the delivery of the policy related work (including the NSAs and NoBos monitoring) while some other activities – mainly related to the IPA and EUR Med Rail project as well as delivering assistance to Member States, candidate countries and stakeholders – were postponed to 2022, as explained above. Technological developments and trends in the sector also appear to be ongoing challenges - rather than hindering factors - to which the Agency has been able to respond as part of its objective to support innovation deployment and promote harmonisation, albeit with limitations associated with the role of the working parties in integrating change and innovation.

In comparison, market trends – and specific railway sector business decisions – have led to high number of authorisation applications (particularly conformity to type) that posed important resourcing challenges to the Agency. As mentioned above, the prioritisation given to the authority tasks and to achieving the objective of performing the role of the Union authority has negatively impacted the delivery of the other objectives.

No unexpected effects outside those already considered as directly or indirectly resulting from the Agency activities were identified.

Efficiency

Concerning **ERA's use of actual resources**, based on data from the annual activity reports covering the period 2016-2021, the Agency has allocated around 850 FTEs with a total expenditure of around EUR 136.7 million to support the preparation and delivery of all the relevant activities to implement the 4th Railway Package.

More specific data on the preparatory actions of the 4th Railway Package activities related to the authority tasks (including the development of the OSS and the various supporting activities) suggest a total of around 57-72 FTEs with a budget of EUR 10.5 to 12.5 million for the period up to June 2019. Not including any support activities, since June 2019, around 223 FTEs have been directly allocated to the implementation of the 4th Railway Package authority and policy activities with a total budget of EUR 35.7 million. This includes 87 FTEs allocated for the delivery of the authority tasks and 136 FTEs for the policy tasks.

The Agency largely mobilized the necessary human and financial resources for delivering its new authority tasks, but this was largely the result of ERA's prioritisation of the delivery of the new authority tasks over the policy related tasks, with a corresponding reallocation of resources. This reallocation delayed the delivery or reduced the scope of other important Agency tasks under ERA Regulation, most notably the monitoring of NSAs and NoBos as well as the screening and removing of obsolete national rules (see Sections 3 and 4). Due to budget constraints, important activities such as the development of the Safety Information Sharing System (ISS) and the analysis of consistently collected data on accident precursors had to be put on hold.

Once adopted[67] and fully implemented, CSM ASLP will enable the development of railway safety in a genuine prevention mode of accidents and of their causes. It will convert monitoring of accident outcomes into monitoring of the causes of accidents and the prevention of occurrence with collective learning and actual prevention processes. However, the successful and smooth implementation of the CSM will be strongly influenced by the availability of the Safety Information Sharing System.

The current formats and tools on railway safety occurrence reporting are not technology-proof and the expectation on future better common safety methods for occurrence reporting in Europe is not matched by an appropriate enabling tool. This prevents the EU from having a pro-active system of learning from failures before they turn into accidents and incidents.

This was necessary given that, since the adoption of the 4th Railway Package, ERA has faced the challenge of an establishment plan cap and limits to the capacity for recruiting of additional resources, together with an increasing demand for authority related tasks alongside an ongoing and increasing demand for the policy related tasks. Moreover, the Agency is faced with an internal competition over the same limited pool of technical expertise to cover, on one hand, the policy support for the key rail interoperability and

[67] Adoption expected for 2026

safety objectives and, on the other hand, the time-bound delivery of VAs and SSCs, with critical impact on the competitiveness of rail operations in Europe.

ERA estimations from 2024 show an increasing workload in the field of the authorisation tasks (see Figure 26 and Figure 27), especially linked to the ambitious ERTMS onboard retrofitting programmes including Automatic Train Operation (ATO) and Future Railway Mobile Communication System (FRMCS) and DAC rollout programmes in Europe. The Agency and the NSAs will face high pressure to allocate appropriate resources to these vital tasks.

Figure 26. Estimated increase in vehicle authorisations

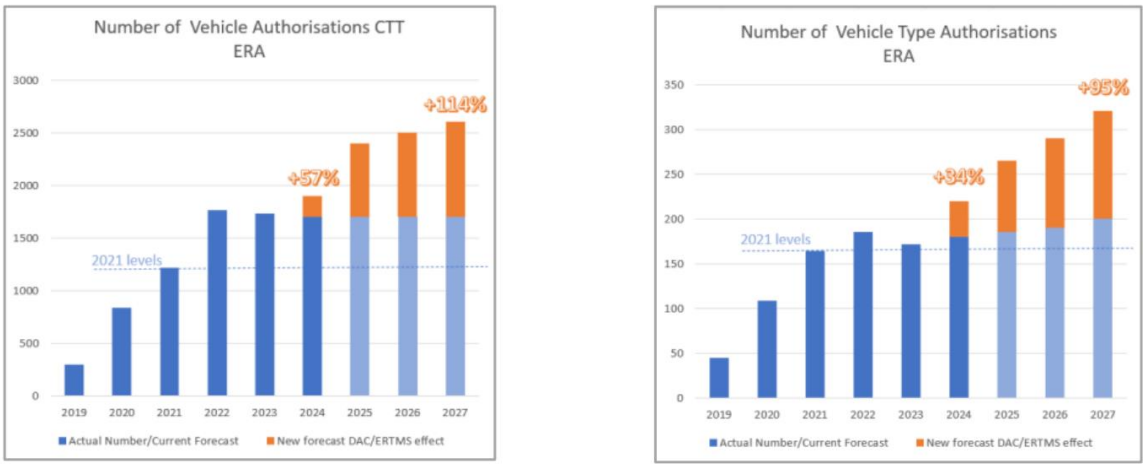
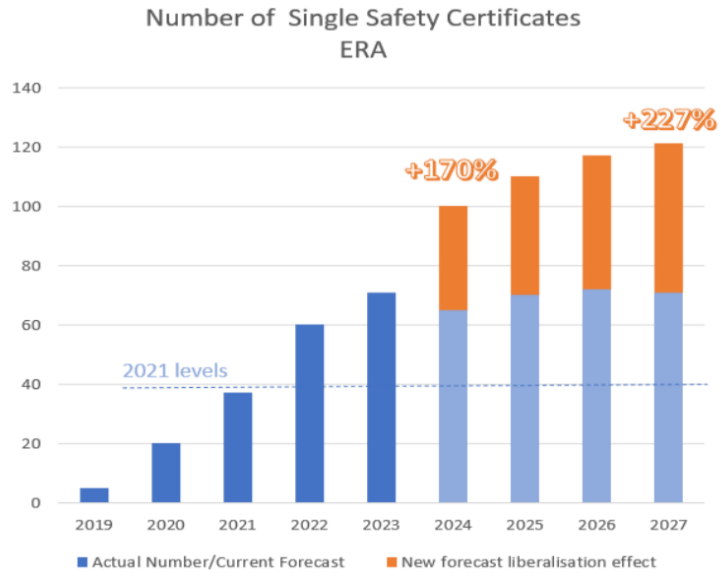


Figure 27. Estimated increase in Single Safety Certificates



The responses to the surveys largely support the view (as well as the input provided by the Agency itself) that resources limitation mainly affect the delivery of the policy related roles and responsibilities for which there are no legally set deadlines.

The responses provided to the surveys show a clear agreement among all stakeholder groups that the Agency has insufficient resources to deliver on the screening of national rules and even less in relation to the monitoring of NSAs.

In contrast, most NSAs (6 out of 11) that contributed to the survey considered that the Agency has had sufficient resources to deliver on the processing of applications and the

operation of OSS. This view is not shared by most national authorities (8 out of 12) and railway sector representatives that shared their views (8 out of 8), where comments provided suggest that budget cuts had a negative impact on most domains. National authorities referred to examples concerning both the OSS operation and pointed to the significant time needed to address issues/problems reported in some cases while representatives of railway equipment manufacturers and wagon keepers (UNIFE (Union of European Railway Industries), UIP) considered that the resource limitations have a negative impact in the delivery of all Agency's tasks.

This analysis suggests that these stakeholder concerns are largely valid, as ERA's prioritisation of authority tasks over policy tasks and resource constraints have had tangible effects on the efficiency of certain processes, such as timely monitoring of NSAs and NoBos and the screening and removal of outdated national rules.

Furthermore, the resource limitation had other implications, for example the OSS development was delayed and linking of registers (ERADIS, ERATV) with the OSS was not as extensive as initially planned. The OSS and the relevant registers do not automatically communicate to each other, and do not use documents in machine-readable formats but pdfs. As a result, human intervention is required to assess the information, which leads to duplicate content, increases the level of documentation required from the applicants, and slows down the overall process, thereby reducing its efficiency.

On the Agency's capability and flexibility to rapidly respond to resource needs due to uncertainties related to the different transposition dates of the technical pillar of the 4th Railway Package, there was no evidence suggesting that significant resourcing issues/challenges have been experienced due to uncertainties arising from the delayed (multiple) transposition dates by Member States.

The analysis of the **Agency's HR procedures** points to various efforts for an effective response to this human resource challenge with different levels of success. From the recruitment perspective, the Agency faced difficulties in fully implementing the establishment plan, especially in the period 2017-2018 where coverage was less than 90%. This has been improved and the implementation of the establishment plan reached 96% in 2021. The Agency has also outsourced some of the authority related workload using the pool of experts, although this has also not delivered the level of resources expected, putting further pressure on ERA resources.

Overall, in view of the challenges posed, the analysis suggests that existing HR procedures have had a positive contribution towards supporting the delivery of ERA's responsibilities.

On the efficiency of the working methods as set out in Chapter 2 of ERA Regulation, the analysis of the costs of the working methods and the resulting outputs did not point to significant inefficiencies. Some comments from stakeholders concerned potential opportunities to improve the efficiency of working parties. The Commission and oneNSA pointed out that there may be room for reducing the time needed for a recommendation if there was less emphasis by ERA on reaching a consensus among all involved and if ERA adopted a more assertive top-down approach, coming up with specific solutions aiming to steer the working parties towards what's needed in less time.

On the cost-efficiency of the organisation and management of the Agency, the analysis indicates that there have already been improvements made in terms of the share of resources allocated to administrative tasks. Still, ERA compares unfavourably in relation to other EU Agencies in terms of the share of non-operational resources allocated (Table 6). This is partly a reflection of the fact that, as all decentralised Agencies, ERA must fulfil a set of administrative functions which are independent of the size and type of operations delivered.

Table 6. Analysis of ERA's share of non-operational staff, 2016 and 2019 - 2021, compared to other 6 EU agencies

Agency	Total number of staff (2021)	Share of non-operational staff (2016)	Share of non-operational staff (2019)	Share of non-operational staff (2020)	Share of non-operational staff (2021)
ERA	184	29.8%	30.4%	28.4%	25.8%
EASA	731	18.1%	15.9%	16.0%	20.9%
EMSA	252	29.0%	28.4%	28.0%	n.a.
ECHA	586	25.4%	20.3%	19.9%	19.2%
ENISA	76	33.3%	29.5%	26.71%	35.5%
EEA	213	22.6%	18.2%	20%	15%
EIOPA	166	24.5%	21.4%	18.3%	16.1%

Source: Ricardo Evaluation support study 2023

The Agency introduced a number of changes in 2018 including a new organisation and operation structure with a new organigram[68], with the aim of making the Agency more effective, efficient and better tailored to its new roles and responsibilities. ERA moved from clearly defined units focusing on different aspects of its work and working largely independently (Interoperability Team, Safety Team and Economic Team (including ERTMS)) to a more integrated organisational structure, following a matrix approach that has provided greater flexibility in the allocation of resources and response to fluctuations in the demand for authority activities (putting aside the possible negative implications).

ERA has adopted an efficiency strategy aiming to identify possible efficiency gains to address resource constraints. It also identified a range of measures and actions to deliver in this area and introduced monitoring tools to help assess its effectiveness and efficiency and take corrective action. The Strengthening Plan adopted in 2022 has identified areas where there is scope for further efficiency gains that are necessary in view of the resource constraints faced by the Agency. In this effort, the Management Board – as the supervising entity - has played an active and constructive role, being actively engaged in the definition of a new intervention logic of ERA intended to more effectively link the Agency's activities with its objectives.

The **role of the Management Board**[69] in ensuring the efficiency of the Agency is seen by its members and railway sector representatives as positive, primarily through its collaborative scrutiny of the SPDs and screening of the proposed annual budget. The SPD

[68] https://www.era.europa.eu/agency-you/agency/organisation_en

[69] The Management Board is defined in Section 1.1

for year N includes a multi-annual work programme covering years N, N+1 andN+2, together with the annual programme for year N. The Agency implements its work programme following the principles of the intervention logic, in line with the guidelines provided by the Network of EU Agencies. The intervention logic supports the Agency by emphasising the desired changes and the road to its achievement. It is also a thinking process supporting the Agency to design, reconsider, and adapt its outputs to the most effective one for a determined outcome.

The Management Board discusses and endorses the SPD for the year N by the end of November year N-2. The SPD is then submitted to the Commission who should adopt the Opinion by 1 July of year N-1. ERA then revises the SPD in line with the Commission Opinion and the Management Board adopts the SPD for the year N by the end of November year N-1.

The Management Board also actively supported the Agency in the development of the Strengthening Plan in its effort to identify efficiency gains to address identifying where resources can be reallocated to help meet the Agency's objectives.

Input from stakeholders with relevant experience suggests that the supervisory role of the Management Board was positive. National authorities – a large share of which are also members of the Management Board – believe that it has contributed to the efficient operation of the Agency (13 out of 14), while a slightly lower number thought that the quality of monitoring of the Agency by the Management Board had a positive role on delivery of Agency's responsibilities and achievement of its objectives (9 out of 12). None of the national authorities believed that the Management Board had a negative role on the efficient operation of the Agency. Comments provided by the Belgian representative referred to the positive role of the presence of a dashboard that allows management members to closely monitor the Agency's performance although some authorities (e.g. Sweden) considered that the level of involvement of the Management Board goes beyond the objectives of a long-term strategic development and could be seen as too detailed and possibly counter-productive.

NSAs that responded to the survey largely indicated that they did not have a view on the Management Board's impact (6 out of 13), but most of those that did have an opinion agreed that their impact was positive (4 out of 13). Among railway sector representatives, all seven that provided a response agreed or strongly agreed that the process contributed to the efficient operation of the Agency. 18 out of 25 respondents to the survey (including 6 out of 7 railway sector representatives, 3 out of 7 NSAs and 9 out of 12 national authorities) considered that the Management Board had a positive role. In comparison, survey respondents appeared more sceptical of the role of the Agency organisation and management structure with only 8 out of 21 suggesting a positive role and 4 of them – including two railway sector representatives and two authorities – stating that it actually had a negative role. However, there were no specific explanations provided as to what is the underlying reason for such a negative assessment. It can only be inferred that stakeholders consider that there is scope for further improvements to the Agency management and organisation.

One potential inefficiency identified based on stakeholders input is that the current role of the Executive Board could be considered a duplication of the work of the Management

Board, in the sense that the Executive Board cannot take decisions and, as it is currently organised, it does not help reduce the workload of the Management Board in decision-making. However, this perception could stem from lack of awareness concerning the role of the Executive Board.

The Executive Board's main function is to assist the Management Board, in particular, by preparing the decisions to be adopted by it, to ensure an adequate follow up to the findings and recommendations after investigations and the various internal or external audits. For this reason, the same Management Board Decisions are on the agenda of the meetings of both Executive and Management Board, however with a different purpose. Further, the Executive Board supports and advises the Executive Director in the implementation the Management Board decisions, with a view to reinforcing supervision of administrative and budgetary management.

Further, as stipulated in the ERA Regulation, where necessary, on grounds of urgency, the Executive Board can take certain provisional decisions on behalf of the Management Board, in particular on administrative and budgetary matters, subject to a mandate received from the Management Board.

The **external supervisory mechanisms of the Agency** have all contributed positively to the efficiency of the Agency:

- The European Commission has had a positive role through its close supervision of the Agency's annual planning and budgeting processes, and guidance on the prioritisation of scarce resources in the implementation of 4th Railway Package.
- The Internal Audit Service has investigated and provided actionable recommendations to the Agency on how to reduce inefficiencies in specific areas, including human resources management, project and service management, and information management. These recommendations were mostly accepted by the Agency and have contributed to improving efficiency.
- The European Court of Auditors has reviewed the Agency's accounts each year, providing recommendations to improve the procurement processes and the internal control of ERA. However, their assessment focuses more on the accuracy of the Agency's accounts and the appropriateness of its processes, rather than sources of efficiency gains in human resource management.
- The 4th Railway Package Steering Group provided some benefit to Agency efficiency by collecting relevant stakeholder inputs on the implementation of the 4th Railway Package and improving the coordination between ERA and other rail stakeholders.

As regards the impact of the ERA having a dual seat in Valenciennes and Lille on its working methods and its costs, there is no evidence of any significant cost implications from the dual seat. The costs related to maintaining the Agency's presence in both locations only had a small impact on ERA's resources and costs, representing around 0.3% of ERA's total budget in 2021. At the same time, maintaining premises in Lille – which is much more accessible (via train) and has greater accommodation options – is convenient and less costly for the Management Board members and other external experts and stakeholders participating in working groups. There is no indication that it has any negative impact on the effectiveness of the delivery of the Working Parties. More importantly, following the

COVID-19 pandemic, most recent meetings have taken place online, leading to a significant reduction in costs. This is expected to continue in a hybrid format, allowing ERA to cut down on rental costs and travelling expenses for both staff and stakeholders.

On the aspects/means/actors/stakeholders or processes rendering ERA efficient, the Agency has gradually introduced internal processes and a management system that helps monitoring the use of its resources. ERA had taken a range of measures even before the adoption of the 4th Railway Package towards improved efficiency of its operations, including the implementation of an Integrated Management System and the establishment of more thorough internal control process. Furthermore, the Agency has put in place a process of monitoring its performance against the targets set in the SPDs supported by systematic data collection on the resources used, budget allocations and performance indicators. The Strengthening Plan adopted in 2022 suggests actions focusing on increased digitalisation and leaner internal processes, which according to ERA's estimations can be expected to bring around 1% efficiency savings annually, namely around 1.9 FTE additional savings on an annual basis with internal redeployment and move of staff from administrative to operational activities bringing up to 4 FTE annually. […..] Furthermore, the Strengthening Plan has identified areas where there is scope for further efficiency gains that are necessary in view of the resource constraints faced by the Agency.

In 2025, the Agency has amended its matrix structure to move from 69 projects and services to 23 programmes (67% decrease). This resulted in overall administrative savings linked to activity management estimated at around 1 FTE. Moreover, 46 project managers were assigned to operational tasks since the largest majority of them have a technical profile.

Furthermore, the Agency used the opportunity in 2023 and 2024 to amend its Establishment Plan, in agreement with its Management Board and the Commission services. This allowed converting vacancies previously assigned to assistant administrative roles into administrator positions focused on operational areas under pressure.

In addition, as reported in the Consolidated Annual Activity Reports, between 2023 and 2024 ERA has reduced its administrative FTEs by 1.06% compared with the previous year, and increased its operational FTEs by 1.10%. This represents a net gain of 4.27 FTEs spent in operational matters in 2024, compared to 2023. This suggests that some of the expected efficiency gains from digitalisation and leaner internal processes are starting to materialise, allowing more staff time to be allocated to operational tasks.

Furthermore, the FTEs spent on "ERA Management and Administration" have been steadily going down since 2023, freeing those resources to work on specific programmes and tasks. This decrease has been possible through the streamlining of various tools, including planning, monitoring and reporting. There has been an equally important effort to redirect some administrative tasks to operational ones such as vehicle authorisation.

There is also no evidence or input from stakeholders suggesting that other aspects and actors – including the operation of the working parties, the processes for monitoring NSAs and NoBos or the dual seat – have a clear positive or negative impact on the Agency's efficiency.

On whether the Agency's results/deliverables led to increased administrative burden, the outputs and deliverables of the Agency have not led to lower administrative burden for rail businesses so far. Increased administrative costs linked with the preparation and submission of documents for VA and SSC, and increased fees charged by ERA were identified as the main drivers of burden.

