

Making the railway system  
work better for society.

## 4<sup>th</sup> Railway Package

### What is the 4<sup>th</sup> Railway Package and its technical pillar?

The 4<sup>th</sup> Railway Package is a set of legislative texts designed to complete the single market for rail services (Single European Railway Area). Its overarching goal is to revitalise the rail sector and make it more efficient and therefore competitive vis-à-vis other modes of transport. It comprises a technical pillar and a market pillar which have been negotiated largely in parallel.

The 'technical pillar', which entered into force on 15 June 2016, includes:

- *Regulation (EU) 2016/796 on the European Union Agency for Railways (also known as ERA) and repealing Regulation (EC) n° 881/2004*
- *Directive (EU) 2016/797 on the interoperability of the rail system within the European Union (Recast of Directive 2008/57/EC, also known as Interoperability Directive)*
- *Directive (EU) 2016/798 on railway safety (Recast of Directive 2004/49/EC, also known as Railway Safety Directive)*

Further information on the legislation can be found on EUR-LEX website: <https://eur-lex.europa.eu>, where it is possible to read the above legal texts in any EU official language.

### What are the benefits of the technical pillar of the 4<sup>th</sup> Railway Package?

The technical pillar is designed to boost the competitiveness of the railway sector by significantly reducing the costs and the administrative burden for railway undertakings wishing to operate across Europe. In particular, it will:

- *save rail companies from having to file costly multiple applications in the case of operations beyond one single Member State. ERA will issue vehicle authorisations for placing on the market and safety certificates for railway undertakings, valid throughout the European Union. Today, railway undertakings and manufacturers needed to be certified separately by each relevant national safety authority*
- *create a "One-Stop Shop" which will act as a single entry point for all such applications, using easy, transparent and consistent procedures*
- *ensure that European Rail Traffic Management System (ERTMS) equipment is interoperable*
- *reduce the large number of remaining national rules, which create a risk of insufficient transparency and disguised discrimination against new operators.*

### What are the main changes?

- *ERA has a role in issuing safety certificates and vehicle authorisations and in that regard, can levy fees and charges relating to the processing of applications*
- *All applications for safety certificates, vehicle authorisations and ERTMS trackside approval are to be submitted through the information and communication system managed by ERA ('One-stop shop')*

- *The applicants for a safety certificate, vehicle authorisation or ERTMS trackside approval may request a review of the decision taken by ERA and where relevant, lodge an appeal before the Board of Appeal of ERA*
- *ERA, acting already as the system authority supporting harmonised implementation of ERTMS in the European Union, has a role in the approval of ERTMS trackside solution,*
- *The role of railway undertakings and infrastructure managers in the technical route compatibility processes via the register of infrastructure ('RINF') is re-defined,*
- *The need for cooperation between the different actors of the railway system becomes very important due to the number of interfaces that need to be addressed to ensure a safe railway*

### **Who will be affected by the changes?**

The changes brought by the technical pillar of the 4<sup>th</sup> Railway Package will affect anyone who:

- *manufactures or modifies railway vehicles*
- *authorises vehicles and fixed installations and grants safety certificates*
- *operates trains*
- *manages infrastructure*
- *regulates railway safety or interoperability.*

### **When do the new processes apply?**

The Member States shall transpose the 4<sup>th</sup> Railway Package by the 16<sup>th</sup> of June 2019 or, if notified to the Commission and ERA, by the 16<sup>th</sup> of June 2020. During the period between these two dates, it is possible that different legal regimes will be in place in adjacent countries. This will affect the arrangements for the assessment of applications for vehicle authorisations or safety certificates. If you are affected by this, you are invited to talk to your national safety authority or ERA about your options.

### **What is the pool of experts?**

ERA can identify the need to call for external experts in order to assist it in its assessment tasks after receiving an application for a vehicle authorisation or a safety certificate. External experts may be staff members of the national safety authorities designated by their employer or independent experts. In both cases, those experts must fulfil the same competency requirements.

### **How much do I pay ERA for my vehicle authorisation, safety certificate or ERTMS trackside approval?**

[Regulation \(EU\) 2018/764](#) lays down the fees and charges payable to the Agency for the processing of applications (single safety certificates, vehicle authorisations, ERTMS trackside approval).

## Vehicle authorisation

### When does a vehicle need to be authorised?

A new railway vehicle must be authorised before it can be placed on the market.

If a vehicle is already authorised but is subsequently changed then a new authorisation for placing on the market is required if:

- *the parameters affecting technical compatibility between the vehicle and the area of use have been changed*
- *the overall safety level may be adversely affected by the change*
- *the relevant TSI require it.*

### What is the requirement for a type to be authorised?

A new vehicle type must be authorised. Where changes are made to the type, be it a change to the applicable rules that requires a new authorisation, a change to the design (dependent on the scale of the change) or a change to the area of use, the type requires another authorisation.

