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Guide

Guidelines for the practical arrangements for the vehicle authorisation process

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The present document is a non-legally binding guidance of the European Railway Agency. It is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

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0. Summary table

This table gives an overview of the different practical cases that are expected to be experienced by the applicants and summarises their link to the authorisation cases found in the Implementing Regulation (EU) 2018/545. It also provides, for each case, information to applicants about the need to submit an application for authorisation via the OSS, the tasks that need to be performed and the documentation to be included in the file accompanying the application. The cases are also identified in the flowchart for substage 1-1.

This synthesis table should be seen as giving a consolidated overview of the process and an introduction to the practical arrangements for vehicle authorisation (Implementing Regulation and guidelines) for prospective applicants. The table has been drafted by the Group of Representative Bodies (GRB) with the aim of providing a 'quick start' entry point for applicants to the practical arrangements.

It should be noted that the table gives a legally non-binding overview for the different cases. The legally binding provisions are to be found in the Directive (EU) 2016/797 and in the Implementing Regulation (EU) 2018/545. Supportive references and remarks have been made in the table to assist applicants in finding the related content of the Directive and the Implementing Regulation (including guidelines).

Table 0 : Summary table

Table case	Description of the case	Authorisation case following article 14(1) of IR	Submit an application?	Include requirements capture evidence in the application? (5)	Involve Conformity Assessment Bodies (NoBo & DeBo)?	Involve an assessment body (CSM RA)? (3)	Include the technical files accompanying the EC DoFV in the application?	Include the EC DoFV in the application?	Include the proposer declaration (article 16 of CSM RA; Annex I 18.10/18.12 of IR) in the application? (3)	Remarks - Specific Requests	Authorisation to be issued by the Authorising Entity
1a	Vehicle type authorisation (for a new vehicle type) (AG 3.2.2.19 & 3.3.2.1)	First authorisation (IR article 14(1)(a))	Yes	Yes	Yes	Yes	Yes	Yes	Yes	The applicant may choose to authorise the new type without an authorisation for placing on the market of the first vehicle at the same time. (AG 3.2.2.15)	Vehicle type authorisation (IR article 48) (AG 3.8.2 & Annex IV)
1b	Vehicle authorisation for placing on the market (for the first vehicle of a type) (AG 3.2.2.19 & 3.3.2.1)	First authorisation (IR article 14(1)(a))	Yes	Yes	Yes	Yes	Yes	Yes	Yes	An application for authorisation for placing on the market for the first vehicle of a type will result in both the vehicle type authorisation and the authorisation for placing on the market of the first vehicle. This is done in a single application. (ID article 24(2))	Vehicle type authorisation and/or vehicle authorisation for placing on the market (IR articles 48 & 49) (AG 3.8.2, 3.8.3, Annex IV & Annex V)
2a	Authorisation in conformity to a type (Delivery of a series of vehicles) (ID article 25) (AG 3.2.2.15 and 3.3.2.1)	Authorisation in conformity to type (IR article 14(1)(e))	Yes	No (5) The process for requirements capture should also cover the manufacturing phase	Yes Manufacturing phase to be under the surveillance of Conformity Assessment Body(es) (2010/713/EU)	No As long as the aspects related to safety and safe integration between subsystems for the manufacturing phase were already covered by the requirements capture related to the vehicle type / type authorisation and there are no changes in the manufacturing process	No	Yes The EC Declaration(s) of verification are part of the associated documentation to the declaration of conformity to type	No The proposer needs to establish a risk declaration covering the manufacturing phase	Evidence to provide: declaration of conformity to type (and associated documentation) and decisions for non-application of TSIs (IR annex I §18.3 & 18.4) (AG Annex I) The process for requirements capture shall also cover the manufacturing process, however this evidence is not required in the application	Vehicle authorisation for placing on the market (IR article 49) (AG 3.8.3 & Annex V)
2b	Changes to an already authorised vehicle to bring it in conformity to another type version/variant (ID article 25) (AG 3.2.2.15 & 3.3.2.3)	Authorisation in conformity to type (IR article 14(1)(e))	Yes	No (5) The process for requirements capture should also cover the manufacturing phase	Yes Manufacturing phase to be under the surveillance of Conformity Assessment Body(es) (2010/713/EU)	No As long as the aspects related to safety and safe integration between subsystems for the manufacturing phase were already covered by the requirements capture related to the vehicle type / type authorisation and there are no changes in the manufacturing process	No	Yes The EC Declaration(s) of verification are part of the associated documentation to the declaration of conformity to type	No The proposer needs to establish a risk declaration covering the manufacturing phase	Evidence to provide: declaration of conformity to type (and associated documentation) and decisions for non-application of TSIs (IR annex I §18.3 & 18.4) (AG Annex I) The process for requirements capture shall also cover the manufacturing process, however this evidence is not required in the application. Description in AG 3.3.2.3 - 'Bringing a vehicle in conformity to another authorised vehicle type version and/ or vehicle type variant of the vehicle type'	Vehicle authorisation for placing on the market (IR article 49) (AG 3.8.3 & Annex V)
3	Changes in the TSI or National rules pursuant to ID article 24(3) which does not require a change in the design of the vehicle type (AG 3.3.2.1 & 3.3.3)	Renewed vehicle type authorisation (ID article 24(3)) (IR article 14(1)(b))	Yes	No (5)	Yes	Depends on the nature of the changed rules (3) (4)	Yes	Yes	Yes (4) If an assessment body (CSM RA) is involved, the proposer needs to establish a risk declaration	Scope of the evidence to be included in the file accompanying the application for authorisation limited to the changed rules. (ID article 24(3)) The renewal of vehicle type authorisation only requires verification of the changed parameters for which the new rule renders the existing vehicle type invalid	Vehicle type authorisation (IR article 48) (AG 3.8.2 & Annex IV)
4	Extended area of use without a change in the design (ID article 21(13)) (AG 3.3.2.1, 3.3.2.2, 3.6.2 & 3.6.3)	Extended area of use (IR article 14(1)(c))	Yes	Yes	Yes	Yes	Yes	Yes	Yes	The checks to be performed by the authorising entity for an authorisation extending the area of use of a vehicle type should be limited to checking that the original vehicle type authorisation still is valid and the technical compatibility between the vehicle and the network for the extended area of use. Checks already carried out at the first authorisation should not be repeated (AG 3.3.2.1) Possibility for the holder to choose to ask for a new type or to create a new variant of the existing type (IR article 14(2)) (AG 3.3.2.2)	Vehicle type authorisation and/or vehicle authorisation for placing on the market covering the extended area of use (IR articles 48 & 49) (AG 3.8.2, 3.8.3, Annex IV & Annex V)

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5a (8)	Extended area of use including a change in the type design which requires a new authorisation (ID article 21(13)) (AG 3.3.2.1, 3.3.2.2, 3.6.2 & 3.6.3) Same holder	New authorisation and extended area of use (IR articles 14(1)(c), 14(1)(d) & 14(2) & 14(3))	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	This is effectively a combination of cases 4 and 6. The application for the combined new and extended area of use authorisations could be sent at the same time in a single OSS application (IR article 14(3)) (AG 3.3.2.1) Possibility for the holder to choose to ask for a new type or to create a new variant of the existing type (IR article 14(2)) (AG 3.3.2.2)	Vehicle type authorisation and/or vehicle authorisation for placing on the market, covering the changes and the extended area of use (IR articles 48 & 49) (AG 3.8.2, 3.8.3 Annex IV & Annex V)
5b (8)	Extended area of use including a change in the type design which requires a new authorisation (ID article 21(13)) (AG 3.3.2.1, 3.3.2.2, 3.6.2 & 3.6.3) New holder	New authorisation and extended area of use (IR articles 14(1)(c), 14(1)(d), 14(2), 14(3) & 15(4))	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	This is effectively a combination of cases 4 and 7. The application for the combined new and extended area of use authorisations could be sent at the same time in a single OSS application (IR article 14(3)) (AG 3.3.2.1) Creation of a new vehicle type by the new holder (IR article 15(4)) (AG 3.3.2.2)	Vehicle type authorisation and/or vehicle authorisation for placing on the market, covering the changes and the extended area of use (IR articles 48 & 49) (AG 3.8.2, 3.8.3 Annex IV & Annex V)
6	Change to the basic design characteristics or vehicle's safety level beyond the criteria of ID article 21(12): <ul style="list-style-type: none"> parameters outside acceptable range in the TSIs the overall safety level of the vehicle may be adversely affected requested by the relevant TSI (ID article 21(12)) (IR article 15(1)(d)) Same holder	New authorisation (IR articles 14(1)(d),14(2) & 14(3))	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	Possibility for the holder to choose to ask for a new type or to create a new variant of the existing type (IR article 14(2)) (AG 3.3.2.2)	Vehicle type authorisation and/or vehicle authorisation for placing on the market covering the changes (IR articles 48 & 49) (AG 3.8.2, 3.8.3, Annex IV & Annex V)
7	Change to the basic design characteristics or vehicle's safety level beyond the criteria of ID article 21(12): <ul style="list-style-type: none"> parameters outside acceptable range in the TSIs the overall safety level of the vehicle may be adversely affected requested by the relevant TSI (ID article 21(12)) (IR article 15(1)(d)) New holder	New authorisation (IR articles 14(1)(d), 15(1)(d), 15(4) & 16(3))	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	Creation of a new vehicle type by the new holder (IR article 15(4)) (AG 3.3.2.2)	Vehicle type authorisation and/or vehicle authorisation for placing on the market covering the changes (IR articles 48 & 49) (AG 3.8.2, 3.8.3, Annex IV & Annex V)
8	Change to the basic design characteristics or vehicle's safety level not beyond the criteria of ID article 21(12): <ul style="list-style-type: none"> parameters outside acceptable range in the TSIs the overall safety level of the vehicle may be adversely affected requested by the relevant TSI (ID article 21(12)) (IR article 15(1)(c)) Same holder	N/A (IR article 15(1)(c), 15(2))	No	N/A (5)	Yes (1)	Yes (6)	N/A (1)	N/A (2)	N/A (7)	Type holder will keep available the relevant information upon request of the authorising entity, NSAs, the Agency or Member States (ID Annex IV §2.6) (IR article 15(2)) Create a new vehicle type version or a new version of a vehicle type variant and provide the relevant information to the authorising entity. The authorising entity shall register in ERATV the new version of the vehicle type or the new version of the vehicle type variant (IR article 15(3)) (AG 3.3.2.2 case c) Applicant may want an assessment body (CSM RA) to provide a judgement that change is not beyond criteria, however this is not mandatory	The authorising entity shall register in ERATV the new version of the vehicle type or the new version of the vehicle type variant, using the information provided by the holder of the vehicle type authorisation (IR article 15(3))

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9a	Change to the basic design characteristics or vehicle's safety level not beyond the criteria of ID article 21(12): <ul style="list-style-type: none"> parameters outside acceptable range in the TSIs the overall safety level of the vehicle may be adversely affected requested by the relevant TSI (ID article 21(12)) (IR article 15(1)(c)) New holder Change to vehicle(s) only (IR article 16) (AG 3.3.2.3)	N/A unless requested by the authorising entity within 4 months of notification of changes (IR article 16(4))	No	N/A (5)	Yes (1)	Yes (6)	N/A (1)	N/A (2)	N/A (7)	The entity managing the change must notify the changes to the authorising entity. This may apply to a vehicle or a number of identical vehicles. The authorising entity may issue, within 4 months, a reasoned decision requesting an application for authorisation in case of a wrong categorisation or insufficiently substantiated information. Notification to be made by means of a dedicated IT tool (AG 3.3.2.3)	N/A
		New authorisation if requested by the authorising entity within 4 months of notification of changes (IR articles 14(1)(d) & 16(4))	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	New holder must notify the changes to the authorising entity. This may apply to a vehicle or a number of identical vehicles. The authorising entity may issue, within 4 months, a reasoned decision requesting an application for authorisation in case of a wrong categorisation or insufficiently substantiated information. Creation of a new vehicle type by the new holder (IR article 15(4)) (AG 3.3.2.2)	Vehicle type authorisation and/or vehicle authorisation for placing on the market (IR articles 48 & 49) (AG 3.8.2, 3.8.3 Annex IV & Annex V)
9b	Change to the basic design characteristics or vehicle's safety level not beyond the criteria of ID article 21(12): <ul style="list-style-type: none"> parameters outside acceptable range in the TSIs the overall safety level of the vehicle may be adversely affected requested by the relevant TSI (ID article 21(12)) (IR article 15(1)(c)) New holder Change to vehicle type only and/or vehicle type and vehicle(s)	New authorisation (IR articles 14(1)(d), 15(4)(d))	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	Creation of a new vehicle type by the new holder (IR article 15(4)) (AG 3.3.2.2)	Vehicle type authorisation and/or vehicle authorisation for placing on the market (IR articles 48 & 49) (AG 3.8.2, 3.8.3 Annex IV & Annex V)
10	Change that introduces deviation from the technical file but does not trigger the criteria of ID article 21(12) (IR articles 15(1)(b) & 16(2)) (AG 3.3.2.1) Same holder	N/A (IR article 15(1)(b))	No	N/A (5)	Yes In case of impact on conformity assessments already performed and need for new checks and verifications (AG 3.3.2.2 cat.b)	Yes (6)	N/A	N/A (2)	N/A (7)	Type holder will keep available the relevant information upon request of the authorising entity, NSAs, the Agency or Member States (ID Annex IV §2.6) (IR article 15(2)) Applicant may want an assessment body (CSM RA) to provide a judgement that change is not beyond criteria, however this is not mandatory	N/A

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11a	Change that introduces deviation from the technical file but does not trigger the criteria of ID article 21(12) (IR articles 15(1)(b) & 16(2)) (AG 3.3.2.1) New holder Change to vehicle(s) only (AG 3.3.2.3)	N/A unless requested by the authorising entity within 4 months of notification of changes (IR article 16(4))	No	N/A (5)	Yes (1)	Yes (6)	N/A	N/A (2)	N/A (7)	The entity managing the change must notify the changes to the authorising entity. This may apply to a vehicle or a number of identical vehicles. The authorising entity may issue, within 4 months, a reasoned decision requesting an application for authorisation in case of a wrong categorisation or insufficiently substantiated information. Notification to be made by means of a dedicated IT tool (AG 3.3.2.3)	N/A
		New authorisation if requested by the authorising entity within 4 months of notification of changes (IR articles 14(1)(d) & 16(4))	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	New holder must notify the changes to the authorising entity. This may apply to a vehicle or a number of identical vehicles. The authorising entity may issue, within 4 months, a reasoned decision requesting an application for authorisation in case of a wrong categorisation or insufficiently substantiated information. Creation of a new vehicle type by the new holder (IR article 15(4)) (AG 3.3.2.2)	Vehicle type authorisation and/or vehicle authorisation for placing on the market (IR articles 48 & 49) (AG 3.8.2, 3.8.3 Annex IV & Annex V)
11b	Change that introduces deviation from the technical file but does not trigger the criteria of ID article 21(12) (IR articles 15(1)(b) & 16(2)) (AG 3.3.2.1) New holder Change to vehicle type only and/or vehicle type and vehicle(s)	New authorisation (IR articles 14(1)(d), 15(4)(d))	Yes	Yes	Yes (1)	Yes	Yes (1)	Yes (2)	Yes	Creation of a new vehicle type by the new holder (IR article 15(4)) (AG 3.3.2.2)	Vehicle type authorisation and/or vehicle authorisation for placing on the market (IR articles 48 & 49) (AG 3.8.2, 3.8.3 Annex IV & Annex V)
12	Change to an authorised vehicle type or vehicle that does not introduce a deviation from the technical files (IR article 15(1)(a)) (AG 3.3.2.1)	N/A (AG 3.3.2.2)	No	N/A (5)	No	No	N/A	N/A	N/A	Need to update configuration management of the vehicle and/or vehicle type	N/A
13	Changes to an already authorised vehicle which are linked to substitution in the framework of maintenance with no change to design/functions (IR article 16(1))	N/A	No	N/A (5)	No	No	N/A	N/A	N/A	Need to update configuration management of the vehicle	N/A
14 (8)	If tests are necessary on the network to obtain evidence of technical compatibility and safe integration of subsystems, and/or technical compatibility with the network (ID article 21(3) & 21(5)) (IR article 19)	N/A Temporary authorisation to use the vehicle for tests on the network issued by the NSA when it is required and specified in the national legal framework of the Member State. (AG 3.3.5)	No				Depending on the national legal framework of the Member State			Should be covered by the Safety Management System of the RU that will operate the test vehicle(s) to perform a risk assessment (AG 3.3.5(a) & (c))	Temporary authorisation issued by the NSA

Legend:
ID - Interoperability Directive (EU) 2016/797
IR - Implementing Regulation (EU) 2018/545
AG - Guidelines for the practical arrangements for the vehicle authorisation process
CSM RA – Implementing Regulation (EU) 402/2013

- Notes :**
- (1) Only the changes and their interfaces with the unchanged parts are to be subjected to the EC verification procedure, covered by the requirements capture process and assessed by the authorising entity and the NSAs for the area of use (where applicable), according to ID Annex IV §2.3.3 (see also AG 3.3.2.1 & 3.3.2.2)
 - (2) Applicant to decide if there is a need to establish a new or an updated declaration, according to ID article 15(5)
 - (3) Assessment body (CSM RA) to be involved in:
 - assessing the requirements capture process for the essential requirement safety and the safe integration between subsystems
 - when the nature of the changes require the application of the Regulation (EU) 402/2013 for a significant change
 - when the mandatory rules explicitly require the application of the Regulation (EU) 402/2013
 - (4) The changes and/or the changed rules may require the application of the risk assessment process set-out in Regulation (EU) 402/2013. In this case, there is a need for involving an assessment body (CSM RA) and the proposer shall establish a risk declaration following article 16 of the Regulation (EU) 402/2013. This will depend on the nature of the change and the changed rules.
 - (5) The requirements capture process should be performed always, no matter of the authorisation case. However, depending on the case, the documentation related to the requirements capture process performed by the applicant does not need to be submitted to the authorising entity
 - (6) Assessment body (CSM RA) to assess requirements capture (confirmation that the process followed by the applicant is enough to ensure that the changes do not have the potential to affect adversely safety)
 - (7) The proposer needs to establish a risk declaration
 - (8) Not covered in flowchart for substage 1-1

1. Introduction

1.1. Background

The 4th Railway Package introduces important changes to the interoperability regulatory framework of the European Union, including the process of issuing vehicle authorisations. These changes are accompanied by the new allocation of tasks and responsibilities between the Agency and the national safety authorities (NSAs).

The recast interoperability directive, Directive (EU) 2016/797 provides two paths for implementation of the vehicle authorisation process, either through the Agency, for the purpose of issuing vehicle authorisations when the area of use is more than one Member State or one Member State when the applicant requests so, or through an individual national safety authority, for the purpose of issuing vehicle authorisation with an area of use limited to one Member State.

The vehicle authorisation process, irrespectively of the selected path, should be managed at various levels, including specific legislation, related guidelines and internal procedures as well as cooperation agreements to be signed off between the Agency and the individual national safety authorities.

The simplified diagram outlining the hierarchy of identified levels on which the vehicle authorisation process should be managed is presented below.

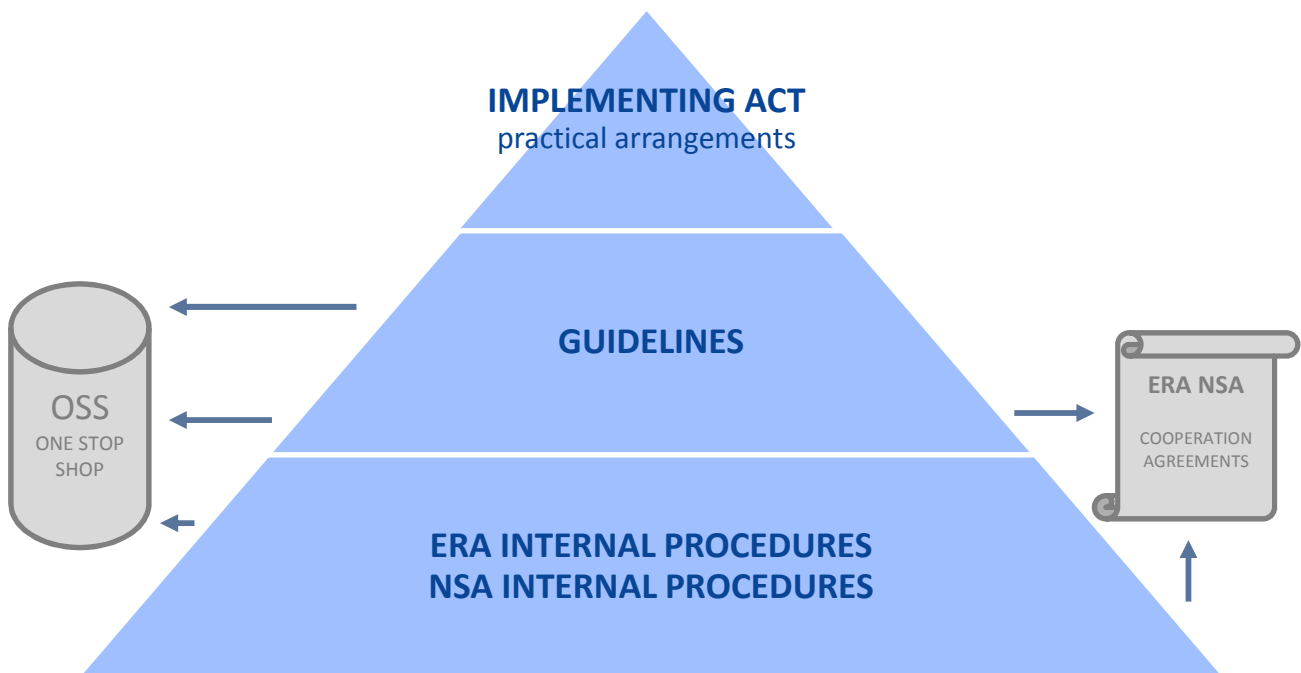


Figure 1: Hierarchy of the levels on which the vehicle authorisation process is to be managed

The breakdown of the requirements covering the vehicle authorisation process between the levels indicated on the diagram reflects following logic:

- › Within the first level, to be covered by the new implementing act “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”, the practical arrangements specifying detailed rules on the vehicle authorisation procedure are set.
- › Within the last two levels, covered by non-legislative documents, including guidelines and internal procedures, the provisions supporting the applicants in the application and authorisation process as well as the provisions detailing internal organisation of the vehicle authorisation process at the level of the Agency and at the level of the individual national safety authorities are defined.

- › Cooperation agreements, as requested by Article 21(14) of Directive (EU) 2016/797 complement the above levels with provisions essential for the effective implementation of the vehicle authorisation process when the close cooperation between different bodies (i.e. the Agency and the relevant national safety authorities) is required.

1.2. Legal base

The Agency has a general obligation to provide technical support in the field of railway interoperability, according to articles 4(i) and 19(3) of Regulation (EU) 2016/796. This includes that the Agency may issue guidelines to facilitate the implementation of railway interoperability legislation. In addition Article 8(1) of the Commission Implementing Regulation (EU) 2018/545 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation specifies that:

'The Agency shall set up, publish and keep up to date guidelines describing and explaining the requirements set out in this Regulation, and make them available to the public free of charge, in all the official languages of the Union. The guidelines shall also include model templates that may be used by the authorising entity and the NSAs for the area of use for the exchange and recording of information and model templates for the application that may be used by the applicant.'

1.3. Scope

The scope of the Commission Implementing Regulation (EU) 2018/545 covers authorisations for area of use:

- › For one or more Member States that are to be issued by the Agency; and
- › That are limited to the network(s) within one Member State where the applicant can request that the authorisation is issued by the National Safety Authority of that Member State or by the Agency (Directive (EU) 2016/797 [2] article 21(8)).

The scope of the "Guidelines for the practical arrangements for the vehicle authorisation process" is the same as for Commission Implementing Regulation (EU) 2018/545 as laid down in Article 21 and 24 of Directive (EU) 2016/797.

Vehicles are defined in Article 2(3) of Directive (EU) 2016/797 as: *"a railway vehicle suitable for circulation on wheels on railway lines, with or without traction; a vehicle is composed of one or more structural and functional subsystems"*. This definition of a vehicle also includes special vehicles such as On Track Machines (OTMs) when they are operated as railway vehicles (i.e. when they are operated in transport mode as defined in the Commission Regulation (EU) 1302/2014, clause 2.2.2(D)). When OTMs are in working mode (this mode is excluded from the scope of the Commission Regulation (EU) 1302/2014 (see clause 2.3.1(D)) they are not covered by the definition of a vehicle as specified in Article 2(3) of Directive (EU) 2016/797.

All vehicles to which Directive (EU) 2016/797 applies, as specified in Article 1 of the Directive, are included in the scope of Commission Implementing Regulation (EU) 2018/545 and are therefore also included in the scope of the "Guidelines for the practical arrangements for the vehicle authorisation process".