According to stakeholders, the delivery of the vehicle authorisation and safety certification process did not lead to a reduction of the effort and costs. The expected reduction in the administrative burden for applicants has not materialised during the initial implementation period of the dual system for VA and safety certification. Rather, administrative costs are reported to be higher compared to those of the 3rd Railway Package by most applicants. An important driver of this outcome is the lack of familiarisation of rail industry stakeholders with the new system. At the same time, it appears that these higher costs are related to the requirements of the 4th Railway Package legal framework rather than to the performance of ERA in implementing and managing those requirements. The level of fees applied by ERA is also perceived by some stakeholders as a driver for increased administrative costs compared to the previous situation in some cases. The ERA Regulation includes the requirement that ERA's fees should be equal to or less than the average fees levied by NSAs. However, given the wide range of charging schemes applied by NSAs, it is likely that ERA charges are perceived as being higher in some cases, especially after the increase of the hourly rate. This feeling is particularly keen for applicants who specified that they previously paid no fees to the NSA (e.g. the French, Estonian and Latvian NSAs do not charge for safety certification) or instead paid a lower fixed fee to the NSA. The German and Dutch NSAs, for example, reported current hourly fees of EUR 120 and 129, respectively, while the previous study on fees and charges (Steer Davis Gleave, 2016) estimated that equivalent hourly fees were at most EUR 200 in some countries and significantly lower in Eastern Europe Member States (less than EUR 20)[70].

Another underlying reason for this effect is the Agency applying the legal requirements in a more systematic and consistent way than some NSAs did in the past.

Further, there are issues related to OSS and with the IT tools including lack of register integration, slow loading times, the time needed to fill out a mapping table, delays in addressing technical issues when submitting the application that also explain the increased administrative costs. The stakeholders report an increased effort and time needed to upload copies of required documentation and the lack of effective links with relevant registers such as ERATV and ERADIS. Both of them are considered to be contributing to higher administrative burden for applicants.

However, it is expected that the digitalisation of the application process (in comparison with the use of hard copies) as requested by some NSAs before the 4th Railway Package, should have introduced some savings in administrative costs.

[70] The study on fees and charges (Steer Davis Gleave, 2016) estimated hourly costs for NSAs as a proxy of their fees. This is considered to be a good proxy since NSAs are not expected to make profit on their operations.

According to rail businesses, the main issue is the impact on costs/resources and time for the vehicle authorisation process as result of the implementation of the 4th Railway Package and less in relation to the safety certification or, even less, ERTMS trackside approval, due to a number of weaknesses of the requirements or the process, including the introduction of CTT and of new higher fees by the Agency[71], unclear definitions or interpretations. The unfamiliarity of the applicants and authorisation entities with the new processes led to an increase in administrative costs, particularly during the transition period.

ERA issues clarification notes with the aim of improving stakeholders understanding of complex regulatory requirements and technical specifications, ensuring consistent interpretation and implementation across Member States. They serve as a practical tool to support the effective and harmonized implementation of EU railway regulations. Clarification notes were issued for example to foster a harmonised EU approach to the safety certification process. The clarification notes provide non-legally binding guidance from ERA and the concerned stakeholders are encouraged to voluntarily apply it. Overall, the clarification notes proved useful for the sector in interpreting and implementing the legal requirements.

However, railway representatives pointed to specific clarification notes[72] issued by ERA, which might have interrupted running projects linked to vehicle authorisation procedures at short notice and add further requirements. In their view, these clarification notes were not subject to appropriate consultation and hence, it was not possible to prepare for and mitigate some of these additional costs. As these notes are not legally binding, they cannot add any additional requirements to those included in the legislation. Rather, due to the clarification provided, the applicants become aware that they might have misinterpreted the requirements and for example a different document would be required for the application file. This would potentially lead to the interruption of the authorisation procedure and increase the costs. Evidence collected indicates that the adoption of the dual system for vehicle authorisation and safety certification has not yet led to actual reductions in processing time for the majority of authorisation and certification applications. Most stakeholders reported that time to market (and related opportunity costs) has increased during this initial implementation period, particularly for first and new vehicle authorisations, even though ERA has managed to deliver authorisation and certification within the legally binding deadlines.

The ERTMS trackside approval process is still at the early stages, considering timescales are different compared to those of VA and SSC, and the evidence is limited. However, the initial feedback from stakeholders is mostly positive. As a negative aspect, stakeholders highlighted the extended scope of the approval process, beyond the TSI checks.

The overall impact of the dual system for authorisation and certification, and the ERTMS trackside approval process on the provision of cross-border rail services also lacks evidence for a conclusive answer. The analysis suggests however that the potential of the

[71] In comparison to those applied by NSA prior to the adoption of the 4th Railway Package for authorisation and certification processes.

[72] The notes mentioned by sector representatives were the Clarification note Authorisation of vehicles equipped with CCS train protection, Clarification note from the 29th of June 2021, Clarification note ERA1209/119 V1.0 - Authorisation of vehicles with ETCS set of specifications #1

new roles and processes in terms of facilitating cross-border services has not been fully exploited.

The inputs to the targeted survey suggest an overall increase in the administrative costs incurred for both authorisation and certification activities in comparison to the situation before the 4th Railway Package:

- For new or first vehicle authorisations, the large majority of applicants that responded to the survey reported an increase in administrative costs (45 out of 62) and the required human resources (48 out of 66). Only a few (6 out of 62) reported a decrease in administrative costs.
- For safety certification, fewer applicants that responded to the survey reported increases in administrative costs, but still more than half of the responses indicated an increase (35 out of 61). Those observing an actual decrease were only 11 out of 61.

Further, concerning the lack of familiarity with the new processes, as in some countries ERA's enhanced role was only fully adopted in October 2020, some applicants were only beginning to apply the new processes at the time of the targeted survey and other consultation activities, which led to more time spent on preparing the applications.

While no significant administrative or adjustment costs were identified as a direct consequence of policy tasks, the lack of progress on some policy tasks, and in particular the insufficient delivery on screening and removing obsolete national rules, has limited efficiency gains on authorisation and certification tasks.

The four case studies[73] analysed in the evaluation support study point to specific limitations of the new authorisation and certification processes, notably multi-country applications,

The two first case studies present the experience of two **large rail vehicle manufactures** with locomotive and trainset authorisations. Large manufacturers tend to operate across the EU and are likely to benefit from multi-country authorisations issued by ERA. These manufacturers did not report any benefits in terms of regulatory costs and highlighted a few limitations. Most limitations are related to a **persistent lack of harmonisation of railway rules**. Both manufacturers indicated their preference for ERA as authorisation entity and expected a positive change in the next years.

The third case study illustrates the experience with **wagon authorisations**. Since these vehicles tend to be used internationally, one would expect these to benefit from multi-country applications issued by ERA. Despite this, the case study does not show evidence of cost savings so far, but a persistent cost variability depending on the assessment criteria, which shows **lack of coordination between authorities**.

The fourth case study illustrates a **multi-country safety certification**, which is also expected to benefit from multi-country applications issued by ERA. This case study shows evidence provided by a consulted railway undertaking of actual cost benefits. These derive from **time savings of interacting with a single interlocutor** (ERA), rather than multiple NSAs.

[73] Case study 1 – Locomotive authorisation; Case study 2 – Trainset authorisation; Case study 3 – Wagon authorisation; Case study 4 – Safety certification

but also to some strengths and benefits of the new procedures, with impacts on regulatory costs.

Authorisation and certification costs reported under these case studies could not be used to reliably assess cost changes against the baseline, because of comparability limitation with the cost figures reported under the 2013 IA study. As such, there is no sufficient evidence on the basis of these case study costs to complement stakeholder views regarding impacts on regulatory costs for the industry. In terms of potential simplifications leading to cost reductions, a streamlined procedure for extending the area of use of old vehicles was for example suggested by the case studies to reduce the burden of these authorisations.

On whether **the role of the Agency in terms of supporting harmonisation** through TSIs and CSMs and the elimination of national rules brought savings for both authorisation entities and rail businesses, progress was made in both areas and the TSIs activity reduces costs by ensuring a single set of EU specifications for manufacturers rather than many national ones, however it was difficult to estimate the actual cost savings during the evaluation period.

This may be related to the fact that these cost savings can only be indirect and take place in the long term. In addition, delays in the process of harmonising national rules and the development of relevant registers such as the SRD have limited the impact of these activities up to this point. The costs in VAs are further increased by the remaining redundant national rules – those that are often more controversial. Current practices of some Member States to transfer national rules to other documents such as Network Statements or company policies limit the effectiveness of the clean-up programme and related cost savings.

On how the actual effects and positive impacts compare to the actual costs and any negative impacts in terms of orders of magnitude/in size, the data limitations and the inability to quantify the costs and benefits for the railway sector mean that it is not possible to provide a clear answer as to whether the costs and benefits are comparable in terms of order of magnitude.

Evidence collected from potentially affected stakeholders points to the presence of some negative impacts in terms of additional costs for rail businesses and relevant authorities. The new authorisation and certification process and the clean-up of national rules were identified by stakeholders as areas with potentially higher negative impacts.

For the railway sector, the total costs associated with the VA and safety certification applications submitted to ERA for the period June 2019 - 2022 are estimated at EUR 21.3 million.

NSAs also pointed to some negative impacts related to the new authorisation and certification process in place, however, no evidence of actual negative costs impacts was found. When it comes to regulatory costs for NSAs, the expected cost reductions did not materialise essentially due to the increased number of vehicle authorisations requested.

The stakeholders also mentioned the increased cost of sharing data across platforms and potentially higher data errors due to a lack of integration of the different EU rail registers.

It appears that there were no direct cost savings for the railway sector from the new authorisation and certification process under the dual system – or at least for most of the

railway businesses. Considering what has already been delivered, ERA has made good use of the resources made available – which were less than initially planned. It has delivered in all the relevant areas and objectives, even though to different extents, i.e., authorisation tasks were prioritised over policy tasks. The effects and impacts achieved were delivered at a moderate cost.

Coherence

The Agency's mandate is largely consistent with the broader legislation and specific initiatives aiming at creating the SERA. ERA's objective of ensuring high levels of interoperability across the EU railway system is fully consistent with the liberalisation process and relevant infrastructure development initiatives, being a key enabler of these policies.

There is overall coherence between the Agency's mandate and the EU policy priorities reflected in the EU Green Deal and the Sustainable and Smart Mobility Strategy (SSMS) – but also with several UN SDGs.

When looking at coherence with the EU Green Deal, ERA's objectives indirectly contribute to the achievement of two Green Deal objectives, to increase the EU's climate ambition for 2030 and 2050 (including a target of a 90% reduction in transport's emissions by 2050 relative to 1990) and to accelerate the shift to sustainable and smart mobility.

There are also clear and direct links with SSMS priorities. For example, the general objective of ERA is aligned with both Flagship 3 and Flagship 8 initiatives, which include reference to SERA and support its acceleration.

ERA's objective to ensure a high level of rail safety and interoperability in the EU and promote safety culture is directly linked with the SDG 11 (Sustainable Cities and Communities) which calls for the provision of safe, affordable, accessible and sustainable transport systems by 2030, in particular by expanding public transport. There is a further indirect alignment with SDG 9 Industry, Innovation and Infrastructure, target 9.1 on the basis that ERA's role facilitating the harmonised deployment of ERTMS and interoperable railway systems is supportive of developing 'quality, reliable, sustainable and resilient infrastructure, including regional and cross-border infrastructure'. Indirect positive linkages were also identified between SDG 11 and ERA's objectives to contribute to developing SERA and eliminate operating barriers, and between SDG 9 (Industry, Innovation and Infrastructure) which calls for the enhancement of scientific research and greater encouragement of innovation with associated funding and ERA objectives to ensure a high level of rail safety and interoperability and reduce time to market. The promotion of innovation in the rail sector can be expected to indirectly contribute to the broader objective to accelerate the shift to sustainable and smart mobility.

The ERA objective of eliminating operating barriers, facilitate the entrance of new railway undertakings and suppliers of rail equipment into markets is indirectly aligned with SDG 16, related to the promotion of peace, justice and strong institutions, in particular target 16.6 that requires development of effective accountable and transparent institutions. Through the development of the OSS to help eliminate administrative barriers and the removal of national barriers ERA contributed to making the relevant procedures transparent to stakeholders. ERA also demonstrates transparent reporting as to its activities

and progress against targets through a Communications and Dissemination Plan. There is a further consistency, albeit an indirect one, with SDG 11 on the basis that an opening of the rail market and associated expansion of rail services should also positively contribute to the provision of safe, affordable, accessible and sustainable transport systems by 2030.

No significant inconsistencies were identified in the legal framework and operation of ERA besides the important trade-offs in the delivery of the authority and policy tasks due to the resource constraints faced by the Agency. NSAs and railway sector representatives also highlighted the resources challenges faced by the Agency due to budget constraints and establishment cap. Railway sector representatives indicated that this limits ERA's ability to deliver the ambitious objectives set by the European Commission, while one NSA commented that ERA is subcontracting out its core business to private companies. Consequently, ERA had to reallocate resources from the policy to the authority tasks to ensure the processing of applications within the timetable set by the ERA Regulation.

This reallocation of resources has had a direct impact on the capacity of the Agency to deliver on other objectives and roles, including in relation to the monitoring of NSAs and the screening of national rules. More concretely, the NSAs monitoring conducted by ERA in the first three-year cycle (2019-2021) focused only on some priority aspects considered to be essential to get assurance on the safety level achieved by Member States, i.e., staff competence management within NSAs, and NSA supervision activities, including supervision strategy and planning, integration of a risk-based approach for prioritising supervision activities, and delivery of supervision of the safety performance of relevant actors of the railway system. This was a decision taken by the ERA Management Board for a "targeted scope of audits" and it was justified by the significant resource constraints faced by the Agency and the objective that had been set in 2017 to complete an audit of all EU NSAs within the three-year cycle.

Nonetheless, these trade-offs also had some positive impact in the form of sharing of learnings between different tasks, enabling experience gained from authorisation to support policy development and thus seeking to avoid any contradictions between the two different functions.

Other contradictions include some NSAs and national authorities pointing to possible conflicts of interest between ERA's equal footing to all NSAs as an authorisation authority and its parallel task of monitoring the NSAs, including assessing its own cooperation with NSAs. However, so far there is no evidence suggesting any bias in the monitoring of the NSAs by the Agency. Further, the 4th Railway Package introduces NoBos monitoring but not Assessment Bodies (AsBos) monitoring despite these being juridically equal.

Reflecting the relatively limited experience so far, more harmonisation of the approaches of different Member States and technical suppliers in implementing the Regulation would have been beneficial, as well as a more coherent approach for trackside and on-vehicle ERTMS equipment giving more consideration of the impacts on the complete value chain.

Overall, the ERA mandate appears to be largely coherent with the broader legislation and specific initiatives aiming at creating SERA. No internal coherence issues have been identified.

4.2 HOW DID THE INTERVENTION MAKE A DIFFERENCE AND TO WHOM?

EU added value

The enhanced role of ERA has brought several **benefits** that would not be possible to achieve on the basis of national action only. The main areas where benefits of intervention at EU level have been identified include:

- **Vehicle authorisation and safety certification processes**. Due to action at EU level, harmonised and standardised procedures have been established for both these processes, with the aim of reducing the costs for those procedures or at least making them more efficient at EU level. To this end, a common IT tool in the form of the One-stop shop application was rolled out.

  Among the 13 NSAs that expressed their views on this, 7 indicated that Member States alone could address the long and costly certification and authorisation procedures either completely or to a significant extent. In comparison, only 3 out of 17 national authorities felt this was the case indicating they could to some extent and a further 5 indicating to a limited extent or not at all. Only 1 out of 9 railway sector representatives considered that Member States alone could address the long and costly certification and authorisation procedures, with 6 stating they could in fact only address this to a limited extent.

  Stakeholder views were mixed specifically with regards to reducing costs and the duration of the VA process. Among the NSAs that responded to the survey, 5 out of 13 stated that action at Member State level could deliver on reducing costs and duration of the VA process to a significant extent, whilst another 3 stated only to a limited extent. 4 out of 17 national authorities that replied also stated to a significant extent, however another 6 indicated only to a limited extent or not at all. Of the 9 railway sector representatives, 5 stated that Member State action could only deliver reduced costs and duration to a limited extent, compared to just 1 stating completely.

  From those in favour of EU action, the French NSA stated that the Agency and EU action brings added value on new tasks related to the 4th Railway Package, including reduced costs or reduced delays for vehicle authorisation processes for railway undertakings operating in more than one Member State. The Polish NSA added that it would be hard to envisage joint authorisation procedures without the existence of EU level action.

  In comparison, the Luxembourgish NSA stated that this can still be done by Member States quite easily, but the process is most likely quicker with the Agency's involvement. The Portuguese national authority pointed out that in some cases, costs and duration of the VA process could be lower/shorter than it is now when considering the authorisation case of extension of the area of use – however this is area specific e.g. Iberian Peninsula. In view of the German NSA, the new involvement of ERA has helped with the multi-country aspect but has also brought higher costs than what could have been achieved at Member State level only. Finally, the representative of European Rail Infrastructure Managers (EIM) stated that in the short-term costs may increase but they should reduce in the long run.

Similarly to the VA process, stakeholder views were mixed with regards to reducing costs and the duration of the safety certification process. 4 out of 13 NSA respondents indicated that action at Member State level could deliver on this to a significant extent, whereas another 3 stated only to a limited extent or not at all. For national authorities, 3 out of 17 indicated Member State level action alone could deliver to a significant extent, whilst another 5 highlighted to a limited extent or not at all. Finally, 5 out of 9 railway sector representatives stated only to a limited extent.

The French NSA added that the Agency and EU action brings added value on new tasks related to the 4th Railway Package, including reduced costs or reduced delays for SSC processes for railway undertakings operating in more than one Member State. The Luxembourgish NSA added that this can be done by Member States quite easily, but the process is quicker with the Agency involvement. The Polish NSA commented that it would be hard to envisage joint certification procedures without action at EU level.

It has to be noted that the answers from NSAs and national authorities were potentially focusing on the costs associated with single country applications, hence not considering the benefits for multi-country applications.

Finally, the railway sector representative EIM stated that in the short-term costs may increase due to the EU level action, but they should decrease in the long run.

Even though stakeholders input suggests that the expected cost savings from the EU level action and the Agency central role have not been as evident to this point with the majority of applicants indicating actual cost increases, this suggests that the reported increase in the costs experienced to this point does not mean that there should not be benefits arising from the introduction of multi-country authorisations and safety certification and the more harmonised and centralised approach followed under ERA (as initially expected). Nor does it mean that individual railway business may have not already experienced these specific benefits. However, to this point, such benefits have not arisen at an aggregate level due to various limitations in the initial stages of the implementation of process and the lack of familiarity of applicants with the new processes introduced by the 4th Railway Package.

- **Assessment** and where necessary, **removal of national rules**. Action at EU level has ensured that there is a systematic process to deliver consistent assessments of compatibility of national rules with the relevant TSIs and CSMs.

  Most respondents to the survey supported EU level action when looking at the elimination of redundant national rules. 7 out of 13 NSA respondents stated action at Member State level could only deliver this to a limited extent or not at all (compared to just 2 who indicated to a significant extent), along with 11 out of 17 national authorities and 7 out of 9 railway sector representatives. The French NSA added that EU level activities that decrease barriers such as reducing national rules bring significant added value.

- **Monitoring of NSAs and NoBos**: the structured, harmonised and systematic monitoring process identifies deficiencies and areas for improvement in operation of these bodies and triggers appropriate reaction to ensure a minimum level of capacity. This effect would not be possible - at least to the same extent and for all NSAs - based

on national action only. Further, mutual confidence between NSAs, NoBos and ERA is vital for the monitoring process to work and the leading role of ERA in the monitoring process facilitates the sharing of experience between NSAs and NoBos. The majority of stakeholders that expressed their views were in favour of EU level action with regards to ensuring a **coordinated approach to monitoring of performance and decision-making of NSAs and NoBos**. Out of the 13 NSA respondents, 9 stated Member State action alone could only deliver to a limited extent or not at all. 12 out of 17 national authorities agreed, having stated only to a limited extent or not at all, along with 7 out of 9 railway sector representatives. The Portuguese national authority added that the NSA monitoring process is an area which would not be possible to deliver without the presence of the roles and responsibilities assumed by ERA under the 4th Railway Package.

- Harmonised deployment of **ERTMS** trackside equipment. ERA, being the system authority for ERTMS, has the best competence to ensure harmonised deployment of the system thanks to its ERTMS trackside approval process.

