

The 4th Railway Package

A guide for stakeholders

March 2020

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1. Foreword

Since 1991, the European railway sector is constantly being reformed by the European Union. The largest initiative is the 4th Railway Package, which was adopted in 2016. It is by far the largest and most complex legal initiative.

The 4th Railway Package consists of a political and a technical pillar which introduce substantial reforms for all stakeholders concerned.

The implementation of the political pillar is now completed. However, the implementation of the technical pillar is still in full swing. 8 out of 28 Member States have transposed the Directives and Regulations of the technical pillar by 16th June 2019, the remaining Member States will have to do so by 16th June this year.

Given the numerous initiatives launched by the European Commission and the European Union Agency for Railways as well as the scope of reforms, EIM has prepared this “Guide for Stakeholders” to explain the main political and technical reforms. It complements the information of the EU institutions and is meant to consolidate the understanding of the reforms.

The Guide has been written and designed for infrastructure managers, but it also takes a wider angle to address issues of other stakeholders in the rail market.

The first version of this Guide was drafted for the members of EIM in October 2017. This updated version is meant to serve all market actors in the best possible manner.

As usual, EIM guides are a collective exercise of the delegates, experts and the staff of EIM. We are keen to deliver high added value to our members but also our customers and other stakeholders. Therefore, your comments on how to further improve this guide and any of the information contained thereon are highly welcomed.

I personally invite you to also check our ‘knowledge station’ on our website www.eimrail.org.

Enjoy the read.



Monika Heimig
Executive Director

Brussels, March 2020

2. The 4th Railway Package

<p>What does it contain?</p>	<p>The 4th RP consists of various legal texts and documents¹. Only the directives and the regulations are mandatory for the sector:</p> <ul style="list-style-type: none"> - 3 directives; - 3 regulations; - 1 general communication; - 3 impact assessments; - 3 reports; - 3 staff working documents. <p>The 4th RP is split in two pillars:</p> <ol style="list-style-type: none"> 1. The political pillar addresses market opening (governance of rail infrastructure managers, tendering of public service contracts and access to national rail passenger markets); 2. The technical pillar addresses interoperability, safety authorisation, ERTMS track-side certification but also the reduction of national rules and the increased role of the EU Agency for Railways (ERA) to deliver authorisations and certifications.
<p>Why was it proposed?</p>	<p>The 4th Railway Package (RP) is meant to achieve the following objectives:</p> <ul style="list-style-type: none"> - Achieve cost reductions; - Remove administrative and technical barriers; - Increase competitiveness; - Accelerate the processes of vehicle authorisation and safety certification; - Harmonise the implementation of ERTMS. <p>The EC quantifies the benefits of the 4th RP on its website²:</p> <ul style="list-style-type: none"> - Over €40bn of financial benefits for citizens and companies by 2035 (combined with structural reforms); - Provision of up to about €16bn additional passenger-km; - 20% reduction in the time to market for new RUs³; - 20% reduction in the cost and duration for the authorisation of rolling stock; - Total savings for companies of €500 million until 2025.

¹ All documents are available via http://ec.europa.eu/transport/modes/rail/packages/2013_en.htm

² http://europa.eu/rapid/press-release_IP-13-65_en.htm

³ RUs = railway undertakings

<p>What are the milestones?</p>	<p>The overview of the milestones of the 4th RP is shown below:</p>		
	<p>4th Railway Package</p>	<p>Entry into force</p>	<p>Transposition</p>
	<p>Political pillar</p>		
	<p>DIR (EU) 2016/2370 'Governance'</p>	<p>24/12/2016</p>	<p>25/12/2018</p>
	<p>REG (EU) 2016/2338 'PSO'</p>	<p>24/12/2016</p>	<p>-</p>
	<p>Technical pillar</p>		
	<p>DIR 2016/797 'Interoperability'</p>	<p>26/05/2016</p>	<p>16/06/2019(*)</p>
	<p>DIR 2016/798 'Safety'</p>	<p>15/06/2016</p>	<p>16/06/2019(*)</p>
<p>REG (EU) 2016/796 'ERA'</p>	<p>15/06/2016</p>	<p>-</p>	
<p>(*) 16/06/2020 for some MSs</p>			
<p>Why is it important?</p>	<p>The 4th RP brought by substantial reforms:</p>		
	<ul style="list-style-type: none"> - New governance rules for the railway sector; - Increased scrutiny powers of the Regulatory Bodies; - Revised independence requirements between integrated and non-integrated infrastructure managers; - Liberalisation of national rail passenger markets; - Non-discriminatory access to rolling stock; - Shift of technical and safety rule-making from national to EU level with the ERA issuing single safety certificates and vehicle authorisations as well as ERTMS track-side tender approvals; - A new system of fees and charges of the ERA for its certification, authorisation and approval activities; - Reduction of national rules by the ERA; - Creation of new tools and processes by the ERA. 		