### Does a vehicle need to be authorised to be used for tests on the network?

Temporary authorisation to use the vehicle for tests on the network is only required where specified by the Member State's legal framework. In such a case, the national legal framework should specify the process to be followed.

Even where there is no requirement for temporary authorisation the risks of operating a vehicle that is being used for tests have to be managed, which – in addition to temporary authorisation where applicable – normally involves a combination of

- *application of the railway undertaking's safety management system*
- *assessment of the safety risks relating to the use of a vehicle that has not yet been confirmed to comply fully with the essential requirements and*
- *conducting the tests on the network in accordance with the infrastructure manager's arrangements for tests on the network.*

### To whom should I apply for a vehicle authorisation?

The application is made through the One-stop shop. When the area of use is limited to one Member State the applicant chooses the authorising entity responsible for issuing the authorisation, to be either the Agency or the national safety authority for the Member State. In all cases where the authorisation is for vehicle having an area of use covering more than one Member State the authorising entity is the Agency.

In the case of an authorisation in conformity to type, it is beneficial if the authorising entity is the same entity that issued the vehicle type authorisation.

Where the applicant has a choice of authorising entity and has made its selection, the applicant is not able to change its choice unless the initial application is terminated and the applicant triggers a new application to the other authorising entity. In such a case, the applicant has to restart the whole authorisation process from the beginning.

### **How does the Agency take account of local factors relevant to my authorisation?**

Where the Agency is authorising entity it is required to consult the concerned national safety authority for the area of use, who checks aspects of the application applicable to the area of use that falls within its Member State.

### **How long does it take for an application to be processed?**

The authorising entity is required to carry out a completeness check of the application within one month, and to make a decision no later than four months after acknowledging the file is complete. This time scale may be extended if the assessment has to be suspended in order for the applicant to resolve a justified doubt. The time scale for a suspension is agreed with the applicant and is proportionate to the difficulty of providing the information requested to address the justified doubt.

### **Do I have to use English when I apply for authorisation?**

If the application is for an area of use limited to one Member State and the national safety authority is the authorising entity then the provisions for language in the relevant national legal framework apply. The language policy should be indicated in the application guide produced by that national safety authority.

In other cases the application and the file accompanying the application may be submitted by the applicant in any one of the official languages of the Union. Nonetheless the Agency and the national safety authorities concerned with the area of use can request that the applicant translates parts of the file accompanying the application. In order to reduce the need for translation and to facilitate exchanges during the assessment it is recommended to use English or a commonly agreed language for the assessment of the application. When applicable the choice of language for the assessment should be made during pre-engagement.

### **What is pre-engagement?**

Pre-engagement is an optional stage that comes before the submission of an application for authorisation, where the applicant submits details of its proposed application so that a baseline can be agreed at an early stage in the process of developing the application. The benefits can include:

- *facilitating early contact between the parties*
- *developing the relationship between the authorising entity, the concerned national safety authorities for the area of use and the applicant*
- *verifying that the applicant has been provided with sufficient information so that it knows what is expected from it, including establishing the scope of the application*
- *reaching a common understanding for the interpretation of the applicable rules (in particular transition clauses) to establish the baseline for the applicable rules and*
- *making it clear how the vehicle authorisation process will be conducted and how decisions will be made.*

### **When would an application be rejected?**

An application would be rejected if the applicant did not address a matter identified by the authorising entity and/or concerned national safety authorities for the area of use as a “type 4” issue, within the timeframe set by the entity raising the issue.

A “type 4” issue raises a serious concern on the content of the application file, such that it needs to be amended before the authorisation decision can be made.

**What can I do if I disagree with the decision?**

The applicant may use the one-stop shop to request a review of the decision within one month from the date of receipt. The request shall include a list of issues that have not been properly taken into consideration during the process. The review shall be concluded within two months of the date of receipt of the request.

**What different kinds of authorisation are available?**

‘First authorisation’ applies to a new vehicle type – including variants and versions – and the first vehicle of a new vehicle type

‘Renewed vehicle type authorisation’ is used when the design of a vehicle type has not changed but there is a change to the applicable rules that includes a requirement for renewal of the authorisation. The scope of the authorisation is limited to the changed rules.

‘Extended area of use’ is required where the design of the vehicle has not changed but the area of use is extended.

‘New authorisation’ applies when a change has been made to an already authorised vehicle and/or vehicle type that requires authorisation. The scope of the authorisation is limited to the changes.

‘Authorisation in conformity to type’ is used for a vehicle or a series of vehicles that conform to an already authorised and valid vehicle type. The authorisation is given on the basis of a declaration of conformity to that type.