  Among the 13 NSAs respondents to the survey, 8 considered Member State action alone could only ensure consistent development of telematics and ERTMS deployment, harmonised ERTMS solutions to a limited extent or not at all, compared to only 2 that indicated it could completely or to a significant extent. National authorities exhibited similar views, with 12 out of 17 having stated to a limited extent or not at all and only 1 to a significant extent. A large majority of railway sector representatives (8 out of 9) also indicated Member State action alone could only deliver this to a limited extent or not at all.

  The Latvian NSA added that the role of the Agency and EU level action is very important for ERTMS projects as they are at the EU level. The Portuguese national authority also stated that the consistent development of telematics and ERTMS deployment is an area which will not benefit without the presence of the roles and responsibilities assumed by ERA under the 4th Railway Package.

In all above areas, the action at EU level was also more impactful in terms of organising and coordinating the necessary dialogue and cooperation among the relevant actors in the sector across the EU (e.g. NSAs and NoBos cooperation networks) and the access to the relevant technical and EU wide expertise needed to support the development of TSI and CSMs.

Further, the problems identified in the 2013 Impact Assessment could only be solved to a limited extent if addressed only at Member States level. The extent would vary depending on the specific problem under consideration. In the case of authorisation and certification processes, Member States could improve them to a limited extent given the ongoing work and cooperation agreements between neighbouring NSAs covering also multi-country authorisations. However, their actions would not be as comprehensive and harmonised as in the case of ERA's involvement and would not ensure the same level of benefits across the EU.

Furthermore, there would be neither an incentive nor obligation for Member States to remove national rules and reduce the overall fragmented legal framework across the EU. As a result, individual action by Member States alone would not be sufficient to remove

the barriers for new market entrants and the cooperation and support for integration would be limited.

Member States would most likely be able to address certain aspects of safety in the respective national network, but to a lesser extent interoperability across the EU, besides perhaps among those with extensive rail or territorial linkages. At the same time their intervention would lack an EU-wide perspective in developing technical specification and – especially for the Member States with reduced resources – deprive them of the capacity and expertise brought by ERA.

National funding could serve, to some extent, as an important driver for innovation and modernisation of the railway sector. However, the results would be fragmented and not deliver the enhanced geographical and market scope for new technologies that would result from action at the EU level. Moreover, the result from national funding would not ensure that new technologies are based on commonly applied technical specifications across the EU.

In conclusion, action at EU level has brought benefits in comparison to action only at national level. EU level action has led to the establishment of harmonised and standardised procedures for vehicle authorisation and safety certification and the presence of a common IT system and data registers that support the application process and the more effective monitoring of the implementation of the 4th Railway Package. Further, it has also ensured a harmonised, systematic and structured approach in the screening and removal of national rules as well as to the monitoring of NSAs and NoBos.

National action would most likely be able to address certain aspects of safety in the respective national networks, however it would not be expected to have the same impact in terms of promoting interoperability across the EU (besides perhaps among those Member States with extensive rail/ territorial linkages).

4.3 IS THE INTERVENTION STILL RELEVANT?

Relevance

The consideration of needs identified in the 2013 Impact Assessment and at the time of the adoption of the 4th Railway Package (i.e. lengthy and costly authorisation and certification procedures, discrimination against new market entrants, a lack of modernisation and innovation in the rail sector and the need to ensure safe and interoperable railway operations) and the assessment of the objectives of the intervention has revealed that the problems are still valid today.

Even though the efforts to address these needs have resulted in improvements in some areas (i.e., in safety performance and some progress in ERTMS deployment), the original objectives of the Agency – and the need for the respective actions - continue to be relevant. This finding is also supported by stakeholders, with the majority agreeing that there is still a need for action to address the needs initially identified. For example, 14 out of the 16 national authorities that replied to the survey, 8 out of 9 railway sector representatives and 136 out of 206 railway businesses indicated that the objective to reduce the length and cost of procedures remains relevant to the current problems and needs of the railway sector.

Only 8 NSAs (out of 14) expressed disagreement with this view although most agreed that there were still cost issues associated with the certification and authorisation procedures.

Concerning the key elements of the 4th Railway Package (i.e. the dual system, the OSS and the harmonised implementation of the ERTMS), the evaluation showed that they meet the needs of the EU railway sector, even if they have not yet fully achieved their objective and delivered the expected benefits.

The introduction of the dual system was aimed to promote a harmonised approach to processing the applications for VAs and SSCs while also providing flexibility for applicants to use the NSAs in the case of single country applications. Following the implementation of the dual system, the volume of work of the Agency linked to the new authority tasks increased over time. An important share of this increased volume was related to multi-country applications with an area of use in multiple Member States. This has supported in particular those applicants planning to run cross-border operations.

There was significant level of support across all stakeholder groups concerning the relevance of the dual system of the 4th Railway Package. The stakeholder consultation indicated that the dual system is considered appropriate with recognition of the benefits of its introduction. First, ERA can coordinate NSAs across different Member States and overrule NSAs if there are discrepancies in the way issues are handled. When combined with the OSS, it is a simpler system for those wanting to operate in multiple countries. Second, no stakeholders considered that the NSAs should not be involved in the process of authorisation/certification, i.e., that this should only be a responsibility of the Agency. One NSA noted that language could be a particular challenge for ERA in the future, given that applications for authorisation/certification can be submitted in any of the EU languages, and ERA staff still needs to be able to read the documents even if NSAs are involved in authorisations/certifications.

Overall, the stakeholder consultation revealed that the dual system, although it is not yet operating optimally, does work better with both ERA and NSAs involved. Among the respondents to the targeted consultation, 133 out of 221 respondents agreed or strongly agreed that the operation of the dual system with the enhanced role for the Agency and shared responsibility between ERA and the NSAs meets the need of the sector (including 7 out of 13 NSAs, 17 out of 17 national authorities, five out of nine railway sector representatives and 107 out of 185 railway businesses). This setup better meets the sector's needs while aligning with the objectives of the 4th Railway Package.

The development and operation of OSS was aimed at streamlining and managing applications in a fair and transparent way. It should allow users to track progress and interact with both ERA and NSAs (for single Member States applications) from the pre-engagement stage through to an authorisation or certification being issued. It has been in operation since June 2019 and, despite the current limitations in terms of the functionalities and the interfaces with ERA registers and NSAs own systems, the input amongst users has in general been positive. There was a high-level agreement across all stakeholder groups that OSS meets the needs of the railway sector (12 out of 14 NSAs, 13 out of 16 national authorities, eight out of nine railway sector representatives and 153 out of 203 railway businesses agreed or strongly agreed; in total 186 out of 242 respondents to the survey). Further to this, the existence of a programme of continuous improvement of the OSS

suggests that there is capacity and plan to ensure that it meets the changing needs of the authorisation and certification process and of the sector more broadly.

More effective and faster adoption of technological developments in the areas of automation, digitalisation, adoption of greener/sustainable solutions and new mobility solutions will be key in the modernisation of the EU railway sector, delivering on decarbonisation targets and strengthening its competitiveness. All this points to the ongoing and even enhanced need to increase the pace of modernisation and innovation in the railway sector and to reduce time to market. This is also a conclusion supported by most stakeholders that contributed to the targeted consultation. Nine out of 14 NSAs, 13 out of 15 national authorities, five of out of nine railway sector representatives and 157 out of 199 railway businesses (total of 184 out of 237 respondents) agreed or strongly agreed that modernisation and innovation in the railway sector are happening at a slow pace. Simultaneously, stakeholders pointed out that that slow and costly procedures - with specific reference made to the lengthy process for including innovations in TSIs and the need for extensive, detailed checks - are also a contributing factor to slow modernisation and innovation.

At the same time though, there was some discord about the relevance of this objective for the Agency. 10 out of the 15 national authorities that expressed their views agreed, as did railway businesses (114 out of 192), but a significant share of NSAs (5 out of 13) disagreed (compared to 4 out of 13 who agreed) while the most common response from railway sector representatives was neutral (5 out of 9). The main point made in that respect was that reducing time to market of innovation should not be considered a core task and objective of the Agency.

According to targeted survey, 8 out of 10 NSAs, 11 out of 16 national authorities, 6 out of 8 railway sector representatives and 123 out of 172 railway businesses (in total 148 out of 206 respondents), agreed or strongly agreed that the harmonised implementation of ERTMS meets the needs of the railway sector, as it is fundamental to the achievement of SERA.

5. WHAT ARE THE CONCLUSIONS AND LESSONS LEARNED?

5.1 CONCLUSIONS

The Commission has carried out an evaluation covering the scope required by Article 82(1) and (2) of ERA Regulation, i.e. the role of the Agency, its impact, effectiveness, efficiency, coherence, EU added value, relevance, as well as the implementation of the ERA Regulation with a particular focus on the functioning of dual system for vehicle authorisation and safety certification, the one-stop shop and the harmonised implementation of ERTMS in the Union.

However, it should be noted that the implementation of the 4th Railway Package had not reached its full potential during the evaluation period. The learning curve of stakeholders to adjust to the changes of the 4th Railway package had not yet been completed during the evaluation period, meaning that cost and time saving effects did not materialise yet. Further, despite extensive and thorough consultation activities, there were insufficient

quantitative data on costs of authorisation and certification for applicants as well as on time and costs to NSAs for processing applications.

Despite these limitations, the evaluation provides a comprehensive snapshot of the existing information and a consistent analysis of the aspects required by Article 82(1) and (2) of ERA Regulation.

The evaluation identified a series of issues as problematic:

- The operation of the new system has not yet delivered, for the majority of applicants, the administrative burden and broader cost savings expected at the time of the adoption of the 4th Railway Package. There are multiple drivers for this result:
    - At the initial stages of the implementation of the process, there was a limited experience and familiarity with the new process and the OSS of many applicants.
    - The limited capacity and cooperation by some NSAs in the processing of applications, as part of the dual system. The limited level of use by a large share of applicants of multi-country applications – with the exception of wagon authorisations – and the preference for multiple single country application has also prevented further cost savings from materialising.
    - Comparatively higher hourly fees charged by the Agency in comparison to most national authorities. This is combined with what appears to be a more thorough and more demanding approach adopted by the Agency for checking relevant documentation together with some practical limitation of the OSS in terms of the handling of documentation.
    - Significant delays were accumulated in the development of some registers. RINF and SRD did not fully deliver the expected outcomes in terms of both facilitating route compatibility checks and providing clarity on applicable national rules. Further, similar data is required by different EU rail registers due to the lack of integration between them and with the OSS. This leads to further complexity, increased cost of sharing data across platforms and potentially higher data errors.
- Since the adoption of the 4th Railway Package, ERA has faced the challenge of an establishment plan cap and limits to the capacity for recruiting of additional resources, together with an increasing demand for authority related tasks alongside an ongoing and increasing demand for the policy related tasks. The Agency largely mobilized the necessary human and financial resources for delivering its new authority tasks, but this was largely the result of ERA's prioritisation of the delivery of the new authority tasks over the policy related tasks, with a corresponding reallocation of resources. This reallocation delayed the delivery or reduced the scope of important policy related tasks (including development of TSI, cleaning of national rules, NSAs and NoBos monitoring) with implications on the contribution of the Agency towards harmonisation across the EU and supporting interoperability. Indirectly, this also has had negative impacts on the achievement of the Agency's objective of reducing authorisation and certification time and costs since their fast delivery depends on the high level of harmonisation on the basis of TSIs (i.e. absence of multiple national rules

to assess compliance with) and the relevant capacity of actors involved in the context of the dual system – including NSAs and NoBos.

- With regard to the removal of obsolete national rules, there have been significant delays in the process in relation to the initial deadline of November 2018. The stakeholders see the main benefits of the process to be the actual reduction in the number of national rules, the stimulus given by the ERA to Member States in terms of questioning the relevance of their national rules, as well as the guidance provided by ERA, which helps to form a common understanding of the remaining areas where national standards remain relevant and how harmonized EU legislation should relate to these remaining standards. At the same time there is a clear agreement among all stakeholder groups that the Agency has insufficient resources to deliver on the screening and removal of national rules.
- The Agency monitoring activities have been partly delivered. The findings from the first and second NSA audit cycle highlighted a poor performance of some NSAs, which results in weak oversight of the railway system in those Member States, creating potential gaps which could lead to significant non-conformities being left unnoticed for years. Without well-functioning NSAs carrying out their role of oversight, the effectiveness of the SSC system might be compromised. The NSA monitoring process is not adequate to identify such wider potential issues due to its limited scope which does not cover the performance of other stakeholders having an important safety role like railway undertakings, infrastructure managers, NIBs or Member States authorities.
- ERA has completed the first three-year full monitoring cycle for NoBos (2019-2021) over the course of which it issued in total 14 audit/inspection reports. Therefore, in this first cycle, ERA audited only 23% of the total number of NoBos under its mandate. For the cycle 2022-2024 ERA issued 10 audit/inspection reports in 2022 and another 11 in 2023. Therefore, auditing all 68 NoBos in the period 2022-2024 was not be achieved, which reflects the difficulties in securing adequate resources for this task.
- There is a lack of a comprehensive assessment of the implementation of rail safety and interoperability legislation, which is supported by national action plans and capacity-building initiatives provided by ERA, As a result, there are variations in NSA performance and safety levels across Member States.
- Although the Agency is empowered under Article 35 of ERA Regulation to perform complex assessments of practical implementation of rail safety and interoperability legislation which could cover all relevant actors, this process was designed as an ad hoc task performed on a specific request of the Commission and not as a regular monitoring process. As a result, the current budgetary envelope of the Agency does not include the necessary resources to perform such complex assessments at Member State level on a regular basis.

Summary of the conclusions per evaluation criterion

Effectiveness. ERA had a positive contribution in all of the areas where it was expected to play a role in the context of the 4th Railway Package, and it has also had a positive role

towards the development of the SERA, even though the level of contribution has not been in all areas at the level expected.

Considering its new authority role, ERA has successfully established, without delays or major disruptions, the necessary procedures and mechanisms – including the OSS platform – to support the issuing of authorisations for placing railway vehicles and vehicle types in the EU market, issuing of SSCs for railway undertakings and the approval of ERTMS systems.

However, the operation of the new system has not yet reduced, for the majority of applicants, the administrative burden and not yet delivered the broader cost savings expected at the time of the adoption of the 4th Railway Package.

It appears that there were no direct cost savings for the railway sector from the new authorisation and certification process under the dual system – or at least for most of the railway businesses. This means that the net benefits of the intervention expected in the 2013 Impact Assessment have not yet materialised. However, any such assessment is premature since an important driver of the additional costs reported can be linked to the limited experience with the implementation of the dual system by many applicants at the time of the survey.

ERA made good progress in terms of the development of the relevant registers and databases that can - among others - facilitate the submission and processing of applications, in line with the expected outcomes of the 4th Railway Package, although with some ongoing limitations in terms of integration of registers which leads to complexity, increased cost of sharing data sharing and risk of data errors.

The Agency has effectively delivered activities related to the promotion and enhancement of safety and interoperability across the EU, including a range of relevant technical outputs (e.g. TSIs, CSTs, CSMs and the use of CSIs). However, resource constraints have led to the decision to prioritise the delivery of authority tasks with a negative impact on the delivery of some policy tasks including the monitoring of NSAs and NoBos, and the removal of obsolete national rules, both important elements in the process of eliminating operating barriers, enhancing interoperability and reducing the time and costs of the authorisation process. Therefore, ERA did not meet in full the objective of screening and effective removal of national rules as well as of limitations concerning the monitoring of NSAs and NoBos.

In June 2024, 796 national rules relevant for VA and fixed installations remained in EU Member States, down from 13 459 in January 2016. Removing these additional rules will require considerable effort by personnel with detailed technical and operational knowledge, while there is in parallel a significant demand for work on TSIs, CSMs, safety certification and VA. At the same time, the process for screening and removing obsolete national rules was incomplete, limiting the effectiveness of the authorisation and safety certification process.

The legal uncertainty during the process of screening and removing the obsolete, national rules and the creation of gaps in legislation (i.e. areas no longer covered by national rules but not adequately covered by EU legislation) may lead to negative impacts in terms of increased workload for infrastructure managers and railway undertakings, and higher

administrative costs for both authorisation entities and applicants. These cost impacts could not be quantified on the basis of available evidence.

Overall, considering the Agency's contribution towards the effective functioning of SERA, the objective to perform the role of the Union authority has been largely achieved and there was a positive contribution towards maintaining safety levels on the basis of the relevant activities delivered, including the monitoring of Member States' performance, development of the recommendation CSM ASLP and the activities to promote safety culture. However, the CSM for occurrence reporting are not matched by an appropriate enabling tool and resources. There is a historical accumulation of safety-related IT tools based on different technologies, lacking a consistent approach.

However, ensuring and enhancing interoperability, eliminating operating barriers and overcoming the fragmented set of national frameworks is still work in progress. When it comes to the objective to support the rail sector competitiveness and innovation, the level of contribution to this point has been lower than expected. The alleged higher time and costs for authorisation and certification were identified as an obstacle in the uptake of new technologies. At the time of the evaluation, the limited familiarity with the new process of authorisation and safety certification contributed to higher administrative burden and longer processing times, indicating that the dual system has not yet delivered the intended efficiency gains.

Finally, considering the role of ERA in the Western Balkans, its activities funded by the IPA programme are considered by the local NSAs and the TCT to have had a positive contribution in supporting the implementation of the TCT Rail Action Plan that is intended to align the Western Balkan's railway system with that of the EU. ERA has positively contributed to the international stream of work by successfully managing the IPA and EUMedRail grants and supporting neighbouring countries.

Efficiency. The delivery on the Agency objectives presented under "effectiveness" took place on the basis of a reduced level of resources available and used by ERA. The resources made available for the implementation of the 4th Railway Package were significantly less than expected in the 2013 Impact Assessment[74].

In terms of internal efficiency of ERA's operation and human resources, the gradual introduction, during the evaluation period, of internal processes and management systems have had a positive contribution. However, there is still scope for further efficiency gains in areas identified by the Agency's own Strengthening Plan adopted in 2022.

The analysis of the Agency HR procedures points to the positive role of a more flexible non-hierarchical matrix-type structure facilitating the reallocation of staff to authority tasks, while the recruitment of new staff has improved over time ensuring a share of filled positions in comparison to the establishment plan above 90% since 2019. However, the use of the Pool of Experts tools has delivered much less than expected in terms of access

[74] The actual increase of human resources for ERA was 19 FTEs in the five-year period 2016-2021 in comparison to the 55 additional FTE expected in the 2013 Impact Assessment. The total expenditure has increased from EUR 27 million in 2016 to EUR 29.7 million in 2021 (10% increase). This is considerably lower than the expected 33% increase of the ERA budget in the 2013 Impact Assessment.

to resources to support the delivery of authority tasks (7-10% of the total workload in comparison to an expectation of up to 25%).

There are still areas where efficiency improvements are possible and could help achieve the same results with less resources, as identified in the Agency's own Strengthening Plan, although there is no indication of significant inefficiencies. This mainly concerns the share of resources allocated to administrative tasks/functions but also the need for more effective use of ICT and resource management tools.

The Management Board had a positive role along with external supervisory mechanisms (European Commission including its Internal Audit Service, and European Court of Auditors). A potential internal inefficiency was identified in the duplication of some parts of work between the Management Board and the Executive Board.

Considering the dual seat Valenciennes – Lille, there is no evidence of any significant cost implications and based on the recent reduction to the rent, there is limited scope for further cost cuts.

Relevance. The key problems/needs identified in the 2013 Impact Assessment and at the time of adoption of the 4th Railway Package are all still valid today. The efforts to address these needs - including in the context of the implementation of the 4th Railway Package - have resulted in some improvements since 2016. However, further effort is needed to deliver the 4th Railway Package and fully meet its objectives.

Overall, ERA's objective to reduce time to market of innovation is relevant to the identified and ongoing need to enhance the pace of innovation in the sector. As an EU authority, ERA's role in this area is expected to come both through its direct role on the time and costs of the authorisation and certification process (and the impact on the time to market for innovation), through its expected role in facilitating, coordinating the process of the development of harmonised technical specifications and its broader role as technical advisor. Furthermore, it can come also through its mandated role (Article 40 in the ERA Regulation) in identifying related research needs and promoting research and innovation activity (including through its involvement in the Joint Undertaking) and ensuring that these are consistent with the policy priorities, the development of SERA and ensuring interoperability and safety.