3. The Governance Directive (EU) 2016/2370

<p>How did the EU governance legislation evolve?</p>	<ul style="list-style-type: none"> - In 1991, the EC published Directive 91/1991/EEC to introduce the principle of accounting separation; - In 2001, the EC published the First Railway Package to trigger the liberalisation of the rail freight market. The package consisted of several Directives, of which 2001/12/EC and 2001/14/EC are the most relevant ones. Both introduced separation principles between IMs⁴ and RUs via stronger accounting separation as well as the definition of capacity allocation and charging as so-called ‘essential functions’ of IMs; - In 2012, the EC published Directive 2012/34/EU, consisting in a ‘Recast’ of the First Railway Package. It regulates the principles of fair access to the infrastructure and to rail-related services, the financial architecture of the IM and it further strengthens the powers of Regulatory Bodies.
<p>What is 2016/2370 about?</p>	<ul style="list-style-type: none"> - In 2016, the EC launched a substantial reform of the rail sector, not least to take stock of the various changes to EU legislation since 1991. - The so-called 4th Railway Package (RP) addresses this reform in the governance pillar via Directive EU 2016/2370. It amends ‘Recast’ Directive 2012/34/EU aiming at completing the Single European Railway Area. - It sets new common rules on: the governance of RUs and IMs, infrastructure financing and charging, conditions of access to railway infrastructure and services, the prohibition of access discrimination and the regulatory oversight of the rail market.
<p>What are the main changes?</p>	<p>The main changes in 2016/2370 are summarised below:</p> <ul style="list-style-type: none"> - New, enlarged, definition of “infrastructure manager”; - Stronger independence requirements for the infrastructure manager; - Principles of accounting separation and financial transparency; - Increased regulatory oversight; - Obligation for infrastructure managers to set-up coordination mechanisms with its stakeholders at least once a year; - Mandatory participation in the European network of infrastructure managers, called ‘PRIME’⁵.

⁴ IMs = infrastructure managers

⁵ PRIME (platform of rail infrastructure managers in Europe) was founded in 2013 by several rail infrastructure managers on a voluntary basis. With the adoption of the 4th Railway Package in 2016, the platform became a formal EU expert group, bringing together all EU rail infrastructure managers and the EU Commission. PRIME members exchange on issues of joint interest as well as ongoing and upcoming legislative initiatives related to rail infrastructure management. Since its set-up, PRIME is co-chaired by the EC and a high-level representative of a European IM. Further information can be consulted here: https://webgate.ec.europa.eu/multisite/primeinfrastructure/prime-news_en

<p>How has the concept of the IM evolved in 2016/2370?</p>	<p>The infrastructure manager is the body/firm responsible for:</p> <ul style="list-style-type: none"> - Charging: collection of track access charges; - Operation: path allocation; traffic management; - Maintenance: works to maintain the conditions and capability of the existing infrastructure; - Renewals: major substitution works on the existing infrastructure which do not change its overall performance. <p>In addition, the 4th Railway Package clarifies that the infrastructure manager is responsible for participating in the development of the railway network as determined by the Member State.</p>
<p>Which role will Regulatory Bodies have in the future?</p>	<p>Since 1991, the role of the Regulatory Bodies has been successively enlarged by the EC. The latest reform in 2016/2370 introduced substantial changes, which are also relevant for rail infrastructure managers:</p> <ul style="list-style-type: none"> - Power to adopt binding decisions, including power to impose penalties; - Broader number of issues under its remit, including: <ul style="list-style-type: none"> o Regulation of most of the activities of the IM; o Compliance checks of independence and transparency requirements. - Power to carry out audits; - Power to monitor financial flows; - Power to make information requests.
<p>What are coordination mechanisms?</p>	<p>Rail infrastructure managers will also have the responsibility to set up coordination mechanisms among themselves as well as vis-à-vis their customers.</p> <p>The scope of these mechanisms will have to cover the following aspects:</p> <ul style="list-style-type: none"> - The needs of applicants regarding maintenance and development of the infrastructure; - Multi-annual contracts between the government and the IM; - Network Statement; - Issues of intermodality and interoperability; - Conditions for access to and use of the infrastructure as well as of the quality of the services offered by the IM.
<p>Why does the EC address financial flows?</p>	<p>The EC also addressed the issue of financial flows between IMs and RUs in integrated railway groups to create a stronger level playing field between all IMs, whether they are separated or integrated.</p> <p>The new requirements on financial flows regulate 3 aspects:</p> <ul style="list-style-type: none"> - Income from the IM can be used only to finance the business of an IM; - Dividends can only be paid to the owner of the IM (including private shareholders) but not to entities which are part of a vertically-integrated undertaking (holding);

	<ul style="list-style-type: none"> - IMs and RUs may not grant loans to each other either directly or indirectly.
<p>Will the EC adopt further legal initiatives?</p>	<p>Yes, it will. In fact, 2016/2370 foresees that the EC shall adopt at least 4 'implementing acts':</p> <ul style="list-style-type: none"> - Implementing acts on the exclusion of regional/local rail infrastructure without strategic importance from the scope of the Directive (article 2(4) of 2016/2370) (implementing acts on a case-by-case basis⁶); - Implementing acts on the termination of the exemption for isolated railway lines of less than 500 km and with a different track gauge to that of the main domestic network from the scope of the Directive (article 2(8a) of 2016/2370); (implementing acts on a case-by-case basis⁷); - Implementing acts for the economic equilibrium test for new domestic passenger services (article 11(4) of 2016/2370). This implementing act can now be found under Commission Implementing Regulation (EU) 2018/1795⁸; - Implementing acts on common principles and practices for the Regulatory Bodies⁹ (cooperation, regulation of disputes, etc.) (article 57(8) of 2016/2370).
<p>What are the next steps?</p>	<ul style="list-style-type: none"> - By 31st December 2024, the Commission shall evaluate the impact of this Directive on the rail sector.

