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 (Text with EEA relevance)

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union[(1)], and in particular Article 21(9) thereof,

Whereas:

(1) The practical arrangements for the vehicle authorisation process referred to in Directive (EU) 2016/797 should reduce the complexity, length and cost of the vehicle authorisation process, provide uniform conditions for harmonising the vehicle type authorisation and/or vehicle authorisation for placing on the market in the Union and foster collaboration among all the parties involved in the vehicle authorisation process. In order to reduce length and cost of the vehicle authorisation process, the time frames should practically be kept as short as possible.

(2) Taking into account the experience gained by national safety authorities ('NSAs') in the authorisation process and in the preparation of the cooperation agreements referred to in Article 21(14) of Directive (EU) 2016/797, early contact with the applicant in the form of coordination ('pre-engagement') is recognised as good practice to facilitate the development of the relationship between the parties involved in the vehicle authorisation process. Such pre-engagement should be offered before an application for a vehicle type authorisation and/or vehicle authorisation for placing on the market is submitted, with the aim of enabling the authorising entity and the concerned NSAs for the area of use to become familiar with the project. In order for the applicant to be aware of what to expect, that pre-engagement should clarify to the applicant the applicable rules, provide the applicant with the details of the vehicle authorisation process, including the process of decision-making, and verify that the applicant has received sufficient information. The applicant is responsible for ensuring that all the requirements are met when submitting its application for vehicle type authorisation and/

or vehicle authorisation for placing on the market. In performing its duties, it is assisted by other entities such as conformity assessment bodies, suppliers and service providers.

(3) With a view to providing economies of scale and reducing administrative burden, vehicle type authorisation should enable the applicant to produce a number of vehicles of the same design and facilitate their authorisation. The vehicle type identifies the design that will be applied to all vehicles corresponding to that type. Every new vehicle type should follow the process of authorisation and a new type should only be created if it is authorised.

(4) The concepts of variant and version of a vehicle type should be introduced in order to provide the possibility of identifying options for configuration or changes during the life cycle of the vehicle within an existing type, the difference between variants and versions being that variants require an authorisation while versions do not.

(5) In order to ensure that the vehicle type continues to meet the requirements over time and that any changes to the design that affects the basic design characteristics are reflected as new variants and/or versions of the vehicle type, the process of configuration management of the vehicle type, should be used. The entity responsible for the configuration management of the vehicle type is the applicant that received the vehicle type authorisation.

(6) As far as vehicles are concerned, it is necessary to have a configuration management process limited to changes that are not managed through the configuration management process of an authorised vehicle type.

(7) The European Union Agency for Railways (the 'Agency') should set up guidelines describing, and where necessary, explaining the requirements set out in this Regulation. The guidelines should be updated, published and made available to the public free of charge. With the aim of harmonising the approach to the exchange and recording of information through the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796 of the European Parliament and of the Council[(2)], the guidelines should also include model templates set up by the Agency in cooperation with the NSAs.

(8) The Agency and the NSAs should implement internal arrangements or procedures to ensure that the requirements of the vehicle authorisation process are fulfilled.

(9) Considering that return of experience is recognised as a good practise, the NSAs and the Agency should be encouraged to share any related relevant information. With a view to provide such service, the Agency should establish a protocol and procedures for the recording and exchange of information among the Agency and NSAs.

(10) To avoid any duplication of assessment and to reduce the administrative burden and cost for the applicant, the Agency and the NSAs should take into account the cooperation agreements and multilateral agreements concluded pursuant to Article 21(14) and (15) of Directive (EU) 2016/797, where relevant.

(11) The Agency and the NSAs should register all relevant information and the documented reasons for the decision in the one-stop shop, in order to justify the decisions at each stage of the vehicle authorisation process. If the Agency and the NSAs have their

own information management systems for the purposes of the assessment, they should ensure that all relevant information is transferred to the one-stop shop for the same reasons. In order to facilitate the communication between the interested parties, the guidelines of the Agency and the NSAs should provide practical arrangements for those communications which are not relevant for the decision-making process and which therefore do not need to be submitted through the one-stop shop.

(12) Where the intended area of use for the vehicle type is limited to a network or networks within one Member State, the authorisation is valid without extension of the area of use for vehicles travelling to stations in neighbouring Member States with similar network characteristics, when those stations are close to the border. In such a case, the applicant may submit their application for a vehicle type authorisation and/or vehicle authorisation for placing on the market to the Agency or the NSA. Where the Agency acts as the authorising entity it is to consult the relevant NSAs in accordance with Article 21(8) of Directive (EU) 2016/797 and take into account the relevant cross-border agreements.

(13) Where the Agency acts as the authorising entity, the applicant should, without prejudice to the provisions of point 2.6 of Annex IV to Directive (EU) 2016/797, have the right to submit its application to the Agency in one of the official languages of the Union. During the course of the assessment, the NSAs should have the right to address documents pertaining to the assessment to the Agency in a language of its Member State, without any obligation to translate them.

(14) The Agency and the NSAs should develop internal arrangements or procedures for managing the issuing of vehicle type authorisations and/or vehicle authorisations for placing on the market with a view to reducing the administrative burden and costs for the applicant. In that respect, the applicant should have the possibility to submit copies of documents in the application file. The original documents should be available for verification by the Agency and the NSAs following the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market.