Coherence. The ERA mandate appears to be largely consistent with the broader legislation and specific initiatives aiming at creating SERA. In particular, the ERA objective of ensuring high levels of interoperability across the EU rail infrastructure and equipment is fully consistent with the liberalisation process and relevant infrastructure development initiatives, being a key enabler of these policies.

The Agency's mandate appears also to be in line with the EU policy priorities, as these are reflected in the EU Green Deal and the SSMS[75], and also with the relevant UN SDGs. No internal coherence issue was identified between the provisions of the ERA Regulation.

EU added value. Action at EU level has brought benefits, compared to action at national level alone. EU level action has led to the establishment of harmonised and standardised procedures for VA and safety certification and the presence of a common IT system and

[75] EUR-Lex - 52020DC0789 - EN - EUR-Lex

data registers that support the application process and the more effective monitoring of the implementation of the 4th Railway package. EU level action has also ensured a harmonised, systematic and structured approach in the screening and removal on national rules when assessing compatibility with the relevant TSIs. It has also ensured a systematic approach to the monitoring of NSAs and NoBos.

National action would most likely be able to address certain aspects of safety in the respective national networks but not deliver the same in terms of promoting interoperability across the EU (besides perhaps among those Member States with extensive rail/ territorial linkages).

Overall, even though during the period covered by this evaluation not all results and impacts of the implementation of the legal framework have taken effect and not all actors involved have developed the relevant experience, the findings of this evaluation show that more streamlined procedures for VA and safety certification would have increased the added value and the benefits of ERA action. Moreover, a more expedite effective delivery of its key policy related tasks and responsibilities, with particular focus on the cleaning of national rules and monitoring of NSAs and NoBos, would have ensured that ERA meets in full the expectations of their role in the dual system.

5.2 LESSONS LEARNED

The evaluation highlighted several challenges in the current system:

- Insufficient performance of some NSAs, which leads to hardly expecting any improvement of the overall safety situation in affected Member States. Furthermore, the NSAs face difficulties in finding staff with the required level of knowledge and competence and in the absence of external support they cannot properly cope with the lack of in-house expertise.
- Insufficient monitoring and reporting of the implementation of relevant actions in response to the deficiencies identified during the NSAs audits, especially for NSAs facing greater capacity limitations and deficiencies.
- The absence of comprehensive monitoring, whereby information from different activities (e.g. SSCs, VAs, safety data, etc.) - is consistently reviewed and acted upon, doesn't allow to systematically track progress and integrate feedback to support continuous improvement of safety oversight across the EU.
- Limited collection and analysis of data by the Agency on the operation of the dual system, including on time and costs incurred by NSAs for processing of applications.
- Despite limitations related to the available data, the collected information and stakeholders' views confirm the complex and less effective VA and safety certification processes, particularly in the operation of the dual system, due to less efficient national part of the process including unnecessary assessments at national level, lack of integration of registers between them and with the OSS, and duplication of requested documentation and checks to be performed.

- Lack of clear deadlines for NSAs to respond to the delivery of their own assessments as part of single or multi-country applications processed by ERA impact on expediting the authorisation and certification process.
- Redundant national rules have a negative impact on the effectiveness of the VA and safety certification process and contribute to cross-border bottlenecks. Further, the visibility of the accepted national rules is not sufficient to reduce uncertainty around applicable rules to support the authorisation and certification process.
- Limited analysis and inconsistent reporting on safety performance at Member State level and inconsistent application of the EU rail safety framework.
- Insufficient involvement of ERA in occurrence information collection and analysis to support early identification of emerging safety risks.
- Constraints on ERA's authority and capacity to perform policy tasks, develop and share knowledge and expertise as well as to fully support national actors (including NSAs and NoBos) in terms of capacity building.
- Resource allocation challenges and limitations in delivering ERA's mandate, especially on the delivery of the policy tasks, due to the priority given by the Agency to the authority related responsibilities and indirectly on reducing time and costs for authorisation and certification. The Strengthening Action Plan had not yet led to full exploitation of efficiency gains, as evidenced by persistent administrative workloads and partial redeployment of staff to operational tasks.
- Insufficient scope of the projects supporting the implementation of the TCT Rail Action Plan that is intended to align the Western Balkan's railway system with that of the EU, as well as insufficient ERA role and contribution towards enhancing railway safety and interoperability outside the EU.

ANNEX I: PROCEDURAL INFORMATION

- **General information**

The lead DG is the Directorate-General for Mobility and Transport (MOVE), Unit C4 Rail Safety and Interoperability.

DECIDE reference number: PLAN/2020/9063.

- **Organisation and timing**

The evaluation was coordinated by an Interservice Steering Group (ISG). The Commission services participating in the ISG were the Secretariat-General, Legal Service, DG Human Resources and Security, DG Budget, DG Environment, DG Climate Action, DG for Internal Market, Industry, Entrepreneurship and SMEs, and relevant units of DG Mobility and Transport.

The ISG met 5 times: on 15 December 2020, 6 January 2022, 4 March 2022, 8 July 2022, and on 27 June 2025. It was consulted throughout the different steps of the evaluation process, notably on the consultation documents, deliverables of the support study and on the draft Staff Working Document. When necessary, bilateral discussions were organised with the concerned services.

- **Evidence, sources and quality**

The evaluation is based on several sources of evidence, using both quantitative and qualitative data. This includes:

- Stakeholder consultation activities (see Annex 5).
- Evaluation support study carried out by an external contractor (Ricardo).
- Commission experience in implementing the technical pillar of the 4th Railway Package.
- Reports and information provided by ERA.

Annex II provides an overview of the methodology used, as well as issues regarding the quality of the evidence gathered, through both desk and field research.

ANNEX II. METHODOLOGY AND ANALYTICAL MODELS USED

Process

This evaluation was based on a methodology consistent with the Better Regulation Guidelines and Toolbox, with the support of an external study[76]. Following the publication of the evaluation roadmap[77] on 1 March 2021, the Commission launched the process for contracting the external study. The terms of reference provided the scope and draft evaluation questions to address the five evaluation criteria: effectiveness, efficiency, coherence, EU added value and relevance, and developing the approach proposed in the evaluation roadmap.

This annex describes the methodology applied for the evaluation.

Methodological framework

The external study further developed the initial **intervention logic**, providing the foundation for building a comprehensive evaluation framework. It was used to capture the logic of the Regulation and the causal chain linking objectives, activities, inputs and expected outcomes.

An **evaluation matrix** (see Annex III) was developed that sets out the following aspects for each evaluation question:

- **Operational sub-questions**: These break down the evaluation questions into smaller, measurable aspects.
- **Indicators**: Identify the measures/metrics that correspond to each operational sub-question. These may be qualitative or quantitative.
- **Evaluation approach and success/judgement criteria**: Outline the methodology used to answer evaluation questions and form the conclusions.
- **Potential data sources**: Sources of data and information used to inform the indicators. As far as data was available, information was triangulated from several sources for each indicator aiming to have at least input from two different sources for cross-checking.

The evaluation matrix was reviewed several times during the study, taking into account Commission inputs as well as evidence collection activities (desk research, interview programme, survey responses and data requests), to reflect the identification and review of data sources, as well as updated evidence needs and gaps and the improved understanding of the mechanisms and structures leading to better targeted questions.

Following the conclusion of the evidence collection activities (i.e., interview programme, targeted survey, OPC, direct data requests, and desk research) and the analysis of the findings, the intervention logic was updated. Further, the evaluation matrix was expanded to produce a final version of the matrix integrating with the updated understanding of evidence sources and gaps. This was used to inform the selection of success criteria and indicators used for each evaluation question.

[76] Ricardo (2023), Evaluation support study

[77] EU Agency for Railways – European Commission evaluation of the Agency's work

Evidence collection

Desk research was used throughout the course of the evaluation to address the following objectives:

- Identify and collect qualitative and quantitative evidence to support the analysis of the evaluation questions.
- Identify any information gaps and propose how to manage these gaps through targeted consultation activities.
- Identify and collect data used as input to the evidence analysis, and for the other indicators identified in the evaluation matrix that are used to support the analysis.

The **field research** has been structured within the context of a stakeholder consultation strategy, which relied on a combination of stakeholder engagement tools, including targeted surveys and interviews, direct data requests and an analysis of other consultation activities led by the Commission (OPC). The approach to the targeted surveys and interviews was refined following the exploratory interviews which took place during the inception phase of the evaluation. More details on the stakeholders' consultation are provided in Annex V.

The evaluation support study had a duration of 14 months (November 2021-December 2022). It included various consultation activities that took place between April and September 2022. The findings from these consultation activities were mostly used for the analytical part of this report, i.e. section 4. Further, ERA provided additional data that were used mainly for an extensive description of how the situation evolved between June 2019 and June 2024 (section 3 of this report), hence going beyond the period covered by the evaluation support study. These additional data were also used to update, when relevant, the other sections of the report. Throughout the report findings from the Consolidated Annual Activity Reports 2017-2023 were considered, where relevant.

Shortcomings and limitations of the analysis

There are certain limitations that need to be taken into account when considering the findings presented and the resulting conclusions, which are summarised below:

- The analysis took place in a period where the implementation of certain key aspects of the 4th Railway package was still incomplete (e.g. national rules cleaning, monitoring of NSAs and NoBos)[78], and the level of experience with the operation of the dual system for authorisation and certification was relatively limited. This allowed to capture possible issues and limitations of the implementation of the system to this point. However, it also meant that the comparison with the expected benefits (as identified in the 2013 Impact Assessment that supported the 4th Railway Package) was possibly premature and probably overstates the weaknesses and limitations of the system that was still work in progress. There was a learning curve concerning the

[78] It should be noted that these are not one-off processes that had to be completed by a given date (which has not been the case), but ongoing processes for the Agency reflecting the evolution of new TSIs and the continuous monitoring of the NSAs and NoBos performance as part of the implementation of the dual system. However, the fact that the initial round of these processes has not been delivered as initially planned (before the launch of the dual system) has played an important role in the level of achievement of some of key outcomes.

implementation of the various processes by ERA, NSAs and applicants and this was reflected in the input provided. Input related to cost impacts (and the comparison with the 3rd Railway Package) was influenced by the limited experience of some respondents with the new system and they were unable to make a comparison or suggested that more time was needed.

- The evaluation support study commissioned by the Commission had a duration of 14 months (November 2021–December 2022). It included various consultation activities that took place between April and September 2022. The findings from these consultation activities were mostly used for the analytical part of this report, i.e. section 4. Further, ERA provided additional data that were used mainly for an extensive description of how the situation evolved between June 2019 and June 2024 (section 3 of this report), hence going beyond the period covered by the evaluation support study. These additional data were also used to update, when relevant, the other sections of the report. Throughout the report findings from the Consolidated Annual Activity Reports 2017-2023 were considered, where relevant.
- The analysis of the actual costs related to authorisation and certification was limited by the fact that input provided from railway sector was limited and mainly qualitative. It was sought through follow up interviews with survey respondents to collect more specific cost data, however the response rate was low. As a result, cost estimates provided are uncertain.
- In addition, while there were detailed data on applications processed by ERA (provided by ERA), the data available in terms of the time and costs for NSAs applications was more limited. As a result, the assessment made is mainly qualitative on the basis of input from applicants and NSAs.
- Availability of data was a challenge affecting in particularly the effectiveness and efficiency criteria. Where quantitative data was available, it was used to make estimations and was complemented by stakeholder opinions and positions. Information gathered from different sources, including input from stakeholders were compared and triangulated whenever possible. In the case when available data and literature was limited, consultation responses were relied upon to answer the evaluation questions and are indicated throughout this report.

Taking this into account, certain conclusions – particularly in relation to the costs/costs savings – are tentative. These may likely change (improve) over time; further assessment will be necessary at a later stage.

Development of the evaluation points of comparison

Two points of comparison were defined to inform the evaluation.

Point of comparison - baseline scenario

The baseline scenario for this evaluation is based on the assumption that **the 4th Railway Package would not have been adopted**, including both the ERA Regulation, but also Directives 2016/797 and 2017/798. This is because, the two Directives include extensive cross-references to the ERA Regulation and their implementation is dependent on the ERA Regulation.

The baseline scenario covers relevant contextual aspects, as well as aspects directly related to the role of the Agency in the implementation of the 4th Railway Package. It is based primarily on the review of the 2013 Impact Assessment study and the 2011 Evaluation of Regulation 881/2004, but also on input received during the interviews with stakeholders.

For each aspect considered, the assumed evolution under the baseline scenario is presented and, where possible, how the relevant parameters that have been used to assess the performance of the Agency may have been expected to evolve in the absence of the 4th Railway Package.

Table 7. Baseline scenario assumptions

Key aspect covered	Baseline scenario definition /assumptions	Assumed/expected impact on evolution of relevant indicators	Comment/ observations on the basis of desk/field research
Legal framework	Safety and Interoperability Directives would not be revised/updated (namely the 3rd railway package will remain including Agency Regulation 881/2004 as amended by Regulation 1335/2008) Additional guidance/recommendation and delegated acts to be developed to improve implementation.	n/a	
Level of demand for authorisation, certification and ERTMS approval activity	Demand for certifications (including in terms of multi-country authorisations) to remain the same over time for given level of demand for rail services (IA) No discernible/clear impact of COVID on demand levels. Assumption is that it would be the same under the baseline and 4th Railway Package scenario. Demand for authorisation (including in terms of multi-country authorisations) to reduce slightly as vehicle designs	**Number of certifications** (including cases covering multiple countries) to remain stable at around 2015 levels while **total number of authorisations** to reduce slightly Expect demand for ERTMS trackside approval to increase	Data from ERA suggest a three times higher number of applications for VAs (mainly linked to conformity to type applications) than expected during the period 2019-2022; ERA expects this to stabilise over the coming period. No similar observation in relation to safety certifications or ERTMS trackside approval

Key aspect covered	Baseline scenario definition /assumptions	Assumed/expected impact on evolution of relevant indicators	Comment/ observations on the basis of desk/field research
	become more standardised over time. Demand for ERTMS installation approvals to increase on the basis of increased adoption of relevant technologies/equipment		
Process for vehicle authorisations, approvals of ERTMS trackside equipment tenders and safety certificates (new ERA role)[79]	Assume situation on the basis of previous (3rd) railway package to continue • No ERA role besides recommendations/ guidance and indirect contribution through the review of national rules and TSI development • Approvals of ERTMS trackside equipment tenders performed by IMs; • No option for a single multi-country application *(in the case of passenger transport – available for freight since 3rd railway package)* Information submission requirements and procedures set by individual NSAs with limited harmonisation and variation in approach and no single point of reference/IT tool at EU level (i.e. no OSS platform)	see below	Certain Member States (DE, FR) report ongoing work to reduce authorisation/ certification costs were possible (DE referring to the use of the series authorisation approach for vehicle of same type) and coordination and cross-acceptance among some neighbouring countries
Authorisation and certification timescales and costs	Gradual/slow tidy up of national rules on the basis of previous ERA mandate and activities together with extension of TSI rules on the basis of ERA activities should contribute to improvements and decreased variation of authorisation processes	Small reduction to the **average duration of authorisation** for each type leading to increased efficiencies. Difference between **average authorisation costs** and presumed minimum achievable authorisation costs to reduce over time	

[79] Where relevant, it is mentioned whether this represents a new role for the Agency, a pre-existing role without changes or an area with enhanced role for the Agency.

Key aspect covered	Baseline scenario definition /assumptions	Assumed/expected impact on evolution of relevant indicators	Comment/ observations on the basis of desk/field research
	No specific activity in terms of certification to be taken	**Certification time and costs** to remain the same (average of 4.5 months)	
NSAs capacity and approach to implementation of legislation concerning certification/ authorisation	Assume NSA staffing levels to increase to a limited extent with only two Member States (IT, PL) indicating intention to increase staffing and others potentially to follow Staffing levels in some Member States to remain an obstacle in the processing of applications NSA technical expertise, approach to implementation of EU legislation, and acceptance of authorisations/ certification granted by other NSAs to continue to vary (depending also on their size) but generally improve on the basis of experience additional guidance and technical support from the Agency	**Total NSA staff numbers** to remain similar to 2015 levels at around 500 staff (2011) Small reduction to the **overall time/costs for processing authorisation and certification** as a result of learning and additional guidance	
Evolution of national rules on safety and interoperability (pre-existing but strengthened role in the 4th Railway Package)	ERA monitoring of national rules and process of gradual elimination so that only essential rules remain – gradual/slow elimination to be expected (between 2020-2025 in the case of national safety rules 2018-2020 for national safety rules according to the indicative time plan presented in the 2013 Impact Assessment RDD and Notification IT to operate but no IT system to manage national rules review process (access/classification/information on the review process)	**Number of national technical and safety rules** to reduce only to a limited extent from 2015 levels (circa 11,700 in total plus additional 800 estimates technical operational rules and rules for maintenance) Level of variation/ discrepancy of national rules from the TSIs to reduce over time on the basis of the Agency activities with some positive impact on associated authorisation costs but remain sizeable	Desk research pointed to around 14,000 national technical rules for VA in total in January 2016 and circa 1400 national safety rules (submitted by MSs through NOTIF-IT)
Technical support/ recommendations on railway safety and interoperability (including TSI development) (pre-existing ERA role)	ERA role in developing recommendations to EC on the basis of the work of working parties (as defined in Regulation 881/2004) to continue Some harmonisation expected though the	Work/performance on TSI development to remain as before 2015 (as reflected in the conclusions of the 2011 evaluation report) Ongoing delivery of outputs and extension of TSI scope to have a	

Key aspect covered	Baseline scenario definition /assumptions	Assumed/expected impact on evolution of relevant indicators	Comment/ observations on the basis of desk/field research
	ongoing development and extension of the scope of TSIs reducing the need to assess vehicles against national rules	positive impact in terms of the reduction of the time/effort needed for authorisation/certification	
Monitoring of national bodies (new ERA role)	No ERA mandate to monitor decision-making and capacity of NSAs Light touch role of the Agency on the basis of exchange of practices and peer review and the role of the NSA network	Capacity and performance of NSAs in delivering their responsibilities concerning safety and interoperability (including monitoring of NoBos, interpretation/application of safety and interoperability Directive) to continue to vary	
Monitoring of NoBos (existing but strengthened role)	ERA monitoring role but only in a consultative manner to national authorities with requirement for follow up/action to address deficiencies	Capacity and performance of NoBos in terms of authorisation/ certification to continue to vary (as reflected in the conclusions of the 2011 evaluation)	
Monitoring of safety and interoperability performance (existing role)	ERA to continue reporting on safety and interoperability performance (as before) but with less access to information/data (that are expected to be provided via the new registers/datasets developed and managed by ERA	ERA capacity to monitor safety and interoperability performance and outputs and quality of technical support to EC and Member States to remain as before 2015 (as reflected in the conclusions of the 2011 evaluation)	
Datasets/registers	ERA to be responsible for registers concerning authorised vehicle types, national rules but to continue to rely on the provision of information from NSAs and national authorities	Despite action to address some of the data gaps, the expected to remain with ongoing implications on the capacity to monitor progress with interoperability/safety and the processing of applications.	
International cooperation and support of candidate countries	Assume reduced role of the Agency in the absence of the 4th Railway Package	Level of support from ERA for the harmonisation and integration of candidate countries with SERA to remain at the same reduced level	Level of ERA support to candidate countries also driven by the IPA programme priorities and funding
ERA internal capacity/ resources/ management structures and procedures	Assume no fundamental changes to the Agency's management/HR structures or the role of the management board	ERA to maintain capacity to deliver on its roles and responsibilities before the adoption of the 4th Railway	

Key aspect covered	Baseline scenario definition /assumptions	Assumed/expected impact on evolution of relevant indicators	Comment/ observations on the basis of desk/field research
	ERA staff numbers to remain at the 2016 level (155 FTE) with similar skills and capacity in the absence of new mandate/roles No direct involvement and no experience in the authorisation/certification and ERTMS approval process and focus on the policy related tasks. Budget and EU contribution to remain at the level similar to 2016 with no income from authorisation/certification fees	Package with focus on policy related tasks Limitations on effectiveness and efficiency on delivering its role not related to authorisation activities to be partly addressed over time	

Point of comparison - 4th Railway Package implementation

In addition to the baseline scenario, information concerning the expected achievement/delivery under the **preferred policy option** (i.e. combined option 4+6 in the 2013 Impact Assessment) has been used to provide the basis for assessing the performance of the Agency in relation to its **effectiveness** and **efficiency**.