⁶ The implementing acts can be accessed via the EURLex website: <https://eur-lex.europa.eu>

⁷ The implementing acts can be accessed via the EURLex website: <https://eur-lex.europa.eu>

⁸ The implementing act can be accessed via the EURLex website: <https://eur-lex.europa.eu>. Search for "Commission Implementing Regulation (EU) 2018/1795"

⁹ This implementing act has not been published, yet. Once it is published, it can be accessed via the EURLex website: <https://eur-lex.europa.eu>

4. The PSO Regulation (EU) 2016/2338

<p>How did the EU PSO legislation evolve?</p>	<p>In 2007, the EC published its first regulation on PSO (public service obligation), i.e. 1370/2007 on the award of public service contracts for domestic rail passenger services.</p> <p>In 2016, it reviewed 1370/2007 with 2016/2338 as regards the award of public service contracts for domestic rail passenger services to ensure that the principle of competitive tendering is respected by limiting the cases of direct award and by granting the tools to:</p> <ul style="list-style-type: none"> - New entrant railway undertakings to compete (access to rolling stock and information); - Independent bodies and regulatory bodies to monitor the award (control of performance-based exemptions).
<p>What is 2016/2338 about?</p>	<p>The new PSO Regulation aims at:</p> <ul style="list-style-type: none"> - Facilitating the opening of the rail market for domestic/international passenger services; - Setting the principle that public service contracts for public passenger transport services should be awarded based on a competitive, transparent, non-discriminatory tendering procedure open to all operators.
<p>How will the new processes look like?</p>	<ul style="list-style-type: none"> - Competitive tendering will become the norm for public service contracts by December 2023; - If contracts are directly awarded between 2019 and 2023, they will have to include performance and quality targets.
<p>What are the main milestones for market opening?</p>	<ul style="list-style-type: none"> - December 2019: the principle of mandatory competitive tendering for public service contracts is enshrined but direct awards are still legal until 2023; - December 2023: competitive tendering becomes the norm. Direct awards are still possible until this date if duly justified and with a maximum duration of 10 years; - December 2033: no more direct awards in the market – if no exception applies.
<p>Will there be exceptions to the principle of competitive tendering?</p>	<p>Legislation will allow for several exceptions to the principle of competitive tendering of public service contracts:</p> <ul style="list-style-type: none"> - Existing exemptions: <ul style="list-style-type: none"> o De minimis¹⁰ – based on the value of the contract; o Emergency; o Exceptional circumstances; o In-house.

¹⁰ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Acc0016>

	<ul style="list-style-type: none"> - Performance-based exemption, in the case of <ul style="list-style-type: none"> o specific characteristics of the network or the rail market (e.g. complexity, technical / geographical isolation) and o improvement of performance (quality of service or cost-efficiency)
What is the contract value for which the exception would be allowed?	<p>There are two main thresholds for direct awards regarding PSOs:</p> <ul style="list-style-type: none"> ▪ average annual value of < 1.000.000 EUR ▪ public rail passenger transport services of < 7.500.000 EUR
Why does the Regulation regulate Rolling Stock?	<p>Regulation (EU) 2016/2338 aims at ensuring effective and transparent access to rolling stock, which remains one of the biggest sources of discrimination in the rail market;</p> <p>Competent authorities will now have the power to take all “appropriate measures” to enforce non-discriminatory access to rolling stock for all operators.</p>
What are the risks?	<p>Most of the EU Member States do not have significant experience with the competitive tendering process for public service contracts (PSC). So far, only the UK and Sweden have a proven track record with PSCs;</p> <p>Furthermore, competitive tendering processes risk to be a high administrative burden for Member States with smaller networks;</p> <p>Finally, the considerable number of exceptions which have been granted to competitive tendering may in the long-term jeopardise the effective liberalisation of passenger services in Europe.</p>
What are the next steps?	<p>Within six months after 25 December 2020, Member States shall provide the EU Commission with a progress report, highlighting the implementation of any award of public service contracts which complies with the new rules.</p>

5. The Interoperability Directive (EU) 2016/797

<p>How did the EU interoperability legislation evolve?</p>	<p>Technical interoperability is at the core of virtually every reform of the EU railway sector. To create the single European railway area with smooth cross-border train operations, the EU decided to impose the harmonisation of technical interfaces and subsystems in the form of technical specifications for interoperability¹¹.</p> <p>The first such Directive was adopted in 1996 with 1996/48/EC, which was amended 5 years later by 2001/16/EC, then amended 3 years later by 2004/50/EC, then again 4 years later by 2008/57/EC, then again in 2009 by 2009/131/EC and finally again in 2011 by 2011/18/EU.</p>
<p>What is 2016/797 about?</p>	<p>Directive 2016/797 extends the scope of interoperability while introducing a new process for European vehicle authorisations and for ERTMS trackside approvals. For that purpose, ERA has been given an enhanced role and is developing several new tools and processes, such as:</p> <ul style="list-style-type: none"> - A One-Stop-Shop (OSS)¹² as IT-portal for all stakeholders submitting their applications for vehicle authorisation; - A Board of Appeal (BoA)¹³ dealing with litigation issues; - Databases¹⁴, such as the Register of Infrastructure (RINF), the Single Rules Database (SRD), etc.
<p>What is the scope of 2016/797?</p>	<p>The Directive applies to:</p> <ul style="list-style-type: none"> - the entire Union rail system; - 'tram-trains' as far as they operate on rail infrastructure; <p>It does NOT apply to (unless a Member State decides otherwise):</p> <ul style="list-style-type: none"> - Local public transport systems (metros, trams and other light rail systems); - Privately owned railway infrastructure (incl sidings); - Local, historical or touristic infrastructure and vehicles; - Light rail infrastructure which are used occasionally; - Vehicles primarily used on light rail infrastructure.
<p>What are the main changes?</p>	<p>The main changes in 2016/797 are summarised below:</p> <p>ERA:</p> <ul style="list-style-type: none"> - The Agency will issue vehicle authorisations and approve ERTMS trackside tenders; <p>TSIs:</p> <ul style="list-style-type: none"> - The cases for possible non-application of TSIs is reduced; <p>RUS/IMs:</p> <ul style="list-style-type: none"> - The role of RUs and IMs in the technical route compatibility processes via the register of infrastructure ('RINF') is re-defined.