**What does it mean to be the holder of the vehicle type authorisation**

The holder of the vehicle type authorisation is the person that has applied for and received the vehicle type authorisation, or its legal successor. They are responsible for the configuration management of the vehicle type.

The holder of the vehicle type authorisation is considered to be capable of managing changes to the type that do not require authorisation in accordance with the criteria set out in Article 21(12) of [Directive \(EU\) 2016/797](#). Where changes are made to an authorised vehicle type that introduce a deviation from the technical files accompanying the EC declarations for verification for the subsystems, and those changes are made by someone who is not the holder of the vehicle type authorisation, then a new vehicle type shall be created and the entity managing the change shall become the applicant. If an authorisation is given that person becomes the holder of the type authorisation for the new vehicle type.

Similarly, where changes are made to an already authorised vehicle that introduce a deviation from the technical files accompanying the EC declarations for verification for the subsystems but do not require authorisation in accordance with the criteria set out in Article 21(12) of [Directive \(EU\) 2016/797](#), and those changes are made by someone who is not the holder of the vehicle type authorisation, then the entity making the changes is required to notify the authorising entity of the changes that have been made. The holder of the vehicle type authorisation is not required to submit such notifications.

**Where a new type arises from a change, is the holder of the vehicle type authorisation responsible for the unchanged aspects of the design?**

The applicant becomes the new holder of the modified type, and is responsible for the modification and its safe integration. The new holder of the type is responsible for the whole type, for example it is responsible for making changes according to TSIs when relevant.

The arrangements are intended to allow people other than the original designer to change older vehicles. If original documentation from previous regime isn't fully available the process can still be applied in this way.

### **Are there other tasks to be performed after authorisation in order to use a vehicle?**

For authorisation the applicant demonstrates the compatibility of the vehicle with the networks of the area of use.

After authorisation, route compatibility is checked by evaluating vehicle data against the information from the Register of Infrastructure and/or the infrastructure manager. These are simple cross-checks. Some particularities of a network may require tests, but this should be seen as an exception

### **What is the role of the Notified Body (NoBo) in monitoring changes to the vehicle type during the manufacturing process?**

NoBos have to apply surveillance and audits of manufacturing process according to the relevant modules defined in [Commission decision 2010/713/EU](#). The NoBo has to be informed if changes are made that affect the manufacturing process; it checks that certificates remain valid.

### **Where will the vehicle be defined?**

The vehicle will be defined in ERATV, also the requirement freeze will happen there. ERATV is currently undergoing some technical re-development in order to harmonise it with the One-stop shop.

### **Is there a type authorisation for the control-command and signalling subsystems?**

No, type authorisation only applies to vehicles.

### **Can an authorisation be revoked?**

An authorisation can be revoked as a temporary safety measure applied by the authorising entity. The criterion for revocation is that the vehicle type (i.e. the design) is proven not to have met the essential requirements at authorisation. Revocation is therefore an action to be taken to deal with defective design or manufacture of a vehicle type or vehicles of a vehicle type. It is not to be used in the case of failure to meet the essential requirements due to actions or inactions of the safety management system of the railway undertaking or entity in charge of maintenance (e.g. a safety management system that does not properly control maintenance leading to vehicles no longer meeting the essential requirements).

In case of a revocation of a vehicle type authorisation there is no automatic revocation of the vehicle authorisation for placing on the market for vehicles of that type. The decision to revoke vehicle authorisation(s) for placing on the market for vehicles belonging to a vehicle type for which the authorisation has been revoked should be taken on a case by case basis.

## Safety certification

### To whom should I apply for a safety certificate?

The application is made through the One-stop shop. When the area of operation is limited to one Member State the applicant chooses the safety certification body responsible for issuing the safety certificate, to be either the Agency or the national safety authority for the Member State. In all cases where an area of operation covers more than one Member State the safety certification body is the Agency.

Where the applicant has a choice of safety certification body and has made its selection, the applicant is not able to change its choice unless the initial application is terminated and the applicant triggers a new application to the other safety certification body. In such a case, the applicant has to restart the whole safety certification process from the beginning.

### How long does it take for an application to be processed?

The safety certification body is required to carry out a completeness check of the application within one month, and to make a decision no later than four months after acknowledging the file is complete. This time scale may be extended if the assessment has to be suspended. The time scale for a suspension is agreed with the applicant and the national safety authorities concerned with the area of operation and is proportionate to the difficulty of providing the information requested.

### Do I have to use English when I apply for a safety certificate?

If the application is for an area of operation limited to one Member State and the national safety authority is the safety certification body then the provisions for language in the relevant national legal framework apply. The language policy should be indicated in the application guide produced by that national safety authority.