Table 1 in section 2.2 summarises the expected performance for the different aspects of the intervention and identifies relevant targets and benchmarks that have been used to **assess the performance of the Agency in its implementation of the 4th Railway Package**.

It should be noted that the 2013 Impact Assessment focused primarily on the expected cost impact for the railway sector, the Agency and the NSAs, and provided quantitative (and monetised) estimates of the total cost and cost savings expected (expressed as present value). These estimates have been based on a number of assumptions, related to the level of authorisation/certification activity, that are not in line with the actual level of activity. They are also based on cost assumptions concerning the authorisation/certification procedures that are not necessarily comparable with the actual processes and approach adopted.

Furthermore, the 2013 Impact Assessment did not identify quantitative benchmarks for other parts of the implementation of the 4th Railway Package and provided relatively brief qualitative description of the expected impacts. Additionally, in some areas there is no explicit mention of the expected performance, but it is possible to derive the expected impact on the basis of the 2013 Impact Assessment and the text of the ERA Regulation.

Evidence analysis

The data collected was analysed with the aim to respond to the evaluation questions, using the following approach.

- **Effectiveness** (see Table 8 in Annex III)

The primary aim of the assessment of effectiveness is to evaluate where the Agency stands in terms of achieving its objectives and the factors that have contributed to this progress (or led to a lack of progress in certain areas). The assessment was based on a detailed analysis of the progress made since 2016, against the ERA objectives (both specific and general).

The assessment was based on the analysis of data on the development of railway safety and interoperability across the SERA during the evaluation period from EU statistical sources, ERA annual safety and interoperability performance reports. The objective was to indicate the progress made in terms of EU railway safety and improving SERA interoperability over the evaluation period. Further, data from the Agency's Annual Activity Reports and its SPDs were analysed, regarding the delivery of the ERA activities that were expected to contribute directly or indirectly to the specific objectives. This analysis was complemented with qualitative input from stakeholders on the extent of the Agency's contribution towards the objectives.

- **Efficiency** (see Table 9 in Annex III)

The objective of the analysis of the efficiency was to assess how the resources allocated to support the delivery of ERA's role compare with benefits that arose from ERA's extended role. It also assessed how any other costs produced for the rail system and other stakeholders compare with the said benefits. Furthermore, the analysis examined the role of the processes and mechanisms in place (working methods, organisational aspects, human resources and other tools) and the impact of external drivers on the efficiency of the Agency's operations and the delivery of the expected results.

The work of the Agency was analysed to this point concerning the development of TSIs and the progress made in the screening and elimination of the national rules. Then inputs from the rail sector (including manufacturers and railway undertakings) were used on the resulting cost savings that have arisen as a result of the Agency's outputs to this point. Information was collected from the Agency and the NSAs (through survey/data requests) on the resources allocated for the development of the necessary structures and tools implementing the 4th Railway Package (e.g. OSS, guidance documents). In addition, Annual Reports, SPDs produced by ERA were reviewed as well as other documents (e.g. Management Board meeting), supplemented with input from interviews with Agency management/staff concerning the presence of issues/problems and the role of the availability of relevant resources in that respect.

The analysis from the effectiveness criterion was used, which examined the outcomes of the implementation of the Fourth Railway Package and the achievement of its objectives and compare them with the respective costs of the implementation of the Fourth Railway Package based on the assessment of cost impact analysis in the previous questions.

Due to data limitation, it has not been possible to quantify all costs and benefits to develop a benefit-cost ratio. Thus, qualitative analysis was used. Input from the Agency/authorities/rail undertakings was used to identify areas where further cost savings (either in the preparatory actions or in the implementation) could be achieved without an impact on the achievement of the objectives.

- **Relevance** (see Table 10 in Annex III)

The focus of the analysis of the relevance of ERA was on understanding whether the initial activities of the Agency were still relevant in view of the current needs of the rail sector, and expected economic, societal, environmental, technological, and policy developments. Key aspects to examine were the extent to which the technical pillar of the 4th Railway Package and its associated provisions, are still appropriate in view of the needs of the rail sector.

It was also assessed if any new needs/problems have arisen, to determine if the original problem definition is still relevant. This involved analysing relevant indicators and was supported by desk research (e.g. studies analysing the current trends and future of rail transport) and input from stakeholders to identify whether the new trends may have introduced new needs/problems in regard to rail safety, interoperability and ERTMS deployment. Based on logical analysis and input from relevant stakeholders (e.g. representative bodies, standardisation bodies, EU institutions, applicants, RISC Member State representatives, NSAs, NIBs, civil society), it was then examined how the specific

objectives correspond to the identified needs (whether they are still appropriate and/or ambitious enough).

- **EU-added value** (see Table 11 in Annex III)

The assessment of the EU added value examined the extent to which the extended role of ERA has brought specific and additional benefits beyond that which would have been possible based on potential action at other levels (e.g. national, regional, local etc.).

Input from the desk research was used to inform the analysis of the specific contribution of EU action, regarding the benefits associated with a single consolidated legislative framework and the removal of unnecessary administrative and technical barriers. Field research (e.g. surveys with applicants, NSAs and RISC representatives, interviews with the Agency, representative bodies, EU institutions) used to complement this analysis by obtaining input on the specific benefits brought by the presence of EU action.

The baseline developed in the context of the support study was drawn upon to assess the potential impact of national level action on addressing the underlying problems which the Agency has been tasked to manage (e.g. long and costly authorisation and certification procedures). Moreover, input from key stakeholders was used to determine the type of national actions which would have been adopted, and the expected impact of these actions (in the case that the Agency's mandate had not been extended in 2016, to take further EU-level action).

- **Coherence** (see Table 12 in Annex III)

The assessment of the coherence aimed to identify the external and internal coherence of the Agency. The coherence of the Agency's mandate with the other interventions to create the SERA and EU rail policy is closely linked to the coherence of the Agency's key activities (e.g. VA and safety certification, OSS and implementation of ERTMS) with the other interventions to create the SERA. Further, two dimensions of the external coherence were explored, i.e., the coherence of the Agency's mandate and key activities with the other interventions to create the SERA and EU rail policy, and the coherence of the Agency's mandate and objectives with the Green Deal and the ambitions towards smart and sustainable transport. The internal coherence, i.e. the extent to which the Agency's provisions, activities and priorities are consistent with one another, was also assessed.

The analysis largely involved a desk-based mapping exercise, comparing the mandate and objectives of the Agency with EU rail policy, and in particular, the interventions to complete the SERA. This aimed at identifying the level of consistency regarding ambition and scope, as well as capturing any overlaps or contradictions. The coherence of the scope and ambition of the objectives of the Agency with EU rail policy was also explored through engagement with stakeholders.

ANNEX III. EVALUATION MATRIX AND, WHERE RELEVANT, DETAILS ON ANSWERS TO THE EVALUATION QUESTIONS (BY CRITERION)

Table 8. Evaluation matrix - effectiveness questions

EQ1. To what extent has the Agency managed to achieve its objectives contributing to the development and effective functioning of the Single European Rail Area, with regards to: **a. Maintaining a high level of railway safety and interoperability in the EU** **b. Eliminating operating barriers and overcoming the fragmented set of national frameworks and rules** **c. Supporting rail sector competitiveness and innovation deployment by reducing administrative costs of authorisation processes, operating and running rail service and reducing time to market for innovation** **d. Performing the role of Union authority responsible for issuing authorisations for placing in the market railway vehicles and vehicle types, issuing SSCs for railway undertakings and issuing ERTMS system approvals.**			
	Operational questions	**Indicators**	**Data sources**
1a	To what extent has the Agency contributed to promoting an effective approach to railway safety by: - Developing requirements for a common EU approach to safety management? - Promoting and monitoring the implementation of a common EU approach to safety management? - Dissemination and training activities? - To what extent has the Agency contributed towards ensuring vehicle interoperability by: - Developing/delivering relevant TSIs? - Supporting the deployment of ERTMS systems compliant with TSIs? - Supporting the deployment of telematics applications for passengers and freight compliant with TSIs?	Quantitative indicators: Output indicators - Number of CSMS, CSIs and TSIs developed - Length of new tracks equipped or contracted with ERTMS (European Train Control System (ETCS) and/or Global System for Mobile Communications – Railway (GSM-R)) in SERA - Degree of implementation of TAP and TAF functions - Portion of TEN-T core network and rail freight corridors equipped with ERTMS Result/ Impacts - Number of railway fatalities and injuries and number of serious accidents reported Qualitative indicators: - Level of compliance with SMS requirements - Level of compliance with TSIs	• Desk research • Analysis of relevant documentation (e.g. ERA Annual Activity Reports, ERA SPDs, ERA annual safety and interoperability performance reports, EU Statistical Pocketbook, key policy documents) • Targeted surveys and interviews with key stakeholders (e.g. NSAs, ERA, railway undertakings and other industry etc.).

		- Extent that stakeholders agree/disagree that the Agency has had a positive role in the development and adoption of TSI, CSMS, CSIs - Extent that stakeholders agree/disagree that the Agency contributed to a more effective approach to railway safety and interoperability through its specific activities.	
1b	To what extent has the Agency contributed to eliminating operating barriers and overcoming the fragmented set of national frameworks and rules: - By supporting the harmonisation of national rules for railway safety, vehicle operation and ERTMS deployment? - By providing dissemination and training support for the implementation of the EU framework?	Quantitative indicators: Outputs - Number of national rules analysed - Number of Member States with rules cleaned up and published in the RDD and SRD - Number of training modules delivered via the ERA Academy annually - Number of dissemination activities implemented annually by ERA. Qualitative indicators: - Extent that stakeholders agree/disagree that the Agency contributed to improving the coherence of national rules and framework Extent that stakeholders agree/disagree that the Agency's actions on disseminating and training support have contributed to implementing the EU safety and interoperability framework.	• Desk research • Analysis of relevant documentation (e.g. ERA Annual Activity Reports, ERA SPDs, ERA annual safety and interoperability performance reports, EU Statistical Pocketbook, key policy documents) • Targeted surveys and interviews with key stakeholders (e.g. NSAs, ERA, railway undertakings and other industry etc.).
1c	To what extent has the Agency supported rail sector competitiveness: - By reducing the costs for SSC approvals/ vehicle (and vehicle type) approvals/ ERTMS trackside equipment approvals? - By contributing to reducing the costs of operating and running rail services (e.g. through the reduction of opportunity costs as a result of reduced time for authorisation) To what extent has the Agency supported the deployment of rail sector innovation:	Quantitative indicators: Outputs: - Time and associated costs for safety certifications, authorisations and ERTMS equipment approvals by ERA and NSAs - Number of TSI developed in relation to innovative products (technologies/material/etc) - Number of activities related to Shift2Rail/EU Rail Joint Undertaking. Results/impacts	• Desk research • Analysis of relevant documentation (e.g. ERA Annual Activity Reports, ERA SPDs, ERA annual safety and interoperability performance reports, Report on the competitiveness of the rail supply industry, key policy documents) • Targeted surveys and interviews with key stakeholders (e.g. NSAs,

	- By identifying and facilitating the uptake of new technologies (equipment/material) and digitalisation through the adoption of relevant technical specifications and other relevant standards - By reducing the time for the uptake and deployment of new vehicle and equipment - By supporting relevant innovation initiatives (including as part of the Shift 2Rail/EU Rail Joint Undertaking).	- Level of reduction on respective costs for obtaining SSC/VA/ERTMS in comparison to the situation prior to the implementation of the 4th Railway Package - Level of reduction on costs for operating and running rail services linked to the Agency activities - Number of new vehicle types and ERTMS equipment types deployed in SERA. Qualitative indicators: - Extent that stakeholders agree/disagree that the submission of applications to the Agency has contributed to: o Speeding up and reducing the cost of deploying rail sector innovation o Speeding the approval of ERTMS trackside equipment - Extent that stakeholders agree/disagree that the Agency has facilitated the adoption/market uptake of innovative technologies and promotion of digitalisation in the sector - Extent that stakeholders agree/disagree that ERA's support to the following activities have contributed to the development of innovation in the rail sector.	ERA, railway undertakings and other industry etc.).
1d	Has the Agency successfully performed the role of Union authority responsible for: - Issuing authorisations for placing in the market railway vehicles and vehicle types - Issuing SSCs for railway undertakings; - Approving ERTMS trackside systems. How has the functioning of the Agency in this role contributed to: - Higher quality standards applied in the processing of applications? - Increased flexibility of the application process?	Quantitative indicators to include: Outputs • Total number of applications submitted and processed by ERA for: o Safety certificates. o Vehicle and vehicle type authorisations. o ERTMS trackside equipment approvals. • % of multi-country applications • Proportion of decisions taken according to the legal framework deadlines. Qualitative indicators:	• Desk research • Analysis of relevant documentation (e.g. ERA Annual Activity Reports, ERA SPDs, ERA annual safety and interoperability performance reports, Report on the competitiveness of the rail supply industry, key policy documents) • Analysis of data from OSS and registers • Targeted surveys and interviews with key stakeholders (e.g. applicants, NSAs, ERA, competent authorities.).

		• Extent that stakeholders agree/disagree that the Agency has fulfilled its role as Union authority responsible for these approvals, certifications and authorisations • Extent that stakeholders indicate preference to submit applications to ERA • Extent that stakeholder consider that ERA involvement has led to improvement to the quality of the application process • Level of flexibility in application procedures (e.g. shortened/light procedure for application approvals by NSAs or ERA under specific conditions).	
EQ2. Which factors have contributed to/hindered the achievement of general and specific objectives?			
2a	What external drivers/parameters have played a positive or negative role in the implementation of ERA activities and the achievement of ERA's objectives, such as: • Technology developments related to rail vehicles or infrastructure (e.g. increased need for authorisation for systems based on new/advanced technologies) • Market developments (level of demand for railway services) including the impact of COVID.	Qualitative indicators: Stakeholder stated views on the impact of market developments on ERA activities Stakeholder stated views on the impact of technology developments on ERA activities Extent that stakeholder consider that the COVID-19 pandemic had a negative impact on the delivery of ERA objectives.	• Desk research • Analysis of relevant documents such as: ERA SPDs and Annual Activity Reports 2016-2022.Management Board, Commission and IAS opinions/reports, Industry position documents) • Targeted surveys • Targeted interviews
2b	What internal factors have had an impact on the implementation of the 4th Railway Package and the Agency's operation and achievement of its objectives, including: • Speed of transposition of 4th Railway Package by Member States • Access to resources • Agency's working practices, • Interaction/cooperation with national authorities What other internal drivers/parameters related to the implementation of the 4th Railway package and the Agency's operation have played a positive or negative role	Qualitative indicators: • Level of impact of the internal factors in the effective delivery of the Agency's responsibilities and achievement of objectives • Extent that stakeholders consider that identified internal parameters had a significant impact on the delivery of the Agency's objectives.	• Desk research • Analysis of relevant documentation (ERA Annual Activity Reports, ERA SPDs, Management Board, Commission and IAS opinions/reports, Industry position documents • Targeted surveys • Targeted interviews.

	in the implementation of ERA activities and the achievement of ERA's objectives?		
EQ3. What actual observed effects (positive and negative impacts) has the Agency achieved? Have there been any unexpected or unintended effects?			
3	What, if any, have been the direct effects of the functioning of the Agency to this point in relation to: • Elimination of redundant national rules • Delivering a single information and communication system for all the applications across Europe • Monitoring performance and decision-making of NoBos and NSAs • Reducing the cost and duration of the VA and safety certification • Ensuring development of telematics and ERTMS deployment and harmonised ERTMS technical solutions • Achieving high level of technical, operational and safety harmonisation in the railway sector • Promoting rapid deployment of innovation across the rail sector Have there been any side-effects in the railway market that were not expected? (e.g. employment impacts)? Have there been any unintended (positive or negative) effects as a result of the new role of the Agency in the economic, social and environmental domains?	Quantitative indicators: • Number of applications for safety certification, authorisations and ERTMS approvals processed (and level of increase in relation to the baseline (without the 4th Railway Package) and in comparison to the targets set in the 2013 IA study) • Number of national rules reviewed/eliminated (comparison with the baseline and the targets set in the IA study) • Level of cost and time reductions achieved from the VA and safety certification (in comparison to the target of 20% stated in the IA) Qualitative indicators to include: • Extent that Agency activities have led to increased coherence/harmonisation of the legal framework • Extent that Agency activities have reduced time to market • Stakeholder views regarding unintended and unexpected impacts of the Agency's functioning on the rail industry • Stakeholder views regarding unintended and unexpected impacts of the Agency on broader society (e.g. environmental, social impacts etc.).	• Desk research • Analysis of relevant documentation (ERA Annual Activity Reports, ERA SPDs, Impact assessment of the Regulation on the European Union Agency for Railways, ERA Safety and Interoperability Reports) • Targeted surveys • Targeted interviews.
EQ4. How has the OSS impacted the: **a. Time needed to obtain approvals?** **b. Transparency and visibility of the approval process and decisions for applicants?**			

4a	What has been the impact of the introduction of the OSS on: • The overall time needed to obtain approvals when applications are submitted to ERA or NSAs? • The predictability of the time needed for each step of the approval process?	Quantitative indicators: • Change in time needed to obtain an SSC and vehicle/vehicle type authorisation. Qualitative indicators: • Stakeholder (applicant) perception of the impact of the introduction of OSS on the overall time needed.	• Desk research • Analysis of relevant documentation (OSS process documentation) • Targeted surveys • Targeted interviews
4b	What has been the impact of the introduction of the OSS on the: • Transparency of the steps of the approval process and their requirements? • Predictability of the outcome of the approval process?	Qualitative indicators: • Level of information available on the requirements and steps of the approval process • Availability of guidance material assisting the preparation of applications • Availability of information for applicants regarding the state of their applications • Stakeholder (applicant) perception of the impact of the introduction of the OSS on the: o Transparency/clarity of the approval process o Predictability of the outcome of the approval process.	• Targeted surveys • Targeted interviews
EQ5. Have the enhanced role of the Agency for vehicle authorisation and safety certification and the harmonised implementation of ERTMS (including the extension of area of use or area of operations and the operation of the dual system) delivered the expected outcomes? In particular, have the provisions: **a. Reduced administrative burden across the Union's rail sector?** **b. Improved the time to market for the deployment of rail innovation?** **c. Impacted the provision of cross-border rail services?**			
5a	Has the operation of the dual system contributed to the reduction of the administrative burden for applicants? What were the main factors driving changes in administrative costs?	Quantitative indicators: Output • Total number of applications due to the issue of SSCs for multiple Member States by ERA • Total number of applications due to the issue of vehicle (type) authorisations for multiple Member States by ERA Qualitative indicators:	• Desk research • Analysis of relevant documentation (ERA Annual Activity Reports, ERA SPDs, Data on the use of OSS/ERADIS) • Data requests to stakeholders • Targeted surveys