¹¹ <http://www.era.europa.eu/Core-Activities/Interoperability/Pages/TechnicalSpecifications.aspx>

¹² <https://oss.era.europa.eu/logon.html>

¹³ https://www.era.europa.eu/agency/board-appeal_en

¹⁴ https://www.era.europa.eu/registers_en

<p>How does the new processes look like?</p>	<p>Directive 2016/797 defines the procedure for vehicle authorisations and ERTMS track-side approvals:</p> <ul style="list-style-type: none"> - The final procedure for vehicle authorisation is defined in the VA implementation Regulation (EU) 2018/545 published on 4th April 2018 and the corresponding guidance¹⁵; - Directive 2016/797 foresees that all applications for national and international vehicle authorisations as well as for the approval of ERTMS track-side equipment tenders have to be submitted to the ERA via its IT portal (One-Stop-Shop, OSS)¹⁶; - The applicant can still choose the NSA as authorising entity if the area of use is limited to one Member State; - The ERA can outsource the processing of applications to individual experts via a pool of external experts (incl. those of NSAs); - The recommendation of NSAs involved in the application procedure will have to be taken into consideration by the ERA with all approvals; - The ERA invoices fees & charges for the processing of the applications following a pre-defined calculation method; - In the case of a positive opinion, the ERA will grant the vehicle authorisation or the approval of the ERTMS track-side component tender to the applicant; - Following the positive decision of the ERA, the NSA will then continue processing the ERTMS track-side equipment tendering.
<p>Is there a transition period?</p>	<ul style="list-style-type: none"> - During the first six months of 2019, the industry has been actively preparing for the transposition of the technical pillar of the 4th RP by June 2019. Only 8 Member States transposed the 4th Railway Package by 16th June 2019: Italy, the Netherlands, France, Bulgaria, Finland, Greece, Rumania and Slovenia. The remaining 18 EU Member States will have to transpose the Safety and Interoperability Directives by 16th June 2020. NB: Two Member States do not have a railway system (Malta and Cyprus). - Vehicle authorisations are amongst the lengthiest and costly processes in the railway sector (up to 2 years or more). With the new EU vehicle authorisation procedure since 16th June 2019, the ERA proposed a 1-year shadow-running phase, which started on 16th June 2018. - These are particularly important for all pending applications with NSAs and their further processing by the ERA from 16th June 2019 onwards. The ERA and virtually all NSAs have defined the modalities to transfer applications and the re-/processing by ERA of those parts already assessed by the NSAs. - In addition, ERA has signed a cooperation agreement with almost all national safety authorities.

¹⁵ For both procedures to work in practice, a so-called 'pre-engagement phase' (a sort of commitment on the date for submissions) has been designed but which can only be applied once the practical arrangements themselves have been agreed upon.

¹⁶ Directive 2016/797 stipulates that all applications, whether they are national or international, will have to be submitted and processed via the ERA IT tool. This will then also involve cases which are handled by national actors only (i.e. the NSA and the national applicant) for national vehicle authorisations. This will imply that NSAs review their processes.

<p>Which role do NSAs have?</p>	<ul style="list-style-type: none"> - The NSA will issue vehicle authorisations for single country applications (1 Member State only) when selected by the applicant; - The NSAs remain responsible for the supervision of the railway actors at national level; - For all other cases, the role of the NSA will be limited to the assessments for the defined area of use based on national rules (if any); - The same system of cooperation between the Agency and the NSA also exists for ERTMS track-side approvals. <p>☞ This 'dual system' requires that the ERA has concluded a cooperation agreement with each NSA.</p>
<p>How much does the new procedure cost?</p>	<ul style="list-style-type: none"> - The Interoperability Directive foresees that the ERA will charge for its services. - The Commission Implementing Regulation (EU) 2018/764¹⁷ was approved on 2nd May 2018, regulating the fees and charges payable to the European Union Agency for Railways and their conditions of payment.
<p>What is the role of the Appeal Body?</p>	<ul style="list-style-type: none"> - The Interoperability Directive stipulates that the ERA and the NSAs take full responsibility for the authorisations they issue; - In the case of litigations related to a vehicle authorisation, the applicant shall refer its case to a so-called 'Board of Appeal' of the ERA; - This body will be composed of experts which are appointed by the Management Board of the ERA (Member States/NSAs, EC, ERA); - In the case of diverging views between the ERA, the NSAs and/or the applicant, the Board of Appeal shall provide an opinion; - The ERA invoices fees & charges for the opinion of the Board of Appeal to the plaintiff. <p>The Commission Implementing Regulation (EU) 2018/867 was approved on 13th June 2018 laying down the rules of procedure of the Board(s) of Appeal of the European Union Agency for Railways.</p>
<p>What are the open issues?</p>	<p>There are several open issues:</p> <ul style="list-style-type: none"> - In 2018, the EC reduced the budget allocation for all EU agencies by 10%. This has an impact on available resources, the quality and quantity of vehicle authorisations to be processed, but also the future fees and charges invoiced by the ERA to the sector; - The transition in 2019 of only 8 Member States underscored the income forecast of the Agency; - Member States must have transposed Directive 2016/797 into national law to allow the sector to submit applications with the ERA; - The role of RINF in the route compatibility checks between RUs and IMs is considered to be insufficient;