1.4. Objectives

This document is intended to provide guidance for authorising entities, NSAs for the area of use, holders of the vehicle type authorisation, entities managing change, applicants and other concerned parties for the application of the vehicle authorisation process specified in Commission Implementing Regulation (EU) 2018/545 as laid down in Article 21 and 24 of Directive (EU) 2016/797. The "Guidelines for the practical arrangements for the vehicle authorisation process" aims to support a consistent implementation of the railway vehicle authorisation and railway vehicle type authorisation process.

In order to facilitate the reading of the "Guidelines for the practical arrangements for the vehicle authorisation process" the structure of the information has been based on the structure of Commission Implementing Regulation (EU) 2018/545 and the text of the regulation has been included in the "Guidelines for the practical arrangements for the vehicle authorisation process" with the following legend:

Legend:

Yellow shaded text with a frame corresponds to the proposed text for the Commission Implementing Regulation (EU) 2018/545 referred to in Article 21(9) of the recast interoperability directive (EU) 2016/797.

Normal text corresponds to the non-legislative acts supporting the Commission Implementing Regulation (EU) 2018/545.

Links to web-pages have been introduced where appropriate to facilitate for the reader. However, it should be recognised that it has only been introduced for informative purposes; the Agency has no control over such content and it could be subject to change at any time.

In addition to the “Guidelines for the practical arrangements for the vehicle authorisation process” there is a standalone document: “Catalogue of examples - Examples for the practical arrangements for the vehicle authorisation process”. This document complements the guideline by providing examples that can be used to illustrate the practical application of Commission Implementing Regulation (EU) 2018/545 and the “Guidelines for the practical arrangements for the vehicle authorisation process”.

1.5. Management of the document

It is envisaged to regularly review and when necessary update and/ or amend the “Guidelines for the practical arrangements for the vehicle authorisation process” according to the experience gained in the implementation of the vehicle authorisation process according to the Commission Implementing Regulation (EU) 2018/545.

It is proposed to perform a review of the document once every 1-2 years depending on the amount and importance of the change requests received. A lesser regularity could be considered if no further need is deemed necessary.

Users, being any stakeholders or national safety authorities, can introduce requests for changes to the “Guidelines for the practical arrangements for the vehicle authorisation process” using the ‘Comment sheet’ provided in Annex XIX of this document, and sending it to VAFeedback@era.europa.eu.

The change requests will be reviewed by the Agency taking into account to the needs identified in the course of the implementation of the vehicle authorisation process.

The Agency will assess the change requests and propose when relevant a draft updated version of the “Guidelines for the practical arrangements for the vehicle authorisation process” to the NSA Network and the Network of Representative Bodies for a three months consultation.

After this consultation, the Agency will review the comments received and publish a revised version of the “Guidelines for the practical arrangements for the vehicle authorisation process” on its website.

The Agency can also propose a revision on its own initiative. In such case, the Agency will follow the same process and also send the relevant draft updated version of the “Guidelines for the practical arrangements for the vehicle authorisation process” to the NSA Network and the Network of Representative Bodies.

The Agency should, when possible, coordinate the review and the consultation with the stakeholders for the “Guidelines for the practical arrangements for the vehicle authorisation process” and the “Catalogue of examples - Examples for the practical arrangements for the vehicle authorisation process”.

2. References, definitions and abbreviations

2.1. Reference Documents

Table 1 : Table of Reference Documents

	[Ref.] Title	Reference	Version / date
[1]	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	(EU) 2016/796	11-05-2016
[2]	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 (recast)	(EU) 2016/797	11-05-2016
[3]	DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on railway safety (recast)	(EU) 2016/798	11-05-2016
[4]	COMMISSION IMPLEMENTING REGULATION on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009	(EU) 402/2013	30-04-2013
[5]	DIRECTIVE 2008/57/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 June 2008 on the interoperability of the rail system within the Community (Recast)	2008/57/EC	17-06-2008
[6]	COMMISSION IMPLEMENTING DECISION of 4 October 2011 on the European register of authorised types of railway vehicles (2011/665/EU)	2011/665/EU	04-10-2011
[7]	COMMISSION REGULATION (EU) No 321/2013 of 13 March 2013 concerning the technical specification for interoperability relating to the subsystem 'rolling stock — freight wagons' of the rail system in the European Union and repealing Decision 2006/861/EC	(EU) 321/2013	13-03-2013
[8]	ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary	ISO 9000:2015	2015
[9]	COMMISSION REGULATION (EU) No 1302/2014 of 18 November 2014 concerning a technical specification for interoperability relating to the 'rolling stock — locomotives and passenger rolling stock' subsystem of the rail system in the European Union	(EU) 1302/2014	18-11-2014
[10]	Commission Implementing Decision (EU) 2015/2299 of 17 November 2015 amending Decision 2009/965/EC as regards an updated list of parameters to be used for classifying national rules	(EU) 2015/2299	17-11-2015
[11]	COMMISSION REGULATION (EU) 2015/995 of 8 June 2015 amending Decision 2012/757/EU concerning the technical specification for interoperability relating to the 'operation and traffic management' subsystem of the rail system in the European Union	(EU) 2015/995	08-06-2015
[12]	COMMISSION REGULATION (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union	(EU) 2016/919	27-05-2016
[13]	COMMISSION DECISION of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council (2010/713/EU)	2010/713/EU	09-11-2010
[14]	COMMISSION DECISION of 9 November 2007 adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC (2007/756/EC)	2007/756/EC	09-11-2007
[15]	COMMISSION NOTICE The 'Blue Guide' on the implementation of EU products rules 2016 (2016/C 272/01)	2016/C 272/01	26-07-2016
[16]	ISO/IEC 17000:2004 Conformity assessment -- Vocabulary and general principles	ISO/IEC 17000:2004	2004
[17]	ISO 9001:2015 Quality management systems -- Requirements	ISO 9001/2015	2015
[18]	The Luxembourg Protocol to the Convention on International Interests in Mobile Equipment on Matters specific to Railway Rolling Stock, adopted in Luxembourg on 23 February 2007	-	23-02-2007

Table 1 : Table of Reference Documents

[Ref.]	Title	Reference	Version / date
[19]	COMMISSION IMPLEMENTING REGULATION (EU) 2018/545 of 4 April 2018 on 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	(EU) 2018/545	04-04-2018
[20]	DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)	2014/30/EU	26/02/2014
[21]	REGULATION (EU) 2016/1628 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC	(EU) 2016/1628	14/09/2016
[22]	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	(EU) 2018/761	16/02/2018
[23]	COMMISSION REGULATION (EU) NO 201/2011 of 1 March 2011 on the model of declaration of conformity to an authorised type of railway vehicle	(EU) 201/2011	01/03/2011
[24]	REGULATION (EC) NO 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC	(EC) 1907/2006	18/12/2006
[25]	Catalogue of examples - Examples for the practical arrangements for the vehicle authorisation process	ERA-PRG-005/02_374	1.0

2.2. Definitions and abbreviations

The general terms and abbreviations used in the present document can be found in a standard dictionary.

Specific terms and abbreviations either defined below or can be found in chapter 3.2.2.

Table 2 : Table of Terms

Term	Definition
Agency	The European Railway Agency (ERA) such as established by the Regulation (EC) No 881/2004 of the European Parliament and of the Council of 29 April 2004 establishing a European railway agency, as last amended by Regulation (EC) No 1335/2008 [2].
Commission	The European Commission, in particular DG MOVE
Union law	The Union law is the system of European laws operating within the member states of the European Union. The Union law is published in the Official Journal of the European Union and can be accessed free of charge through EUR-Lex (https://eur-lex.europa.eu/homepage.html), and it is published daily in the 24 official EU languages.

Table 3 : Table of Abbreviations

Term	Definition
4RWP	Fourth Railway Package
CCS	Control Command and Signalling
CSM	Common Safety Method
DeBo	Designated Body

Table 3 : Table of Abbreviations

Term	Definition
EC	European Commission
EMC	Electromagnetic Compatibility
ERADIS	European Railway Agency Database of Interoperability and Safety
ERATV	European Register of Authorised Types of Vehicles
ERTMS	European Railway Traffic Management System
ETCS	European Train Control System
EU	European Union
EVN	European Vehicle Number
GSM-R	Global System for Mobile Communications – Railway
ID	Identification
ISV	Intermediate Statement of Verification
NoBo	Notified Body
NSA	National Safety Authority
NVR	National Vehicle Register
OSS	One Stop Shop
OPE	Operational
QMS	Quality Management System
OTM	On Track Machine
RA	Risk Assessment
RINF	Register of Infrastructure
RST	Rolling Stock
SMS	Safety Management System
TEN	Trans-European Network
TSI	Technical Specification for Interoperability
URVIS	Unique Rail Vehicle Identification System
WAG	Wagon

3. Content of the practical arrangements

3.1. Recitals

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 Union¹, 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 timeframes 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.

¹Directive (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 (recast) (OJ L 138, 26.5.2016, P. 44 -101)

(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 Council¹, 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.

¹Regulation (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 (OJ L 138, 26.5.2016, p. 1)

(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.

(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 Council¹ 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/EC².

¹Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (OJ L 191, 18.7.2008, p. 1)

²Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system (OJ L 235, 17.9.1996, p. 6).

3.2. Chapter 1 - General provisions

3.2.1. 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;
 - (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.

Relevant references to Directive (EU) 2016/797:

- › Article 1
- › Article 2
- › Article 21
- › Article 24
- › Annex I

Relevant references to Regulation (EU) 2016/796:

- › Article 12

The effective implementation of these arrangements should serve the aim of greater harmonisation of the approach to vehicle authorisation at European Union level, making the procedures for issuing vehicle authorisations more consistent and efficient among the authorising entities.

The practical arrangements set out in the document aim to put in place and maintain an effective and efficient process with the various entities collaborating in order to:

- › Take decisions on the issuing of vehicle authorisations;
- › Harmonise the practices of the entities issuing vehicle authorisations across the EU (irrespective of the area of use); and
- › Bring more consistency and transparency for the applicant, in particular when the process involves an authorising entity and one or more NSAs for the area of use.

The practical arrangements set out in Commission Implementing Regulation (EU) 2018/545 according to Article 21 of Directive (EU) 2016/797 should apply for vehicle type authorisation/ authorisation for placing on the market of vehicles intended to be operated in the Union rail system as defined by Article 2 of Directive (EU) 2016/797.

This should apply without prejudice of the potential exclusion by Member States as mentioned in Article 1(4) (a) of Directive (EU) 2016/797.

Article 2 of Directive (EU) 2016/797 defines network as “*means the lines, stations, terminals, and all kinds of fixed equipment needed to ensure safe and continuous operation of the Union rail system*”.

The Annex I of Directive (EU) 2016/797 states that the Union's network includes "1. (c)[...] *interconnecting lines between high-speed and conventional networks, lines through stations, accesses to terminals, depots, etc. [...](h) freight hubs, including intermodal terminals*".

It should be noticed that those definitions and scope have not been changed as compared to Directive 2008/57/EC.

Access to ports and terminals are therefore in the scope of Directive (EU) 2016/797 (as they were in the Directive 2008/57/EC). Authorisation for placing on the market according to Directive (EU) 2016/797, especially Article 21, applies also on these parts of the network. This applies without prejudice of the potential exclusion by Member States as mentioned in Article 1(4) (a) of Directive (EU) 2016/797.

3.2.2. Article 2: Definitions

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

Relevant references to Directive (EU) 2016/797:

- › Article 2
- › Article 21
- › Article 24
- › Article 57
- › Annex III

Relevant references to Regulation (EU) 2016/796:

- › Article 12

3.2.2.1. (1) Authorising entity

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

The role of authorising entity is performed by:

- › The Agency in the case of vehicle type authorisation and/ or vehicle authorisation for placing on the market to be issued for an area of use covering one or more Member States; or
- › The national safety authority in the case of vehicle type authorisation and/ or vehicle authorisation for placing on the market to be issued for an area of use limited to the network(s) within one Member State and where the applicant has requested this in accordance with Article 21(8) of Directive (EU) 2016/797.

In the case of vehicle type authorisation and/ or vehicle authorisation for placing on the market in respect of vehicles having an area of use covering more than one Member State it is the Agency that should have the role of the authorising entity.

If a wagon to be authorised is compliant with paragraph 7.1.2 of the Annex of the WAG TSI regulation (EU) 321/2013, the assessments of the Agency acting as authorising entity, when the applicant has applied for an authorisation with an area of use covering more than one Member State, will cover the additional conditions that the wagon should meet and no involvement of the NSAs for the area of use should be necessary (no applicable national rules).

3.2.2.2. (2) Basic design characteristics

(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').

The basic design characteristics describe the important/ significant elements of the design of a vehicle type. They are the consequence of conformity of a vehicle design to rules covered by:

- › Directive (EU) 2016/797 (TSIs, national rules);
- › Other directives which are also applicable to railway vehicles (e.g EMC Directive 2014/30/EU, non-road mobile machinery emissions Regulation (EU) 2016/1628, etc.).

Basic design characteristics are necessary:

- › In order to establish if a vehicle belongs to and is in conformity with a vehicle type; and
- › To establish whether the changes to an already authorised vehicle and/ or vehicle type trigger the criteria in article 21(12)(a) of Directive (EU) 2016/797 for when a new authorisation is needed, and as a consequence, to identify to which of the categories described in Article 15 of Commission Implementing Regulation (EU) 2018/545 (see section 3.3.2.2) the change belongs.

The basic design characteristics for a vehicle type are a result of the combination of the parameters of the subsystems of which it is composed and their interaction when integrated into a vehicle design. The TSIs identify the parameters that require harmonisation for interoperability; other aspects of the vehicle's design that are not harmonised may also be considered as basic design characteristics.

The definition of the list of basic design characteristics will be done in three steps:

- › In the framework of the limited revision of the Commission Regulation (EU) 1302/2014 (TSI LOC&PAS), Commission Regulation (EU) 321/2013 (TSI WAG) and Commission Regulation (EU) 2016/919 (TSI CCS), the working parties will draw up the lists of basic design characteristics that will be included in the TSIs. This includes the definition of the thresholds for each basic design characteristic that requires a new authorisation.
- › In a second step, the basic design characteristics that are covered in legislation other than the Directive (EU) 2016/797 will be also identified.
- › Finally, based on the return of experience from vehicle authorisation for placing on the market and/ or vehicle type authorisation, the remaining parameters of a vehicle type that are not already covered but need to be considered a basic design characteristic will be identified.

At the time of publication of this guideline, the basic design characteristics to be taken into account are those referred to in Article 48(c) of Regulation (EU) 2018/545. This includes the revised TSIs as described in the first bullet point of the previous paragraph. The process to identify the additional basic design characteristics described in the second and third bullet point of the previous paragraph (other Union law and return of experience) will involve stakeholders through the relevant working parties, working groups, task forces or workshops. It will be a collaborative and transparent process similar to that of the limited revision of the TSIs, and the outcomes of the process will be reflected in a legal text.

It is important to differentiate between the terms used to describe the parameters for vehicles i.e. “basic design characteristics” and “basic parameters”:

- › Basic design characteristics are defined in Article 2(2) of Commission Implementing Regulation (EU) 2018/545.
- › “Basic parameters” are defined in Directive (EU) 2016/797 Article 2(12) as “any regulatory, technical or operational condition which is critical to interoperability and is specified in the relevant TSIs”.

The basic parameters covered by TSIs are those that need to be harmonised to meet the objectives of Directive (EU) 2016/797. This includes the parameters necessary to ensure technical compatibility between vehicle and network, and their values. For each basic parameter, the requirement(s) are defined either through a TSI rule or through a national rule (e.g. open point in the TSI). These should be checked by the NoBo/ DeBo before authorisation as required by the relevant TSIs and/ or national rules.

For vehicles that are in the scope of Directive (EU) 2016/797 and in the scope of the TSIs, the list of basic parameters and the values of these parameters for each category of vehicle will be revised by the working parties for the limited revision of the Commission Regulation (EU) 1302/2014, Commission Regulation (EU) 321/2013 and Commission Regulation (EU) 2016/919. As mentioned previously, the revised TSIs will identify the basic design characteristics that are a result of its requirements on the vehicle design.

For vehicles that are in the scope of Directive (EU) 2016/797 but that are not (and not intended to be) covered by TSIs (e.g. Tram train, metric track gauges) the national rules should further detail those basic design characteristics that are a result of its requirements on the vehicle design. This includes the parameters necessary to ensure compatibility between vehicle and network, and their values.

Basic design characteristics in the context of the TSIs could be:

- › A subset of characteristics needed for technical compatibility with their range when applicable. Such basic design characteristics evolving out of the range specified trigger a new authorisation, pursuant to Article 21(12) of Directive (EU) 2016/797 and Article 15 of Commission Implementing Regulation (EU) 2018/545.
- › A subset of characteristics relevant for the operation of the vehicle (restrictions, conditions of use).

Other characteristics resulting from conformity to TSI requirements might not be considered as basic design characteristic (e.g. width of the seats).

The Annex II of the Decision 2011/665/EU on ERATV and the register itself will be modified in order to be consistent with the list of basic design characteristics.

3.2.2.3. (3) Configuration management

- (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;

Configuration management of a vehicle

The scope of the configuration management for a vehicle is limited to the changes specified in Article 16 of Commission Implementing Regulation (EU) 2018/545. For more information on changes to an already authorised vehicle, see chapter 3.3.2.3. The keeper of the vehicle or of the entity entrusted by that keeper should be responsible for the configuration management of the vehicle, this should apply without prejudice to the responsibilities assigned to the:

- › Entity in charge of maintenance for the vehicle; and
- › Railway undertaking using the vehicle.

Configuration management of a vehicle type

The scope of the configuration management of the vehicle type covers all aspects for the design of the vehicle(s) belonging to that vehicle type. For more information on changes to an already authorised vehicle type see chapter 3.3.2.2. The holder of the vehicle type authorisation is responsible for the configuration management of the vehicle type; this is further explained in sections 3.2.2.6 (definition of holder of the vehicle type authorisation) and 3.2.3.3 (responsibilities of the holder of the vehicle type authorisation).

3.2.2.4. (4) Date of receipt of the application

(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;

3.2.2.5. (5) Entity managing the change

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

3.2.2.6. (6) Holder of the vehicle type authorisation

(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;

If a company ceases to exist due to circumstances such as bankruptcy and this company is a holder of vehicle authorisation then this should be treated as an asset of the company and the legal successor becomes the holder of the vehicle type authorisation. How assets of a company are dealt with in the event that a company ceases to exist is regulated in national legislation.

For those vehicle types that have been authorised before the relevant date, the holder of the vehicle type authorisation will be established on the basis of:

- › Who is registered as the holder of the vehicle type in ERATV; or
- › If the vehicle type is not registered in ERATV, the holder of the vehicle type will be established in accordance with the provisions of Article 15(5) of the Commission Implementing Regulation (EU) 2018/545 and only in the event of a change.

It should be noted that the provisions of Article 15 of Commission Implementing Regulation (EU) 2018/545 should be taken into account also for vehicle types authorised before the relevant date when establishing who is the holder of the vehicle type authorisation based on the ERATV registration.

If changes have been made as specified in Article 15(4) of Commission Implementing Regulation (EU) 2018/545 it is no longer the same vehicle type and the ERATV registration is not valid for the changed vehicle type. The definition of vehicle type in Article 2(26) Directive (EU) 2016/797 is: " 'type' means a vehicle type defining the basic design characteristics of the vehicle as covered by a type or design examination certificate described in the relevant verification module;" which supports that when changes have been made to the basic design characteristics it is no longer the same vehicle type and it is therefore not covered by the related ERATV registration.

For any given vehicle type, there can only be one holder of a vehicle type authorisation. The reason for this is to ensure a clear responsibility for the vehicle type (i.e. the design) and for the configuration management of that vehicle type. However, two series of vehicles of the same design could have two different holders of the authorisations to place the (individual) vehicles (of the series) on the market. It follows that they are different vehicle types although each vehicle type is defined by the same (identical) basic design characteristics.

3.2.2.7. (7) Justified doubt

(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 the NSAs for the area of use concerning the information provided by the applicant in its application;

A justified doubt:

- › Is an issue classified as a ‘type 4’, as specified in Article 41(1)(d) of Commission Implementing Regulation (EU) 2018/545 and where there is a justification with supporting evidence;
- › Raises a serious concern on the content of the application file;
- › Is considered to have the potential to result in the rejection of the application unless the applicant agrees to provide further information as specified in Article 42 of Commission Implementing Regulation (EU) 2018/545; and
- › Gives the possibility to suspend the assessment and to extend the time frame, as specified in Article 34(6) of Commission Implementing Regulation (EU) 2018/545.

The authorising entity and/or the concerned NSAs for the area of use raising a justified doubt should clearly mention that it is a justified doubt when identifying such a ‘type 4’ issue so that the applicant is made aware. The authorising entity and/or the concerned NSAs for the area of use raising a justified doubt should indicate to the applicant which elements of the application file require an action from the applicant and also provide a justification. The management of a justified doubt should be carried out through the issues log referred to in Article 41 of Commission Implementing Regulation (EU) 2018/545. Further details about the use of the issues log are provided in chapter 3.7.11.

For further information about issues to be classified as ‘justified doubt’, see chapter 3.7.12.

3.2.2.8. (8) National safety authority for the area of use or NSA for the area of use

- (8) ‘national safety authority for the area of use’ or ‘NSA for the area of use’ means the national safety authority when it performs one or more of the following tasks:
- (a) the assessments specified in Article 21(5)(b) of Directive (EU) 2016/797;
 - (b) the consultations requested in Article 21(8) of Directive (EU) 2016/797;
 - (c) issues the temporary authorisations, when required, for using the vehicle for tests on the network and takes measures to ensure that the tests on the network can take place as specified in Article 21(3) of Directive (EU) 2016/797;

If there are no national rules to be applied, there is no need to involve the NSAs for the area of use, other than:

- › To assess that the area of use for the concerned Member State is correctly specified; and/ or
- › To issue the temporary authorisation to use the vehicle for tests on the network when it is required by the national legal framework of the Member State.

In the case of a vehicle that is to be authorised for an area of use covering only one Member State, the NSA of the concerned Member State can be the authorising entity if the applicant chooses this. However, the role of authorising entity is a different role as compared to that of the NSA for the area but in the case where the NSA is the authorising entity the roles are performed by the same entity. If later on there is a need to extend the area of use to another Member State, the Agency should be the authorising entity for the extended area of use.

3.2.2.9. One-stop shop

‘one-stop shop’ means the information and communications system operated by the Agency as referred to in Article 12 of Regulation (EU) 2016/796.

The one-stop shop constitutes:

- › A single entry point through which the applicant should submit its application and the file accompanying the application for vehicle type authorisation, vehicle authorisations for placing on the market and single safety certificates;

- › A common information-exchange platform, providing the Agency and national safety authorities with information about all applications for authorisations and single safety certificates, the stages of these procedures and their outcome, and, where applicable, the requests and decisions of the Board of Appeal;
- › A common information-exchange platform, providing the Agency and national safety authorities with information about requests for approvals by the Agency in accordance with Article 19 of Directive (EU) 2016/797 and applications for authorisations of trackside control-command and signalling subsystems involving European Train Control System (ETCS) and/ or Global System for Mobile Communications – Railway (GSM-R) equipment, the stages of these procedures and their outcome, and, where applicable, the requests and decisions of the Board of Appeal; and
- › An early-warning system able to identify at an early stage the needs for coordination between decisions to be taken by national safety authorities and the Agency in the case of different applications requesting similar authorisations or single safety certificates.

3.2.2.10. (9) *Pre-engagement*

(9) 'pre-engagement' means a procedural stage preceding the submission of an application for authorisation performed upon request of the applicant;

3.2.2.11. (10) *Pre-engagement baseline*

(10)'pre-engagement baseline' means the opinion of the authorising entity and of the concerned NSAs for the area of use on the pre-engagement file;

3.2.2.12. *Reasonable assurance*

'reasonable assurance' means that the authorising entity has reached the confidence that the applicant and the actors supporting the applicant have fulfilled their responsibilities.

Reasonable assurance is a legal concept and mainly used within finance and auditing. It is relevant to use for vehicle authorisation as it is a more process oriented check rather than a detailed assessment. Although the authorising entity should reach the confidence that the applicant and the actors supporting the applicant have fulfilled their responsibilities it is not necessary for them to establish with absolute certainty that this is the case. The level of engagement required by the authorising entity to reach a reasonable assurance should be proportional and take account of the:

- › Complexity and risk associated with the vehicle/type being authorised (in respect to the design or the changes to the design that are being authorised);
- › Quality of the evidence and documentation supplied by the applicant;
- › Return of experience related to technical and operational matters in vehicles with a similar design and/ or similar components that may be relevant; and
- › Confidence gained in the applicant, based on experience from meetings etc.

The detailed assessments are performed by the conformity assessment bodies and therefore there is no need for the authorising entity to duplicate those assessments.

The actors supporting the applicant include any entity making a significant contribution to ensuring, assuring or verifying that the vehicle type or vehicle being authorised meets the essential requirements. They include but are not limited to: the applicant(s) that have performed the placing on the market of the subsystem(s) of which the vehicle and/ or vehicle type is composed, NoBos, DeBos, Assessment Bodies (CSM RA), contractors and sub-contractors.