		• Stakeholder perception of the impact of the dual system in reducing/increasing administrative burden.	• Targeted interviews
5b	Have the provisions of the ERA regulation contributed towards improving the time to market for the deployment of rail innovation? What were the main factors driving changes in application processing times?	Quantitative indicators: • Time required for SSC (issue, renewal, suspension and amendment) by ERA and NSAs • Time required for vehicle and vehicle type authorisation (issue, renewal, amendment, suspension and revoke) by ERA and NSAs • Time required for ERTMS equipment approval by ERA and NSAs. Qualitative indicators: • Extent that stakeholders agree/disagree that the submission of applications to the Agency has contributed to speeding up and reducing the cost of deploying rail sector innovation.	• Desk research • Analysis of relevant documentation (ERA Annual Activity Reports, ERA SPDs) • Data requests to stakeholders • Targeted surveys • Targeted interviews
5c	Have the provisions of the ERA regulation had an impact on the provision of cross-border rail services?	Qualitative indicators to include: Extent that stakeholders agree/disagree that the submission of applications to the Agency has contributed to deploying cross-border services.	Key pieces of literature and data sources to include: ERA Annual Activity Reports 2014-2019; ERADIS (data on licences to provide rail transport services and number of multi-country SSCs) Action plan to boost long distance and cross-border passenger rail This will be complemented by surveys and interviews with key stakeholders (e.g. Rus, manufacturers and NSAs). Data requests to stakeholders (e.g. Rus, manufacturers and NSAs) will also be circulated.
EQ6. How effective have the new processes put in place regarding the Agency's technical support been, with regard to achieving the Agency's objectives. In particular: **a. How effective is the monitoring by the Agency of NSAs and NoBos?**			

b. Has the Agency's technical support in the field of railway safety and interoperability been effective? Has the expected support been delivered/provided within the legal deadlines set out on Article 10 of Regulation (EU) 2016/796?			
6a	To what extent has the Agency exercised its new powers of monitoring NSAs and NoBos? To what extent have the new monitoring practices led to: • harmonisation of performance, organisation and decision making of the NSAs? • harmonisation of performance of NoBos?	Quantitative indicators: • Number of inspections and audits of NSAs and NoBos • Number of deficiencies and recommendations identified in reports issued for NSAs and NoBos. Qualitative indicators: • Extent that stakeholders agree/disagree that the Agency's monitoring activities contributed to improving the operation of NSAs and harmonising their performance • Extent that stakeholders agree/disagree that the Agency's monitoring activities contributed to improving the operation of NoBos and harmonising their performance.	• Desk research • Analysis of relevant documentation (ERA Annual Activity Reports, ERA SPDs, ERA Reports on Railway Safety and Interoperability (Performance) in the EU) • Targeted surveys • Targeted interviews
6b	How far have technical opinions and studies contributed towards improving safety-related or interoperability-related rules or procedures? Have technical opinions been issued& published within the legally defined timeframe (issued two months of receipt of the request and made public within one month after they are issued)? Have all technical opinions published from 2018 onwards been complemented by an impact assessment?	Quantitative indicators: • Number of technical opinions (with/without IAs) issued in the fields of rail safety and rail interoperability • Proportion of technical opinions issued and made public within the legally defined timeframes. Qualitative indicators: • Factors causing delays in the issue and publication of technical opinions • NSA views on the quality of ERA technical opinions • NSA views on the extent to which ERA technical opinions have supported the improvement of rail safety and interoperability.	• Desk research • Analysis of relevant documentation (ERA Annual Activity Reports, ERA SPDs, ERA opinions, guidance documents, webinars for industry, NSA Network, ERA attendance at NB-Rail meetings and monitoring of NoBo activities) • Targeted surveys • Targeted interviews • Data requests from ERA
EQ7. Do the various IT tools and databases (registers) put in place by ERA sufficiently contribute to the delivery of overall ERA objectives? How far has the Agency's responsibility to set up EU-level registers led to the: **a. Establishment of specific registers with safety and interoperability related data taking into account user needs?** **b. Use of the Agency's registers by relevant rail stakeholders?** **c. Data completeness in these registers?**			

7a	To what extent have the new tools and EU-wide registers put in place by ERA considered specific user needs of the following processes: • ERA's internal processes • Processes of national bodies • Processes of industry stakeholders.	Qualitative indicators: • Feedback process applied in the development of the tools to integrate user needs • Stakeholder views on the added value of individual ERA-developed tools with regards to promoting rail safety • Stakeholder views on the added value of individual ERA-developed tools with regards to promoting rail interoperability.	• Desk research • Analysis of relevant documentation (ERA Annual Activity Reports, ERA SPDs, Relevant Information on the IT tools and their use and registers available via the ERA website) • Targeted surveys • Targeted interviews • Data requests from ERA
7b	To what extent have ERA registers been accessed and used by stakeholders?	Qualitative indicators: • Types of stakeholders using the ERA-developed tools • Stakeholder views on the extent to which registers are easy to use.	
7c	Did the use of ERA Registers lead to extended data availability (i.e. increased country coverage) To what extent have the ERA registers improved data completeness with respect to situation prior to the adoption of the 4th Railway Package?	Quantitative indicators to include: Level of data completeness in each of the registers developed by ERA (in comparison to comparable national databases), where relevant. Qualitative indicators to include: Stakeholder views on the completeness of the content of individual tools.	
EQ8. How is ERA activity in the Western Balkan region under the IPA programme contributing to the overall objective of enhancing cooperation and support to these countries in view of future or potential EU membership?			
	How far has the technical support provided by ERA contributed to institution building in the railway sector in Western Balkan countries? How far have ERA activities promoted rail safety in Western Balkan countries? To what extent have ERA activities (including the IPA summit) been an effective tool to engage with relevant stakeholders in the Western Balkan region?	Quantitative indicators: Outputs • Number of trainings and workshops delivered (and number of participants) in Western Balkan countries Results/Impacts • Change in rail safety performance in Western Balkan countries • Level of adoption of relevant acquis by Candidate countries • Existence and operation of the institutional framework (NSA, NIB, regulatory body) Qualitative indicators:	• Desk research • Analysis of relevant documentation (ERA Annual Activity Reports, ERA SPDs, Rail Action Plan for Developing a Regional Rail Strategy in the Western Balkans and progress reports, ERA internal IPA activities documentation) • Interview with key stakeholders (e.g. Permanent Secretariat of the Transport Community Treaty,

		• Candidate countries authorities views on the usefulness of ERA's support activities in:
		  ○ Improving rail safety
		  ○ Institutional capacity building
		• Converging with EU law on rail operations and safety.
			Western Balkan NSAs, DG NEAR).

EQ9. Are the working practices of the Agency as set out by Regulation (EU) 2016/796 sufficiently supporting the Agency's objectives and sector needs? **a. What has been the contribution of the developed working groups and parties in achieving the Agency's objectives and sector needs on the themes of TSIs, CSTs, CSMs and the use of CSIs?** **b. Are the working parties created under Article 5 of Regulation (EU) 2016/796 sufficiently inclusive and representative?**			
9a	What have been the contributions of the working groups and parties in achieving the Agency's objectives? How have the working parties supported the improvement of rail safety in the SERA? How have the working parties supported the improvement of rail interoperability in the SERA?	Quantitative indicators: • Number of meetings held (by each working party); • Number of working party deliverables (i.e. recommendations, studies, technical opinions etc.); • Number of TSIs, CSTs, CSMs and CSIs developed/revised. Qualitative indicators: • Stakeholder views on the contributions in terms of rail safety brought by the working parties on CSTs, CSMs, CSIs. • Stakeholder views on the contributions in terms of rail interoperability brought by the working party on TSIs.	• Desk research • Analysis of relevant documentation (ERA Annual Activity Reports, ERA SPDs, ERA Report on Railway Safety and Interoperability in the EU 2016-2022, Agency documentation on the work conducted by working parties since 2016) • Targeted surveys • Targeted interviews
9b	To what extent are ERA stakeholders sufficiently represented in the various working parties?	Quantitative indicators: • Participation of individual Agency stakeholders in working parties. Qualitative indicators to include: • Balanced representation of all relevant Agency stakeholder groups in the working parties.	

Table 9. Evaluation matrix - efficiency questions

Operational questions	Indicators	Data sources
EQ10. Has the role of the Agency in terms of the harmonisation through TSIs and elimination of national rules brought savings for the railway sector?		
10.1 To what extent has the Agency's enhanced role under the 4th Railway Package in terms of the development and revision of TSIs has brought savings to the railway sector? How significant where they? 10.2 To what extent has the Agency's work on the elimination of national technical rules has brought cost/time savings for the railway sector? How significant where they?	Quantitative indicators: • Number of developed TSIs • Evolution on the number of national rules. Qualitative indicators: • Extent that stakeholders agree/disagree that the Agency has contributed to a greater level of harmonisation. • Extent that stakeholders agree/disagree that the role of the Agency in the elimination of national rules brought cost savings for the railway sector.	• Desk research • Analysis of relevant documentation (ERA Annual Activity Reports, Management Board meeting minutes, 2013 Impact Assessment support study) • Targeted surveys • Targeted interviews
EQ11. What were the actual resources used/spent to achieve the positive impacts?		
What have been the resources (human/financial) allocated by the Agency, the NSAs and industry for the development of the necessary support structures and procedures (i.e. OSS, development of guidance documents, training etc.)?	Quantitative indicators: • Total expenditure (in EUR) by the Agency to develop the new procedures/structures to implement the Fourth Railway Package • Total human resources (in FTE) allocated by the Agency to develop the new procedures/structures to implement the 4th Railway Package • The change in total human resources (in FTE) allocated by NSAs to implement the 4th Railway Package	• Desk research • Analysis of relevant documentation (ERA SPDs, ERA Annual Activity Reports, Management Board meeting minutes, 2013 Impact Assessment support study) • Input provided by ERA staff
EQ12. What were the costs of actual negative impacts, if any, to which the Agency's role as per Regulation (EU) 2016/796 has given rise and how high were they? Whom did they fall upon?		

12.1 Has the delivery of the Agency's new/enhanced role in relation to each of the following led to any negative impacts in the form of longer timescales, costs or other negative impacts: - Authorisation/certification and ERTMS approval process - Screening/elimination of national rules 12.2 How significant are those impacts? 12.3 Which stakeholders (authorities, NoBos, railway undertakings, infrastructure managers, others) experienced negative impacts as a result of the new role of the Agency? How significant were they?	Quantitative indicators: • Evidence from stakeholders on the scale cost increases (in EUR) resulting from the new/enhanced role of the Agency in the case of verification/certification/application process. Qualitative indicators: • Presence (or not) and significance of negative impacts from the implementation of the ERA Regulation and the enhanced role of the Agency for specific categories of stakeholders.	• Desk research • Targeted surveys • Targeted interviews
EQ13. Were the additional human and financial resources allocated to the Agency in the run up to the coming into operation of the 4th Railway Package sufficient and adequate to achieve its new tasks? If not, how has this impacted delivery of the Agency's tasks under Regulation (EU) 2016/796?		
13.1 What have been the additional human and financial resources that were made available to ERA in the period up to June 2019 in preparation for the entry into force of the Fourth Railway Package? 13.2 Were the additional resources available sufficient to allow the Agency to adequately prepare in relation to: • Implementation of all necessary practical arrangements in order to be able to deliver its role concerning VAs, SSCs, ERTMS trackside approvals • The development, testing and operation of the OSS service • Development of the necessary support structures and tools (for businesses, authorities) • Other necessary activities to support (directly or indirectly) the implementation of the new tasks related to vehicle authorisation, trackside approval and SSC activities. 13.3 How do they compare with the initially expected additional financial resources (according to the impact assessment)? 13.4 Have there been any specific areas where available resources proved to be insufficient? Did this mean that any of the preparatory tasks were not completed, only partially completed or delayed?	Quantitative indicators: • Additional human resources (in FTE) made available to the Agency during the period 2016 – 06/2019 • Additional financial resources (in EUR) made available to the Agency during the period 2016 – 06/2019 • Number (share) of the Agency's tasks related to the 4th Railway Package preparation completed on time. Qualitative indicators: • Presence (or not) and significance of delays/issues/problems for the development of the necessary infrastructure (OSS) and support mechanisms related to the availability of resources. • Presence (or not) and significance of issues/problems in the implementation/delivery of the Agency's responsibilities concerning certification/authorisation/approval related to the availability of resources. • Presence (or not) and significance of issues/problems in the implementation/delivery of the Agency's responsibilities concerning other policy tasks related to the availability of resources.	• Desk research • Analysis of relevant documentation (ERA SPDs, ERA Annual Activity Reports, Management Board meeting minutes, 2013 Impact Assessment support study) • Targeted surveys • Targeted interviews

EQ14. Are the working methods as set out in Chapter 2 of Regulation (EU) 2016/796 efficient?		
14.1 What have been the costs (human/financial resources) associated with each of the working methods: • Setting up and operation of the working parties • Development of recommendations and guidelines on TSIs • Consultation activities • Impact assessments • Studies/opinions • Visits to Member States. 14.2 Are the costs associated with each of the above justified on the basis of the outputs produced and their contribution to meeting their respective objectives?	Quantitative indicators: <u>Input</u> • Total (annual) budget and human resources (in FTE) allocated and cost per unit (where relevant) to each of the following: o Setting up and operation of the working parties o Development of recommendations and guidelines on TSIs o Consultation activities o Impact assessments o Studies/opinions o Visits/audits and technical support provided to NSAs and NoBos. Qualitative indicators to include: • The extent that stakeholders consider that costs of each of the working practices are justified/not justified.	• Desk research • Analysis of relevant documentation (ERA SPDs, ERA Annual Activity Reports) • Targeted surveys • Targeted interviews
EQ15. To what extent has the organisation and management of the Agency been cost-efficient? What has been the role of the management and executive board, the 4th Railway package steering group and the supervision by the European Commission in ensuring the efficiency of the Agency activities?		
15.1 What have been the total human/financial resources allocated to the organisation and management activities of the Agency (e.g. administration staff)? 15.2 What share of the total human/financial resources does this represent? How do they compare with other EU agencies with a similar role/structure (e.g. EASA, EMSA?) 15.3 How effective are the internal and external monitoring and assessment processes in place in ensuring the efficient delivery of the Agency's responsibilities?	Quantitative indicators: • Share of human and financial resources allocated to organisation and management aspects. Qualitative indicators: • Presence of relative performance (KPI) indicators monitoring efficiency and mechanisms to act upon. • Extent that stakeholders consider that internal and external monitoring procedures ensure the efficient operation of the Agency.	• Desk research • Analysis of relevant documentation (ERA SPDs, ERA Annual Activity Reports, Opinions/decisions of the management board, the EC and 4th Railway Package Steering Group, Similar documents from other EU agencies) • Targeted surveys • Targeted interviews • Input from Agency staff

15.4 Are there relevant indicators in place to help monitor the efficiency of the Agency's operation? 15.5 What has been the role of each of the following in ensuring the efficiency of the Agency's activities: - The management and executive board - The 4th Railway Package steering group - The European Commission.	• Extent that organisation and management resources are considered appropriate by stakeholders to ensure the efficiency of the Agency's operations.	
EQ16. To what extent does the Agency's human resources management contribute to the achievement of its objectives?		
16.1 Do the current human resources management and staffing activities (including recruitment processes, agreements with national authorities, training, career management) ensure availability of the necessary resources and expertise (in quantity/quality) to deliver on ERA's activities, tasks and objectives? 16.2 Have there been any disruptions/delays to the delivery of the activities and objectives of the Agency due to absence of necessary/appropriate human resources (in terms of numbers and relevant expertise)?	Quantitative indicators: <u>Input</u> • Evolution of Agency staff (total and by level) • Number of external staff (seconded national experts, experts from NSAs) • Gender balance within the Agency • Staff turnover rate • Number of cases where limited availability of resources led to problems/delays • Number of ERA actions that had to be postponed/cancelled due to lack of resources. Qualitative indicators: • Extent that relevant stakeholders (Agency staff, Management Board, national authorities) agree/disagree that the Agency's human resources management processes have ensured access to required resources.	• Desk research • Analysis of relevant documentation (e.g., ERA SPDs, ERA Annual Activity Reports, ERA Strengthening Plan) • Targeted surveys • Targeted interviews • Input from Agency staff
EQ17. What is the impact of the dual seat (Lille and Valenciennes) on ERA's working methods and its costs?		
17.1 How do the dual headquarters impact the delivery of ERA's outputs? In what way? 17.2 What are the costs of operating the dual ERA headquarter structure?	Quantitative indicators: • Number of meetings taking place annually in the Lille premises and participation of ERA staff.	• Desk research • Analysis of relevant documentation (e.g., ERA SPDs, ERA Annual Activity Reports) • Targeted surveys

	• Mission and travel costs incurred by the Agency as a result of the dual seat. • Additional costs of retaining and operating a dual seat structure (overhead costs). Qualitative indicators: • Extent that the dual seat is considered to have an impact (positive/negative) on the delivery of ERAs outputs • Types of practical issues related to the dual seat • Views of ERA staff on the practical issues affecting their workflow related to the dual seat.	• Targeted interviews • Data requests to Agency staff
EQ18. To what extent is the Agency's internal organisation sufficiently capable and flexible to rapidly respond to resource needs due to uncertainties related to the dual transposition dates of the 4th Railway Package technical pillar?		
18.1 How has the level of workload for certification/authorisation changed during the period since June 2019? 18.2 Have the differences in the transposition of the 4th Railway Package affected the demand for authorisation/certification activities and if so, to what extent? 18.3 Has the Agency ensured access/availability to necessary additional resources to respond to the changes in the workload for certification/authorisation? 18.4 What were the implications in terms of the delivery of the policy related tasks as a result of fluctuation in demand for authorisation/certification?	Quantitative indicators: • Allocation of FTEs for authorisation work vs rail related policy tasks. Qualitative indicators: • Frequency of gaps between resources needed to address level of demand and resources available. • Frequency of cases where limited availability of resources led to problems/delays to the processing of applications. • Extent that relevant stakeholders (Agency staff, Management Board, national authorities) agree/disagree that the Agency has appropriate mechanisms to respond to future variations in demand. • Extent that allocation of resources on authorisation/certification tasks has affected the delivery of other tasks.	• Desk research • Analysis of relevant documentation (e.g., ERA SPDs, ERA Annual Activity Reports, ERA Strengthening Plan) • Targeted surveys • Targeted interviews • Data requests to Agency staff
EQ19. Which aspects/means/actors/stakeholders or processes render the Agency more or less efficient?		

19.1 Which specific internal processes and structures of the Agency (including IT tools, working methods under Chapter 2) are more or less cost-effective? How significant is their role in the Agency's overall efficiency? 19.2 What has been the role of stakeholders/actors involved in the implementation of the 4th Railway Package and the Agency's processes (e.g. NSAs, NoBos) that have a positive/negative impact on the costs and efficiency of the Agency's processes? How significant are these?	Qualitative indicators: • Relative contribution (positive/negative) of the different Agency's operations in its overall cost-efficiency • Presence and significance of a positive/negative role of specific stakeholders in the efficiency of the Agency operations.	• Desk research • Analysis of relevant documentation (e.g., 2011 Evaluation of Regulation 881/2004 establishing the European Railways Agency, ERA Strengthening Plan) • Targeted surveys • Targeted interviews • Data requests to Agency staff
EQ20. Have the Agency's results/deliverables led to increased regulatory burden? If so, is there room to simplify or reduce any unnecessary costs?		
20.1 Have any of the following Agency's activities/processes led to new/additional regulatory burden for any stakeholders (rail businesses and NSAs): - authorisation and certification activities - policy tasks. 20.2 What are the drivers of these additional costs? 20.2 Could any of the above cost drivers be simplified/eliminated without any impact on the effectiveness of the process?	Quantitative indicators: • Case studies on regulatory costs for railway businesses related to authorisation and certification outputs by ERA. Qualitative indicators to include: • Share of stakeholders that consider that ERA processes and procedures have led to an increase/decrease in the regulatory costs.	• Desk research • Analysis of relevant documentation (e.g. 2013 Impact Assessment, ERA Annual Activity Reports, ERA SPDs, ERA Strengthening Plan) • Targeted surveys • Targeted interviews • Data requests to Agency staff
EQ21. How do the actual effects and positive impacts compare to the actual costs and any negative impacts in terms of orders of magnitude/in size? Were they achieved at a "reasonable" cost?[80] Could the same results have been achieved with less funding/lower cost/less staff?		
21.1 How do the costs for the Agency and authorities for the implementation of the 4th Railway package compare with the level of achievement of the expected results and the impacts? 21.2 Are they in line with the expected costs and savings at the time of the adoption of the 4th Railway Package (according to the impact assessment)?	Quantitative indicators: • Total costs for the Agency and for authorities over the period 2016-2021 and per type. • Total savings for rail undertakings, ERA and authorities over the period 2016-2021. • Ratio of costs to benefits.	• Desk research • Analysis of relevant documentation (e.g. 2013 Impact Assessment, Annual Activity Reports, ERA Strengthening Plan) • Targeted surveys • Targeted interviews

[80] 'Cost' means in case of programmes/actions any financing provided and in case of other policies administrative/monitoring/compliance/enforcement costs.

21.3 Were there aspects of the costs for the implementation of the 4th Railway Package that could have been avoided with no impact on the effectiveness, in terms of: • Level of funding from the EU budget. • Resources/staff allocated.	Qualitative indicators: • Extent that the costs incurred are justified by the benefits and outcomes achieved • Presence and significance of possible cost savings.	• Data requests to Agency staff

Table *10*. Evaluation matrix - relevance questions

EQ22. Do the original objectives and activities of the Agency correspond to the current needs of the rail sector in the Union and in the foreseeable future? Does the introduction of the dual system for VA and safety certification, the OSS and harmonised implementation of ERTMS meet the needs of the rail sector in the Union?