¹⁷ <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv%3AOJ.L.2018.129.01.0068.01.ENG>

	<ul style="list-style-type: none"> - The sector (CER, EIM, UNIFE, EPTTOLA, UIRR, FEDECRAIL) published a ‘RINF Vision Paper’¹⁸ (www.grbrail.eu \ Position Papers) which has yet to be assessed by the EC and by ERA¹⁹; - National technical rules (NTRs) which have not been notified to the EC until 16th of June 2016 or do not comply with the new legislation and EU criteria will have to be deleted from the relevant register; - Furthermore, national rules should not only be reduced but replaced by a harmonised European solution. The Single Rule Database tool which is due to contain all national rules after the cleaning up process is still to be created. This may create an unclear framework which rules apply and are in line with EU legislation. <p>☞ According to the ERA, the number of NTRs was reduced from 14,312 in January 2016 to 1,026 in June 2019.²⁰</p>
<p>What are the next steps?</p>	<ul style="list-style-type: none"> - 16/06/2020: ERA to issue vehicle authorisations in all Member States which have transposed 2016/797 into national law on that date.
<p>How many applications did the Agency receive?</p>	<ul style="list-style-type: none"> - In September 2019, the ERA received a total of 183 requests, 172 for vehicle authorisation, 8 for safety certification and 3 pre-engagements for ERTMS trackside approval. - In February 2020, the ERA received 339 requests on conformity to type, 9 pre-engagement files and 7 new authorisations in the area of vehicle authorisations.

¹⁸ The RINF Vision Paper can be accessed here: www.grbrail.eu \ Position Papers. The main considerations are:

- Stabilisation and completion of the existing RINF;
- RINF is the tool to carry out the assessment of the route compatibility allowing the use of authorized vehicles;
- Insurance that RINF is sufficiently complete in due time with a proper level of data accurateness;
- After the full development of a new RINF 2.0, the switch towards the new version should be made without any negative consequences on the existing arrangements, with a clear cut-off plan agreed amid the actors;
- No use of RINF for cleaning up national rules.

¹⁹ Various IMs of EIM) consider that the requirements for technical compatibility of the vehicle with the network are part of the NTRs and should be fully transparent to allow the ERA, the NSA and the authorizing entity to exercise their respective role without the IM. In the case of a limitation of the IM to pre-engagement, there is a risk of a lack of knowledge of the NSA and the authorizing entity (e.g. in the case of changes to the vehicle).

²⁰ See the ERA report on the National Technical Rules published here: https://www.era.europa.eu/sites/default/files/activities/docs/evaluation_report_va_national_rules_en.pdf

6. The Safety Directive (EU) 2016/798

<p>How did the EU safety legislation evolve?</p>	<p>In 2004, the Railway Safety Directive 2004/49/EC was adopted to create a common European regulatory framework for safety, i.e. the tasks and responsibilities related to a safety management system (SMS).</p> <p>The Directive introduced common safety methods (CSMs) developed by ERA to provide a common approach to assess the level of safety and performance of all actors (RUs, IMs, wagon keepers, etc.) on EU and Member State level. It introduced a certification scheme for entities in charge of maintenance (ECM) of freight wagons and required Member States to develop a system of national safety rules.</p> <p>Directive 2004/49/EC was complemented by Directive 2008/57/EC (interoperability) and 2008/68/EC (inland transport of dangerous goods).</p> <p>The EC adopted EC Regulation 445/2011/EU to introduce a system of certification of entities in charge of maintenance for freight wagons.</p>
<p>What is 2016/798 about?</p>	<p>Directive 2016/798 extends the scope of safety whilst centralising supervision on EU level. This is achieved by making ERA the single body for granting the single safety certificate and by creating new bodies, tools and processes to allow ERA to exercise its new mandate.</p>
<p>What is the scope of 2016/798?</p>	<p>The Directive applies to:</p> <ul style="list-style-type: none"> - the entire Union rail system; - ‘tram-trains’ as far as they operate on rail infrastructure. <p>The Directive does NOT apply to²¹:</p> <ul style="list-style-type: none"> - Local public transport systems (metros, trams and other light rail systems); - Member States may exclude privately owned railway infrastructure (incl sidings), local, historical or touristic infrastructure and vehicles, light rail infrastructure occasionally used as well as vehicles primarily used on light rail infrastructure.
<p>What are the main changes?</p>	<p>The main changes in 2016/798 are summarised below:</p> <p>ERA:</p> <ul style="list-style-type: none"> - The Agency will issue the single safety certificate; - Clarification of the role and responsibilities of the railway actors; - National safety authorities continue to have a supervisory role. <p>RUs/IMs:</p> <ul style="list-style-type: none"> - Directive 2016/798 states clearly that “each actor is responsible for its own part in the railway system”, but the need for cooperation between RUs and IMs increases due to the number of interfaces that need to be addressed to ensure the railway being safe.