In other cases the application and the file accompanying the application may be submitted by the applicant in any one of the official languages of the Union. Nonetheless the national safety authorities concerned with the area of operation can request that the applicant translates parts of the file accompanying the application (i.e. the evidence demonstrating compliance with the notified national rules). In order to reduce the need for translation and to facilitate exchanges during the assessment it is recommended to use English or a commonly agreed language for the assessment of the application. When applicable the choice of language for the assessment should be made during pre-engagement.

### What is pre-engagement?

Pre-engagement is an optional stage that comes before the submission of an application for safety certificate, where the applicant submits details of its proposed application so that a baseline can be agreed at an early stage in the process of developing the application. The benefits can include:

- *facilitating early contact between the parties*
- *developing the relationship between the safety certification body, the concerned national safety authorities for the area of operation and the applicant*
- *verifying that the applicant has been provided with sufficient information so that it knows what is expected from it, including establishing the scope of the application*
- *reaching a common understanding for the interpretation of the applicable rules (in particular transition clauses) to establish the baseline for the applicable rules and*
- *making it clear how the safety certification process will be conducted and how decisions will be made.*



## What is the evidence should the safety certification body expect for checking compliance with Technical Specifications for Interoperability (TSIs)?

The railway undertaking is expected to provide evidence on:

- *the decision processes for triggering application of the TSIs (within change control management and, identification of relevant TSIs (in addition to national technical rules and other standards)*
- *the process for implementing, and ongoing monitoring of relevant TSIs (national technical rules and other standards), where appropriate showing how these are applied throughout the lifecycle of any equipment or operation*
- *how the safety management system facilitates corrective action when it is found that standards and other requirements are not being adhered to.*

## Could a new railway undertaking who never operated before be granted a safety certificate?

The safety certification body should during the assessment take into account the fact that it is impossible to verify all aspects of the new railway undertaking's safety management system. It should then factor on the railway undertaking's capability to operate and that its safety management system provides evidence of this. Subsequently after the award of the certificate the relevant national safety authority, based on the outcome of the assessment, may wish to put a higher priority on the supervision of the new railway undertaking to ensure that the safety management system is adequate in controlling the risks and confirm its ability to operate safely (e.g. during the first year following the granting of the safety certificate the national safety authority undertakes targeted audits/inspections).

## Does the safety certification body have the right to request (supplementary) information after receiving the application for safety certification or to perform audits or inspections in railway undertaking's premises?

[Regulation \(EU\) 2018/763](#) empowers the safety certification and the national safety authority (or authorities) concerned by the intended area of operation to undertake audits and inspections on the sites of applicants for a safety certificate.

They may also request for any supplementary information during the assessment.

## Which information should be included in the application for a safety certificate?

The content of an application for a safety certificate is specified in Annex I to [Regulation \(EU\) 2018/763](#). The required information shall be provided by an application for a safety certificate by filling in the electronic forms in the One-stop shop.

## Can a safety certification body rely on an external assessment for the granting of safety certificate?

The safety certification body is responsible for the safety certificate it issues. Nonetheless, the safety certification body can delegate some of its assessment tasks to external experts. The safety certification body must ensure that the experts are competent enough for performing the delegated tasks. In any case, the safety certification body takes the final decision over the issue of the safety certificate.

## Is a network statement sufficient to demonstrate co-operation between railway undertaking and infrastructure manager?

The network statement aims to provide all current and potential railway undertakings wishing to operate train services on the infrastructure with a single source of relevant information on a fair and non-discriminatory basis. The network statement is intended to fulfil the requirements of [Directive 2012/34/EU](#).



In the present context, “co-operation” means the need for and commitment from the railway undertaking and the infrastructure manager to co-operate on issues where they have shared interfaces that are likely to affect the putting in place of adequate risk control measures. The management of shared risks associated with the activity of the railway undertaking and the infrastructure manager is a key element of their safety management system.

The detailed co-operation arrangements resulting from the management of shared risks does not necessarily appear in a network statement.

### **What are the mandatory certifications for railway undertakings?**

The EU regulatory framework only requires for a safety certificate for those railway undertakings seeking to be granted access to the railway infrastructure. Should a railway undertaking plays another role in the railway system (e.g. entity in charge of maintenance), it may be required to provide other certificates, authorisations, etc.

### **Should a licence and/or safety certificate be issued for shunting operations?**

All those companies (i.e. railway undertakings as defined in [Directive 2012/34/EU](#)) whose principal business is to provide transport services must hold a licence. Those companies which carry out rail transport services but not as a principal activity are not required to obtain a licence.

However, the safety on the whole rail system must be respected by any company that uses the rail system (irrespective of whether it is a principal activity of the company or not). Therefore the requirements of the Railway Safety Directive (e.g. safety certification, SMS) applies also to those companies which are otherwise not licensed and would not fall under [Directive 2012/34/EU](#).