3.2.2.13. (11) Requirements capture

(11)'requirements capture' means the process of identification, assignment, implementation and validation of requirements performed by the applicant in order to ensure that relevant Union and national requirements are complied with. Requirements capture may be integrated in the product development processes;

The scope of the requirements capture process is the requirements covering the design of the vehicle for its life cycle which are necessary to ensure that the vehicle will comply with relevant Union law and national requirements, under the conditions of use for which it has been designed and with an appropriate maintenance. However, not all the design requirements to cover the life cycle of the vehicle are to be dealt with at the authorisation stage (e.g. contractual requirements with no effect on essential requirements and/or safe integration, requirements necessary to ensure the maintainability, requirements to facilitate the de-commissioning and disposal process, etc.).

The requirements capture process should cover the identification of design requirements, but also their specification, implementation, verification and validation.

The activities related to the capture of the requirements are normally integrated in other existing processes already set-up by the manufacturers/ suppliers for the development of the products, such as quality management, safety management, requirements management etc. It is not necessary to have a dedicated process related to the requirements capture.

3.2.2.14. (12) Safe integration

(12)'safe integration' means the fulfilment of the essential requirement on safety as specified in Annex III of Directive (EU) 2016/797 when combining parts into its integral whole, such as a vehicle or a subsystem as well as between the vehicle and the network, with regards to the technical compatibility;

In the framework of vehicle type authorisation and/ or vehicle authorisation for placing on the market, the term 'safe integration' can be used to cover:

- › Safe integration between the elements composing the mobile subsystem. This is fully in the scope of the TSIs covering a subsystem. Where there are no explicit technical rules covering this matter, the TSIs may adopt a risk based approach and require the application of Commission Implementing Regulation (EU) 402/2013 specifying to which acceptable level the risk should be controlled;
- › Safe integration between mobile subsystems that constitute a vehicle; and
- › Safe integration for the network-vehicle interface with regards to technical compatibility.

Safe integration between mobile subsystems

The interfaces between subsystems within vehicles should be specified in the TSIs and/ or national rules but as this is not always considered necessary to achieve the objectives of Directive (EU) 2016/797, not all interfaces are fully covered by TSIs and/ or national rules.

By properly controlling the identified risks related to the integration between mobile subsystems using the harmonised risk assessment process specified in Commission Implementing Regulation (EU) 402/2013, as prescribed in Article 21(3) of Directive (EU) 2016/797, in conjunction with the application of existing technical requirements, the safe integration between mobile subsystems can be ensured.

Safe integration for the network-vehicle interface, with regards to technical compatibility

Technical compatibility is one of the essential requirements.

Each side of the network-vehicle interface is managed by different actors therefore a harmonised approach is required and the interface parameters should be specified in the TSIs and/ or national rules; this means that the technical compatibility at the network-vehicle interface should be ensured by the application of the

relevant requirements (TSIs and/ or national rules). For the network-vehicle interface safe integration is part of technical compatibility.

Therefore, it follows that:

- › At this interface, Commission Implementing Regulation (EU) 402/2013 should be applied only when called up by the TSIs and/ or national rules for aspects of safe integration not covered in the TSIs and/ or national rules (if any).
- › For the network-vehicle interface both technical compatibility and safe integration are demonstrated by verification of conformity with the TSIs and/ or national rules.
- › No other verification/ assessment/ "safety case" should be required (as it would compromise interoperability).
- › If any entity is of the opinion that technical compatibility (including safe integration) is not fully covered by the TSIs and/ or national rules then the procedure for dealing with deficiencies in the TSIs and/ or national rules should be followed.

3.2.2.15. *Vehicle type*

For the definition of vehicle type, see Article 2(26) of Directive (EU) 2016/797.

Vehicles should belong to a vehicle type and the vehicle type should be authorised at the same time as the first vehicle of that vehicle type is authorised for placing on the market and before vehicles are authorised in conformity to type.

The vehicle type authorisation can take place either: at the same time as the first vehicle of that vehicle type is authorised for placing on the market or without a vehicle of that vehicle type being authorised for placing on the market. When authorising a vehicle type, a vehicle of that vehicle type may be used for the verification and validation of the conformity with the essential requirements of the applicable legislation. That vehicle does not have to be authorised for placing on the market. It is the choice of the applicant in its request if the vehicle used for verification and validation of the vehicle type should be authorised for placing on the market or not.

Any vehicle(s) that are produced and placed on the market and that are in conformity with an authorised vehicle type should receive an authorisation for placing on the market on the basis of a declaration of conformity to that authorised vehicle type submitted by the applicant, see chapter 3.3.2.1.

While railway infrastructure and projects for fixed installations tend to be specifically designed "one off" for a specific route or geographical location, individual vehicles are usually manufactured in series of identical vehicles of the same vehicle type.

Authorising entities issue the authorisation to a series of vehicles (set of identical vehicles) on the basis of a declaration of conformity to vehicle type submitted by the applicant, see chapter 3.3.2.1.

If a vehicle type is authorised and further vehicles are authorised for placing on the market on the basis of conformity to the vehicle type, and where applicable clearly specifying the vehicle type variant and vehicle type version, then all vehicles of that vehicle type can be considered to be compatible with networks that form the intended area of use.

The concept of vehicle type must not be confused with the concept of product type within the "new approach" or a subsystem type.

The concept of vehicle type applies to a vehicle design as a whole not to a specific subsystem. A vehicle may contain more than one subsystem, in which case, the characteristics of a vehicle type is the combination of characteristics of subsystems and their interaction with each other when integrated together in a vehicle design.

Because of the interaction between subsystems it cannot automatically be assumed that the characteristics of individual subsystems can be added together to become the characteristics of a vehicle.

3.2.2.16. (13) Vehicle type variant

(13) 'vehicle type variant' means an option for the configuration of a vehicle type that is established during a first authorisation of the vehicle type in accordance with Article 24(1) or changes within an existing vehicle type during its life cycle that require a new authorisation of the vehicle type in accordance with Articles 24(1) and 21(12) of Directive (EU) 2016/797;

A vehicle type can include variations of the design (e.g. platform).

Vehicle type variants are different options for a design covered by a vehicle type (i.e. if the holder of the vehicle type authorisation wants to add a vehicle type variant to an already authorised vehicle type it has to apply for a new authorisation), so if the design of the vehicle type is changed to include a new variant it is still the same vehicle type.

3.2.2.17. (14) Vehicle type version

(14) 'vehicle type version' means an option for the configuration of a vehicle type or type variant or changes within an existing type or type variant during its life cycle, created to reflect changes to the basic design characteristics that do not require a new authorisation of the vehicle type in accordance with Articles 24(1) and 21(12) of Directive (EU) 2016/797;

It is a configuration or a modification that constitutes a change to the basic design characteristics of the vehicle type or of a vehicle type variant and it is below the threshold for a new authorisation according to Articles 24(1) and 21(12) of Directive (EU) 2016/797, then a vehicle type version will have been created.

Vehicle type versions follow the stages of evolution of vehicle type over time i.e. the same vehicle type may have several different versions over time. So if a vehicle type is changed to a new vehicle type version it is still the same vehicle type. This should also apply to the documentation covering a vehicle type.

The extension of an area of use of an already authorised vehicle type should be considered as a new vehicle type version or as a version of a variant of a vehicle type, as:

- › The definition of vehicle type variant in article 2(13) of Commission Implementing Regulation (EU) 2018/545 limits the possibility to create variants to the authorisation cases first or new (pursuant to articles 14(1)(a) and 14(1)(d) of Commission Implementing Regulation (EU) 2018/545); and
- › The area of use is part of the basic design characteristics of the vehicle type (see Article 48(c)(ii) of the Commission Implementing Regulation (EU) 2018/545).

The extension of an area of use always requires an authorisation following article 21(13) of Directive 2016/797 and article 14(1)(c) of Commission Implementing Regulation (EU) 2018/545.

See also chapter 3.3.2.2 of this document for further guidance concerning changes to a vehicle type.

3.2.2.18. (15) Vehicle authorisation for placing on the market

(15) 'vehicle authorisation for placing on the market' means the decision issued by the authorising entity based on a reasonable assurance that the applicant and the entities involved in the design, manufacture, verification and validation of the vehicle have fulfilled their respective obligations and responsibilities in order to ensure conformity with essential requirements of the applicable legislation or to ensure conformity with the authorised type enabling that the vehicle may be placed on the market and may be used safely in the area of use according to the conditions for use and other restrictions, when applicable, specified in the vehicle authorisation and in the vehicle type authorisation;

As specified in Article 24(2) and 25(1) of Directive (EU) 2016/797 a vehicle type authorisation may be issued before or at the same time as the vehicle authorisation for placing on the market. If an applicant requests for a vehicle to be authorised for placing on the market then the authorising entity when issuing the authorisation for placing on the market should at the same time issue the vehicle type authorisation. See also chapter 3.2.2.15.

3.2.2.19. (16) Vehicle type authorisation

(16) 'vehicle type authorisation' means the decision issued by the authorising entity based on reasonable assurance that the applicant and the entities involved in the design, manufacture, verification and validation of the vehicle type have fulfilled their obligations and responsibilities in order to ensure conformity with the essential requirements of the applicable legislation enabling that a vehicle manufactured according to this design may be placed on the market and may be used safely in the area of use of the vehicle type according to the conditions for use of the vehicle and other restrictions, when applicable, specified in the vehicle type authorisation and to be applied to all vehicle authorised in conformity to this type;

Vehicle type authorisation and vehicle authorisation for placing on the market are two different authorisations, but they can take place simultaneously, upon the applicant's request, according to Article 24(2) of Directive (EU) 2016/797, see also chapter 3.2.2.15.

3.2.2.20. (17) Relevant date

(17) 'relevant date' means 16 June 2019, except as regards those Member States that have notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797 that they have extended the transposition period of that Directive, in which case the relevant date is 16 June 2020.

3.2.2.21. Validation

According to ISO 9000/2015 validation is:

"The confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled."

It should be noted that:

- › The objective evidence needed for validation is the result of a test or other form of determination such as performing alternative calculation or reviewing documents.
- › The word "validated" is used to designate the corresponding status.
- › The use conditions for validation can be real or simulated.

According to the *Guideline ISO 9000/2015 Plain English Definition* <http://www.praxiom.com/iso-definition.htm> "validation" is explained as following:

"Validation is a process. It uses objective evidence to confirm that the requirements which define an intended use or application have been met. Whenever all requirements have been met, a validated status is established. Validation can be carried out under realistic use conditions or within a simulated use environment."

There are several ways to confirm that the requirements which define an intended use or application have been met. For example you could do tests, you could carry out alternative calculations, or you could examine documents before you issue them."

3.2.2.22. Heavy rail infrastructure

Heavy rail infrastructure, by opposition to “light rail infrastructure”, is formed of any part of the infrastructure included in Union’s network, which falls in the scope defined in Article 1(3) of Directive (EU) 2016/797, i.e. any infrastructure not used by metros, not functionally separate from the rest of the Union rail system and not exclusively used by trams and light rail vehicles as defined in Article 2 (29) of Directive (EU) 2016/797.

Article 2 of Directive (EU) 2016/797 defines light rail vehicles according to technical criteria regarding crashworthiness and strength of vehicle.

3.2.3. Responsibilities

3.2.3.1. Article 3: Responsibilities of the applicant

The applicant shall submit its application for vehicle type authorisation and/or vehicle authorisation for placing on the market in accordance with the provisions of this Regulation.

It is the responsibility of the applicant to ensure that the relevant requirements from applicable legislation are identified and met when submitting its application for vehicle type authorisation and/or vehicle authorisation for placing on the market

Relevant references to Directive (EU) 2016/797:

- › Article 2(22)
- › Article 21
- › Article 24

For the definition of ‘applicant’ see Article 2(22) of Directive (EU) 2016/797. This definition contains three different applicants:

- › The first part of the definition refers to the applicant for authorisation (authorisation for the placing in service of fixed installations as specified in Article 18 of Directive (EU) 2016/797; vehicle authorisation for placing on the market as specified in Article 21 of Directive (EU) 2016/797; vehicle type authorisation as specified in Article 24 of Directive (EU) 2016/797).
- › The second part of the definition refers to the applicant that establishes the EC Declaration for Verification for subsystems as specified in Article 15 of Directive (EU) 2016/797.
- › The third part of the definition refers to the applicant requesting Agency approval of trackside ERTMS as specified in Article 19 of Directive (EU) 2016/797.

The ‘applicant’ referred to in Commission Implementing Regulation (EU) 2018/545 is the applicant for authorisation for vehicle authorisation for placing on the market as defined in Article 2(22) of Directive (EU) 2016/797, as specified in Article 21 of Directive (EU) 2016/797 and/ or for vehicle type authorisation as specified in Article 24 of Directive (EU) 2016/797.

The ‘applicant’ referred to in Commission Implementing Regulation (EU) 2018/545 can also be the ‘proposer’ referred to in the fourth bullet point of Article 3(11)1 of Commission Implementing Regulation (EU) 402/2013 when there is a need to apply the risk management and/or risk assessment process described in the regulation. It states that the ‘proposer’ is “an applicant for an authorisation for the placing in service of

(1) According to Article 3(11) of Regulation 402/2013, ‘proposer’ means one of the following :

- (a) a railway undertaking or an infrastructure manager which implements risk control measures in accordance with Article 4 of Directive 2004/49/EC;
- (b) an entity in charge of maintenance which implements measures in accordance with Article 14a(3) of Directive 2004/49/EC;
- (c) a contracting entity or a manufacturer which invites a notified body to apply the ‘EC’ verification procedure in accordance with Article 18(1) of Directive 2008/57/EC or a designated body according to Article 17(3) of that Directive;
- (d) an applicant for an authorisation for the placing in service of structural sub-systems

structural sub-systems”, taking into account the fact that under Directive (EU) 2016/797, mobile sub-systems are not anymore authorised but placed on the market. It should be noted that the use of the methodology described in Annex I of Commission Implementing Regulation (EU) 402/2013 for the requirements capture process of the essential requirement “safety” and for the safe integration between subsystems is mandatory. For this reason, in most of the cases, the ‘applicant’ for a vehicle type authorisation and/ or vehicle authorisation for placing on the market will also be the ‘proposer’.

Responsibilities of the ‘applicant’ referred to in Commission Implementing Regulation (EU) 2018/545

The applicant for vehicle type authorisation and/ or vehicle authorisation for placing on the market takes the responsibility for the vehicle type and/ or vehicle as a whole (vehicle types/ vehicles can be composed of several subsystems) to ensure that the relevant Union and national requirements are identified and complied with. However, other actors (conformity assessment bodies, applicant(s) for the purpose of Article 15 of Directive (EU) 2016/797 etc.) remain responsible for their respective parts, see Article 4 of Directive (EU) 2016/798.

In case of changes to an already authorised vehicle type and/ or vehicle, the applicant for the new authorisation is responsible for the new design and the new vehicle type as a whole. However, the existing holder of the vehicle type authorisation is still responsible for the unchanged parts of the design and the new applicant is responsible for the changes it introduces and the interfaces with the unchanged parts of the design of the vehicle type.

Responsibilities of the applicant for the purpose of Article 15 of Directive (EU) 2016/797

The applicant for the purpose of Article 15 of Directive (EU) 2016/797 performs the EC verification procedure and establishes the EC declaration of verification for a subsystem and is responsible that the subsystem meets all requirements of the relevant Union law and any relevant national rules. In the case of mobile subsystems it takes the responsibility that those mobile subsystem(s) it has placed on the market meet the essential requirements.

There is no requirement for authorisation for placing on the market for mobile subsystems. Mobile subsystems are placed on the market by the applicant as specified in Article 20 of Directive (EU) 2016/797.

3.2.3.2. Article 4: Responsibilities of the authorising entity

1. The authorising entity shall issue vehicle type authorisations and/or vehicle authorisations for placing on the market ('the authorisations') in accordance with Articles 21, 24 and 25 of Directive (EU) 2016/797 and with the provisions of this Regulation.
2. For the purposes of issuing or refusing an authorisation, the authorising entity shall:
 - (a) Coordinate the assignment of the tasks to the relevant parties and the setting up of coordination arrangements between them;
 - (b) Undertake an assessment of the application file to reach the reasonable assurance that the vehicle type and/or vehicle conforms to the applicable laws;
 - (c) Compile any supporting documentation, the results of all relevant assessments and the documented reasons for its decision to issue or refuse the authorisation, in accordance with this Regulation.
3. In case the Agency is the authorising entity, it shall coordinate the activities of the NSAs for the area of use related to vehicle type authorisation and/or vehicle authorisation for placing on the market.
4. The authorising entity shall provide pre-engagement at the request of the applicant.
5. The authorising entity shall carry out its tasks in an open, non-discriminatory, transparent way and shall exercise professional judgment, be impartial and proportionate, and provide documented reasons for any decision.

6. The authorising entity shall establish internal arrangements or procedures for managing the issuing of a vehicle type authorisation and/or a vehicle authorisation for placing on the market. Those arrangements or procedures shall take into account the agreements referred to in Article 21(14) of Directive (EU) 2016/797 and where relevant, multilateral agreements as referred to in Article 21(15) of Directive (EU) 2016/797.
7. Where the applicant indicates under Article 5(2) that the validity of the type authorisation has been affected the authorising entity shall update the ERATV accordingly.
8. Where the applicant indicates in its application that the intended area of use of the vehicle(s) or the vehicle type includes stations in neighbouring Member States with similar network characteristics, when those stations are close to the border, the authorising entity shall:
 - (a) receive confirmation from the NSAs of the neighbouring Member States that the relevant notified national rules and the obligations pertaining to the relevant cross-border agreements are met, before issuing the vehicle type authorisation and/or vehicle authorisation; and
 - (b) specify in the issued authorisation that the vehicle type authorisation and/or vehicle authorisation is also valid to such stations without an extension of the area of use.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Relevant references to Regulation (EU) 2016/796:

- › Article 20
- › Article 21

Relevant references to Directive (EU) 2016/798:

- › Article 16

‘Arrangement’ means the practicalities that need to be set up for managing the issuing of a vehicle type authorisation and/ or a vehicle authorisation for placing on the market, such as how many meetings, in which place, attendees to the meetings (e.g. the concerned NSAs for the area of use, the applicant, the conformity assessment bodies - NoBo, DeBo – on request of the applicant and/or other involved parties, etc.). This is different from the cooperation agreements referred to in article 21(14) of the Directive (EU) 2016/797.

3.2.3.3. Article 5: Responsibilities of the holder of the vehicle type authorisation

1. The holder of the vehicle type authorisation shall be responsible for the configuration management of the vehicle type and the accompanying file for the decision issued in accordance with Article 46.
2. Without prejudice of Articles 53 and 54, the holder of the vehicle type authorisation, as part of the configuration management of the vehicle type, shall inform the authorising entity that issued the vehicle type authorisation about any changes in Union law that affect the validity of the type authorisation.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24
- › Article 26

The holder of the vehicle type authorisation is responsible for establishing and maintaining (throughout the life of the vehicle type) a file containing all details of the design of the vehicle type (drawings, calculations etc.) including the vehicle type variants and vehicle type versions of that vehicle type.

As the holder of the vehicle type authorisation is the applicant that received the vehicle type authorisation it has those responsibilities specified for the applicant, see chapter 3.2.3.1.

Any changes to the already authorised vehicle type should be processed by the holder of the vehicle type authorisation according to Article 15 of Commission Implementing Regulation (EU) (EU) 2018/545, see chapter 3.3.2.2.

The principles of general product legislation should also apply: “The person who carries out the changes becomes then the manufacturer with the corresponding obligations”. The entity managing the modification has the choice to take the responsibility for the changed vehicle type and/ or vehicle or to leave it with the existing holder of the vehicle type authorisation. The concept of fragmenting responsibility for the design between different actors should not be supported.

In the event of a change to a vehicle type and where there is a new applicant that becomes the holder of the vehicle type authorisation for a new vehicle type based on an existing vehicle type:

- › The new holder of the vehicle type authorisation is primarily responsible for the new design and the new vehicle type as a whole.
- › The initial holder of the vehicle type authorisation remains liable for the unchanged parts of the design and the new holder of the vehicle type authorisation is liable for the changes it introduces and the interfaces with the unchanged parts of the design of the vehicle type.
- › The new holder of the vehicle type authorisation is solely responsible for the configuration management of the new vehicle type.

The monitoring of that the entity managing the change/ the potential applicant/ the applicant has correctly applied the provisions of Commission Implementing Regulation (EU) 2018/545 for the management of changes and the configuration management of the vehicle type and/ or vehicles (right categorisation of the change, right decision on whether a new authorisation is required according to the criteria specified in Article 21(12) of Directive (EU) 2016/797, correct use of Commission Implementing Regulation (EU) 402/2013 etc.) is done by the NSAs through controls during their supervision activities and as part of the conformity assessments by conformity assessment bodies during the manufacturing of vehicles in conformity to the vehicle type. The conformity assessment bodies have a role in the monitoring of the changes in the framework of the surveillance of the manufacturing process: changes in a vehicle type that affect an on-going manufacturing process must be taken into account by the conformity assessment body, to ensure that vehicles are manufactured in conformity to the changed vehicle type (when necessary).

3.2.3.4. Article 6: Responsibilities of the infrastructure manager

1. In the area of use, the infrastructure manager’s responsibilities in the framework of vehicle type authorisation and/or vehicle authorisation for placing on the market, based on the information provided by the applicant according to Article 18, shall be limited to the identification and provision of the following:
 - (a) operational conditions to be applied for the use of the vehicle for tests on the network;
 - (b) necessary measures to be taken on the infrastructure side to ensure safe and reliable operation during the tests on the network;
 - (c) necessary measures in the infrastructure installations to perform the tests on the network.
2. The concerned infrastructure managers for the area of use shall:
 - (a) support the applicant for the conditions to use the vehicle for tests on the network;

- (b) provide information on the infrastructure in a non-discriminatory way for using the vehicle for tests on the network;
- (c) identify and provide conditions and measures to use the vehicle for tests on the network within the given timeframe specified in Article 21(3) and 21(5) of Directive (EU) 2016/797 based on the information provided by the applicant;
- (d) by agreement with the applicant, participate in the pre-engagement.

Relevant references to Directive (EU) 2016/797:

- › Article 2(44)
- › Article 21
- › Article 24

Relevant references to Directive (EU) 2016/798:

- › Article 4
- › Article 9
- › Article 12

Relevant references to Directive 2012/34/EU:

- › Article 3(1)
- › Article 47

The Commission Implementing Regulation (EU) 2018/545 specifies the responsibilities and requirements to be complied with by the infrastructure manager in the framework of the railway vehicle authorisation and railway vehicle type authorisation process. The infrastructure manager has no other role in the framework of the railway vehicle authorisation and railway vehicle type authorisation process and should not impose any technical requirements on the design of a vehicle or request that the applicant performs tests on the network, see also chapter 3.3.5.

However, the infrastructure manager can have different roles based on its various interests:

- › Applicant for the purpose of Article 21 and 24 of Directive (EU) 2016/797 for its own vehicles.
- › Operator of its own mobile railway infrastructure construction and maintenance equipment.
- › Keeper for the purpose of Article 2(21) of Directive (EU) 2016/797.

The role of the infrastructure manager in the framework of the vehicle authorisation for placing on the market and vehicle type authorisation process is focused on providing the necessary elements to allow the applicant to conduct the tests on the network that are necessary to complete the assessment of the requirements:

- › Provide information on the infrastructure which is needed to perform the conformity assessments (e.g. track geometry for running dynamics tests);
- › Provide track access for tests on the network (allocation of capacity to actually perform the tests on the network);
- › Provide, where necessary, and based on the information provided by the applicant (namely test specifications, sequence of tests on the network, etc.), the additional operational conditions for the vehicle to be applied during the tests on the network. This includes conditions and restrictions for use due to the fact that not all systems of the test vehicle may have been fully verified and validated when the tests on the network begin (e.g. avoid operation in degraded modes of the traction system such as a reduced number of converters);

- › This will also have an impact on the allocation of capacity and slots (e.g. it may be necessary to restrict the circulation of trains on the adjacent track, or to block a given section of the line in which the tests on the network are being conducted); and
- › Take the necessary measures on the infrastructure side to allow the applicant to conduct the tests on the network that are needed for the conformity assessments (e.g. changes in the voltage in the catenary, permission to over speed in certain sections of the test line, etc.), taking into account aspects such as safety and capacity restrictions, limit excessive wear or damage to the infrastructure, etc.

The conditions for use and other restrictions to be applied during the tests on the network are separated from the conditions of use and other restrictions that will be included in the issued authorisation (see chapter 3.3.6):

- › Identified by the applicant;
- › Resulting from the assessment process; and
- › Resulting from the assessment by the authorising entity and/ or the concerned NSAs for the area of use.

Infrastructure manager, fees and charges

The infrastructure manager, according to Article 47 of the Directive 2012/34/EU, is required to make publically available the content of its Network Statement.

The charges for the infrastructure manager's tasks (including providing information about the infrastructure, and also the ways in which the infrastructure manager shall provide the information) are specified by the above mentioned Directive. More detailed provisions regarding fees and charges should be part of the agreements between railway undertakings and infrastructure managers.