Operational questions	Indicators	Data sources and methods
22.1 To what extent are the problems/needs identified at the time of the adoption of Regulation (EU) 2016/796 still relevant today? Namely, are there still problems/needs related to: • Long and costly authorisation and certification procedures • Discrimination against new entrants (e.g. discriminatory access to infrastructure, technical/regulatory barriers) • Need to ensure safe and interoperable railway operations • Lack of modernisation and innovation in the railway sector. 22.2 Have any new needs emerged (or are any expected to emerge) in relation to the effective functioning of the rail sector in the EU, as a result of technological, economic, societal, environmental and policy trends that were not considered at the time of the expansion of the Agency's mandate, including:	Qualitative and quantitative indicators relating to the existing problems/needs and problems/needs which may have emerged since 2016, including: • Authorisation and certification data (e.g. valid SSCs issued) • Rail safety data (e.g. significant rail accidents and casualties, fatality risk of rail transport) • Interoperability data (e.g. ERTMS deployment, time spent on cross-border operations) • Innovation and modernisation data (e.g. level of funding for new technologies and innovation) • Decarbonisation (e.g. percentage of electrified network).	• Desk research • Analysis of relevant documentation (e.g. ERRAC - Rail 2050 Vision; ERA - Report on a compelling vision for the target railway system; EC – Rail Market Monitoring Survey; key policy documents) • Targeted surveys • Targeted interviews

Operational questions	Indicators	Data sources and methods
• Technological developments (e.g. artificial intelligence (AI) applications, autonomous train operations, emerging communication systems and technologies (5G), innovative design of rail vehicles) • Changing transport demand/modal shift (as a result of trends in oil prices/car ownership/high-speed rail infrastructure) • Digitalisation and new service offerings (e.g. Mobility as a Service (MaaS), temporary capacity restriction (TCR)). • Increasing focus on decarbonisation (e.g. electrification of railways, alternative fuel use • Demographic trends (e.g. urbanisation and associated rail connectivity • COVID-19 and associated socio-economic impacts (e.g. train capacity changes, freight demand changes) • Policy developments (e.g. European Green Deal, SSMS). 22.3 Are the specific and operational objectives of the Agency still relevant in view of the current and new problems/needs identified? 22.4 Does the technical pillar of the 4th Railway Package still meet the current needs and new problems/needs identified through its: • Introduction of the dual system for VA and safety certification • Creation of the OSS • Harmonised implementation of the ERTMS. 22.5 Is there a need for new objectives or activities to better reflect the new problems/needs?	Other needs may only be possible to address in a qualitative manner; these include: • The extent to which stakeholders agree that the existing objectives of the Agency are relevant for the new problems/needs arising. • The extent to which stakeholders agree that changes to the objectives of the Agency are needed.	

Table *11*. Evaluation matrix - EU added value questions

EQ23. What are the benefits of intervening at EU level and offering a harmonised decision-making at the EU level? In light of the above rationale, what evidence is there on actual EU added value having been created, also in terms of order of magnitude of the added value?

Operational questions	Indicators	Data sources
23.1 To what extent (e.g. fully, partly, not at all) is EU added value seen as a benefit for achieving the following objectives? • Ensured a harmonised safety and interoperability framework across the EU • Development of harmonised ERTMS and telematics deployment • Helped overcome fragmentation of national frameworks and rules • Lead to efficiencies for applicants (reduction in costs and duration of VA and safety certification) • Ensured greater cooperation, communication and information exchange • Lead to a coordinated approach to monitoring of performance and decision-making of NSAs and NoBos • Promoted innovation and research across the rail sector. 23.2 What are the specific additional benefits arising from EU-level action taken by the Agency in terms of the above expected benefits, in terms of: • Effectiveness towards the achievement of the objectives/benefit • Efficiency/costs of achieving these objectives. 23.3 Are there other benefits that have arisen as a result of action at EU level?	Quantitative indicators relating to the benefits of EU-level action through the Agency, including: • Number of objectives of the Agency, as outlined in the provisions of Regulation (EU) 2016/796, where EU action is expected to bring significant added value / or has brought significant added value to date • Number of objectives of the Agency, as outlined in the provisions of Regulation (EU) 2016/796, EU action is expected to bring at least some added value/ or has brought some added value to date • Number of activities of the Agency, as outlined in the provisions of Regulation (EU) 2016/796, where EU action is not expected to bring added value/ or has brought limited or no added value to date. Qualitative indicators: • Level of evidence available, indicating that EU-level action brought specific additional benefits beyond what national action could achieve • The extent to which stakeholders agree that EU intervention as a result of the Agency has increased the effectiveness and efficiency of each activity.	• Desk research • Analysis of relevant documentation such as the Impact assessment accompanying the proposals for the 4th Railway technical pillar • Targeted surveys with stakeholders such as representative bodies, standardisation bodies, applicants, EU institutions, NSAs, and RISC Member State representatives • Targeted interviews
23.4 How would Member State action alone have contributed towards addressing the underlying problems to date, namely: • Long and costly authorisation and certification procedures	Quantitative assessment which draws upon the baseline description, and the expected action at the Member State level without EU intervention, in particular:	

Operational questions	Indicators	Data sources
• Discrimination against new entrants (e.g. discriminatory access to infrastructure, technical/regulatory barriers) • Critical importance of safe and interoperable railway operations • Lack of modernisation and innovation. 23.5 Assuming that none of the measures put forward by the Agency were adopted, what could be expected to be the situation to date in regard to: • The development of national-level measures to facilitate improvements in interoperability and safety • Progress made in supporting the implementation of the ERTMS and telematics system • The development of non-discriminatory national-level authorisation procedures.	• Authorisation and certification data (e.g. certificates issued) • Costs related to authorisation and certification processes. Qualitative assessment of the expected level of action taken by Member States to facilitate a harmonised approach to VA and ERTMS deployment, and enhance interoperability and rail safety across the EU, drawing upon stakeholder views.	

Table *12*. Evaluation matrix - Coherence questions

EQ25. To what extent is the Agency's mandate coherent with the other interventions to complete the creation of the SERA and EU rail policy in general? To what extent is the dual system for VA and safety certification (i.e. with both the Agency and NSAs issuing certificates and licences), the OSS and harmonised implementation of ERTMS coherent with the other interventions to complete the creation of the SERA?

Operational questions	Indicators	Data sources
25.1 Are the overall objectives and mandate of the Agency consistent with EU rail policy, in relation to: • Opening the rail transport market to competition • Improving the interoperability and safety of national networks • Developing rail transport infrastructure. 25.2 Are the specific objectives, operational objectives and activities of the Agency consistent with the other interventions to complete the	Qualitative assessment to determine: • The consistency of the purpose, ambition and scope of the Agency's mandate and objectives with the objectives and procedures of the market pillar and Action plan to boost long-distance and cross-border passenger rail services and the TEN-T proposal • The consistency of the dual system for VA and safety certification, the OSS and harmonised implementation of ERTMS with the objectives of	• Desk research • Analysis of relevant documents such as key legislative texts and policy documents, ERA SPDs • Targeted consultation with stakeholders such as EU institutions, representative bodies, civil society • OPC.

Operational questions	Indicators	Data sources
creation of the SERA, including the market pilla' of the 4th Railway Package, specifically in relation to: • Cross-border agreements • Obligations of infrastructure managers to report to RINF and input in other databases • Liberalisation of cross-border operations.	the Action plan to boost long-distance and cross-border passenger rail services and the TEN-T proposal.	
25.3 Are the objectives of the Agency in line with those of the Green Deal, e.g. in relation to: • Addressing transport-relating GHG emissions • Encouraging multimodal transport • Supporting the role of automated and connected mobility • Improving the pricing of transport, to capture external costs • Enhancing the production and deployment of sustainable alternative transport fuels • Addressing transport-related congestion and air pollution, particularly in cities. 25.4 Are the Agency's objectives in line with the Commission's ambitions in the SSMS, e.g. in relation to: • Boosting low-carbon fuels and related infrastructure • Making interurban and urban mobility more sustainable and healthier • Greening freight transport • Making connected and automated multimodal mobility a reality • Innovation, data and AI for smart mobility • Reinforcing the single market • Making mobility fair and just for all • Enhancing transport safety and security.	Qualitative assessment to determine: • Level of consistency of the purpose, ambition and scope of the Agency's mandate and objectives with the objectives of the Green Deal and EU-level ambition towards smart and sustainable transport. • Presence of consistency of the Agency objectives activities with the UN SDGs.	• Desk research • Analysis of relevant documents such as key legislative texts and policy documents, ERA SPDs • Targeted consultation with stakeholders such as EU institutions, representative bodies, civil society • OPC.

Operational questions	Indicators	Data sources
25.5 Are there any contradictions between the Agency's objectives and the objectives of the Green Deal and ambitions towards smart and sustainable transport? 25.6 Are the Agency's activities and objectives coherent with the UN sustainable Development Goals?		
25.7 Are there any contradictions/conflicts or overlaps among the different functions/units of the Agency, in terms of: • Priorities and activities • Resource allocation. 25.8 Are there any contradictions/conflicts or overlaps in the provisions, structures/mechanisms and activities of the Agency, related to each of the following: • The dual system for vehicle authorisation and safety certification; • The operation of the OSS; • The harmonised implementation of ERTMS. 25.9 Do any of the above contradictions and overlaps affect the achievement of the Agency's objectives including: • Ensured a harmonised safety and interoperability framework across the EU; • Development of harmonised ERTMS and telematics deployment; • Helped overcome fragmentation of national frameworks and rules; • Led to efficiencies for applicants (reduction in costs and duration of VA and safety certification); • Ensured greater cooperation, communication and information exchange; • Led to a coordinated approach to monitoring of performance and decision-making of NSAs and NoBos;	Qualitative indicators aiming to determine the existence/significance of internal inconsistencies: • The presence and importance of overlaps, contradictions and inconsistencies between the roles/activities of the Agency. • The impact of any existing overlaps, contradictions and inconsistencies on the achievement of the Agency's objectives.	• Desk research • Analysis of relevant documents such as key legislative texts and policy documents, ERA SPDs • Targeted consultation with stakeholders such as EU institutions, representative bodies, civil society • OPC.

Operational questions	Indicators	Data sources
• Promoted innovation and research across the rail sector.		

ANNEX IV. OVERVIEW OF BENEFITS AND COSTS [AND, WHERE RELEVANT, TABLE ON SIMPLIFICATION AND BURDEN REDUCTION]

TABLE 1. Overview of costs and benefits identified in the evaluation

		Citizens/Consumers		Businesses (railways sector)		National Safety Authorities		ERA	
		Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Cost description:									
Direct compliance costs (adjustment costs, administrative costs, regulatory charges)									
Administrative cost: vehicle authorisation costs – average, including all fees and administrative costs	Recurrent	- - -	-	Below EUR 110,000 per authorisation, with costs of less than EUR 10,000 the most common value. However, costs of more than EUR 250,000 per authorisation were also reported.		Quantitative estimates not available	Labour costs for National Safety Authorities related to the authorisation procedure	Quantitative estimates not available	Labour costs for ERA related to the authorisation procedure
Administrative cost: vehicle authorisation costs – first/new authorisations for wagons	Recurrent	-	-	Costs of around EUR 8,000 per authorisation		Quantitative estimates not available	Labour costs for National Safety Authorities related to the authorisation procedure	Quantitative estimates not available	Labour costs for ERA related to the authorisation procedure
Administrative cost: vehicle authorisation costs – authorisations in conformity to type	Recurrent	-	-	Costs of around EUR 2,000 per authorisation		Quantitative estimates not available	Labour costs for National Safety Authorities related to the authorisation procedure	Quantitative estimates not available	Labour costs for ERA related to the authorisation procedure

Administrative costs: safety certification	Recurrent	-	-	Less than EUR 100,000 with the majority indicating costs in the range of EUR 10,000 to 60,000		Quantitative estimates not available	Labour costs for National Safety Authorities related to the safety certification procedure	Quantitative estimates not available	Labour costs for ERA related to the safety certification procedure
Administrative costs: ERTMS trackside approval	Recurrent	-	-	Quantitative estimates not available		Quantitative estimates not available	Labour costs for National Safety Authorities related to the trackside approval	Quantitative estimates not available	Labour costs for ERA related to the trackside approval
One-Stop shop (OSS)	Recurrent	-	-	Quantitative estimates not available		Quantitative estimates not available		In 2024 0.5 million and 1.5 FTE (i.e., equivalent of EUR 190 000).	Labour costs for ERA for development and maintenance of OSS
Benefit description:									
Cost reduction for authorisation/certification following harmonisation through TSIs and CSMs and the elimination of national rules.	Recurrent			Quantitative estimates not available		Quantitative estimates not available		Quantitative estimates not available	

TABLE 2: Simplification and burden reduction (savings already achieved)

*Report any simplification, burden reduction and cost savings **achieved already** by the intervention evaluated, including the points of comparison/ where available (e.g. REFIT savings predicted in the IA or other sources).*

	Citizens/Consumers		Businesses (railways sector)		National Safety Authorities		ERA	
	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Direct compliance costs (adjustment costs, administrative costs, regulatory charges)								
Type: recurrent **For all vehicle types (except freight wagons) reduction of the average time to deliver an authorisation compared to the targets, i.e., 22% reduction from 24 months baseline of authorisation time to 18.7 months.**			Quantitative estimates not available		Quantitative estimates not available		Quantitative estimates not available	
Type: recurrent **Reduction of the actual number of national rules**			Quantitative estimates not available	Reduction of costs and removal/ reduction of restrictions for cross-border traffic	Quantitative estimates not available		Quantitative estimates not available	

PART II: II Potential simplification and burden reduction (savings)

	Citizens/Consumers		Businesses (railways sector)		National Safety Authorities		ERA	
	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Description: Direct compliance costs (adjustment costs, administrative costs, regulatory charges)								
Type: recurrent **Better integration of the different EU rail registers such as ERADIS, ERATV, and EVR with the One-Stop Shop.**	-	-	Quantitative estimates not available		Quantitative estimates not available		Quantitative estimates not available	

ANNEX V. STAKEHOLDERS CONSULTATION - SYNOPSIS REPORT

This stakeholder consultation synopsis report provides a summary of the outcome of the stakeholder consultation activities which were carried out as part of the evaluation pursuant to Article 82(1) of the ERA Regulation. It provides a basic analysis of the responses of stakeholder groups involved in the consultation process and a summary of the main issues which they raised. Stakeholder involvement was vital for the evaluation in order to collect facts and data, to assess the performance of the Agency, to identify possible issues and draw lessons for possible improvement.

The **consultation strategy** was developed from the start of the process in December 2020 and included as **key stakeholders** the following groups:

- Members of the Agency's Management Board
- Members of the Rail Safety and Interoperability Committee (RISC)
- Public authorities (national, regional or local level)
- Rail infrastructure managers
- Railway undertakings
- Rail freight corridors
- Shift2Rail Joint Undertaking and its successor Europe's Rail
- Associations representing the EU rail sector
- Trade Unions

Other relevant stakeholders were:

- International organisations, namely Intergovernmental Organisation for International Carriage by Rail (OTIF) and Organisation for cooperation between railways (OSJD)
- NGOs and interest organisations (consumer/environmental/safety organisations, etc.)
- 3rd countries, namely Western Balkan partner countries and Eastern Partnership countries
- Researchers and academia
- Interested citizens

The **stakeholder consultation activities** performed included the following:

- The **Evaluation Roadmap** was open for comments between 1 March and 29 March 2021[81].

[81] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12619-EU-Agency-for-Railways-European-Commission-evaluation-of-the-Agencys-work_en

- Four **targeted online surveys,** aimed at NSAs, Member State representatives, Applicants/users of ERA services, and Railway sector representative bodies. The survey ran from 5 April 2022 to 31 May 2022 and received 256 responses.
- **Targeted stakeholder interviews** were conducted with 42 stakeholders during April to July 2022 (including 5 exploratory interviews).
- The **OPC** was open between June 2022 and September 2022. 30 responses and one position paper were received.

Stakeholder consultation tools used

Table 13 provides an overview of the stakeholder consultation tools used throughout the evaluation support study, including which stakeholders were targeted and the intended role within the evaluation impact assessment. Further details are provided in Table 14.

Table 13. Overview of stakeholder consultation tools used

Activity	Stakeholders involved	Role within the support study/input provided
1. Exploratory interviews	ERA Management Board (BE, NL, ES) NSAs (EBA (DE)) Representative bodies from the EU railway sector (UNIFE, CER (Community of European Railway and Infrastructure Companies)) ERA staff (Executive director/ Corporate Assurance and Performance Unit/ Executive Office and Communication Unit)	• Discussion on objectives of the Agency and the structures and mechanisms in place – used to inform the intervention logic / evaluation matrix • Initial input on the performance/operation of the Agency helping to identify relevant topics for further analysis • Identification of data needs/availability • Development of stakeholder consultation tools (survey, interviews)
2. Targeted survey	NSAs Member State representatives Applicants/users of ERA services Railway sector representative bodies	Online surveys gathering inputs to support the qualitative and quantitative analysis of evaluation questions, including the effectiveness of ERA's activities, the time spent and cost of the authorisation /certification and approval processes under the 4th Railway Package and the other ERA activities (monitoring, national rules, technical support). Also understanding of relevance, coherence and EU added value of ERA's operations.
3. Targeted interviews	All stakeholder groups	Interviews used to crosscheck and complement the information from the desk research and the targeted surveys including further inputs into qualitative and quantitative analysis of ERA's operations (including in terms of impacts of costs/time from the use of the dual system). Explore

Activity	Stakeholders involved	Role within the support study/input provided
		the impact of the ERA management structure and procedures and interaction/ cooperation with other actors; practical experience with use of the OSS; effectiveness and efficiency of ERA operations, relevance and coherence of ERA's objectives and activities, and EU added value. They have also been used to obtain input from other stakeholders (e.g. trade unions, candidate country representatives, international organisations) not covered by the survey.
4. Ad hoc data requests	All stakeholder groups (where appropriate)	Information requests to collect specific information from ERA staff (a first such request has already been submitted) and if needed, EU institutions, NSAs and applicants also. Ad hoc requests to enable filling of identified data gaps that emerge after desk research and other field research activities; requesting additional information/ clarifications; or as a means to improve geographical balance of targeted consultation respondents if deemed necessary. Over 10 requests for further information were sent to the railway sector respondents of the survey to get further clarity on their answers. Additionally, the Agency was contacted for additional requests for input on several occasions.
5. Presentations to RISC	NSA Member State representatives of the RISC[82] Key experts from the railway sector representative bodies	Obtain further inputs, validate the assumptions and analysis and present findings and conclusions
6. Consultation activities carried out by the EC	OPC and the feedback to the evaluation and fitness check roadmap	Quantitative and qualitative analysis of impacts

[82] Railway interoperability and safety committee.

Evaluation roadmap

A total of 10 contributions were received on the Evaluation roadmap. Industry respondents (from 'company/business organisations' and 'business associations') contributed just over half of the submissions (2 and 4 respectively), with the remaining responses spread over several different stakeholder categories i.e., one EU citizen, one NGO and two 'other'.

By country of origin, there were 6 respondents from Belgium, two from Spain, one from Norway and one from the Netherlands.

Key findings from the roadmap

There were several general comments in support of the proposed initiative, which underlined the need to evaluate the work of the EU Agency for Railways. All stakeholders agreed with the approach and recognised the significance of this EC initiative.

From their perspective, companies/business associations (Zeleros Hyperloop, HyperloopTT[83], CER, UNIFE[84], EIM[85] and NSA Norway[86]) appreciate and strongly supported both the evaluation as such as well as the Agency in the improvement of its working practices.

Other stakeholder types were also supportive of this initiative. NSA Norway believes the roadmap on the evaluation of the work of the EU Agency for Railways overall covers the necessary points. EDF[87] considers the ERA working party tasked with reviewing and amending the TSI-PRM very useful for implementing the Regulation to advance accessibility of rail infrastructure and rolling stock for persons with disabilities. Oficina española del Corredor Mediterraneo[88] highlighted that the achievement of a SERA is an ambitious and necessary objective to increase the presence of the train in passenger mobility and freight transport in Europe, interoperability being the vector that allows achieving this objective.

Targeted Consultation Activities

Targeted Online Surveys

A total of 256 survey responses were received. Table 14 provides an overview of the survey responses received by stakeholder type.