²¹ unless Member States decide otherwise

	<p>Safety Alerts IT Tool:</p> <ul style="list-style-type: none"> - In September 2016, ERA launched a Safety Alerts IT Tool (SAIT). However, an improved interface between European and national occurrence reporting should be achieved with the 'Information Sharing System' as part of the CSM on ASLP²² (see below). <p>Common Safety Methods for the Assessment of the Safety Level and Safety Performance – CSM ASLP:</p> <ul style="list-style-type: none"> - Art. 6 (1)(d) of Directive 2016/798 provides the legal basis for a new CSM “for assessing the safety level and the safety performance of railway operators at national and Union level”. - The ERA plans to submit its final CSM recommendation by December 2020 to the EC, which would then be followed by a 3-months public consultation. The final publication is due by end of 2021.
<p>How do the processes look like?</p>	<ul style="list-style-type: none"> - The implementing act on practical arrangements for the single safety certification applies on 16th June 2019²³; - The implementing act on practical arrangements foresees that all applications for national and international safety certifications will have to be submitted to the ERA via its One-Stop-Shop (OSS); - The ERA will be responsible for multi-country safety certifications (the single safety certificate) and can also be responsible for single country safety certificates - if the applicant chooses so; - The ERA can outsource the processing of the applications to individual experts via a pool of external experts (incl. those of NSAs); - The recommendation of NSAs involved in the application procedure will have to be taken into consideration by the ERA for all approvals; - The ERA invoices fees & charges for the processing of the applications for safety certification following a pre-defined calculation method; - In the case of a positive opinion, the ERA will grant the safety certification to the applicant and allocates a so-called EIN (European Identification Number)²⁴.
<p>Which role do NSAs have?</p>	<ul style="list-style-type: none"> - The NSAs will issue safety certifications for single country applications (one Member State only) - if selected by the applicant; - The concrete role of the NSAs in the safety certification procedure consists in checking the application as regards their respective national part. For this system to work, the ERA must have concluded a cooperation contract with each NSA; - NSAs will keep the supervision role, which consists in overseeing the continued compliance with all legal obligations by RUs and IMs to use a SMS (safety management system), in line with the CSM developed by the ERA; - NSAs will have to exchange information and coordinate their supervision activities for international operations of the RUs with the Agency; - NSAs will also have to exchange information with the ERA as regards their supervision activities;

²² ASLP = Assessment of the Safety Level and Safety Performance

²³ or on 16th June 2020 in case of a one-year extension granted by the EC to a Member State

²⁴ https://www.era.europa.eu/sites/default/files/registers/docs/technical_doc_ein_codification_en.pdf

	<ul style="list-style-type: none"> - NSAs will also have to report to the ERA within the scope of the new mandate of the ERA to monitor and audit them (as well as other bodies, such as ECMs, NoBos²⁵, etc.).
<p>How much does the new procedure cost?</p>	<ul style="list-style-type: none"> - The ERA Regulation foresees that ERA will invoice the applicant for the services provided under the Safety Directive; - The rules for fees and charges are laid down in Commission Implementing Regulation (EU) 2018/764. It is noted that procedures for the assessment of SMS already exists in the EU and for which fees & charges are levied by NSAs.
<p>What is the role of the Appeal Body?</p>	<ul style="list-style-type: none"> - The Safety Directive requires that the ERA and the NSAs take full responsibility for the certifications they issue; - In the case of litigations related to a safety certification, the applicant shall refer its case to a so-called 'Board of Appeal'²⁶ of the ERA; - This body is composed of experts, appointed by the Management Board of the ERA (Member States/NSAs, EC, ERA); - In the case of diverging views between the ERA, the NSAs and / or the applicant, the Board of Appeal shall provide an opinion; - The ERA invoices fees & charges for the opinion of the Board of Appeal to the plaintiff.
<p>What are the open issues?</p>	<p>There are several open issues:</p> <ul style="list-style-type: none"> - The EU has reduced the budget allocation for all EU agencies by 10%. This has an impact on ERA in terms of available resources, the quality and quantity of vehicle authorisations to be processed but also the fees and charges which ERA will invoice to the applicants; - The EU is empowered to adopt implementing and delegated acts and to change TSIs, CSMs or safety certification processes. This 'secondary act' follows a shorter timescale and a 'limited' consultation procedure. This means that changes may be more frequent, making the legal and technical framework less predictable; - Member States must have agreed on the date for the transition period; - Member States must have transposed Directive 2016/798 into national law to allow the sector to submit applications for safety certification with the ERA; - National safety rules (NSRs) which have not been included in the revision of TSI OPE or notified to the EC until 16th of June 2016 or which do not comply with the new legislation and EU criteria have to be deleted from the relevant register. Furthermore, national rules should not only be reduced but replaced by a harmonised European solution. The Single Rules Database (SRD)²⁷, which shall contain all national rules after the cleaning up process, is still pending. This may create an unclear situation regarding which rules apply and are in line with EU legislation; - Current agreements of non-EU Member States (e.g. Switzerland, Norway, others) with EU Member States regulating safety certification

²⁵ NOBO = notified body. For further information on NoBos, please consult: https://www.era.europa.eu/activities/conformity-assessment_en; https://www.era.europa.eu/agency/stakeholder-relations_en#meeting2; <file:///C:/Users/direction/Downloads/NB-RAIL%20Coordination%20Group%20Rules%20of%20Operations.pdf>

²⁶ https://www.era.europa.eu/agency/board-appeal_en

²⁷ https://www.era.europa.eu/activities/national-rules_en

	<p>will become void and require these non-EU Member States to conclude an agreement directly with the ERA by June 2020.</p> <ul style="list-style-type: none"> - ERA's IT portal One Stop Shop (OSS) must be fully operational and stable to process all applications for safety certification.
<p>What are the next steps?</p>	<ul style="list-style-type: none"> - 16/06/2020: ERA will issue safety certificates in all Member States which have transposed 2016/797 into national law on that date.