An applicant can decide to involve the infrastructure manager during the authorisation process (e.g. to anticipate issues that can appear for route compatibility checks) but this is not always applicable and is subject to applicant's request/ need. The route compatibility check referred to in Article 23(1)(b) of Directive (EU) 2016/797 regarding the checks to be performed by a railway undertaking before the use of authorised vehicles is not part of the authorisation process.

3.2.3.5. Article 7: Responsibilities of the NSAs for the area of use

1. For the purposes of issuing a vehicle type authorisation and/or a vehicle authorisation for placing on the market, the NSAs for the area of use shall be responsible
 - (a) for their part of the assessment in accordance with Article 40;
 - (b) for issuing an assessment file to the authorising entity pursuant to Article 40(6).
2. In undertaking its responsibilities, the NSAs for the area of use shall carry out its tasks in an open, non-discriminatory, transparent way and shall exercise professional judgment, be impartial, proportionate, and provide documented reasons for conclusions reached.
3. The concerned NSAs for the area of use shall provide pre-engagement at the request of the applicant.
4. The NSAs for the area of use shall share with the Agency and all other NSAs all information resulting from return of experience related to technical and operational matters that may be relevant for the issuing of a vehicle type authorisation and/or vehicle authorisation for placing on the market such as:
 - (a) information received pursuant to Article 4(5)(b) of Directive (EU) 2016/798;
 - (b) non-compliance with essential requirements that may lead to amendment or revocation of an authorisation in accordance with Article 26 of Directive (EU) 2016/797;
 - (c) deficiencies in a TSI in accordance with Article 6 of Directive (EU) 2016/797.

5. The NSAs for the area of use shall establish internal arrangements or procedures for managing the issuing of a vehicle type authorisation and/or a vehicle authorisation for placing on the market. Those arrangements or procedures shall take into account the agreements referred to in Article 21(14) of Directive (EU) 2016/797 and where relevant, multilateral agreements as referred to in Article 21(15) of Directive (EU) 2016/797.
6. The NSAs for the area of use shall set up, publish and keep up to date guidelines describing their language policy, communication provisions and the process for temporary authorisation when required according to the national legal framework and make them available to the public free of charge.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Relevant references to Directive (EU) 2016/798:

- › Article 16

Without prejudice to their responsibilities, the concerned NSAs for the area of use as appropriate should decide on the nature and extent of their respective contributions before the submission of an application for a vehicle type authorisation and/ or vehicle authorisation for placing on the market when the applicant so requests in accordance with Commission Implementing Regulation (EU) 2018/545 and should communicate their cooperation and coordination arrangements to the applicant.

The NSA(s) for the area of use should have arrangements in place within their respective organisation for providing competent resources to complete the tasks assigned to them with quality and within the timeframes specified.

The information that should be recorded and exchanged

As provided by Article 7(4) of Commission Implementing Regulation (EU) 2018/545, the purpose of the recording and exchange of information is that the NSAs for the area of use should share with the Agency and all other NSAs all relevant information resulting from return of experience related to technical and operational matters that may be relevant for the issuing of a vehicle type authorisation and/ or vehicle authorisation for placing on the market. Information that may be relevant for the issuing of a vehicle type authorisation and/ or vehicle authorisation for placing on the market is information that can be used by the authorising entity and/ or the NSAs for the area of use to raise issues according to Article 41 of Commission Implementing Regulation (EU) 2018/545, in particular type 4 issue where there is a justified doubt.

The listed information in Article 7(4) of Commission Implementing Regulation (EU) 2018/545 only represents some typical type of information to be shared and does not form an exhaustive list. Other relevant information resulting from return of experience related to technical and operational matters that could be relevant for the issuing of a vehicle type authorisation and/ or vehicle authorisation for placing on the market might exist and should also be subject to those recording and exchanging provisions between the NSAs for the area of use and the Agency. It has to be noted that the scope of the information resulting from return of experience should cover both technical and operational aspects.

3.2.3.6. Article 8: Responsibilities of the Agency

1. The Agency shall set up, publish and keep up to date guidelines describing and explaining the requirements set out in this Regulation, and make them available to the public free of charge, in all the official languages of the Union. The guidelines shall also include model templates that may be used by the authorising entity and the NSAs for the area of use for the exchange and recording of information and model templates for the application that may be used by the applicant.

2. The Agency shall establish a protocol and procedures for the recording and exchange of information referred to in Article 7(4). Other affected or concerned parties may have access to relevant information, provided that the confidentiality of information is safeguarded.

Relevant references to Regulation (EU) 2016/797:

- › Article 4(i)
- › Article 19(3)

Protocol for recording and exchange of information

The origin of information resulting from return of experience are the activities performed by the NSAs for the area of use, in particular the supervision carried out following Article 17 of Directive (EU) 2016/798 and Commission Delegated Regulation (EU) 2018/761 on CSM on supervision. In the course of these activities, a NSA for the area of use might detect itself, or be made aware by a railway undertaking, or any other relevant actor, of a technical and/ or operational matter that may be relevant for the issuing of a vehicle type authorisation and/ or vehicle authorisation for placing on the market, see chapter 3.2.3.5.

In such a case, the NSA for the area of use should immediately record and share the relevant information with all other NSAs and the Agency.

Regarding information received pursuant to Article 4(5)(b) of Directive (EU) 2016/798, a voluntary tool called the Safety Alert IT system (SAIT) has been developed and implemented by the Agency to cover these exchanges of information between operational actors only (operational actors being railway undertakings, infrastructure managers, entities in charge of maintenance and all other actors having a potential impact on the safe operation of the Union rail system, including manufacturers, maintenance suppliers, keepers, service providers, contracting entities, carriers, consignors, consignees, loaders, unloaders, fillers and unfillers), therefore excluding NSAs and the Agency. The communication by operational actors of such information to the NSAs and the Agency therefore follows another protocol, which is currently mostly informal.

Regarding information received about non-compliance with essential requirements or deficiencies in a TSI (Article 7(4)(b) and (c) of Commission Implementing Regulation (EU) 2018/545), the protocols and procedures provided by Article 11, 16 and 26 of Directive (EU) 2016/797 and Article 6 of Directive (EU) 2016/797 respectively should be followed by the NSAs for the area of use. These protocols and procedures cover the requirement to record and exchange such information with the other NSAs and the Agency.

All NSAs for the area of use and authorisation entities, should take into account the information resulting from the return of experience shared as regards the on-going as well as future applications for vehicle type authorisation and/ or vehicle authorisation for placing on the market. When such information related to technical and operational matters is subject to a Joint Network Secretariat (JNS) procedure, the authorising entity and/ or the NSAs for the area of use should take into account the outcomes of the JNS procedure.

Such information could be used by the authorising entity and/ or the NSAs for the area of use in the course of an assessment of an application. It should be used also by the authorising entity during the pre-engagement stage of an application to inform the applicant about the identified risk(s), allowing to anticipate its consideration in term of design and/ or area of use for instance.

The information could also be relevant for other actors, such as potential applicants, manufacturers, and conformity assessment bodies. In such cases, if the NSA for the area of use or any other NSA or the Agency as authorising entity decides so, the information should be communicated also to those other actors. To this end, the NSA for the area of use, or any other NSA or the Agency as authorising entity deciding to share the information with other actors should ensure that the confidentiality of information is safeguarded by removing any reference to individual, company name and/ or by using a generic denomination of a product/ part.

An IT tool to support the recording and exchange of information

In order to support the implementation of this requirement, the Agency is currently investigating the possibility of putting in place an IT tool that would be suitable to facilitate the recording and exchange of information; including a specification of the required features of the IT tool such as a detailed taxonomy and confidentiality aspects required to share such information with other affected parties.

3.2.4. Article 9: Use of an authorised vehicle

After performing the checks referred to in Article 23 of Directive (EU) 2016/797, a railway undertaking or an infrastructure manager may use a vehicle in the area of use, according to the conditions for use of the vehicle and other restrictions specified in the vehicle type authorisation and/or the authorisation for placing on the market.

Relevant references to Directive (EU) 2016/797:

- › Article 22
- › Article 23
- › Article 47
- › Article 48
- › Article 49

Relevant references to Directive (EU) 2016/798:

- › Article 4
- › Article 9

Checks before use of an authorised vehicle should be limited to those checks specified in Article 23 of Directive (EU) 2016/797. The railway undertaking or infrastructure manager that intends to use the vehicle should be responsible for performing the compatibility check between the vehicle(s) and the intended routes and also to perform the compatibility check between trains and routes, covering the elements set out in TSI OPE (clause 4.2.2.5 and Appendix D of the Commission Regulation (EU) 2015/995).

This route compatibility check should be based on the data collected in RINF and the vehicle data specified in the issued authorisation and in the full accompanying file for the decision issued in accordance with **Error! Reference source not found.** of Commission Implementing Regulation (EU) 2018/545, including the conditions of use and other restrictions, by means of parameters and procedures described in the relevant TSI OPE (pursuant to Article 4(3)(i) of Directive (EU) 2016/797). In the case where the infrastructure register does not exist or is incomplete, the relevant information on the infrastructure, including any temporary restrictions, should be supplied by the infrastructure manager free of charge and within a reasonable time.

The following figure provides an overview of this process:

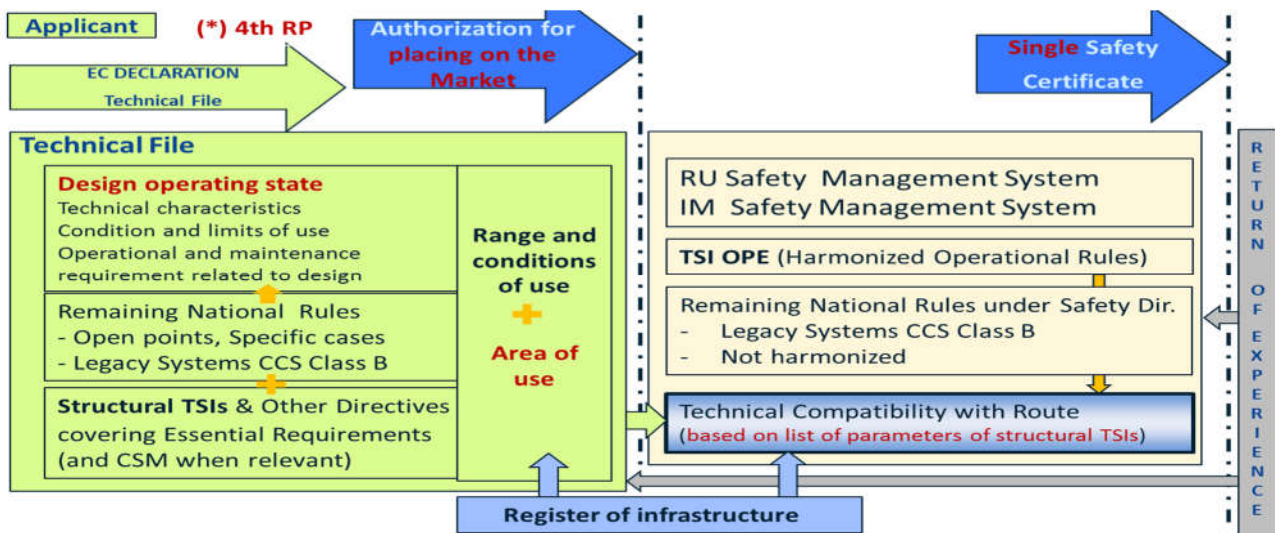


Figure 2: Overview of the checks before the use of an authorised vehicle

The compatibility of a vehicle with the network(s) in the area of use is checked at the vehicle authorisation level on the basis of TSIs, national rules and the relevant CSM, which is why a vehicle is authorised for a certain area of use. These checks should not be repeated by the railway undertaking or the infrastructure manager intending to use the vehicle as part of the compatibility check between the vehicle(s) and the intended routes, as the area of use of the vehicle is defined in the issued authorisation. Specificities for a given line section are identified in RINF (or provided by the infrastructure manager when RINF does not exist or is incomplete, free of charge and within a reasonable time).

In particular cases, such as for exceptional consignment, specific operational conditions and additional information about the configuration of the train and the infrastructure might be necessary (e.g. additional more precise values of parameters, such as the specific profile of the loaded vehicle(s)). In such a case, the infrastructure manager and the railway undertaking should agree in advance on these specific operational conditions. The infrastructure manager should provide the relevant necessary information about the infrastructure.

The TSIs are being revised in order to implement the requirements derived from Directive (EU) 2016/797 and will provide:

- › Definition of the parameters relevant for route compatibility within an area of use in the structural TSIs;
- › An amendment to the TSI OPE Commission Regulation (EU) 2015/995 regarding the procedure to be followed for the route compatibility check covering:
 - Route compatibility check and train composition; and
 - Vehicle information and route information to be used.
- › And amendment to clause 4.9 of TSIs LOC&PAS and WAG;
- › An update and/ or amendment to the relevant registers (e.g. RINF), if required; and
- › Corresponding guidelines.

When tests on the network are necessary to perform compatibility checks with the route the railway undertaking or the infrastructure manager that intends to use the vehicle should lodge a request to the concerned infrastructure manager. The procedure to perform such tests on the network should be described and communicated by the infrastructure manager. These tests on the network should take place within three months of the request and the railway undertaking or the infrastructure manager that intends to use the vehicle and the concerned infrastructure manager should cooperate to execute them. These tests on the network should be:

- › Seen as an exception and only take place when strictly necessary to perform the route compatibility check, the technical compatibility of the vehicle with the network has already been demonstrated within the vehicle authorisation process; and
- › Should not repeat tests on the network that have already been performed during the vehicle authorisation process.

It is recommended that the applicant involves the concerned infrastructure manager at an early stage of the vehicle authorisation process in order to identify the need for such future tests on the network and any other potential issues that can impact the checks before the use of the vehicle by future railway undertaking(s) as referred to in Article 23 of Directive 2016/797. This is left to the discretion of the applicant.

The railway undertaking or infrastructure manager that intends to use the vehicle should also check that the vehicle is properly integrated in the composition of the train where it is intended to operate. This check involves using the safety management system set out in Article 9 of Directive (EU) 2016/798 and in Commission Regulation (EU) 2015/995 (for full operational compatibility i.e. for train composition, braking performance etc.).

3.2.5. Article 10: Language

1. Where the vehicle type authorisation and/or vehicle authorisation for placing on the market is to be issued in accordance with the provisions of Article 21(5) to (7) of Directive (EU) 2016/797, the applicant shall:
 - (a) submit the application and the file accompanying the application in one of the official languages of the Union;
 - (b) translate parts of the file accompanying the application upon request, in accordance with point 2.6 of Annex IV to Directive (EU) 2016/797. In this case, the language to be used is determined by the NSA and indicated in the guidelines referred to in Article 7(6).
2. Any decision concerning the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market taken by the Agency, including the documented reasons for the decision and where applicable, the issued vehicle type authorisation and/or vehicle authorisation for placing on the market shall be provided in the language referred to in point (a) of paragraph 1.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Point 2.6 of Annex IV

Where the vehicle type authorisation and/ or vehicle authorisation for placing on the market is to be issued in accordance with the provisions of Article 21(5) to (7) of Directive (EU) 2016/797

The application and the file accompanying the application will be submitted by the applicant in one of the official languages of the Union. The Agency and the concerned NSAs for the area of use can request that the applicant translates parts of the file accompanying the application in accordance with point 2.6 of Annex IV of Directive (EU) 2016/797. The language to be used when determined by the concerned NSAs for the area of use is indicated in the guidelines referred to in Article 7(6) of Commission Implementing Regulation (EU) 2018/545.

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. The choice of language for the assessment should take into account:

- › The language used for the application (i.e. if it is possible to use this language as the language for assessment then the need for translation can be reduced).

- › The language competency (i.e. competence in the language at a level which is appropriate for the full understanding of the file) of the applicant; and of the members of the assessment team.

When applicable, the choice of language for the assessment should be made during pre-engagement.

For the part of the assessment of an application for vehicle type authorisation and/ or vehicle authorisation for placing on the market carried out under the national legal framework by the concerned NSAs for the area of use, all requests by the concerned NSAs for the area of use for documents to be translated by the applicant should be based on the requirements of the national legal framework of the Member State as indicated in the guidelines referred to in Article 7(6) of Commission Implementing Regulation (EU) 2018/545 and whether the NSA for the area of use has the effective and efficient capability (sufficient staff competence in the language of the applicant at a level which is appropriate for the full understanding of the file) to deal with the file in the language of the applicant. If the NSA for the area of use does, it should not ask for a translation unless this is required in the national legal framework of that Member State as indicated in the guidelines referred to in Article 7(6) of Commission Implementing Regulation (EU) 2018/545. If the NSA for the area of use does not have staff with the appropriate language skills, it can ask the applicant to provide a translation in the working language of that NSA for the area of use.

The NSA for the area of use should indicate in the guidelines referred to in Article 7(6) of Commission Implementing Regulation (EU) 2018/545 what the language policy is for that Member State.

The language used can be different for the application phase, the assessment phase and the outcome of the authorisation process as follows:

1. File accompanying the application in the official language of the Union used by the applicant for its application and, if requested by the authorising entity and/ or the concerned NSAs for the area of use, fully or partially translated by the applicant into the following languages:
 - › EU part: English or the commonly agreed language.
 - › National part(s): translated by the applicant upon request by the concerned NSAs for the area of use using the language determined by the NSA for the area of use as indicated in the guidelines referred to in Article 7(6) of Commission Implementing Regulation (EU) 2018/545, or English or the commonly agreed language if permitted by the national legal framework of that Member State.
2. Assessment (exchange of comments/ request for information/ issues):
 - › EU part: English or the commonly agreed language.
 - › National part(s): English or the commonly agreed language.
 - › Coordination meetings between the concerned NSAs for area of use/ the authorising entity/ applicant: English or the commonly agreed language. This includes meetings, phone calls, emails, letters and the issues log.
3. Outcomes:
 - › Authorising entity's assessment report as specified in Article 39(5) of Commission Implementing Regulation (EU) 2018/545: English or the commonly agreed language.
 - › Assessment reports from the concerned NSAs for area of use as specified in Article 40(6) of Commission Implementing Regulation (EU) 2018/545: NSA's language, English or the commonly agreed language, if permitted by the national legal framework of the Member State as indicated in the guidelines referred to in Article 7(6) of Commission Implementing Regulation (EU) 2018/545.
 - › Final assessment report including documented reasons for the decision as specified in Article 45(4) and 45(5) of Commission Implementing Regulation (EU) 2018/545: The official language of the Union used by the applicant for its application.
 - › The issued vehicle type authorisation and/ or vehicle authorisation for placing on the market: The official language of the Union used by the applicant for its application.

Where the vehicle type authorisation and/ or vehicle authorisation for placing on the market is to be issued in accordance with the provisions of Article 21(8) of Directive (EU) 2016/797

The provisions for language in the national legal framework in the concerned Member State applies.

The NSA should indicate in the guidelines referred to in Article 7(6) of Commission Implementing Regulation (EU) 2018/545 what the language policy is for that Member State.

3.2.6. Article 11: Vehicle authorisation process for tram-trains on the Single European Railway Area

1. For the purpose of a tram-train vehicle type authorisation and/or a tram-train vehicle authorisation for placing on the market intended to be operated in the Union rail system, without prejudice to Article 1 of Directive (EU) 2016/797, and when no technical specification for interoperability ('TSI') applies to the concerned tram-train vehicle or tram-train vehicle type as described by the Article 1(5)(b) of Directive (EU) 2016/797, Member States may use a procedure provided for in its national legal framework regarding the tram-train vehicle type authorisation and/or tram-train vehicle authorisation for placing on the market. In such a case, the applicant shall refer to the national framework of the Member State concerned regarding the procedure to follow for the tram-train vehicle type authorisation and/or tram-train vehicle authorisation for placing on the market.
2. In case of a tram-train vehicle type authorisation and/or a tram-train vehicle authorisation for placing on the market intended to be operated in the Union rail system for cross-border operation, and when no TSI applies to the concerned tram-train vehicle type, the applicant shall apply to the authorising entities designated by the Member States involved, which shall cooperate with a view to issuing a tram-train vehicle type authorisation and/or a tram-train vehicle authorisation for placing on the market.
3. In other cases, a tram-train vehicle and tram-train vehicle type in the scope of Directive (EU) 2016/797 shall be authorised according to the procedure set out in this Regulation.

Relevant references to Directive (EU) 2016/797:

- › Article 1
- › Article 2
- › Article 13
- › Article 14
- › Article 21
- › Article 24

Tram-train is a concept which allows for a combined operation on both light-rail infrastructure and heavy-rail infrastructure, as defined by Article 2 of Directive (EU) 2016/797.

A “tram-train vehicle type” is in the scope of the directive (“case of an authorisation of tram-train vehicle type on heavy rail” as expected in the issue description above) when:

- › It is a tram-train vehicle type which does not fulfill the criteria for “light rail” (Directive (EU) 2016/797 Article 1(3) and 2(18));
- › It is a tram-train vehicle type with an area of use including “heavy rail infrastructure” (not limited to a “transit to be effected on confined and limited section of heavy rail for connectivity purpose only”); and
- › Not functionally separate from the rest of the Union rail system and intended only for the operation of local, urban or suburban passenger services.

When one of the criteria is not fulfilled, it means that the “tram train vehicle type” concerned is not in the scope of Directive (EU) 2016/797. In this case, authorisation of these vehicles are subject to purely national procedures, which may request the (partial or total) application of some TSIs.

Member States may exclude from the scope of the Directive (EU) 2016/797:

- › Light rail infrastructure occasionally used by heavy rail vehicles under the operational conditions of the light rail system, where it is necessary for the purposes of connectivity of those vehicles only; and
- › Vehicles primarily used on light rail infrastructure but equipped with some heavy rail components necessary to enable transit to be effected on a confined and limited section of heavy rail infrastructure for connectivity purposes only.

If the tram-train vehicle type is part of the exclusion of the scope of Directive (EU) 2016/797, the applicant should follow purely national provisions put in place in each Member State. In case of conflict between the authorising entity and the applicant regarding the categorisation of a vehicle, the applicant can bring an appeal to the relevant appeal body.

“Private” in Article 1(4)(a) of Directive (EU) 2016/797 does not cover infrastructure owned by regional authorities.

When tram-trains use railway infrastructure, compliance with all essential requirements should be ensured, as well as compliance with the expected safety level on the relevant lines. For cross-border cases, competent authorities should cooperate.

Assessment in case of authorisation of tram-train vehicles for cross-border operation

The process for authorising tram-trains for cross-border operation can follow the principle of simultaneous authorisation (Article 26(6) of Directive 2008/57/EC): the applicant can apply to several Member States at the same time (in parallel). Following procedures/agreements established between authorising entities, a “leading” authorising entity issues the first authorisation and the other authorising entities issue “simultaneously” the authorisations for the extended area of use. In this case, authorising entities should cooperate with a view to simplify the procedure and minimise administrative efforts.

The applicant should:

- › Apply to a first Member State, according to its national provisions; and
- › Apply for an extension of area of use to the other Member States.

The authorising entity for tram-trains should:

- › Assess the file;
- › Cooperate with the other concerned authorising entities; and
- › Issue the authorisation.

In the case of a cross-border agreement, Article 21 of Directive (EU) 2016/797 will not apply, and the purely national procedure(s), with potentially a different authorising entity than the NSA can be involved in the authorisation process. In the case of cross-border operation, Article 1(5)(c) of Directive (EU) 2016/797 states that the authorising entities from the Member States involved should cooperate for issuing the vehicle type authorisation and/ or vehicle authorisation for placing on the market. In this case, the Agency is not the competent authority and the applicant should not apply to the Agency.

In the case of cross-border operation of tram-trains, the authorising entities (NSA or other competent entity) of the concerned Member States should put in place cooperation agreements or cooperate on a case-by-case basis (and put in place the necessary procedures), vis-à-vis cross-border agreements.

The principle of mutual recognition applies and national rules related to tram-trains have to be notified and classified according to Article 13 and 14 of Directive (EU) 2016/797. This means that it is possible to consider this case as an extension of the area of use for the other Member State, therefore limiting the additional work required.

3.2.7. Article 12: Cross-border agreements

1. The NSAs shall make publicly available on their website the procedure to be followed regarding cross-border agreements for the authorisation to cover stations in the neighbouring Member States, pursuant to Article 21(8) of Directive (EU) 2016/797, in particular:
 - (a) any existing cross-border agreements between NSAs that may have to be used;
 - (b) the procedure to be followed where such cross-border arrangements do not exist.
2. For a cross-border agreement on the process to issue an authorisation to cover stations in the neighbouring Member States, pursuant to Article 21(8) of Directive (EU) 2016/797, the NSAs shall specify the procedure to be applied, and shall at least provide the following details:
 - (a) the procedural stages;
 - (b) the timeframes;
 - (c) the technical and geographical scope;
 - (d) the roles and tasks of the parties involved; and
 - (e) the practical arrangements for the consultation with the relevant parties.

Relevant references to Directive (EU) 2016/797:

- › Article 21

3.3. Chapter 2 - Stage 1: preparation of the application

For description of the process, see Annex XVIII the flowchart for Stage 1.