Table 14. Survey responses received by stakeholder type

Stakeholder group	Number of responses	Stakeholders covered
NSAs	14	BE, DE, EE, FI, FR, HR, IE, IT, LT, LU, NL, SK, Other: CH, NO
Member State competent authorities (including	17	BE, DE, DK, EE, EL, ES, FI, FR, IE, LT, LU, PL, PT, SE, SK, SL, Other: NO

[83] Hyperloop technology development companies

[84] Association representing the European Rail Supply industry

[85] The European Railway Infrastructure Managers – representing European railway infrastructure managers

[86] Representing national safety authority in Norway

[87] European Disability Forum - Representing persons with disability

[88] Organisation representing companies/social groups in Valencia (ES) lobbying a rail corridor for freight.

Stakeholder group	Number of responses	Stakeholders covered
ministries of transport or other transport agencies)[89]		
Industry / Railway sector representatives	9	FEDECRAIL; NB-Rail; UNIFE; ACRI; AERRL; ANIE ASSIFER; EIM; CER; UIP Rail
Railway businesses (applicants for VA, SSC or ERTMS trackside approval registered in ERA One Stop Shop)[90]	215	• railway undertakings (112) • rail vehicle or rail equipment manufacturers/suppliers (or its authorised representative) (60) • rail infrastructure managers (11). • 60 railway businesses described themselves as 'other'. This group included wagon keepers (11), NoBos (3), consultancies/advisors (13) and others.
TOTAL	**256**	-

Targeted Interviews

As part of the study, 47 targeted interviews were conducted.

Five **exploratory interviews** were undertaken during the inception phase of the evaluation support study (February 2022). See Table 15 for further details.

Table 15. Exploratory Interviews

Stakeholder	Stakeholder group
Executive Board members (BE, NL, ES)	ERA Executive/ Management Board -Chairs
ERA Staff • Executive Director • Executive Officer • Financial and Procurement Unit • Planning and Approvals Delivery Unit	ERA
Eisenbahn Bundesamt (EBA) - Germany	NSAs
CER	Representative bodies and associations from the railway sector acting at Union level
UNIFE	Representative bodies and associations from the railway sector acting at Union level

Table 16 provides an overview of the **total number of targeted interviews** planned and subsequently achieved by stakeholder type.

Table 16. Total number of interviews by stakeholder type

Stakeholder group	Stakeholder sub-group	Number of interviews	Stakeholders interviewed
EU institutions and other public bodies	EU bodies	1	• DG NEAR

[89] In the presentation of the responses the term "National authorities" refers to the Member States competent authorities, and NSAs to refer to National Safety Authorities.

[90] In the presentation of the responses to the survey the term railway businesses refers to all applicants. Where relevant, the presentation differentiates by type.

Stakeholder group	Stakeholder sub-group	Number of interviews	Stakeholders interviewed
	European public-private partnerships related to rail	1	• Europe's Rail Joint Undertaking
NSAs& NIBs	NSAs	6 + 1 exploratory	• EBA (The German Federal Railway Authority) (DE) [Exploratory + joint targeted interview along with DE RISC members] • Administration des Chemins de fer (Luxembourg government Railway administration) (LU) • Serbian Directorate of Railways (RS) - NSA from Western Balkans • Etablissement pulic de sécurité ferroviaire (EPSF) (French Rail Safety Authority) (FR) • Finnish Transport and Safety Agency (FI) • NSA Belgium (BE)
	NIBs	2	• Safety Investigation Authority (FI) • Comision de Investigacion de Acidentes Ferroviarios (CIAF) Railway Accident Investigation Commission) (ES)
Member State representatives (RISC members)		4	• Federal Ministry for Digital and Transport (DE) [Joint targeted interview along with DE NSA members] • Ministry of Transport and Communications (LT) • Urząd Transportu Kolejowego (Office of Rail Transport) (PL) • Norwegian Ministry of Transport (NO)
ERA		7 + 2 exploratory	ERA Executive Board / Management Board: • Chairperson (BE); Deputy Chair (NL); Management Board Member (ES) [Exploratory]
			• Executive Director; Executive Officer; Financial and Procurement Unit; Planning and Approvals Delivery Unit [Exploratory interview] • Railway Systems Department • Safety and Operations Unit • Railway Interoperability of Vehicles and Infrastructure Unit • ERTMS and Telematics Unit • Resources and Support • Planning and Approvals • Analysis and monitoring
Applicants for VA, safety certification and ERTMS trackside approval		13	Railway undertakings: • Rail Cargo Carrier - Poland Sp. z o.o.

Stakeholder group	Stakeholder sub-group	Number of interviews	Stakeholders interviewed
			• DB Cargo Italia • NS | Techniek | Kwaliteitsmanagement • boxXpress.de • DN Systemtechnik GmbH • Rail Force • CENTRAL RAILWAYS, a.s.
			Rail vehicle or rail equipment manufacturer/supplier: • NEWAG S.A. • Alstom • Siemens Mobility GmbH • Stadler Deutschland GmbH • Geismar GmbH
			Rail infrastructure manager: • National Railway Infrastructure Company
Representative bodies and associations from the railway sector acting at Union level	Organisations representing applicants for VA, safety certification and ERTMS trackside approval	2 exploratory	• CER [Exploratory] • UNIFE [Exploratory]
	Organisations representing transport operators and the wider railways supply chain	3	• European Federation of Museum & Tourist Railways (FEDECRAIL) • International Union of Wagon Keepers (UIP Rail) • EIM
International rail sector organisations		2	• Intergovernmental Organisation for International Carriage by Rail (OTIF) • Permanent Secretariat of Transport Community Treaty (TCT) (for Western Balkan partner countries)
Organisations representing those involved in testing and or validation of industry of products and subsystems		1	• NB-Rail
Civil society	Employees, trade unions and professional organisations active in transport sector	2	• Autonomous Train Drivers' Unions of Europe (ALE)
	Consumers with disabilities		• European Disability Forum (EDF)

Stakeholder group	Stakeholder sub-group	Number of interviews	Stakeholders interviewed
Total		**42 + 5 exploratory**	

Key findings from targeted interviews and online surveys Concerning their practical experience with the VA process under the 4th Railway package, both railway businesses and NSAs consider that the process still has significant limitations. When asked to compare with the previous experience, there are a number of cases where their view is that process has not improved or even deteriorated.

The responses provided by railway businesses and NSAs concerning the new **safety certification process** are largely positive. The larger share of railway businesses (46 out of 73 that provided an answer) considered the quality of the application assessment as positive or very positive. The majority (40 out of 64) indicated that there has been an improvement, in contrast to only 7 that considered that the process is not somehow worse. NSAs were also positive concerning the harmonisation of the approach. There were minimal comments regarding the **dual system**, and those that were provided were largely focused on how the objective is not meeting the needs of the railway sector. Railway businesses had the lowest level of overall agreement of the groups surveyed. The main comments were that more work needs to be done to improve the dual system, OSS and ERTMS harmonisation across the EU. The main limitation and weakness identified in the functionality of the OSS tool includes the increased effort and time needed.

On the **NSAs monitoring**, the opinion of NSAs and national competent authorities was generally positive, with positive feedback given by 10 out of the 12 NSAs that provided a view. The comments highlighted how ERA's monitoring activity stimulates the improvement of NSAs' activity. Some respondents, however, added that the real impact of the initiative will manifest itself in the years to come. Only 2 NSAs and 2 national authorities said their experience was negative.

Only two NSAs, two national authorities, and one railway sector representative provided an answer to the question on **NoBos monitoring**. Overall, the NSAs and national authorities were mostly positive on the effectiveness of the Agency's monitoring of NoBos.

Stakeholders provided a mixed view on the activities of the Agency related to the **review of existing and new national rules**. NSAs had a mixed opinion on the effectiveness of ERA's assessment of national rules and the identification of redundant ones. Railway sector representatives agreed that reducing national rules has resulted in cost savings and expressed a desire for speeding up the cleanup of the remaining rules.

Stakeholders identified the main strength of the process as the possibility offered by this process to ensure transparency of national rules. Stakeholders also expressed a desire for speeding up the clean-up of the remaining rules, which are often the most controversial. The other stakeholders signalled the following negative impacts: creation of gaps in

legislation, i.e. areas no longer covered by national rules but not adequately covered by EU legislation.

Since the adoption of the 4th Railway Package, ERA is in a process of **developing and adapting its registers and databases** to fulfil its new activities and responsibilities.

A significant share of rail sector representatives did not consider most registers as being user friendly. The view of NSAs is relatively more negative than that of the rail industry. Stakeholders also answered a question on whether appropriate guidance and support available for registers and IT tools. Most stakeholders across all groups agreed or had a neutral view on this issue.

There is a balance of positive and negative assessments in relation to the SRD among all stakeholder groups. A larger proportion of NSAs disagreed with ERADIS being an easy tool to use (4 out of 13). Like rail sector businesses, NSAs see RINF as the most difficult to use. Developed to support authorisation functions by ensuring an integration with OSS, ERADIS, ERATV and EVR received an overall positive assessment from rail businesses. Representatives of the rail sector expressed a different view, with most of them disagreeing with this statement for most registers and IT tools.

According to the ERA Regulation, the Agency is responsible for **providing the Commission with recommendations and opinions**. 6 out of 14 NSAs and all industry rail representatives (10 out of 10) provided positive input on the opinions issued concerning both safety- and interoperability-related aspects. NSAs and railway sector representatives also commented on the extent the working groups are appropriate to achieve integration of change requests and innovative solutions.

More positive feedback was provided for the reports on the progress on the safety and interoperability of the EU rail system. Most NSAs (12 out of 14) and all industry rail representatives (10 out of 10) provided a positive assessment (good or very good).

ERA is expected to **promote European experiences, regulations and standards to third parties**. This includes Western Balkans states and Turkey mainly in the context of the implementation and with the use of funds of the European Union's IPA, ERA staff liaise with authorities of non-EU member states, and they promote the EU approach for railways.

ERA successfully delivered of workshops and training of national experts, and other related support was provided. The TCT expressed that ERA supports all TCT rail. They expect the Agency to carry on doing this type of events in the future, as their delivery slowed down during the COVID pandemic. ERA organised two bilateral meetings with Macedonia and Albania, as part of a TCT initiative. Further, ERA has achieved good outcomes in terms of the activities and services it had to provide under the IPA program.

Insights to the role and performance of the Agency in terms of their direct role as **rail innovation promoter** provided by selected stakeholders suggest that ERA has made great contributions to the development and uptake of innovation in the railways sector. The main issue identified was related to the insufficient time/resources of the Agency for these tasks.

All stakeholders were asked to comment on **the extent to which the objectives of the Agency are still relevant** to the current problems and needs of the railway sector. NSAs

showed greater disagreement with the objectives of reducing the time to market of innovation and reducing administrative costs. All other stakeholder groups generally agreed that all objectives are still relevant. National authorities showed the highest level of agreement (14 out of 15) followed closely by railway sector representatives with 8 out of 9 and NSAs with 11 out of 13. Railway businesses also had a majority agreeing that the objective is still relevant (130 out of 198). The majority of respondents seemed to agree that the issues identified at the time of adoption of the 4th Railway Package are still present.

In terms of the **clarity of the VA and safety certification processes**, a large share of railway businesses (36 out of 73 that provided an answer) provided a positive or very positive assessment. Still, 24 made a negative or very negative assessment. Almost half (32 out of 65 that provided a view) considered that there has been an improvement compared the previous situation.

Railway businesses and NSAs were satisfied with **the level of information available on the OSS platform on the approval process**. Most railway businesses (applicants) were satisfied or very satisfied with their ability to apply in the preferred language. Railway businesses articulated that the benefits that many experienced through the harmonised OSS approach are counter-acted by the increased effort required. Businesses call for better interconnection between all the relevant ERA tools to reduce the administrative burden and automate parts of the assessment.

37 out of 72 railway businesses that provided an answer gave a very negative or negative assessment concerning the **predictability of the fees**, while 27 provided a positive assessment. Most NSAs provided a moderate assessment (6 out of 12), with 4 providing a positive assessment and 2 a negative. Only a small share indicated that they have used the pre-engagement process.

Cost savings for the applicants were expected both with the reduced costs linked to the application process as well as with opportunity costs savings from the time that vehicles may remain idle in workshops while being approved. In contrast, an increase in costs and time needed for authorisation and certification activities has been reported.

Ten railway businesses pointed to the **increasing documentation requirements** of the authorisation process through the OSS for the cause of greater time burden. More human resources have been required to prepare and process these documents, leading to greater costs. The key reason for cost increases is the need for CTT whose series had already been authorised.

The shortest and lowest cost applications are for first wagon authorisations. The most expensive are multiple unit passenger trains (EUR 500 000). Most rail businesses reported needing up to 2 FTE for the development and submission of applications.

Most businesses gave average total cost values less than EUR 100 000. One applicant clarified that 20% of their total average costs were associated with preparation and submission of information.

Concerning the **costs for the NSAs**, those were asked to state how their annual costs associated with authorisation activities had changed since the adoption of the 4th Railway Package. The majority of NSAs said that their costs had not changed (9 out of 12). One

NSA reflected that some costs have fallen as ERA has taken over some aspects as the authorizing body.

Both authorities and railway sector representatives provided a negative assessment of the Agency success in reducing the **costs and direction** of VA process. Most NSAs had a negative or very negative view concerning the delivery in this area. National authorities were in relative terms more positive but still largely sceptical. The majority of railway sector businesses considered that ERA activities so far have not contributed to reducing costs and duration of authorisation.

Stakeholders (including national authorities and railway sector representatives) were also asked to provide an assessment of the **effectiveness** of ERA in its role. National authorities appeared quite positive, with 3 out of 17 respondents indicating that ERA was somehow effective in its role concerning authorisation and certification. Only 4 out of 9 railway sector representatives provided input in this area. The dominant issue is the **impact on costs/resources and time** for the vehicle authorisation process as a result of the implementation of the 4th Railway Package.

The 2013 IA that supported the adoption of the 4th Railway package discussed the expected **added value** of EU level action. According to the assessment, action by Member States alone could not ensure the **coherence** of the EU railway market and address divergent interpretation of the legislation. Action at EU level was considered important as it would to ensure consistent implementation.

Stakeholders (including NSAs, national authorities and railway sector representatives) were also asked to comment whether action at Member States level only would deliver results in different impact areas.

Two NSAs stated in interviews that Member State level action could already address the long and costly certification and authorisation procedures alone. Views were mixed with regard to whether Member States can address the continued need to ensure safe and interoperable railway operations across the EU.

The railway sector representatives UNIFE, ACRI and ANIE ASSIFER highlighted that ERA action at EU level brings forward harmonisation and standardisation within the EU. The Member States that consider that action at national level alone could deliver in these areas tend to be from Western European. The ones that consider added value in action at EU level are rather from Eastern Europe.

Most respondents supported EU level action when looking at the elimination of redundant national rules. One NSA added that EU level activities that decrease barriers such as reducing national rules bring significant added value.

Most stakeholders were in favour of EU level action with regards to ensuring a coordinated approach to monitoring of performance and decision-making of NSAs. In their view action at Member State level alone is not sufficient in delivering this. 9 out of the 13 NSA respondents stated that Member State action alone could only deliver to a limited extent or not at all.

Stakeholder views were mixed with regards to **reducing costs and the duration** of the VA and safety certification processes. Stakeholders (including NSAs, national authorities and railway sector representatives) were asked to comment on the **different parameters and mechanisms in the performance of the Agency**. The parameters that are considered by the majority of stakeholder groups to have had an impact on the Agency's performance include **human and financial resources**. Resource availability has been identified as a problematic aspect affecting the effective delivery of the Agency's roles and responsibilities.

NSAs and national authorities' views were equally split when it comes to the sufficiency of resources for the monitoring of NSAs and NoBos. Most railway sector representatives did not have a view.

Most stakeholders did not have a view concerning the role of the **Agency's management and organisations structures**. Among those few that contributed (whether NSAs, authorities or railway sector representatives), the feedback provided was in most cases positive. One common comment made was the ongoing inability to resolve the language issue faced by the Agency.

The performance of NSAs and **the cooperation between the Agency and the NSAs** also received a positive assessment. However, comments concerning the cooperation with the NSAs also suggested that this is sometimes (i.e. in relation to specific NSAs) challenging.

Stakeholders were asked to respond to the question on the **effectiveness of cooperation between the Agency and the railway sector** and the input provided by the stakeholders does not point to a strong positive role of the cooperation with the NSAs. At the same time, most stakeholders that responded considered that the cooperation contributed at least to some extent. This is particularly in relation to the authority related activities.

Open Public Consultation

The OPC was open from 10 June 2022 to 2 September 2022, and a total of 30 responses were received.

Table 17 presents the number of stakeholders that completed the OPC, split by stakeholder group.

Table 17. Classification and number of stakeholders responding to the OPC

Stakeholder group	High level grouping	Number of responses
Business association	Industry	7
Company/business organisation	Industry	10
Public authority	Public authority	4
EU citizen	Citizen	2
Non-EU citizen	Citizen	1
Academic/research institution	Other	2
Consumer organisation	Other	0

Environmental organisation	Other	-
Non-governmental organisation (NGO)	Other	2
Other	Other	2

The geographical distribution of the respondents is the following: Belgium (8), Czechia (7), France (6), Spain (3), Germany (2), the Netherlands (1), Poland (1), Norway (1), Switzerland (1).

Key findings from the OPC

25 out of 30 respondents indicated that the current Agency's mandate is (at least to some extent) adequate for achieving a well-functioning SERA. Three indicated that it is very adequate, 10 indicated is adequate and 12 adequate to a limited extent.

Where it was indicated that the Agency's mandate was only adequate to a limited extent, respondents provided a number of reasons that were not necessarily addressing the adequacy of ERA mandate but referred more to the limitations of ERA in delivering its mandate. More specifically, there was reference to: The mandate of ERA to achieve SERA should consider the increasing digitalisation of rail operations and the new related areas that needs to be covered in terms of interoperability (1 EEA citizen, 1 railway sector business/association). However, the budgetary constraints/limited resources of ERA make it difficult to deliver its mandate (1 railway sector business/association, 1 national authority).

- It would be beneficial for the sector to extend the Agency's mandate to full responsibility for a) national rules cleaning and reduction and b) the ERATV management (1 railway sector business/association)
- The inconsistency in the approach to similar cases/lack of specific country awareness (1 national authority, 2 railway sector business/association)
- The mandate being unnecessarily extensive (1 railway sector business/association)
- The Agency's mandate is not yet sufficient to fully achieve its objectives. It is currently still heavily dependent on the European Commission and NSAs (1national authority).

22 out of 30 respondents indicated that ERA had contributed to higher safety levels. Four indicated that ERA contributed here to only to a small extent and one not at all.

Thirteen contributors considered that the objectives and tasks of the Agency are sufficient to deliver the necessary modernisation of the Union's rail sector within the next 5-10 years. Of those who explained their answers, reasons cited as to why these tasks and goals are not considered to be sufficient included:

- Lack of means and resources from ERA to lead to this result (1 national authority)
- Lack of consideration from the Agency to the operating conditions of rail transport in its entirety (1 civic society) and
- ERA's lack of control over Shift2Rail/Europe's Rail Joint Undertaking (1 railway sector business/association, 1 non-railway business, 1 civic society organisation).

The contributors consider the development of TSI as the most powerful to trigger change in the rail sector, followed by the cleaning up of national rules and the harmonized implementation of ERTMS.

Concerning digitalisation and innovation, the views among the 14 respondents were diverging, some respondents had positive views, while other considered there had not been enough progress.

Ten out of 30 contributors either agreed or strongly agreed that the introduction of the dual system for VA and safety certification met the needs of the rail sector. Nine respondents indicated that there are inconsistencies or overlaps in the functioning of the dual system, while one national authority identified no flaws.

Less than half of the respondents (13 out of 30) indicated that the Agency's role in the VA and safety certification is sufficient.

21 out of 30 respondents indicated that they had observed negative consequences of the enhanced Agency's mandate. Among these, the most cited negative consequences were:

- Increase in direct costs (fees) and indirect costs (legal and technical advice) (1 national authority, 4 civic society, 3 railway sector business/associations)
- Increased complexity of procedures and administrative burden (2 civic society, 5 railway sector business/associations)
- Increased number of participants to be consulted in order to reach agreements (1 national authority)
- Lack of sufficient human resources in the Agency to tackle the new tasks (1 railway sector business/association).