7. The ERA Regulation (EU) 2016/796

<p>How did the EU legislation for the ERA evolve?</p>	<p>The European Railway Agency (ERA) was set up by means of Regulation (EC) no 881/2004 in April 2004 with the aim to improve interoperability and safety of the European rail network. Its main tasks are to harmonise, register and monitor TSIs across the entire European rail network and to set common safety targets for the European railways.</p> <p>In 2006, the EC adopted a decision concerning mandates to ERA for developing TSIs under Directive 2001/16/EC and common safety methods and common harmonised requirements for safety certification under Directive 2004/49/EC.</p> <p>In 2007, the EC adopted a decision concerning a framework mandate to ERA for the performance of certain activities under Directives 96/48/EC and 2001/16/EC.</p> <p>Regulation (EC) no 1335/2008 assigned new tasks to the ERA in response to the changes made to the Railway Safety Directive 2004/49/EC and to the Railway Interoperability Directive 2008/57/EC.</p> <p>In 2010, the EC adopted a decision concerning a mandate to ERA to develop and review TSIs with a view to extending their scope to the entire rail system in the EU.</p>
<p>What is 2016/796 about?</p>	<p>Regulation 2016/796 extends the mandate and tasks of the ERA in line with the scope of Directive 2016/797 (Interoperability Directive) and Directive 2016/798 (Safety Directive).</p> <p><i>De jure</i>, the Agency has become an authority responsible for issuing authorisations for the placing on the market of railway vehicles and vehicle types, for issuing single safety certificates for railway undertakings in the entire European Union and for granting ERTMS trackside approvals.</p> <p>With this new Regulation the Agency has also become the ERTMS system authority.</p> <p>The Agency has also received the mandate to reduce the number of the national technical rules (NTRs).</p>
<p>What are the main changes?</p>	<p>The main changes in 2016/796 are summarised below:</p> <p>ERA:</p> <ul style="list-style-type: none"> - The ERA is a legal body on its own; - The ERA is the only body to issue EU-wide vehicle authorisations, approvals of ERTMS track-side equipment tenders and safety certificates; - The ERA invoices fees & charges for its authorisations, approvals and certificates as well as for its support tools (IT tools, etc.); - The ERA has become the system authority for all registers and databases related to 2016/797, 2016/798 and 2007/59/EC²⁸) and for ERTMS;

²⁸ Directive on the certification of train drivers operating locomotives and trains in the EU railway system

	<ul style="list-style-type: none"> - The ERA can issue opinions, recommendations, technical documents, reports and guidelines; - The ERA has the mandate to supervise and audit NSAs (national safety authorities), ECMS (entities in charge of maintenance), NoBos (notified bodies), as well as to monitor the SMSs (Safety Management Systems) of IMs and RUs; - The role and powers of the ERA to issue and apply EU rules as well as to reject national rules have been strengthened; - The ERA can conclude agreements with non-EU countries (cooperation agreements, etc.); - The ERA will be involved in R&D. <p>Member States:</p> <ul style="list-style-type: none"> - The powers of the Member States to issue and apply national technical and safety rules are reduced while those of the ERA have been strengthened. <p>Registers:</p> <ul style="list-style-type: none"> - The role of the infrastructure register ('RINF') has been strengthened and will be used for pre-operational route compatibility checks; - The ERA will set up a new tool for change control management (CCM) related to the telematic TSIs (TAF and TAP); - The European vehicle register (EVR) must include information²⁹ relevant for people with reduced mobility (PRM) and will incorporate all national vehicle registers; - The ERA will have to develop a single rules database (SRD)³⁰ which will replace several existing registers (Reference Document Database (RDD) and Notification IT (NOTIF-IT)). <p>Other tools</p> <ul style="list-style-type: none"> - The Agency developed the one-stop-shop tool as electronic portal to submit applications for safety certification, vehicle authorisation and ERTMS trackside approval; - The ERA developed a new 'instrument' for the exchange of safety-related information between the different actors and bodies³¹ (COR SAIT and COR SMD).
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²⁹ This information shall consist - at least - of the technical characteristics, including vehicle identification, Member State of registration, Member States where the vehicle is authorised, manufacturing, references to EC declarations of verification, EC declaration of verification issuing body (the applicant), owner, keeper, ECM, registration status, authorisations for placing on the market, conditions for use of the vehicle and other restrictions on how the vehicle may be used, and those related to accessibility for persons with disabilities and persons with reduced mobility.