3.3.1. Article 13: Requirements capture

1. In accordance with the overall objective of managing and mitigating all the identified risks to an acceptable level, the applicant shall, before submitting an application, undertake a requirements capture process which shall ensure that all the necessary requirements covering the design of the vehicle for its life cycle have been:
 - (a) identified properly;
 - (b) assigned to functions or subsystems or are addressed through conditions for use or other restrictions; and
 - (c) implemented and validated.
2. The requirements capture performed by the applicant shall in particular cover the following requirements:
 - (a) essential requirements for subsystems referred to in Article 3 and specified in Annex III to Directive (EU) 2016/797;
 - (b) technical compatibility of the subsystems within the vehicle;
 - (c) safe integration of the subsystems within the vehicle;
 - (d) technical compatibility of the vehicle with the network in the area of use.
3. The risk management process set out in Annex I to Regulation (EU) 402/2013¹ shall be used by the applicant as the methodology for requirements capture as regards the essential requirements "safety" related to the vehicle and subsystems as well as safe integration between subsystems for aspects not covered by the TSIs and the national rules.

¹Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 (OJ L 121, 3.5.2013, p. 8)

Relevant references to Directive (EU) 2016/797:

- › Article 3
- › Article 4
- › Article 21
- › Article 24
- › Annex III

Article 3(1) of Directive (EU) 2016/797 refers to the relevant essential requirements. The relevant essential requirements for authorisation of vehicles are described in Annex III of the Directive, comprising general requirements (section 1) and requirements specific to each subsystem (section 2).

Why it is necessary to perform the requirements capture

As a result of the “EC” verification procedure specified in Annex IV of Directive (EU) 2016/797, which relies mostly on the conformity assessment procedure carried out by NoBo/ DeBo (certificates of verification), the applicant for the purpose of Article 15 of Directive (EU) 2016/797 establishes an “EC” declaration of verification, which is necessary to place the subsystems on the market. The applicant should declare on his sole responsibility that the concerned subsystem has been subject to the relevant verification procedures and that it satisfies the requirements of relevant Union law and any relevant national rule and meets the essential requirements.

Therefore the “EC” declaration of verification covers a subsystem, and not a vehicle. There is no declaration to be established by the applicant for vehicle type authorisation and/ or vehicle authorisation for placing on the market at the vehicle level.

It is still the responsibility of the applicant for vehicle type authorisation and/ or vehicle authorisation for placing on the market to ensure that the vehicle type and/ or the vehicle satisfies the requirements from relevant Union law, any relevant national rule and meets the essential requirements.

However, the declaration that the subsystems comply with relevant Union law and any relevant national rules is wider than the NoBo/ DeBo certificates because:

- › TSIs contain provisions only to the extent necessary to meet the objectives of Directive (EU) 2016/797;
- › National rules are only allowed for some aspects not covered by TSIs: specific cases not described in the TSIs, open points and compatibility with the existing network;
- › Interfaces between subsystems may not always be fully described in TSIs and national rules; and
- › To design and build a vehicle that meets all essential requirements, there are other requirements that may be necessary to fulfil, such as:
 - In-house design rules (know how);
 - Codes of practice:
 - CEN/CENELEC standards;
 - ISO standards;
 - UIC leaflets;
 - etc.

Therefore, in regards to the vehicle authorisation process there is a need to provide evidence on the requirements capture process followed by the applicant to ensure that at vehicle type and/ or vehicle level, all relevant requirements are met.

The cases of authorisation where the evidence of the application of the requirements capture process are required to be included in the file accompanying the application

The process for the requirements capture should always be performed. However, the evidence of the application of the requirements capture process should be included in the file accompanying the application for authorisation for the authorisation cases first, new and extended area of use.

The aspects that need to be covered by requirements capture

The essential requirements refer to areas that are related to safety, health, accessibility, reliability and availability, technical compatibility and environmental protection (see Annex III of Directive (EU) 2016/797). Where there are no requirements relating to these essential requirements defined in the TSIs and/ or national rules, the applicant is nonetheless required to take appropriate steps to meet them.

The process for the requirements capture should cover all requirements from relevant Union law and any relevant national rule. The process can also be used to cover other requirements (such as contractual requirements). However, the requirements that are out of the scope of the vehicle authorisation process are not required to be covered by the requirements capture process described in the Commission Implementing Regulation (EU) 2018/545 unless they have an impact on the aspects mentioned in the legal text, namely the essential requirements.

The Group of Representative Bodies (GRB), which is a group of associations comprising the companies making up the railway operating community and the supply and manufacturing industry, publishes on its website (<http://grbrail.eu>) an informative listing of the relevant Union law. It should be noted that this list is for information only, and no assurance is given as to its accuracy, completeness or sufficiency.

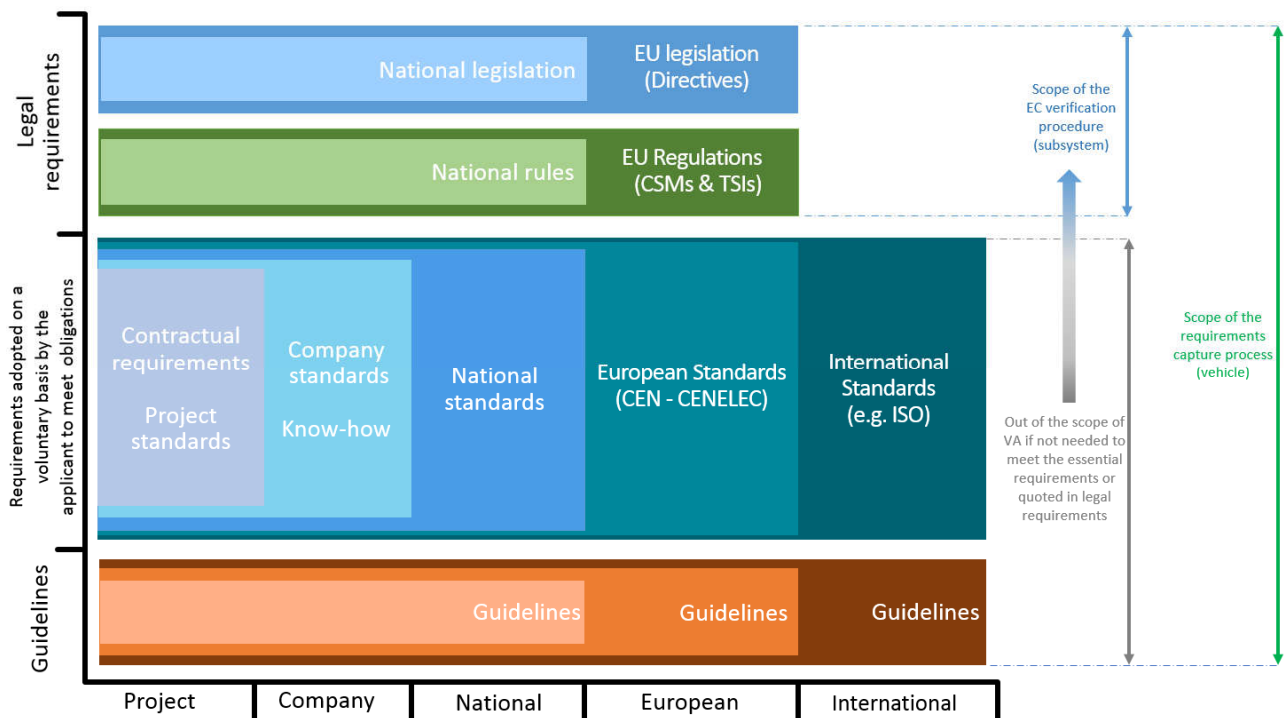


Figure 3: Sources and scope of requirements for vehicle authorisation

Use of mandatory rules (TSIs and national rules) as codes of practice for risk acceptance

In the framework of the requirements capture process and the application of the risk management process described in Annex I of Commission Implementing Regulation (EU) 402/2013, the mandatory rules (TSIs and national rules) can be considered as “codes of practice”, as specified in chapters 2.3.3 and 2.3.4 of Annex I of the Commission Implementing Regulation (EU) 402/2013. In such a case, they can be used as risk acceptance principles.

Benefits of using the risk assessment process set out in Annex I of Commission Implementing Regulation (EU) 402/2013 for the requirements capture process

For the vehicle authorisation process that is currently applied pursuant to Directive 2008/57/EC, the requirements capture as well as the risk assessment process are carried out in different ways in different Member States:

- › Some Member States have national rules specifying how the process shall be performed (including actors, roles and responsibilities); and
- › There is no mutual recognition of the assessments performed by safety assessors (unless Commission Implementing Regulation (EU) 402/2013 is used).

The process for vehicle type authorisation and/ or vehicle authorisation for placing on the market as specified in Directive (EU) 2016/797 will not work if each Member State/ national safety authority/ the Agency have different approaches to the process for requirements capture. From this point of view, the use of the risk assessment process set out in Annex I of Commission Implementing Regulation (EU) 402/2013 for the requirements capture process is beneficial because:

- › The authorising entity and/ or the concerned NSAs for area of use can only challenge the safety assessment report mentioned in Article 15 of Commission Implementing Regulation (EU) 402/2013, by raising a justified doubt (see chapter 3.7.12), if they are able to demonstrate the existence of a substantial safety risk (meaning a non-acceptable safety risk with potential for serious accident). The burden of proof is therefore allocated to the authorising entity and/ or the concerned NSAs for the area of use;
- › The authorising entity and/ or the concerned NSAs for area of use will not be allowed to add extra requirements;
- › Unlike other entities performing independent safety assessments (also known as independent safety assessors), the assessment body (CSM RA) competence is managed using a formal structure (accreditation/ recognition). This will result in the mutual recognition of Commission Implementing Regulation (EU) 402/2013 Article 15 reports;
- › It allows the assessment body (CSM RA) to be “in-house”, limiting the scope of its assessment to ensure that the process of management the risks was properly applied; and
- › It is consistent with the current practice of the industry (capturing requirements and assessing risks mainly at the beginning of a project).

Mandatory use of the risk assessment process set out in Annex I of Commission Implementing Regulation (EU) 402/2013 for the requirements capture process

It is mandatory to use the risk assessment process as defined in Annex I of Commission Implementing Regulation (EU) 402/2013 for the requirements capture of the essential requirement safety for the subsystems and the safe integration between subsystems for aspects not covered by the TSIs and the national rules.

In any case, the Commission Implementing Regulation (EU) 402/2013, should be applied as specified in Article 21(3) of Directive (EU) 2016/797; when required by the TSIs and/ or national rules if:

- › Safe integration between subsystems is not fully covered by the TSIs and/ or national rules; and
- › Technical compatibility of the vehicle with the network is not fully covered by TSIs and/ or national rules.

Requirements capturing and Commission Implementing Regulation (EU) 402/2013 should also be applied in case of change(s) to an already authorised vehicle and/or vehicle type (as is the current practice for the vehicle authorisation process according to Directive 2008/57/EC) including the decision made by the applicant on the significance of the change.

In the case of renewal/ upgrading, even where the changes are deemed to be not significant a new authorisation may be required if the criteria in Article 21(12) of Directive (EU) 2016/797 are met. In this case, there is a need to provide evidence of the application of the requirements capture process, and the provisions of Article 13(3) of Commission Implementing Regulation (EU) 2018/545 apply. This is further described in the flowchart for Stage 1 (Substage 1.1) that can be found in Annex XVII of this guideline, and in guidance to Annex I (points 18.8, 18.10, 18.11 and 18.12).

Requirements capture of essential requirements other than for safety

In order to perform the requirements capture of essential requirements other than safety, the applicant may choose the methodology to be used, although the methodology may be subject to further checks from the authorising entity as specified in Annex II of Commission Implementing Regulation (EU) 2018/545 and the evidence from the application of the methodology will be also assessed by the authorising entity and the concerned NSAs for the area of use as specified in Annex II and III of Commission Implementing Regulation (EU) 2018/545. The extent of the assessments will depend on whether the methodology used is widely used and known (i.e. standardised).

It may be the case that for certain changes that require a new authorisation, there are no safety related aspects. For this case, as specified in Annex I of Commission Implementing Regulation (EU) 2018/545, and in order to establish evidence confirming that the change does not impact safety aspects, the application of the Annex I of Commission Implementing Regulation (EU) 402/2013 is still mandatory. The applicant should also establish a safety assessment report pursuant to Article 15 of Commission Implementing Regulation (EU) 402/2013 and a declaration by the proposer pursuant Article 16 of Commission Implementing Regulation (EU) 402/2013. This is further explained in guidance to Annex I (points 18.8, 18.10, 18.11 and 18.12).

How to apply the methodologies for requirements capture

For the risk assessment process described in Annex I of Commission Implementing Regulation (EU) 402/2013 the details on how to perform the risk assessments can be found in Commission Implementing Regulation (EU) 402/2013.

For a given vehicle authorisation project there may be three different topics to be covered by assessment report(s) issued by an assessment body (CSM RA) and the declaration issued by the proposer (applicant):

- › The application of Commission Implementing Regulation (EU) 402/2013 for a specific subject when this is required by the TSIs/ national rules;
- › The application of Commission Implementing Regulation (EU) 402/2013 for a significant change; and
- › The requirements capture process for the essential requirement “safety” and the safe integration between subsystems if there are safety/ subsystem integration related aspects involved in the authorisation.

In regards to the requirements capture process, when the risk assessment process defined in Annex I of Commission Implementing Regulation (EU) 402/2013 is used, and the relevant assessment report is established by the assessment body (CSM RA) and a declaration is established by the proposer (applicant), pursuant to Article 15(3) of Commission Implementing Regulation (EU) 402/2013:

- › The authorising entity will only assess the aspects described in point 7.1 of Annex II of Commission Implementing Regulation (EU) 2018/545;
- › The NSAs for the area of use do not have any assessment to perform, pursuant to point 5 of Annex III of Commission Implementing Regulation (EU) 2018/545; and
- › The authorising entity and/ or the concerned NSAs for the area of use should not request additional checks, analysis or challenge the mitigation measures applied by the applicant and/or the criteria to determine whether a risk is acceptable or not, unless it is able to demonstrate the existence of a substantial safety risk and raises a justified doubt.

Article 4(3) of Directive (EU) 2016/798 requires that railway undertakings must ensure under their Safety Management System (SMS) that they and their contractors properly apply Commission Implementing Regulation (EU) 402/2013. The authorising entity will only verify the aspects described in point 7.1 of Annex II of the Commission Implementing Regulation (EU) 2018/545; the NSAs for the area of use do not have any assessment to perform, pursuant to point 5 of Annex III of the Commission Implementing Regulation (EU) 2018/545. In any case Article 4(4) of Directive (EU) 2016/798 also places the obligation to apply the Commission Implementing Regulation (EU) 402/2013 directly upon the contractors.

3.3.2. Identify and decide on the authorisation case

The first step is for the applicant, based on the description of the project, to identify and take a decision concerning the authorisation case that is applicable.

3.3.2.1. Article 14: Identification of the relevant authorisation

1. The applicant shall identify and choose the relevant authorisation from the following cases:

- (a) first authorisation: the vehicle type authorisation and/or the vehicle authorisation for placing on the market issued by the authorising entity for a new vehicle type, including its variants and/or versions if any, and, where applicable, the first vehicle of a type, pursuant to Article 21(1) of Directive (EU) 2016/797;
- (b) renewed vehicle type authorisation: the renewal of a vehicle type authorisation pursuant to Article 24(3) of Directive (EU) 2016/797 which does not require a change in design of the vehicle type;
- (c) extended area of use: the vehicle type authorisation and/or the vehicle authorisation for placing on the market issued by the relevant authorising entity for an already authorised vehicle type and/or vehicle in order to extend the area of use without a change of the design, pursuant to in Article 21(13) of Directive (EU) 2016/797;
- (d) new authorisation: the vehicle type authorisation and/or vehicle authorisation for placing on the market issued by the authorising entity after a change of an already authorised vehicle and/or vehicle type, pursuant to Articles 21(12) or 24(3) of Directive (EU) 2016/797;
- (e) authorisation in conformity to type: the vehicle authorisation for placing on the market for a vehicle or a series of vehicles that conform to an already authorised and valid vehicle type on the basis of a declaration of conformity to that type, pursuant to Article 25(1) of Directive (EU) 2016/797. Where applicable, there shall be a clear identification of the vehicle type version and/or the vehicle type variant to which the vehicle or series of vehicles is conform.

2. In cases of vehicle type authorisations pursuant to cases (c) and (d), the applicant, if he is the holder of the existing vehicle type authorisation, shall decide whether the authorisation will result in the creation of:

- (a) a new vehicle type; or
- (b) a new vehicle type variant within the existing type on which it is based.

If the applicant is not the holder of the existing type the authorisation shall result in the creation of a new type in accordance with Article 15(4).

3. An applicant may combine:

- (a) a request for new authorisation with a request for an authorisation for an extended area of use; or
- (b) a request for a first authorisation with a request for authorisation in conformity to type.

The timeframes set out in Article 34(1) and (2) shall apply to the combined application. Where appropriate, it may result in the issuing of several authorisation decisions by the authorising entity.

Relevant references to Directive (EU) 2016/797:

- › Article 4
- › Article 21(1)
- › Article 21(12)
- › Article 21(13)
- › Article 24(3)
- › Article 25(1)

For description of the process, see Annex XVIII the flowchart for Substage 1.1.

The applicant is responsible for the decision concerning the authorisation case that is applicable to the project.

When there is a change in the applicable requirements of the relevant Union law and/ or any relevant national rule, the holder of the vehicle type authorisation, through the configuration management of the vehicle type, should verify if:

- › The vehicle type authorisation remains valid (i.e. if it is still possible to place on the market more vehicles conforming to the authorised vehicle type) e.g. when the transitional provisions of the Union law so allow; or
- › There is a need to request:
 - a renewed vehicle type authorisation; or
 - a new authorisation,and create a new vehicle type, vehicle type variant or vehicle type version.

Vehicles already authorised for placing on the market should normally remain authorised even if the vehicle type authorisation has been rendered invalid by a change in the rules. However, in exceptional cases also the vehicles already authorised for placing on the market may be affected by a change in the rules (Article 4(3)(h) of Directive (EU) 2016/797).

If new versions/ variants are introduced for an authorised vehicle type then those vehicles already authorised for placing on the market should remain authorised without prejudice to the provisions in Article 4(3)(h) of Directive (EU) 2016/797. New vehicles can be built and authorised in conformity to type to all vehicle type variants and vehicle type versions that are still valid (taking into account any changes to the rules). For changes to an already authorised vehicle to bring it in conformity with another/ new version/ new variant of the vehicle type, see chapter 3.3.2.3.

Pre-engagement (Article 22 – Article 24 of Commission Implementing Regulation (EU) 2018/545) will mitigate the risk of making the wrong choices; consequently, the right choice is confirmed in the pre-engagement baseline, if any. Nevertheless, the applicant can decide to change the authorisation case before the issuing of the opinion that establishes the pre-engagement baseline, if any.

First authorisation (case (a))

A first authorisation (for a new design) can be issued for a vehicle type, including its variants and/ or versions, if any, and/ or a vehicle. When a first authorisation is issued for a vehicle then the vehicle type should be authorised at the same time. In this case it is clear that the vehicle is in conformity with the vehicle type so no declaration of conformity to type is required for that vehicle. All other vehicles of that vehicle type will be authorised according to case (e): authorisation in conformity to type.

Renewed vehicle type authorisation (case (b))

The renewed vehicle type authorisation is used where it is necessary to apply a change that has been made to a TSI or national rule to a vehicle type, so that future vehicles conforming to the vehicle type conform to the changed rule. The changed rule itself will determine whether the vehicle type authorisation needs to be renewed.

The renewed vehicle type authorisation is limited to the case where, after assessment against the changed rule(s), it is proven that the vehicle type conforms without any change to the basic design characteristics i.e. without any change to the design.

When there is a change of basic design characteristics, this no longer falls under renewed vehicle type authorisation case, and it should be considered as a change to an already authorised vehicle type, see chapter 3.3.2.2.

For information on when the requirements in TSIs and/ or national rules apply see chapter 3.3.3.

A vehicle type authorisation remains valid for an indefinite period; requiring renewal of the vehicle type authorisation only if a change to the rules specifies that the existing vehicle type authorisations become invalid in respect of a specific parameter. In this case, the renewal of vehicle type authorisation only requires verification of the changed parameters for which the new rule renders the existing vehicle type invalid.

In other words, each of a vehicle type's parameters (its basic design characteristics) retains "grandfather's rights" indefinitely until a new/ updated rule explicitly states that a new requirement for a parameter applies to an existing vehicle type that will need to be rechecked to achieve a renewed vehicle type authorisation.

Extended area of use without change to the vehicle type design (case (c))

For an authorisation extending the area of use of a vehicle type without a change to the vehicle type design, the existing vehicle type authorisation remains valid. This applies irrespective of which legal framework the vehicle type authorisation was issued for, except for the case when the vehicle type authorisation has been suspended or revoked.

On the basis that the vehicle type meets the essential requirements in the original area of use the authorising entity (with input from the concerned NSAs for the area of use) should grant an extension of area of use based on that the applicant provides evidence that the technical compatibility between the vehicle and the network that forms the new part of the area of use has been checked.

The checks to be performed by the authorising entity for an authorisation extending the area of use of a vehicle type should be limited to checking that the existing vehicle type authorisation is still valid and checking the technical compatibility between the vehicle and the network for the extended area of use. Checks already carried out at the first authorisation should not be repeated.

For the checks concerning technical compatibility between the vehicle and the network mutual recognition (cross acceptance) of national rules should be applied where possible in order to avoid unnecessary checks, see chapter 3.3.3.

Extension of area of use requiring change to the vehicle type design

When a vehicle type needs a changed design to enable it to be authorised and operate over an extended area of use in another Member State then the holder of the vehicle type authorisation will need to apply for both a new authorisation (case (d)) and an extension of area of use (case (c)). For this case, the Agency should be the authorising entity. Only the elements of the design that are changed, their interfaces with the unmodified parts and the compatibility with the networks to which the area of use is to be extended should be checked.

The applicant will need to demonstrate that they have taken full account of the effects of the change to the existing design and any limitations and conditions of use of the existing authorisation.

New authorisation (case (d))

A new authorisation is required in the following cases:

- › Changes to an already authorised vehicle type and/ or vehicle that meet the criteria set up in Article 21(12) of Directive (EU) 2016/797.
- › A new vehicle type is created based on an already authorised vehicle type, pursuant to Article 15(4) of Commission Implementing Regulation (EU) 2018/545.

Where changes are made to an already authorised vehicle and/ or vehicle type the analysis described in chapter 3.3.2.2 is applicable.

Chapter 3.3.2.2 describes what applies concerning the choice to be made concerning introducing a vehicle type variant, a vehicle type version or creating a new vehicle type when changes are made to an already authorised vehicle type.

Decision criteria if a new authorisation is required according to the criteria of Article 21(12) of Directive (EU) 2016/797:

- a) *“Changes are made to the values of the parameters referred to in point (b) of paragraph 10 which are outside the range of acceptable parameters as defined in the TSIs”*

Where point (b) of paragraph 10 in Article 21 of Directive (EU) 2016/797 is: *“the values of the parameters set out in the TSIs and, where applicable, in the national rules, for checking the technical compatibility between the vehicle and the area of use”*.

A new authorisation is therefore required if the change brings a network-vehicle interface parameter out of the range specified in the TSIs or the national rules.

- b) *“The overall safety level of the vehicle concerned may be adversely affected by the works envisaged”*

The actors should ensure that “railway safety is generally maintained and, where reasonably practicable, continuously improved” therefore, a change should not be contemplated if it will adversely affect the overall level of safety of the vehicle concerned.

It can thus be inferred that this clause relates to the potential to adversely affect the overall level of safety of the vehicle concerned, and not to whether the change in its real implementation will actually have a negative impact on safety or not.

To evaluate whether the overall level of safety of the vehicle concerned may be affected the applicant should apply Commission Implementing Regulation (EU) 402/2013.

It should be noted that if a change does not affect basic design characteristics, and therefore does not require authorisation on the grounds of rules compliance pursuant to Article 21(12)(a) and/ or (c) of Directive (EU) 2016/797, it may still have the potential to adversely affect the overall level of safety of the vehicle concerned and therefore trigger a new authorisation. This is also described in Annex XVIII, flowchart for Substage 1.1.

- c) *“it is required by the relevant TSIs.”*

See article 4(3)(h) of Directive (EU) 2016/797.

Authorisation in conformity to type (case (e))

The authorising entities issue the authorisation in conformity to type for a vehicle or a series of vehicles on the basis of a declaration of conformity to vehicle type (based on the relevant modules e.g. SD, SH1) submitted by the applicant. The assessments to be performed by the authorising entity for an authorisation in conformity to type are specified in Annex II.

An authorisation in conformity to type can only be issued as long as the vehicle type authorisation remains valid. If a change in the rules renders a vehicle type authorisation invalid, then the vehicle type will need a renewed authorisation before further vehicles can be authorised in conformity to type.