(15) It is necessary to harmonise the categorisation of issues in the assessment process to ensure that the applicant understands the severity of any issues raised by the Agency or by a NSA. That categorisation is particularly important when several NSAs are involved in the process. In order to facilitate the vehicle authorisation process and to reduce administrative burden in cases where there are no applicable national rules, the Agency's consultation with the concerned NSAs for the area of use should be limited to the check of the correct specification of the area use for the Member State concerned. In cases where the technical specifications for interoperability (‘TSIs’) contain specific provisions, the area of use should be able to cover the whole Union network and the checks performed by the Agency should be sufficient.

(16) Vehicles and vehicle types are to remain authorised in accordance with Article 54(2) of Directive (EU) 2016/797 without prejudice to Article 21(12) and 24(3) of that Directive. In the case of renewal or upgrading of those vehicles, the provisions of this Regulation are to apply in accordance with Article 21(12) of Directive (EU) 2016/797.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/545. (See end of Document for details)*

(17) According to Article 54(4) of Directive (EU) 2016/797, the new vehicle authorisation regime is to start from 16 June 2019. However, Member States have the possibility to notify the Agency and the Commission pursuant to Article 57(2) of that Directive that they have extended the transposition period and may in consequence continue to issue vehicle type authorisation and/or vehicle authorisation for placing on the market in accordance with Directive 2008/57/EC of the European Parliament and of the Council[(3)] until 16 June 2020. Between 16 June 2019 and 15 June 2020, two different legal regimes where the authorising entities are different could coexist. It is therefore necessary to clarify how the new regime should apply in addition to the old one where the intended area of use includes one or more of those Member States.

(18) Where a NSA recognises that it will not be able to issue a vehicle type authorisation/ vehicle authorisation for placing in service in accordance with Directive 2008/57/EC before either 16 June 2019, or 16 June 2020 in respect of those Member States that have notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797, the Agency, when acting as authorising entity, should accept the results of the assessment of the NSA in order to avoid any duplication of assessment and additional burden and any delay for the applicant.

(19) In order to facilitate the placing on the market of the vehicles and to reduce administrative burdens, a vehicle type authorisation and/or vehicle authorisation for placing on the market issued by the Agency should be recognised as equivalent to vehicle type authorisation referred to Article 26 of Directive 2008/57/EC and vehicle authorisation for placing in service referred to in Articles 22 and 24 of Directive 2008/57/EC.

(20) TSIs in accordance with Article 4(3)(f) of Directive (EU) 2016/797, as well as national rules, should foresee a gradual transition, in particular taking into account projects at an advanced stage of development as defined in Article 2(23) of Directive (EU) 2016/797.

(21) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 21 of Council Directive 96/48/EC[(4)],

HAS ADOPTED THIS REGULATION:

CHAPTER 1

GENERAL PROVISIONS

Article 1

Subject matter and scope

1 This Regulation lays down requirements to be complied with by:

a the applicant, when submitting, through the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796 of the European Parliament and of the Council, an application for vehicle type authorisation and/or vehicle authorisation for placing on the market;

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/545. (See end of Document for details)*

b the Agency and the NSAs, when processing an application for vehicle type authorisation and/or vehicle authorisation for placing on the market and in relation to pre-engagement;

c the authorising entity, when deciding on the issuing of vehicle type authorisations or vehicle authorisations for placing on the market.

d the infrastructure managers, when providing conditions for the carrying out of tests in their network(s) and providing information for the vehicle authorisation regarding the area of use.

2 This Regulation shall apply without prejudice to Article 21(16) and (17) of Directive (EU) 2016/797.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) ‘authorising entity’ means the entity that issues the vehicle type authorisation and/or vehicle authorisation for placing on the market;

(2) ‘basic design characteristics’ means the parameters that are used to identify the vehicle type as specified in the issued vehicle type authorisation and recorded in the European Register of Authorised Vehicle Types (‘ERATV’).

(3) ‘configuration management’ means a systematic organisational, technical and administrative process put in place throughout the lifecycle of a vehicle and/or vehicle type to ensure that the consistency of the documentation and the traceability of the changes are established and maintained so that:

(a) requirements from relevant Union law and national rules are met;

(b) changes are controlled and documented either in the technical files or in the file accompanying the issued authorisation;

(c) information and data is kept current and accurate;

(d) relevant parties are informed of changes, as required;

(4) ‘date of receipt of the application’ means:

(a) where the Agency acts as the authorising entity, the first working day common to the Agency and to the NSAs concerned with the intended area of use following the acknowledgement of receipt of the application;

(b) where a NSA acts as the authorising entity, the first working day in the Member State concerned following the acknowledgement of receipt of the application;

(5) ‘entity managing the change’ means the holder of the vehicle type authorisation, the keeper or the entity entrusted by them.

(6) ‘holder of the vehicle type authorisation’ means the natural or legal person that has applied for and received the vehicle type authorisation, or its legal successor;

(7) ‘justified doubt’ means an issue classified as ‘type 4’ according to Article 41(1)(d), with a justification and supporting evidence, raised by the authorising entity and/or