³⁰ The ERA will continue to use some current databases, such as the RDD (reference document database) during the process of cleaning up of rules for vehicle authorisations, even after the single rules database has become operational. For safety rules and rules related to fixed installations, NOTIF-IT will be used, together with a tool based on the already available bulk upload tool. This will encourage Member States to submit "cleaned" rules to NOTIF-IT. Once all the rules are fully cleaned, the ERA will proceed with the development of the single rules database (SRD) and the migration to RDD and NOTIF-IT, in line with the requirements of the 4th Railway Package.

³¹ These tools already exist, although their modalities, such as the 'common safety methods on the 'Assessment of Safety Level and Safety Performance' (CSM ASLP), the 'common occurrence reporting' system (COR) and the 'Safety Alert IT-tool' (SAIT). All aim to increase the safety level in the railway sector via comprehensive information gathering and analysis.

<p>How will the future processes look like?</p>	<ul style="list-style-type: none"> - The relevant processes related to vehicle authorisations, approvals of ERTMS track-side equipment tenders and safety certificates are described in the previous chapters.
<p>Will there be a transition period?</p>	<ul style="list-style-type: none"> - No, as a Regulation applies on the date of its entering into force.
<p>How much will the new procedure cost?</p>	<ul style="list-style-type: none"> - The ERA invoices fees & charges for vehicle authorisations, ERTMS trackside approvals and safety certificates issued by its services; - Furthermore, the ERA is expected to apply indirect costs related to applications, such as the usage and maintenance costs of the IT tool Ones Stop Shop (OSS); - The Commission Implementing Regulation (EU) 2018/764 on the fees and charges payable to the ERA and their conditions of payment was published on 2nd May 2018³².
<p>Which role will NSAs have in the future?</p>	<ul style="list-style-type: none"> - The ERA needs to conclude cooperation agreements with the respective NSA in every EU and some non-EU countries; - These cooperation agreements also require the NSA to accept the ERA audit and monitoring tools; - NSAs will have to adapt their respective systems and processes, especially as regards the processing of national applications which must be processed through the ERA IT portal.
<p>What is the role of the Appeal Body?</p>	<ul style="list-style-type: none"> - In the case of litigations related to a safety certification, vehicle authorisation or ERTMS trackside approval, the applicant shall refer its case to a so-called 'Board of Appeal' of the ERA; - This body will be composed of experts which are appointed by the Management Board of the ERA (Member States/NSAs, EC, ERA); - In the case of diverging views between the ERA, the NSAs and / or the applicant, the Board of Appeal shall provide an opinion; - The ERA invoices fees & charges for the opinion of the Board of Appeal to the plaintiff; - The Commission Implementing Regulation (EU) 2018/867 laying down the rules of procedure of the Board(s) of Appeal of the European Union Agency for Railways was published on 13th June 2018.
<p>What are the open issues?</p>	<p>There are several open issues which have been outlined in the previous chapter already. In essence, the main concerns / issues are:</p> <ul style="list-style-type: none"> - Insufficient budget allocation for ERA which may have an impact on the quality and quantity of all authorisations, approvals and certificates to be used by the ERA; - Impact of the budget allocation on the future ERA fees and charges related to the above; - The cooperation of the ERA with the NSAs in these processes (time, double work, competence, redundancies, re-assessments, etc.);

³² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R0764>

	<ul style="list-style-type: none"> - The timely and smooth delivery of various generic processes and IT tools by the ERA; - The new tools developed by the ERA (i.e. common occurrence reporting tool, etc.); - The impact of the ERA on national rules; - The cooperation agreements of the ERA with non-EU Member States.
<p>What are the next steps?</p>	<ul style="list-style-type: none"> - 16/06/2020: ERA to issue vehicle authorisations, ERTMS trackside approvals and safety certificates in all Member States; - 16/06/2021: European Vehicle Register (EVR) expected to be operational.
<p>How has the Agency adapted the internal organisation to the 4th Railway Package?</p>	<ul style="list-style-type: none"> - The ERA has created the Railway Systems Department³³ which forms the core of ERA's system competence. - It is divided into three different units: <ul style="list-style-type: none"> o The Safety and Operations Unit; o The Rolling Stock and Fixed Installations Unit; o The ERTMS & Telematics Unit.

³³ https://www.era.europa.eu/agency/organisation_en

8. Abbreviations

CER	Community of European Railways
COR	Common Occurrence Reporting
CSM	Common Safety Method
DIR	Directive
EC	European Commission
ECM	Entity in Charge of Maintenance
EIM	European Association of Rail Infrastructure Managers
EPTTOLA	European Passenger Train & Traction Operating Lessors' Association
ERA	European Union Agency for Railways (now EUAR)
ERTMS	European Rail Traffic Management System
EUAR	European Union Agency for Railways (former ERA)
EVR	European Vehicle Register database
FEDECRAIL	European Federation of Museum & Tourist Railways
4RP	4 th Railway Package
IM	Infrastructure Manager
MS	Member State
NoBo	Notified Body
NOTIF-IT	Notifications using Information Technology
NSA	National Safety Authority
NSR	National Safety Rule
NTR	National Technical Rule
OSS	One Stop Shop
PSC	Public Service Contracts
PSO	Public Service Obligation
RDD	Reference Document Database
REG	Regulation
RINF	Register of Infrastructure
RU	Railway Undertaking
SAIT	Safety Alerts Information Tool
SMD	Safety Management Data
SMS	Safety Management System
SRD	Single Rules Database
TAF	Telematics Application Freight
TAP	Telematics Application Passenger
UIRR	International Union for Road-Rail Combined Transport.
UNIFE	European rail industry

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