The declaration of conformity to vehicle type (e.g based on module SD or SH1) can only be issued by the applicant after the production of the vehicle or series of vehicles (if the applicant decides to include several vehicles in a single application for authorisation) conforming to the vehicle type. Due to this, it is not possible to apply for an authorisation in conformity to type in advance of a planned production of a vehicle or a series of vehicles, because the declaration of conformity to the vehicle type is part of the file accompanying the application for authorisation.

An applicant for an authorisation in conformity to type should verify whether:

- › There are provisions in TSIs and national rules that may render the vehicle type invalid or impose limitations on the placing on the market of vehicles which do not comply with the latest requirements; and
- › There is enough information (drawings, technical specifications, etc.) related to the design and manufacturing process to sign an EC declaration of conformity to an already authorised type.

Intellectual property rights are not directly linked with the practical arrangements for vehicle authorisation, this is a commercial/ contractual issue. The Directive (EU) 2016/797 and the Commission Implementing Regulation (EU) 2018/545 do not prohibit an entity other than the holder of the vehicle type authorisation from requesting an authorisation in conformity to type as long as they have the necessary information to issue the declaration of conformity to type.

Should an entity who is not the holder of the existing vehicle type authorisation wish to build and apply for a authorisation in conformity to type for new vehicles, they can:

- › Ask the holder of the existing vehicle type authorisation to manage the construction for them. In this case, the existing holder of the vehicle type authorisation remains the holder of the type authorisation for the type; or
- › If they have sufficient information and knowledge: build the vehicles themselves. In this case, they become applicant for the vehicle authorisation for placing on the market (i.e. submit a declaration of conformity to vehicle type based on the relevant modules e.g. SD, SH1 and subject to NoBo/ DeBo assessment), but they do not become the holder of the vehicle type authorisation. It is the sole responsibility of the applicant to ensure that it has enough information and knowledge to build vehicles that are conforming to the authorised vehicle type; the authorising entity should not assess this aspect.

In any case, the applicant should always ensure that the new vehicles meet the essential requirements.

A declaration of conformity to an authorised vehicle type relies on that the QMS certification is kept up to date by the applicant.

Coordination of authorisations - New authorisation combined with extended area of use

For the cases when an application for new authorisation is combined with extended area of use it would be very useful to have a pre-engagement process to discuss the coordination and planning.

There is a need to coordinate authorisations when there is an application for authorisation for extended area of use and for a new authorisation for the same vehicle and/ or vehicle type. In this case both processes can be performed by one applicant at the same time. The sequence to obtain the authorisation should be that the applicant receives the new authorisation before the authorisation for the extended area of use.

However, this should be seen as an administrative process and the assessments and decisions can be processed at the same time by the same assessment team. The application for the combined new and extended area of use authorisations could be sent at the same time but the authorising entity should take care of the correct sequence for issuing the authorisations. The extension of an area of use can only be performed for a vehicle and/ or vehicle type that is already authorised.

In the case of an extension of the area of use from one Member State to a second Member State combined with changes to the vehicle type and/ or vehicle where it is not the intention of the applicant to change the authorisation in the first Member State (e.g. because the changed vehicles will not be operated in the first Member State) or the holder of the vehicle type authorisation wishes to add a vehicle type variant to the vehicle type:

- › There is no need to request a new authorisation in the first Member State because the changes are only necessary for the second Member State; the vehicles that were already authorised in the first Member State will not be changed and will remain in conformity with the authorised vehicle type covering the first Member state;
- › The applicant should apply (to the Agency or to the NSA of Member State 2) for the case of a new authorisation for a new vehicle type or a new vehicle type variant (only if the applicant is the holder of the vehicle type authorisation) covering the changes; and
- › The area of use of the new vehicle type or the new vehicle type variant (only if the applicant is the holder of the vehicle type authorisation) will be limited to the second Member State.

3.3.2.2. Article 15: Changes to an already authorised vehicle type

1. Any changes to an authorised vehicle type shall be analysed and categorised as only one of the following changes and shall be subject to an authorisation as provided below:
 - (a) a change that does not introduce a deviation from the technical files accompanying the EC declarations for verification for the subsystems. In this case there is no need for verification by a conformity assessment body, and the initial EC declarations of verification for the subsystems and the vehicle type authorisation remain valid and unchanged;
 - (b) a change that introduces a deviation from the technical files accompanying the EC declarations for verification for the subsystems which may require new checks and therefore require verification according to the applicable conformity assessment modules but which do not have any impact on the basic design characteristics of the vehicle type and do not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797;
 - (c) a change in the basic design characteristics of the vehicle type that does not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797;
 - (d) a change that requires a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797.
2. When a change falls under point (b) or (c) of paragraph 1, the technical files accompanying the EC declarations for verification for the subsystems shall be updated and the holder of the vehicle type authorisation shall keep available the relevant information upon request of the authorising entity and/or the NSAs for the area of use.
3. When a change falls under point (c) of paragraph 1 the holder of the vehicle type authorisation shall create a new vehicle type version or a new version of a vehicle type variant and provide the relevant information to the authorising entity. The authorising entity shall register in ERATV the new version of the vehicle type or the new version of the vehicle type variant in accordance with Article 50.
4. If the entity managing the change is not the holder of the vehicle type authorisation and the changes made to the existing vehicle type are categorised as (b), (c) or (d) of paragraph 1, the following shall apply:
 - (a) a new vehicle type shall be created;
 - (b) the entity managing the change shall become the applicant; and
 - (c) the application for authorisation of the new vehicle type may be based on the existing vehicle type and the applicant may choose the authorisation case specified in Article 14(1)(d).

Relevant references to Directive (EU) 2016/797:

- › Article 15
- › Article 20
- › Article 21
- › Article 24

Responsibility for managing changes to an authorised vehicle type

Changes to an authorised vehicle type should be covered by the configuration management of the vehicle type. The configuration management of an authorised vehicle type is the responsibility of the holder of the vehicle type authorisation.

The categories of changes to an authorised vehicle type

Decisions made by a (potential) applicant/ entity managing the change concerning the changes to a vehicle and/ or vehicle type based on the four modification categories are different from the decision on the significance of a change to the railway system (in the meaning of Commission Implementing Regulation (EU) 402/2013) to be made by a railway undertaking or infrastructure manager contemplating a change to their part of the railway system (e.g. incorporating into the fleet a new design of vehicle to be operated on certain lines). The decisions involve different actors in different circumstances with different decision criteria; each actor is responsible for its part of the system.

The decision by the proposer on the categorisation of a change to a vehicle and/ or vehicle type may influence the scope of the responsibility. When the entity managing the change decides that the change does not trigger the criteria in Article 21(12) of Directive (EU) 2016/797 and does not introduce a deviation in the technical file(s) accompanying the EC declaration(s) of verification, it only takes responsibility for the management of the change. When the entity managing the change:

- › Decides that the criteria are triggered and a new authorisation is required;
- › Identifies that there is an impact on the technical file(s) accompanying the EC declaration(s) of verification; and/ or
- › Is not the holder of the vehicle type authorisation;

it should establish the EC declaration(s) of verification for the affected mobile subsystem(s) (including non-modified parts) and submit an application for vehicle type authorisation and/ or vehicle authorisation for placing on the market.

This is further described in Annex XVIII, flowchart for Substage 1.1.

(a) Changes that do not introduce a deviation from the technical files accompanying the EC declarations for verification for the subsystems.

This category of change has no impact on the verifications performed and consequently on the design or the documentation that forms the basis for the issued vehicle type authorisation (namely the file accompanying the application for authorisation, which includes the technical files accompanying the EC declaration(s) of verification for the subsystem(s)), therefore it does not have to be included in the configuration management of the vehicle type. However, the change is part of the maintenance of the vehicle(s) and needs to be covered by the configuration management of the vehicle(s).

- (b) Changes that introduce a deviation from the technical files accompanying the EC declarations for verification for the subsystems which may require new checks and therefore require verification according to the applicable conformity assessment modules but do not have any impact on the basic design characteristics of the vehicle type and do not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797.**

This category of change has no impact on the design (basic design characteristics) and does not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797 but it has an impact on the documentation that forms the basis for the issued vehicle type authorisation, therefore it is to be covered by the configuration management of the vehicle type.

This category of change may impact the conformity of the subsystems or the validity of certificates of conformity. The conformity assessment bodies perform the necessary verifications and issue the relevant certificates.

- (c) A change in the basic design characteristics of the vehicle type that does not require a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797.**

This category of change has an impact on the basic design characteristics and it has an impact on the documentation that forms the basis for the issued vehicle type authorisation. The changes to the design do not trigger the criteria set out in Article 21(12) of Directive (EU) 2016/797 for when a new authorisation is required. It is to be covered by the configuration management of the vehicle type. A new version of the vehicle type or a new version of a variant of the vehicle type should be created.

- (d) A change of the vehicle type that requires a new authorisation according to the criteria set out in Article 21(12) of Directive (EU) 2016/797.**

The changes trigger the criteria set out in Article 21(12) of Directive (EU) 2016/797 for when a new authorisation is required, see chapter 3.3.2.1. It is to be covered by the configuration management of the vehicle type. The holder of the vehicle type authorisation can either add a new vehicle type variant to the authorised vehicle type or decide to create a new vehicle type. This is an administrative decision of the holder of the vehicle type authorisation.

This is also applicable for vehicles authorised before the implementation of Directive (EU) 2016/797, see recital (16) of Commission Implementing Regulation (EU) 2018/545.

Extended (changed) area of use

An extension (change) of the area of use has an impact on the basic design characteristics i.e. the design (the area of use is a basic design characteristic specified in the issued vehicle type authorisation). However, for this type of change the case of authorisation should be for the extended area of use pursuant to Article 21(13) of Directive (EU) 2016/797. If this type of change is combined with other changes of the design requiring a new authorisation there should be two authorisation decisions but it can be combined in a single application, see chapter 3.3.2.1.

A change (extension) of the area of use is therefore a change to the design and it has an impact on the documentation that forms the basis for the issued vehicle type authorisation (it may be necessary to perform new conformity assessments according to the national rules for the extended area of use, which may also require updates on the technical files accompanying the EC declarations of verification, in the EC declarations of verification, in the evidence related to the requirements capture etc., even if there are no physical changes in the vehicle and/or vehicle type). It is to be covered by the configuration management of the vehicle type. The changes to the design require an authorisation for the extended area of use pursuant to Article 21(13) of Directive (EU) 2016/797, see chapter 3.3.2.1. The holder of the vehicle type authorisation can either add a new vehicle type version to the existing vehicle type or decide to create a new vehicle type. This is an administrative decision of the holder of the vehicle type authorisation.

If the area of use is to be changed a new vehicle type version or a new vehicle type will have been created because the area of use is a part of the design (basic design characteristic) of a vehicle type and it requires an authorisation for the extended area of use pursuant to Article 21(13) of Directive (EU) 2016/797.

New vehicle type

If a new vehicle type is created it needs to be authorised. This applies irrespective of the change and whether the change would require an authorisation or not. For the applicable case of authorisation see chapter 3.3.2.1.

If the new vehicle type is based on an authorised vehicle type the applicant can apply for a new authorisation even if the applicant is not the holder of vehicle type authorisation for the authorised vehicle type. Only the changes and their interfaces with the unchanged parts should be assessed by the authorising entity and the concerned NSAs for the area of use. See also chapter 3.2.2.6 and 3.2.3.3.

In a case when a change requires a new authorisation according to the criteria set out in Article 24(1) and 21(12) of Directive (EU) 2016/797 the holder of the vehicle type authorisation can either add a new vehicle type variant to the existing vehicle type or decide to create a new vehicle type. This is an administrative decision of the holder of the vehicle type authorisation.

Changes managed by another entity than the holder of the vehicle type authorisation

Should an entity who is not the holder of the existing vehicle type authorisation wish to make a change to the design and/ or to the documentation that forms the basis for the issued vehicle type authorisation (change category (b), (c), (d) or change (extend) the area of use) it can:

- › Ask the existing holder of the vehicle type authorisation to manage the change for them in which case the existing holder of the vehicle type authorisation remains the holder of the vehicle type authorisation; or
- › Manage the change itself. In this case, the entity becomes the applicant and creates a new vehicle type which should be authorised. This entity becomes holder of the vehicle type authorisation for the new vehicle type and takes the responsibility for the configuration management of the new vehicle type.

Another entity can make changes to the vehicle type on behalf of the holder of the vehicle type authorisation as long as the necessary contractual arrangements are put in place. Those contractual arrangements are out of the scope of the practical arrangements for the vehicle authorisation process and the responsibilities assigned to the holder of the vehicle authorisation should not be transferred to another entity through contractual arrangements.

It is possible for another applicant to base its application for a vehicle type authorisation on an already authorised vehicle type in the event of introducing a change categorised as (b), (c) or (d) as specified in Article 16(1) of the Commission Implementing Regulation (EU) 2018/545 to that vehicle type even if this applicant is not the initial holder of the vehicle type authorisation. This applicant can apply for a new authorisation and become the holder of the vehicle type authorisation for a new vehicle type. In this case the applicant will need to ensure that:

- › The vehicle type authorisation for the vehicle type it wishes to base its new authorisation on is still valid for the intended scope of the new authorisation.
- › It has sufficient information concerning the vehicle type to make the change in order for the new vehicle type to fulfil the requirements and for the configuration management of the new vehicle type.

When a new vehicle type is authorised the applicant for the authorisation of the new vehicle type becomes the holder of the vehicle type authorisation. This role cannot be transferred to another entity.

Whether creating a new vehicle type, a new vehicle type variant or a new vehicle type version the verification should cover only: the changes made to the design of the vehicle type, their interface with and their effect on the rest of the vehicle and its behaviour. The rest of the vehicle type design should not be re-checked.

Table 4 : Summary of categories of changes and authorisation cases

Change	Entity managing the change	
	Holder of the vehicle type authorisation	Not holder of the vehicle type authorisation
Category (a)	No change to vehicle type. No authorisation.	
Category (b)	No change to vehicle type. No authorisation. Technical files accompanying the EC declarations for verification of the subsystems should be updated. Information should be made available to authorising entity and/or NSAs for the area of use upon request	Entity managing change becomes the applicant. Create a new vehicle type. Apply for first authorisation or new authorisation.
Category (c)	Create a new version of vehicle type or a new version of a vehicle type variant. Provide relevant information to the authorising entity. The authorising entity registers the new version of the vehicle type or vehicle type variant in ERATV	Entity managing change becomes the applicant. Create a new vehicle type. Apply for first authorisation or new authorisation.
Category (d)	Apply for new authorisation. (May choose first authorisation)	Entity managing change becomes the applicant. Create a new vehicle type. Apply for first authorisation or new authorisation.
Extended area of use	Apply for authorisation for extended area of use. (May choose first authorisation)	Entity managing change becomes the applicant. Create a new vehicle type. Apply for first authorisation or new authorisation + authorisation for extended area of use.

3.3.2.3. Article 16: Changes to an already authorised vehicle

1. Changes to an already authorised vehicle which are linked to substitution in the framework of maintenance and limited to replacement of components by other components fulfilling identical functions and performances in the framework of preventive or corrective maintenance of the vehicle do not require an authorisation for placing on the market.
2. Any other changes to a vehicle shall be analysed and categorised in accordance with Article 15(1).
3. The entity managing the change shall request a new authorisation for placing on the market in accordance with Article 14(1)(d) when a change falls under Article 15(1)(d).
4. If the entity managing changes categorised in accordance with Article 15(1)(b) and (c) to an already authorised vehicle is not the vehicle type authorisation holder it shall:
 - (a) assess the deviations from the technical files accompanying the EC declarations for verification for the subsystems;
 - (b) establish that none of the criteria set out in Article 21(12) of Directive (EU) 2016/797 are met;
 - (c) update the technical files accompanying the EC declarations for verification for the subsystems;
 - (d) notify the changes to the authorising entity.

This may apply to a vehicle or a number of identical vehicles.

The authorising entity may issue, within 4 months, a reasoned decision requesting an application for authorisation in case of a wrong categorisation or insufficiently substantiated information.

5. Every change to a vehicle shall be subject to configuration management under the responsibility of the keeper or of the entity entrusted by it.

Relevant references to Directive (EU) 2016/797:

- › Article 15
- › Article 20
- › Article 21
- › Article 24
- › Article 25

Changes to a vehicle made according to Article 16(4) of Commission Implementing Regulation (EU) 2018/545

When the entity managing the change performs its assessment of the deviations from and the update of the technical file(s) accompanying the EC declaration(s) for verification for the subsystem(s) it should take into account Article 15 and 20 of Directive (EU) 2016/797 and the possible effect of the change on the issued EC declaration of verification and the placing on the market of the concerned mobile subsystem(s).

For guidance on the application of the criteria set out in Article 21(12) of Directive (EU) 2016/797, see chapter 3.3.2.1.

It should be noted that when the entity managing the change makes a change to a vehicle categorised in accordance with Article 15(1)(c), and based on the definition of vehicle type in Article 2(26) of Directive (EU) 2016/797, the vehicle will no longer belong to and be in conformity with the authorised vehicle type.

The changes made by the entity managing the change pursuant to Article 16(4) of Commission Implementing Regulation may require that the NVR registration needs to be updated concerning the information specified in Article 47(3) of Directive (EU) 2016/797. This in particular is applicable if the changes to the vehicle are categorised in accordance with Article 15(1)(c) of Commission Implementing Regulation (EU) 2018/545. Article 47(3)(c) of Directive (EU) 2016/797 requires that the NVR contains a reference to ERATV for the vehicle; in the case where changes have been made to the values of the basic design characteristics of a vehicle (Article 15(1)(c) of Commission Implementing Regulation (EU) 2018/545) the reference to the registration in ERATV will not be applicable for the changed vehicle as it no longer belongs to and conforms to the authorised vehicle type that is registered in ERATV.

The notification should be sent by the entity managing the change to the authorising entity that would be concerned if an application for authorisation would be required, see chapter 3.2.2.1 for guidance on which entity would have the role of authorising entity. In the case where the notification is to be addressed to the Agency acting as authorising entity the notification should be submitted through an IT tool that will be developed by the Agency. In the case where the notification is to be addressed to the concerned NSA acting as authorising entity the entity managing the change should contact the concerned NSA to establish where to send the notification. This IT tool can be used by the NSAs if they have put in place the necessary arrangements together with the Agency.

It is advised that the entity managing the change uses the model template provided in Annex XV for its notification and that the notification contains the information specified in Annex XIII.

For cases where the authorising entity decides to assess a notification Annex XIV provides support for the assessment by giving guidance on the aspects to assess. A model template that can be used by the authorising entity for its reasoned decision concerning a notification is available in Annex XVI.

Where the Agency as authorising entity has received the notification the authorising entity may need to consult with the concerned NSAs for the area of use in those cases where it is necessary to check the parameters according to national rules. The concerned NSAs for the area of use should provide to the authorising entity following its request:

- › A confirmation concerning the completeness and the sufficiently substantiated information provided or a list of the missing information (completeness check); and

- › Inform the authorising entity about the correct or incorrect categorisation concerning the basic design characteristics covered by national rules.

The concerned NSAs for the area of use should respond to the request without undue delay and at least within 3 months of the request for the check of the parameters according to national rules, and within 1 month of the request for the completeness check, in order to give the authorising entity sufficient time to take its reasoned decision within the maximum time frame of 4 months.

Bringing a vehicle in conformity to another authorised vehicle type version and/ or vehicle type variant of the vehicle type

Changes to an authorised vehicle that are made in order to bring the vehicle in conformity to another authorised vehicle type version and/ or vehicle type variant of that vehicle type will require that a new declaration of conformity to the vehicle type is issued by the applicant. This is because the declaration of conformity to type is made to a specific vehicle type version and/ or variant. It will therefore also be necessary for a vehicle authorisation for placing on the market to be issued for the vehicle based on the new declaration of conformity to the vehicle type. In this case it should be treated as an authorisation in conformity to type.

3.3.3. Article 17: Identification of the rules including non-application of TSIs

1. Based on the choice of the authorisation case in accordance with Article 14 and the requirements capture set out in Article 13 the applicant shall identify all applicable rules, in particular the TSIs and national rules.

The applicant shall also consult and take into account the list of TSI deficiencies that is published on the Agency website.

In that case, the applicant shall identify the acceptable means of compliance issued by the Agency that is to be used in conjunction with the TSIs for the vehicle type authorisation and/or vehicle authorisation for the placing on the market process when establishing compliance with the TSIs.

2. The applicant shall identify any case which requires the non-application of TSIs and submit its application to the concerned Member States in accordance with the provisions of Article 7 of Directive (EU) 2016/797. When non-application of TSIs concerns vehicles with an area of use covering more than one Member State, the authorising entity and the concerned NSAs for the area of use of the vehicle have to coordinate with the applicant on the alternative measures to take in order to promote the final interoperability of the project.
3. When a new version of a TSI provides for transitional measures, the applicant may already select requirements from this new version of that TSI during the transitional period, if this new version explicitly allows it.
4. Where, pursuant to paragraph 3, requirements from a newer version of a TSI are selected the following shall apply:
 - (a) the applicant may select the requirements to be applied from different versions of a TSI and shall:
 - i. justify and document the consistency between the sets of requirements selected from different versions of a TSI to be applied;
 - ii. specify the partial selection of requirements from different versions of a TSI in the application for authorisation as required by Annex I;
 - iii. where there is a pre-engagement baseline and where relevant, the applicant shall request to the authorising entity an amendment or update of that pre-engagement baseline for the concerned TSI in accordance with the provisions in Article 24(4).
 - (b) the authorising entity when assessing the application shall check the completeness of the TSI requirements proposed by the applicant;

(c) the applicant shall not be required to submit a request for non-application of the TSI pursuant to Article 7 of Directive (EU) 2016/797 for those requirements.

5. Where this is provided for by the Member State legislation, the applicant may select requirements from different national rules in the same way as laid down in paragraph 3 for TSIs.
6. The applicant and the notified body or bodies may use the acceptable means of compliance referred to in Article 6(3) of Directive (EU) 2016/797 in the context of an EC verification of conformity, pending the adoption of the concerned TSIs.
7. The applicant and the designated body or bodies may use the acceptable national means of compliance referred to in Article 13(2) of Directive (EU) 2016/797 in the context of demonstrating compliance with national rules.

Relevant references to Directive (EU) 2016/797:

- › Article 2
- › Article 3
- › Article 4
- › Article 6
- › Article 7
- › Article 13
- › Article 14
- › Article 15
- › Article 21
- › Article 24
- › Annex III

The applicant is responsible for identifying and ensuring that all applicable requirements are met. This does not prevent the applicant from seeking support, advice or consultancy services from third parties.

Identification of the applicable rules

It should be clear in the rules (in particular for TSIs and national rules) what their scope is and when they apply. The applicable rules are those rules that are in force when the applicant submits its request (the application) through the one-stop shop, pursuant to Article 4(2) of Directive (EU) 2016/797.

To take into account that vehicle authorisation projects often have a long duration from the identification of the applicable rules to the submitting the request through the one-stop shop the rules (TSIs and national rules) should have transition arrangements specified. There is also a possibility for non-application of TSIs according to Article 7 of Directive (EU) 2016/797, the case that would be likely to be applicable in between the design phase and the application for authorisation would be Article 7(1)(a) (“...which is at an advanced stage of development or which is subject to a contract in the course of performance on the date of application of the TSI(s) concerned”).

In any TSI or national rule, it should be clearly stated which of the provisions apply to:

- › Only new vehicle types and subsystems at first authorisation;
- › Existing vehicle types already authorised (which means that a renewed vehicle type authorisation will be required for existing types);
- › Existing vehicles and their vehicle type when there is a new authorisation after a renewal or upgrade; and/ or
- › All vehicles already in service and the transition arrangements for these vehicles.

Requirements that are related to technical compatibility with the network are defined in TSIs (including specific cases) and national rules.

The timescales for the provisions should be different for different parameters depending on the risk/ cost/ time required to implement the change. It should be clearly stated from which date the provisions apply.

In principle, the transition arrangements in the TSIs should also be clear about which versions may be applied. An example is the Regulation (EU) 2016/919 where the TSI containing baseline 3 also allows baseline 2.3.0d to be applied.

The TSIs should in Chapter 7 (that covers the provisions on transition on application of the TSI) make clear for each parameter which versions of the requirements for that parameter may be used in what circumstances.

Vehicles that are authorised for placing on the market and that are not subject to upgrade/ renewal should remain authorised and the TSIs should normally not contain any requirement that would impose changes to these vehicles. In the event of an upgrade/ renewal of a vehicle authorised for placing on the market the TSIs should however indicate when a new authorisation is required and which of the provisions apply. The case when already authorised vehicles are affected by a new TSI is expected to be an exception and would require a strategy that takes into account the expected costs, benefits and repercussions on the stakeholders affected and have suitable transition arrangements (see article 4(3)(f) of Directive (EU) 2016/797). The objective is to gradually achieve the target system (see article 4.4 of Directive (EU) 2016/797).

TSI deficiencies

Deficiencies in TSIs are textual errors, omissions, mistakes in translation or in technical content, or other inconsistencies as referred to in Article 6 of Directive (EU) 2016/797.

Article 6 of Directive (EU) 2016/797 covers the process for handling deficiencies in TSIs.

TSIs deficiencies are classified in the following categories:

1. Typographical errors (spelling, typing errors, computing errors, text with no sense, formatting, missing words, missing figures) as well as evident translation mistakes (i.e. easily detectable in a translated version without doubts by comparison with the original English version).
2. Substantial linguistic and translation deficiencies which may affect the content of the TSI.
3. Technical deficiencies, which need to be analysed by the Agency experts.
4. Critical errors.
5. Critical errors which must be urgently corrected.

Depending on the category of deficiency:

- › The Agency can perform a simple check or deliver a technical opinion that constitutes an acceptable means of compliance.
- › The Railway Interoperability and Safety Committee (RISC) is either simply informed or asked to approve the technical opinion. In the latter case, the opinion of the RISC is recorded in the minutes of the corresponding RISC meeting.
- › Depending on the importance and urgency of the correction, the legal act implementing the amendment can be included in an ongoing revision.
- › Category 1 errors (typographical errors) may be corrected by a corrigendum published on the Official Journal of the European Union (normally within a few weeks).

When deficiencies are discovered in the TSIs, the Agency should be asked to issue an opinion which, under certain conditions, might be published and used by all stakeholders (including industry and notified bodies) as an acceptable means of compliance pending the revision of the TSIs concerned.

The deficiencies in TSIs that have already been adopted are published in the Official Journal of the European Union. The deficiencies in the TSIs which are still in the process of being drafted by the Agency or are in any following approval step cannot be found in the Official Journal of the European Union. However, an updated

list of TSI deficiencies is provided regularly to RISC meetings. The link to the latest version of this updated list can be found on the Agency website:

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

The deficiencies in TSIs published in the Official Journal of the European Union or on the Agency website should be taken into account during the process for requirements capture.

The management of deficiencies in the TSIs concern the correction of the content of the TSIs as specified in Article 5(1) of Directive 2016/797. It does not concern the evolution of the technical documents published by the Agency and referred to in the TSIs. Similarly, this document does not cover the Change Control Management for the ERTMS specifications and documents listed in the TSI on control-command and signalling.

Concerning differences between translated versions of TSIs:

When a mistake of translation is a critical error it will be addressed in a formal process involving a technical opinion of the Agency, European Commission agreement and approval by the Railway Interoperability and Safety Committee (RISC). In considering its Technical Opinion the Agency will not use the English version as the base reference because all the different language versions of the TSIs have the same status.

Non-application of TSIs

Where according to Article 7 of Directive (EU) 2016/797 the Member State(s) have allowed the applicant not to apply one or more TSIs or parts of them this should only be applicable for a particular project covering a specific series of vehicles.

It follows therefore that the vehicle type authorisation will be valid only for the series of vehicles where the Member State(s) have allowed the applicant not to apply one or more TSIs or parts of them. If a manufacturer wants to get a new or later series of vehicles of this type authorised they will need to get a new set of non-application allowances to support a new vehicle type and vehicle authorisation for placing on the market for a vehicle or a series of vehicles authorised in conformity to type.

The guidance for the process for non-application of TSIs is being drafted by the Commission.

TSIs and National rules

The TSIs and their guidelines should indicate clearly the vehicles that are in their scope.

For vehicles that are in the scope of Directive (EU) 2016/797 and in the scope of the TSIs, the Single Rules Database is used to collect the applicable national rules and the Agency should review these national rules.

National rules for vehicles that are in the scope of Directive (EU) 2016/797 and in the scope of the TSIs should be classified by the Agency in accordance with Article 14(10) of Directive (EU) 2016/797 with the aim to facilitate cross-acceptance in different Member States. The applicant should consult the Single Rules Database to retrieve those classifications for the identified applicable national rules. For those national rules that are classified as equivalent for the concerned area of use the applicant can choose to only apply the national rule for one of the concerned Member States. The conformity assessment should be done according to the chosen national rule.

Until the Single Rules Database is ready and populated (migration planned for the end of 2019), the applicant should consult the Reference Document Database, which is nowadays the tool to publish and classify national rules related to vehicle authorisation.

For vehicles that are in the scope of Directive (EU) 2016/797 but that are not (and not intended to be) covered by TSIs (e.g. Tram train, metric track gauges):

- › The national rules should be notified by the Member States;
- › The Agency should examine those national rules (in accordance with Articles 13 and 14 of Directive (EU) 2016/797 and Articles 25 and 26 of the Regulation (EU) 2016/796); and
- › The Single Rule Database (SRD) should contain all national rules.

The Member States should adopt national rules to ensure that vehicles that are not in the scope of the TSIs will meet the essential requirements.

These national rules should be drafted and notified in accordance with Article 14 of Directive (EU) 2016/797, and in particular, should be easily accessible in the public domain and written in terminology that all interested parties can understand.

The extent of parameters to be covered by these rules has to be defined at Member State level, considering also the requirements necessary for the part of the area of use of tram-trains which are not in the scope of Directive (EU) 2016/797 (usually the part related to the operation on light urban part of tram-train operation).

Partial selection of requirements from a newer version of a TSI as compared to the TSI applied for the assessment

As a general principle, taking requirements from different versions of a TSI is not allowed. Each TSI is a “package” that should be complied with as a package. A “patchwork” approach to TSI conformity through the life of the vehicle based on different TSI versions is therefore not allowed unless explicitly permitted/required by the TSI. However, when a part of a vehicle is modified the applicable version of the TSI should be applied to the part that is modified – but not the rest of the vehicle.

Partial selection of requirements from a newer version of a TSI as compared to the TSI that is applied for the assessment (including withdrawn requirements) can happen:

- › From the beginning of the project, due to that the transitional period in a TSI allows the use of old versions; and/ or
- › In the later stages of the process, due to the publication of a new version of a TSI.

If partial selection of requirements from a newer version of a TSI as compared to the TSI that is applied for the assessment (including withdrawn requirements) is possible for a given subsystem, it should be specified in the TSI to what extent it is allowed and the conditions. A NoBo should accept partial selection of requirements from a newer TSI as long as what the applicants request is in conformity with what is specified in the TSI. However, the NoBo is responsible for issuing an EC certificate so it should check the overall consistency of the set of requirements used during the certification process.

Where a TSI in a new version creates a new or changed requirement it should be clear about if and when this applies to vehicles authorised under earlier versions of the TSI.

Where a TSI removes a requirement compared to previous versions, the “package” principle should apply and vehicles authorised according to the old TSI must remain in full conformity with the old TSIs so that their configuration is stable and compatibility at authorisation is preserved. However, where a requirement has been removed because it is not necessary, then a new TSI should declare as part of transition arrangements that conformity of vehicles authorised under the earlier version of the TSI with the removed requirement is no longer required.

Acceptable means of compliance

The authorising entity and/ or NSAs for the area of use should not question the application of acceptable means of compliance or acceptable national means of compliance.

Acceptable means of compliance following a technical opinion issued by the Agency should be made available by the Commission. Acceptable national means of compliance should be made available by the Member States.

It should be noted that:

- › Acceptable means of compliance issued by the Agency are available at the Agency website and/ or are available at the Commission (e.g. RISC list of TSI deficiencies etc.).

- › Article 6 of Directive (EU) 2016/797 deals with deficiencies in the TSIs, meaning that pending the revision of the TSI, the Agency opinion can be used for any project. The “assessment of projects” means verification of conformity.
- › A technical opinion of the Agency is always justified.
- › The procedure to manage TSI deficiencies should consider the “acceptable means of compliance”.
- › A technical opinion issued by the Agency can cover different items such as TSI deficiencies or ways of establishing compliance with TSI. The technical opinion can become an “acceptable means of compliance”.
- › Regarding presumption of conformity there are other documents to be considered (e.g. TSI guidelines).

Innovative solutions

Opinions can also be issued by the Agency in case of innovative solutions (as defined in the TSIs). In such case:

- › The manufacturer informs the Commission how the innovative solution complements/ deviates from TSI requirements;
- › The Agency issues an opinion on the innovative solution at the request of the Commission. The opinion may include non-binding recommendations, if appropriate;
- › The Commission issues an opinion (positive or negative). If negative, the innovative solution cannot be applied;
- › The Agency uses the positive opinion issued by the Commission to amend the TSI; and
- › Applicants and NoBos can use the issued opinion as “acceptable means of compliance”, pending the adoption of the revised TSI.

The authorising entity should accept the above described application of acceptable means of compliance”.

It should be noted that:

- › It should be applied at an early stage during ‘pre-design’, and in principle, it should not be linked to a specific project, as the objective is to revise TSIs.
- › The one-stop shop is not today foreseen as the tool to manage aspects related to innovative solutions.
- › The procedure to correct TSI deficiencies and the procedure for an innovative solutions is independent from the process for vehicle authorisation.

Regarding the procedure for innovative solutions:

- › Innovative solutions are mentioned in the TSIs and there is a description of a procedure in order to revise the TSI taking into account the innovative solution.
- › A technical opinion following a request for an innovative solution is similar to the process of drafting TSIs; representatives from the sector may be consulted.
- › This could be done in a working party (if there is an active working party) or via the network of NSAs and the network of representative bodies; see Article 38(5) of Regulation (EU) 2016/796 (referring to Article 10(2)) mentioning ‘opinions on amendments to any act adopted on the basis of Directive (EU) 2016/797 or Directive (EU) 2016/798’ an “acceptable means of compliance”.

Acceptable national means of compliance:

National means of compliance can be issued by Member States as ways of establishing compliance with national rules. Directive (EU) 2016/797 indicates that it is a national responsibility to define the process to issue national means of compliance:

- › The Member State issues a “acceptable national means of compliance”.
- › The applicant and DeBos can use the “acceptable national means of compliance” issued by the Member State(s).

The “acceptable national means of compliance”:

- › Are linked to a national rule and they should not create a conflict or an overlap with the TSIs.
- › Should be collected via the Single Rules Database according to Article 27 of Regulation (EU) 2016/796 (for transparency and technical consistency with TSIs and national rules).
- › Do not need to be notified, as they are not mandatory. However, under the cleaning up of national rules project any change made to rules or to attached “acceptable national means of compliance” will be subject to an Agency review.
- › The Single Rules Database collects the “acceptable national means of compliance” that is related to a national rule.

A deficiency in a national rule should be resolved by the Member State by issuing a new version of the concerned national rule.

3.3.4. Article 18: Identification and definition of the necessary measures to use the vehicle for tests on the network

The applicant shall identify and define, on the basis of national rules for testing, the necessary measures to use the vehicle for tests on the network.

Relevant references to Directive (EU) 2016/797:

- › Article 13
- › Article 14
- › Article 21

National rules for vehicle authorisation are required to be structured in accordance with the Annex of Decision 2015/2299/EU. In respect of tests on the network, parameter 1.4 “National requirement for testing” of the above decision includes national rules (where they exist) for tests on the network. The national rules recorded against this parameter provide information on what has to be done/ delivered by an applicant to use a vehicle for tests on the network of a Member State.

TSIs and national rules should provide sufficient information on the assessment phases for each requirement.

See chapter 3.4.4 for more details on the use of the Commission Implementing Regulation (EU) 402/2013 by the applicant and/ or the railway undertaking to demonstrate/ ensure safety during the tests on the network.

3.3.5. Article 19: Temporary authorisation to use the vehicle for tests on the network

1. Temporary authorisation to use the vehicle for tests on the network may only be issued by the NSA when it is required and specified in the national legal framework of the Member State.
2. NSAs assessing applications for temporary authorisation to use the vehicle for tests on the network shall do so in accordance with the relevant national legal framework.

Relevant references to Directive (EU) 2016/797:

- › Article 21

When it is necessary to issue a temporary authorisation to use the vehicle for tests on the network the responsibility belongs only to the concerned NSA for the area of use. As specified in Article 21(3) and 21(5) of Directive (EU) 2016/797 the right to request the applicant to conduct tests on the network belongs only to the authorising entity and/ or the concerned NSAs for the area of use. The infrastructure manager should not request that the applicant should conduct tests on the network and should not impose any technical requirements on the design of a vehicle (refer to chapter 3.2.3.4 for the responsibilities of the infrastructure manager).

Tests on the network are often needed in order to provide evidence of conformity as part of the EC verification of subsystems. They therefore have to take place before the vehicle type is authorised and/ or the vehicle is authorised for placing on the market and before the full suite of evidence of compliance with relevant requirements has been compiled. Currently, depending on the concerned Member State and its legal framework, the assurance that the risks of operating the vehicle are being managed is normally provided through a combination of:

- (a) Temporary authorisation to use the vehicle for tests on the network where this is provided for in the national legal framework;
- (b) Application of the railway undertaking's safety management system;
- (c) 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
- (d) Conducting the tests on the network in accordance with the infrastructure manager's arrangements for tests on the network.

Below there are several clarifications on each of the different approaches to manage the risks related to the use of the vehicle for tests on the network, based on the current practices in different Member States.

(a) Temporary authorisation to use the vehicle for tests on the network

This section only applies where the Member State's legal framework specifies that a temporary authorisation is required in order to use the vehicle for tests on the network. In such a case, the national legal framework should specify the:

- › Process to be followed;
- › Documentation required, including the format in which it is to be provided;
- › Decision criteria to be applied for issuing a temporary authorisation to use the vehicle for tests on the network; and
- › Timeframes to be respected by the concerned NSA for the assessment.

It is recommended that the concerned NSA assesses the following detailed elements when deciding whether to issue a temporary authorisation:

- › Compliance with TSIs:
 - Any Intermediate Statement of Verification produced for the project;
 - Valid EC declaration of conformity or suitability for use for any Interoperability Constituents; and
 - All assessments applicable to the scope of the application for temporary authorisation have been done, such as:
 - Design review;
 - Type tests; and
 - Quality management system surveillance.

- › Compliance with national rules:
 - As with TSIs, all assessments applicable to the scope of the application for temporary authorisation to use the vehicle for tests on the network have been done (design review, type tests, quality management system surveillance, etc.).
- › The risk assessment covering both the change to the railway system arising from the tests on the network has an impact on safety and/ or, the demonstration that the aspects of the vehicle design not covered by technical rules or not yet assessed against technical rules (if any) permit safe operation during the proposed tests on the network (see sections “Application of the railway undertaking’s safety management system” and “Assessment of the risks” below).
- › The planning for the tests on the network to be carried out provides a sufficient level of detail and adequate evidence to allow tests on the network to be performed:
 - Safely; and
 - With an adequate level of technical compatibility.
- › The planning for the tests on the network to be carried out should cover at least:
 - The aspects of the tests on the network being dealt with through the railway undertaking’s safety management system;
 - The test specifications that are relevant for the actors involved:
 - Railway undertaking – defining operational matters such as speed and degraded conditions.
 - Infrastructure manager – identifying any special infrastructure conditions required for the tests on the network such as railhead condition, signalling arrangements, feeding arrangements for the electric traction supply and closure of level crossings.
 - The sequence of the tests on the network, including the pass/ fail criteria to conclude one test and initiate the next test;
 - Maintenance of the vehicle during the tests on the network; and
 - Operational documentation required for using the vehicle for tests on the network such as drivers manual.

The timeframe for the concerned NSAs decision is not defined in the Directive (EU) 2016/797 nor in the Commission Implementing Regulation (EU) 2018/545; it is recommended that the NSA takes its decision no more than two months after the receipt of the application. Once the decision has been made, the railway undertaking and infrastructure manager will require time to put in place the necessary arrangements for the tests on the network. The applicant should take into account the time needed for these processes when planning the timing for its application for temporary authorisation to use the vehicle for tests on the network and carrying out the tests on the network.

The concerned NSA should take its decision on the basis of the information that has been supplied by the applicant, although it should also check if there is any relevant information recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545 and take it into account for the arrangements for using the vehicle for tests on the network.

If the concerned NSA concludes that the application is satisfactory it will issue a temporary authorisation to use the vehicle for tests on the network which will be limited to the scope of the tests to be carried out on the network. This limitation may be in respect of a specific test on the network or series of tests on the network, the time period during which tests on the network may be conducted, or other aspects.

Once the time limit has expired, the temporary authorisation is no longer valid and a further temporary authorisation to use the vehicle for tests on the network will be required from the concerned NSA if further tests on the network are needed. When the tests on the network are complete, the applicant should apply for the vehicle type authorisation and/ or vehicle authorisation for placing on the market in the normal way.

The temporary authorisation to use the vehicle for tests on the network is issued for the purposes of testing only: it does not permit a vehicle to be brought into use for the carriage of passengers, freight or for any other purpose for which it is intended to be placed on the market.

If there is a need to have further vehicles authorised for the purposes of carrying out tests on the network under a temporary authorisation and there is no change to the design of the vehicles then, the documents already submitted to the concerned NSA to apply for the temporary authorisation for the first vehicle should be considered valid and should not be re-checked.

If there are changes between the first vehicle(s) to be tested on the network and any subsequent vehicles then the applicant should make a clear statement as to which parts of the documentation submitted for the first vehicle(s) are still valid for the subsequent vehicle(s), and provide the necessary documentation covering the modified aspects, in particular:

- › Changes made on the basis of the results of the tests on the network performed using the first vehicle(s); and
- › Test plan and sequence of tests on the network for the subsequent vehicle(s).

It is recommended that the applicant, the concerned NSA and the infrastructure manager should work together to agree an overall strategy for the temporary authorisation to use the vehicle for tests on the network, so that time scales are not extended by the need to submit a series of applications to cover each stage of the testing separately. Instead a single application defining the testing milestones with pass/ fail criteria for each can form the basis for a single temporary authorisation to use the vehicle for tests on the network and permit the infrastructure manager to put the arrangements in place for the full schedule of tests on the network. It is possible to combine this process with supervision by the concerned NSA where confidence is needed in the effectiveness of the arrangements for using the vehicle(s) for tests on the network.

(b) Application of the railway undertaking's safety management system

Whether or not the national legal framework of a Member State includes the legal requirement for a temporary authorisation to use the vehicle for tests on the network, the railway undertaking operating the vehicles for tests on the network should use its safety management system to manage the risks through the operational planning, asset management and interface arrangements. In the case where the concerned NSA has granted a temporary authorisation to use the vehicle for tests on the network it is not necessary for the railway undertaking to duplicate the evaluation of the elements that form part of the national legal framework for the temporary authorisation to use the vehicle for tests on the network.

For the purposes of using vehicles for testing on a network for the area of use, the safety management system of the railway undertaking should include general arrangements for using vehicles for tests on the network. These will require the preparation of more specific processes and procedures within a test plan which will cover the actual tests on the network to be conducted. If there is no requirement for a temporary authorisation to use the vehicle for tests on the network then it would be expected that the railway undertaking's processes and procedures include the items that would otherwise be specified for a temporary authorisation to use the vehicle for tests on the network (see section "Temporary authorisation to use the vehicle for tests on the network" above). They will in all cases have to apply the Commission Implementing Regulation (EU) 402/2013 to evaluate the impact of using the vehicle for tests on the network and whether they constitute a significant change that requires the application of the risk management process of the Commission Implementing Regulation (EU) 402/2013 (below).

Any residual operational risks arising from the using the vehicle for tests on the network should be managed through the safety management system, for example:

- › Interfaces with the infrastructure manager;
- › The selection of the driver/ driver manager controlling the train movements during the tests on the network;

- › The role of other persons permitted to be on board the train;
- › The arrangements to start and finish the tests on the network including how the vehicle will travel between its stabling location and the test site; and
- › Emergency arrangements including the steps to be taken if any agreed safety parameters are exceeded.

The safety management system will include the processes to be followed to ensure that all parties who can be affected by the tests on the network have been consulted and that the agreed arrangements have been effectively communicated.

(c) Assessment of the risks

The use of a vehicle for tests on the network means that there are aspects of the vehicle that are not fully known, such as the performance of the braking system or the effectiveness of communication between on-board and ground-based systems: this is why the tests on the network are required. The safety management process, which includes risk assessments, provides a structured way of identifying the means to control the risks that would normally be managed through the application of rules, and so may form part of the concerned NSA's process for issuing a temporary authorisation to use the vehicle for tests on the network. Similarly it may be part of the railway undertaking's and infrastructure manager's arrangements for managing safety where no process for issuing a temporary authorisation to use the vehicle for tests on the network exists.

From the point of view of the vehicle and its operation, the proposer can be the applicant for authorisation for whom the tests on the network will provide evidence of compliance with rules, or the railway undertaking who will be responsible for operating the train during the tests on the network. In either case both the applicant and the railway undertaking will have to cooperate to ensure that the evaluation of the risks takes into account the engineering elements of the vehicle and the operational aspects of using the vehicle for tests on the network.

The process of requirements capture and identification of rules that takes place at an early stage of the project will provide a basis for the hazard identification. The hazards that are not yet controlled through compliance with rules may be managed through a combination of risk acceptance principles.

The proposer's assessment of risks should take into account the complexity in order to decide whether a single safety assessment report is sufficient or whether the assessment body (CSM RA)'s assessment should take place in stages as the tests on the network proceeds. Whether conducted as a single or multiple stage process, an on-going review of the validity of the inputs to the risk assessment forms a part of the arrangements for the management of safety. In the case of tests on the network, the results obtained will indicate whether the conclusions of the risk assessment can continue to be used or if a new assessment is required: for example geographical variations in the effectiveness of communications systems may indicate that more detailed tests on the network are required, with the potential need to review the risk assessment to support this.

(d) The infrastructure manager's arrangements for the tests on the network

In order to request track access to use a vehicle for tests on the network the applicant should consult the national rules referred to under parameter 1.4 of Decision 2015/2299/EU. These rules address the national procedural requirements for tests on the network (see chapter 3.3.4), and should describe the:

- › Timeframe for access to the infrastructure; and
- › The required information that the applicant should provide to the infrastructure manager.

The infrastructure manager should evaluate the nature of the tests to be performed on the network and the conditions required in order to identify and provide, within 3 months of the request:

- › Operational conditions to be applied to the vehicle during the tests on the network such as. avoiding operation with the traction system in degraded mode i.e. a reduced number of converters in service on the test train;

- › Any necessary measures to be taken in relation to the infrastructure to ensure safe and reliable operation during the tests on the network (e.g. not causing disruption to traffic); and
- › Any necessary measures in the infrastructure installations during the tests on the network (e.g. higher than usual voltage in the catenary).

The infrastructure manager should provide information on the infrastructure to the applicants and the railway undertakings in a non-discriminatory way. This is achieved through recording the relevant information in RINF, the infrastructure manager's Network Statement, and through the provision of any other relevant information.

If it is needed, the concerned NSAs for the area of use should apply any appropriate measures to ensure that the infrastructure manager(s) allows the necessary tests on the network to take place within the timescales specified above.

The allocation of train paths is a separate process dealt with by the railway undertaking and the infrastructure manager and it is not covered by the practical arrangements for vehicle authorisation.

3.3.6. Article 20: Identification of the intended conditions for use of the vehicle and other restrictions

The applicant shall identify the intended conditions for use of the vehicle and other restrictions linked to the vehicle type.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Conditions for use and other restrictions are part of the design of the vehicle and form the boundaries for how the vehicle is intended to be used. There are three broad stages to the identification of conditions for use and other restrictions:

- › Identified at the design stage;
- › Derived from the conformity assessment; and
- › Imposed by the authorising entity and the concerned NSAs for the area of use.

During the first stage of the vehicle authorisation process (stage 1: preparation of the application, see chapter 3.3), the applicant should identify the intended conditions for use and other restrictions (such as gauge, maximum speed, speed limits arising from the isolation of parts of the braking system, temperature range etc.) that are applicable, taking into account the design of the vehicle and its intended operation conditions.

Conditions for use and other restrictions should be formulated in technical terms, such as basic design characteristics of the vehicle type, not by geographical area (e.g. the line between A and B).

It may be necessary to add further conditions and restrictions as a result of the conformity assessment (stage 3: conformity assessment, see chapter 3.5) in order to comply with the relevant requirements (e.g. limitation in the maximum operating speed in degraded operating conditions such as the unavailability of some brake modules or a limitation in the number of allowed configurations of pantographs, etc.). These conditions and restrictions for use are to be defined by the applicant, in agreement with the concerned assessment bodies.

There may be some restrictions arising from equipment failure, such as a reduction in speed when the air suspension is deflated, that may be identified as part of the conformity assessment against the harmonised standards that are applicable. It is not intended that the effect of every potential component failure is incorporated into the conditions for use and other restrictions. Nonetheless the assessment of these scenarios forms a part of the design process.

Some of the conditions and restrictions for use will be derived from the requirements capture as well as the risk assessment process, in particular, the use of the risk assessment process specified in the Annex I of Commission Implementing Regulation (EU) 402/2013 for the safety related requirements (essential requirement safety within the subsystems and safe integration of subsystems).

The applicant will then compile the file accompanying the application for authorisation and submit the application for authorisation through the one-stop shop (stage 4: submitting the application, see chapter 3.6). All the conditions and restrictions for use identified until this stage should be specified in the application for authorisation.

The authorising entity and/ or the NSAs for the area of use can give further conditions for use and other restrictions as a result of their assessment of the application and the file accompanying the application (stage 5: processing the application, see chapter 3.7).

The issued vehicle type authorisation and/ or vehicle authorisation for placing on the market (stage 6: final documentation and authorisation, see chapter 3.8) should reflect all the conditions for use of the vehicle and other restrictions identified.

The applicant has the possibility to appeal in a case of disagreement with the conditions for use and other restrictions imposed by the authorising entity, see chapter 3.8.5.

Conditions for use and other restrictions:

- › Should be based on the necessary assessments;
- › Might require negotiation and agreement between the applicant, railway undertaking, keeper and/ or infrastructure manager, in particular in the case of exported constraints to operation and/ or maintenance of the vehicle;
- › Should be considered by the user of the vehicle under its safety management system;
- › Need to be clarified before issuing the vehicle type authorisation and/ or vehicle authorisation for placing on the market and should therefore be included in the application for authorisation, pursuant to Annex I of the Commission Implementing Regulation (EU) 2018/545 The authorising entity should include the conditions for use and other restrictions that the applicant has specified in the issued authorisation;
- › Where they are safety related, they should be cross-checked by the concerned assessment body (CSM RA), in order to ensure that they are consistent with the risk assessment process performed by the applicant and do not introduce additional safety risks;
- › Assessment body (CSM RA) role is to check that the risk assessment process set out in Annex I of Commission Implementing Regulation (EU) 402/2013 has been applied when required. It is not the role of the assessment body (CSM RA) to check whether the conditions for use and other restrictions that the applicant has included in the application for vehicle authorisation:
 - May hinder the operation of the vehicle from a commercial point of view or not (e.g. reduction in the maximum operating speed, low mileage between maintenance operations, etc.); or
 - To perform the technical evaluation of possible conditions for use and other restrictions which are necessary to remedy non-conformities with TSIs and/ or national rules.
- › NoBos and/ or DeBos, each for the parts they are responsible for, should also cross-check the conditions for use and other restrictions, in order to confirm that they are consistent with the assessments performed; and
- › The authorising entity and/ or the concerned NSAs for the area of use should not check if the conditions for use and other restrictions (including exported constraints) are reasonable from a commercial point of view (e.g. risk not meeting the contractual obligations of the manufacturer with the railway undertaking by imposing conditions for use and other restrictions that may render the operation of the vehicle difficult). The scope of the assessment should be limited to the consistency, completeness and relevance (including the cross-check by the concerned assessment bodies) of the set of conditions for use and other restrictions.

3.3.7. Article 21: Identification of the conformity assessments

The applicant shall identify the necessary conformity assessments pursuant to the provisions of Annex IV of Directive (EU) 2016/797.

Relevant references to Directive (EU) 2016/797:

- › Article 15
- › Annex IV

Validity of certificates

The objective of the “EC” verification procedure is to demonstrate that the applicable requirements for a subsystem have been fulfilled. It is mostly based on the certificates of verification issued by the conformity assessment bodies. While a type examination certificate of verification for a subsystem is valid, it can be used by applicants as one of the elements that are necessary to establish the EC declaration of verification for the subsystem.

A vehicle type authorisation is mostly based on the type examination certificates for the subsystems that compose the vehicle. However, the validity of the vehicle type authorisation is independent of the validity of the certificates. The circumstances under which a vehicle type authorisation may no longer be valid are described in chapter 3.3.2. and 3.9.2. In particular, TSIs may contain transitional provisions that affect the validity of a vehicle type authorisation irrespective of the validity of the related EC certificates.

The validity/ expiry date of the certificates of verification issued by Notified Bodies should be according to the Implementing Act on module decision.

In the case of changes to an already authorised vehicle type the applicant should inform the conformity assessment body(ies) that holds the technical documentation related to the EC type examination of all the modifications that may affect the conformity of the subsystem with the requirements of the relevant TSIs or the validity of the certificate, as described in Decision 2010/713/EU. However, the applicant can choose a different conformity assessment body to perform the verifications related to the changed vehicle type.

Provisions related to certificates issued by NoBos should apply mutatis mutandis to certificates issued by DeBos.

Intermediate Statement of Verification (ISV)

Roles and responsibilities when there is use of Intermediate Statement of Verification (ISV):

Applicant

- › Decides if there is a need of division of the subsystem into parts; and
- › Specifies for which parts of the subsystem or part of the verification procedure (as defined in the assessment modules) there is a need to have an ISV from the NoBo.

NoBo (ISV)

- › Performs the necessary assessments according to the division of the subsystem or part of the verification made by the applicant; and
- › Issues ISVs.

NoBo (subsystem)

- › Where ISV(s) have been issued, takes them into account before issuing its certificate of verification;
- › Verifies that the ISV(s) cover correctly the relevant requirements of the TSIs;
- › Checks all aspects that are not covered by the ISV(s); and
- › Checks the final testing of the subsystem as a whole.

DeBo (subsystem)

- › Only NoBo is foreseen to issue ISV(s), but mutatis mutandis principle could allow the same approach for DeBo in case of national rules.
- › If the assessment procedures for national rules are not defined by national legislation it is recommended to apply the modules as defined by the corresponding TSIs.

Additional information

An applicant can request that the verifications are done for any part into which it decides to split the subsystem. The breakdown of the subsystem can be done following different criteria, depending on the needs of the applicant.

The NoBo can issue an Intermediate Statement of Verification (ISV) against relevant TSIs covering part of a subsystem or part of the verification procedure (design, production or testing). The verifications should be done only for the following stages of the EC verification procedure:

- › Overall design (e.g. SB design/type examination);
- › Production: manufacturing, constituent assembly and overall adjustment (e.g. SD); and/ or
- › Final testing (e.g. SD).

An ISV can be delivered only if all the relevant TSI requirements are demonstrated (including type tests if necessary, e.g. for SB). Some parts of a subsystem are covered by TSI requirements that can be demonstrated without a need to carry out dynamic tests on a network, and can be covered by ISV(s) (e.g. gauge Commission Regulation (EU) 1302/2014 4.2.3.1 or vehicle structure strength Commission Regulation (EU) 1302/2014 4.2.2.4).

Therefore, ISV(s) can be useful for:

- › Obtaining the temporary authorisation to use the vehicle for tests on the network; and
- › Building up the EC certificate of verification.

ISV(s) are not to be used as a substitute of the EC certificate of verification.

When the NoBo responsible for the subsystem uses ISV(s), it is permissible for the modules used for the ISV(s) and the overall verification assessment to be different.

Maintenance documentation

The processes of vehicle type authorisation and authorisation for placing on the market of vehicles and the subsequent use (including operation and maintenance) of vehicles are two separate processes with different provisions. However, some maintenance documents (e.g. maintenance plan, maintenance instructions) are part of the design of the vehicle type and are needed to keep vehicles of the type in their design operating state whilst in use. The technical file accompanying the 'EC' declaration of verification should include the information needed to maintain the integrity of the design operating state of the vehicle throughout its lifecycle.

Requirements on the maintenance documentation are described in the TSIs.

Therefore, the checks to be performed before authorisation related to maintenance should be limited to those prescribed in the TSIs, and will be covered by the EC certificates issued by the NoBo and the EC declaration of verification issued by the applicant.

For maintenance aspects covered by national rules, the DeBo will perform the work vis-à-vis the NoBo and it will be covered by the EC declaration of verification issued by the applicant. National rules are only allowed to cover aspects related to maintenance for vehicles not in the scope of the TSIs.

The documentation related to maintenance should be included in the file accompanying the application for authorisation compiled by the applicant.

In the case of authorisation for an extended area of use, it is not necessary to add the maintenance records (historical information related to the maintenance of the vehicles) to the application and the file accompanying the application. This aspect is to be managed by the railway undertaking under the provisions of its safety management system.

3.4. Chapter 3 - Stage 2: Pre-engagement

3.4.1. Article 22: Pre-engagement

1. Upon the applicant's request, the authorising entity and the concerned NSAs for the area of use shall handle pre-engagement applications to set the pre-engagement baseline before an application for a vehicle type authorisation and/or vehicle authorisation for placing on the market is submitted. The pre-engagement application shall be formally submitted by the applicant through the one-stop shop and be accompanied by a file containing at least the required information specified in Article 23.
2. The timeframe from the issuing of the opinion referred to in Article 24(2) to the applicant's submission of the application for vehicle type authorisation and/or vehicle authorisation for placing on the market shall not exceed 84 months.
3. The selection of authorising entity made by the applicant for the pre-engagement shall be binding until, either:
 - (a) the concerned application for vehicle type authorisation and/or vehicle authorisation for placing in the market has been submitted by the applicant;
 - (b) the timeframe from the issuing of the opinion referred to in Article 24(2) to the applicant's submission of the application for vehicle type authorisation and/or vehicle authorisation for placing on the market as specified in paragraph 2 has expired; or
 - (c) the applicant has requested to end the pre-engagement.
4. When during the pre-engagement, the applicant wishes to change the authorising entity it shall request the termination of the existing pre-engagement. The applicant may then send a new pre-engagement application to a new authorising entity.
5. The applicant may introduce an application for authorisation through the one-stop-shop at any time during the pre-engagement process. In this case, the pre-engagement phase is terminated.
6. In case of pre-engagement, the points set out in Article 41 related to the identification and the categorisation of issues shall be used, in view of tracking issues raised with the applicant by the authorising entity and, when applicable, the concerned NSAs for the area of use.

Relevant references to Directive (EU) 2016/797:

- › Article 21

The pre-engagement covers all prior formal exchanges of information between the applicant, the authorising entity and the concerned NSAs for the area of use. It is considered good practice to have an early involvement of other parties which do not have a formal role in the vehicle authorisation process in order to facilitate the preparation of the application. This could include, upon the applicant's request:

- › Member State for non-application of TSIs;
- › NoBo for review of the arrangements, including the identification/ confirmation of TSIs applicable to the project;
- › DeBo for review of the arrangements, including the identification/ confirmation of national rules applicable to the project;
- › Assessment body (CSM RA) for review of the arrangements applicable to the project; and
- › Infrastructure manager for the arrangements for tests on the network, where required.

The more informal parts such as setting up meetings, dissemination etc. are not described. The legal text leaves flexibility to the authorising entity/ NSAs for area of use to decide on the nature and extent of their respective contributions to the pre-engagement activities in relation to the level of their contribution on a case by case basis (e.g. only single informative meeting, only exchange of e-mails, only one expert allocated etc.).

The pre-engagement activities should support the setting up of the pre-engagement baseline for the vehicle type authorisation and/ or vehicle authorisation for placing on the market process and foster the exchange of information on the applicable requirements and on the content and maturity level of the file accompanying the application.

Pre-engagement should not be used to perform preliminary assessments of the application by the authorising entity/ the concerned NSAs for the area of use. The assessment of the application by the authorising entity/ the concerned NSAs for the area of use should start when the applicant has sent a complete application through the one-stop shop as described in chapter 3.6.4. However, preliminary discussions between the authorising entity/ the concerned NSAs for the area of use and the applicant can take place after the pre-engagement baseline has been set and before the application is submitted by the applicant.

The pre-engagement phase is not mandatory for the applicant (they can request the authorising entity to take part in the pre-engagement or they can directly submit the application and the file accompanying the application). If the applicant chooses not to submit an application for pre-engagement the steps described in chapter 3.4.1 - 3.4.4 will not be performed and the applicant will not have the benefits of pre-engagement described below.

However, if the applicant requests to have a pre-engagement:

- › It is mandatory for the authorising entity and the concerned NSAs for area of use to provide this service to the applicant, subject to a fee.
- › The applicant is responsible for preparing a proposal for pre-engagement in cooperation with the conformity assessment bodies and the infrastructure manager, as needed.
- › The authorising entity and the concerned NSAs for area of use should decide on the nature and extent of their respective contributions to the pre-engagement activities.
- › The concerned NSAs for the area of use should prepare those arrangements referred to in Article 37(1) of Commission Implementing Regulation (EU) 2018/545, see chapter 3.7.7.
- › The authorising entity should coordinate with the applicant and the concerned NSAs for the area of use, as appropriate, with the aim of discussing the content of the pre-engagement baseline and, if considered to be relevant for the application, if there is any relevant information recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545 and take it into account, see chapter 3.7.10.
- › The authorising entity and the concerned NSAs for the area of use should review and agree the proposed pre-engagement baseline.

Pre-engagement should allow both to have face-to-face meeting(s) with all relevant parties but also to choose alternatives such as telephone/ video conference, to reduce travel time and costs. The applicant should keep records of the meeting(s) by drafting and circulating the minutes for review and approval to all participants. The records of the meeting(s) can be archived in the one-stop shop.

If any non-conformities are identified (see chapter 3.5.7) they should:

- › Be immediately addressed; and
- › Should not be transferred to the application.

However, if at pre-engagement phase there are already known non-conformities, it is important for a smooth development of the authorisation process to give visibility on the issues and to start the relevant discussions on how to deal with them.

For the sake of transparency and clarity of exchanges between the Agency as authorising entity, the concerned NSAs for the area of use and the applicant, the approach to follow in any instance of non-compliance identified at the pre-engagement stage should be recorded and tracked following the same principles used for the authorisation itself (see chapter 3.7.11). The same approach of using an issues log from pre-engagement stage is also strongly recommended if the authorising entity is a NSA. If this approach is used it will facilitate the transfer of knowledge in case the members of the assessment team change i.e. between pre-engagement and the submission of the application for authorisation. The issues from pre-engagement will not be transferred to the application for authorisation but the assessment team can access the issues recorded for the pre-engagement stage through the one-stop shop using the reference to the pre-engagement baseline provided by the applicant in its application.

Pre-engagement is beneficial for:

- › Facilitating early contact between the parties;
- › Developing the relationship between the authorising entity, the concerned NSAs 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 (for more information on the applicable rules see chapter 3.3.3); and
- › Making it clear how the vehicle authorisation process will be conducted and how decisions will be made.

In addition to the mandatory elements of pre-engagement required to be included in the pre-engagement file, the process also offers the potential to engage with the parties described above and others – such as the infrastructure manager or railway undertakings potentially affected by the introduction of the new vehicles – in respect of other aspects that may need to be considered after an authorisation has been issued such as route compatibility assessment.

For description of the process, see Annex XVIII the flowchart for Stage 2.

3.4.2. *Prepare a proposal for pre engagement and consult the conformity assessment bodies.*

The applicant is responsible for preparing a proposal for pre-engagement in cooperation with the conformity assessment bodies and the infrastructure manager, as needed.

3.4.3. *Article 23: Pre-engagement file*

The pre-engagement file accompanying the pre-engagement application shall contain the following:

- (a) a description of the vehicle type and/or vehicle to be authorised, including where applicable the intended variants and/or versions, and a description of the tasks and activities to develop it;
- (b) the applicant's choice of the authorising entity and of the authorisation case or cases pursuant to Article 14;
- (c) a specification of the intended area of use;
- (d) a specification of the anticipated conditions for use of the vehicle and other restrictions identified pursuant to Article 20;
- (e) the applicant's planning for its part of the vehicle authorisation process, including the planning that covers tests on the network, when applicable;
- (f) an identification of the methodology for the process for the requirements capture in accordance with Article 13;

- (g) the list of the rules and requirements identified by the applicant as those that are to be applied in accordance with Article 17 to Article 18;
- (h) a list of the identified conformity assessments pursuant to Article 21, including the modules to be applied and the use of Intermediate Statements of Verification ('ISV'), where applicable;
- (i) a description of the practical arrangements to use the vehicle for tests on the network, where applicable;
- (j) a list of the content of the documentation that the applicant anticipates to submit to the authorising entity and the concerned NSAs for the area of use for the vehicle type authorisation and/or vehicle authorisation for placing on the market;
- (k) a proposal concerning the language to be used for the vehicle authorisation process pursuant to Article 10;
- (l) a description of the applicant's organisation for its part of the vehicle authorisation process including but not limited to the applicant's contact information, contact persons information, requests for setting up coordination and meetings with the authorising entity and the concerned NSAs for the area of use.

In recording the applicant's planning for its part of the vehicle authorisation process (point (e)) the applicant should provide, at an early stage, a breakdown of the activities proposed to support the application for authorisation, in particular the elements that will form a part of the application. This is anticipated to include a first project plan to identify the expected dates for each stage. The applicant may need to update and amend this first project plan at later stages. Chapter 3.4.4 includes further information on the effect of changes to the pre-engagement file which are relevant for the pre-engagement baseline. It will contain the applicant's planning for:

- › Communication arrangements and meetings, if any, with the authorising entity and the concerned NSAs for the area of use;
- › When applicable, the request(s) for non-application of TSIs;
- › Performing conformity assessments and establishing evidence, including a description of the methods of working with the conformity assessment bodies. The identified conformity assessments are to be detailed in list of the identified conformity assessments as specified in point (h);
- › Conducting tests on the network, where relevant, with application(s) for temporary authorisation and the practical arrangements specified in point (i); and
- › Submitting the formal application.

For some items of the pre-engagement file a list is required, whereas for others a description will suffice. For example, a description of planning for using a vehicle for tests on the network will usually include details of location, infrastructure manager, test train operator, matters for which tests on the network are proposed, the vehicles to be used, a reference to the management procedures and confirmation of the extent to which arrangements are in place at the time of preparing the pre-engagement file. It is unlikely that it would be necessary to list the individual tests on the network, the specific dates or the staff members involved.

For the template for the pre-engagement application (including the pre-engagement file), see Annex VII.

3.4.4. Article 24: Pre-engagement baseline

1. Within one month from the date of receipt of the pre-engagement application the authorising entity and the concerned NSAs for the area of use shall inform the applicant that the pre-engagement file is complete or ask for the relevant supplementary information, setting a reasonable deadline for the provision thereof.

2. Where the applicant is informed that their file is complete, the authorising entity and the concerned NSAs for the area of use shall issue through the one-stop shop an opinion on the approach proposed by the applicant in the pre-engagement application no later than two months after the acknowledgement that the file is complete. That issued opinion establishes the pre-engagement baseline, including a determination of the version of the TSIs and national rules that are to be applied for the subsequent application for authorisation without prejudice to paragraph 4.
3. The pre-engagement baseline shall specify which language shall be used pursuant to Article 10.
4. In case of changes affecting the pre-engagement file which are relevant for the pre-engagement baseline, the applicant shall send an amended and updated pre-engagement application only considering the changes and the interfaces with the unchanged parts. This may occur in the following situations:
 - (a) changes to the design or to the assessment methodology resulting from major safety issues;
 - (b) changes in legal requirements invalidating the pre-engagement baseline; or
 - (c) any changes voluntarily introduced by the applicant.
5. The authorising entity and where applicable the concerned NSAs for the area of use shall within 1 month review and issue an opinion on the amended and updated pre-engagement application and record that opinion in an amended and updated pre-engagement baseline.

For the template for the pre-engagement baseline, see Annex VIII.

Pre-engagement baseline – legal status

The pre-engagement baseline is established based on an opinion issued by the authorising entity and the concerned NSAs for the area of use concerning the approach proposed by the applicant in the pre-engagement application.

Legislation takes precedence over the pre-engagement baseline, pursuant to article 4(2) of Directive 2016/797. This means that any changes to legislation will take precedence over the pre-engagement baseline. New/ changed TSIs, national rules and other regulations to be considered in the design of the vehicle should specify their scope and transitional arrangements, see chapter 3.3.3.

The pre-engagement baseline is a legal obligation for the authorising entity and the concerned NSAs for the area of use and if there are errors in the established pre-engagement baseline they can be held liable in the event of negative consequences caused by the error affecting the applicant negatively.

Change of authorising entity during or after the pre-engagement stage

If the applicant wishes to change the authorising entity during or after the pre-engagement stage it will result in the pre-engagement process restarting from the beginning with a new application for pre-engagement.

The rationale for requiring a new application for pre-engagement is that the applicant will have to develop new relationships with the parties involved and agree a new pre-engagement baseline. However, the applicant can reuse the applicable parts of its initial application for pre-engagement.

Timescales for pre-engagement

In order to ensure that pre-engagement does not become an open-ended commitment on the part of the parties involved there is a legally permitted maximum period of pre-engagement of 84 months (this is in order to ensure consistency with transitional periods defined in TSIs and national rules, validity of EC certificates, arrangements with the infrastructure manager, planning, etc.). The 84 months time frame will allow the pre-engagement baselines to be automatically set to “expired” in the one-stop shop and archived. The aim with the time frame is to avoid having inactive and/ or obsolete pre-engagement baselines in the one-stop shop. If the time frame for the pre-engagement baseline expires the applicant can send a new pre-engagement application or can choose to not continue the pre-engagement. This is the choice of the applicant.

It is recommended that the pre-engagement baseline is established no later than:

- › First authorisation: 18 months before the application for authorisation.
- › Extended area of use and new authorisation: 6 months before the application for authorisation.
- › Renewed authorisation: 3 months before the application for authorisation.

Validity of the pre-engagement baseline

In the case of changes affecting the pre-engagement file referred to in Article 23 of Commission Implementing Regulation (EU) 2018/545 it is only those changes referred to in Article 24(4) of Commission Implementing Regulation (EU) 2018/545 that affect the validity of the pre-engagement baseline. In the case of such changes the applicant should send an amended and updated pre-engagement application in order for the pre-engagement baseline to be amended, updated and to keep its validity. The amended and updated pre-engagement application only has to consider the changes and the interfaces with the unchanged parts. Any changes to the pre-engagement file that do not affect the pre-engagement baseline should be communicated by the applicant to the authorising entity and the concerned NSAs for the area of use but do not require an amended and updated pre-engagement application. If the applicant is not sure if a change will affect the validity of the pre-engagement baseline it should contact the authorising entity to discuss the effect of the change.

The validity of the pre-engagement baseline can also be affected by the outcome of activities undertaken by a NSA as part of its supervisory role.

3.5. Chapter 4 - Stage 3: Conformity assessment

All the necessary conformity assessments for vehicle type authorisation and/ or vehicle authorisation for placing on the market are covered by this stage. However, the detailed conformity assessments (subsystems, parts of subsystems, stages of the verifications, Interoperability Constituents) are not developed here. Conformity assessments for subsystems are the responsibility of the applicant for the purpose of Article 15 of Directive (EU) 2016/797. See chapter 3.3.3 for guidance on identification of rules and acceptable means of compliance.

For description of the process, see Annex XVIII the flowchart for Stage 3.

3.5.1. Article 25: Conformity assessment

Each conformity assessment body shall be responsible for compiling the documents and producing all necessary reports related to its conformity assessments performed pursuant to Article 26.

Relevant references to Directive (EU) 2016/797:

- › Article 2
- › Article 15
- › Chapter VI

Conformity assessment bodies (CABs)

“Conformity assessment body”⁽²⁾ is generic terminology defined in the ISO/ IEC 17000 standard. Very frequently, the acronym CAB is used. The term is also defined in Article 2(42) of Directive (EU) 2016/797. Article 2(41) of Directive (EU) 2016/797 also defines the term “conformity assessment”.

(2) “Conformity assessment body” is defined in section § 2.5. of the ISO/IEC 17000 standard as a “body that performs conformity assessment services”.

The Directive (EU) 2016/797 sets out different “conformity assessment bodies”. The role of each of these bodies is to assess the conformity of a product, process, system, etc. against a given set of requirements and/or legislation. In the context of vehicle type authorisation and/or vehicle authorisation for placing on the market, the following conformity assessment bodies can be involved:

- › Notified body (NoBo) notified by a Member State for the assessment of conformity of a structural sub-system against the relevant Union law (TSIs). The NoBo provides thus an independent assessment of the technical compliance with the relevant Union law (TSIs).
- › Designated body (DeBo) designated by a Member State pursuant to Article 15(8) of Directive (EU) 2016/797 for the assessment of conformity against national rules. The DeBo thus provides an independent assessment of compliance against the applicable national rules.

The requirements and responsibilities of NoBos and DeBos are addressed in Chapter VI of Directive (EU) 2016/797.

The notifying authorities are responsible for the assessment, notification and monitoring of conformity assessment bodies, pursuant to article 27 of Directive 2016/797. In the event of a lack of continued fulfilment of the requirements and responsibilities of a NoBo, the notifying entity can restrict, suspend or withdraw the notification of the concerned NoBo, following the provisions of Article 39 of Directive (EU) 2016/797.

Assessment body (CSM RA)

Assessment bodies (CSM RA) are accredited or recognised according to Article 7 of Commission Implementing Regulation (EU) 402/2013 for the assessment of conformity against the Commission Implementing Regulation (EU) 402/2013. The responsibilities of assessment bodies (CSM RA) are addressed in Commission Implementing Regulation (EU) 402/2013.

Assessment bodies (CSM RA) provide an independent assessment of the overall consistency, completeness and sufficiency of the proposer’s risk assessment and risk management activities in order to increase confidence, as a complement to the processes already implemented by the proposer (quality management system, safety management system, etc.), that the system under assessment can deliver the required level of safety.

What is the role of the assessment body (CSM RA)?

The assessment body (CSM RA) does neither perform the risk assessment required in Annex I of the Commission Implementing Regulation (EU) 402/2013 for risk assessment nor provide advice or solutions that could compromise its independence. The proposer is responsible for carrying out all the risk assessment and risk management activities specified in the Commission Implementing Regulation (EU) 402/2013.

The role of the assessment body (CSM RA) is to:

- › Give the assurance that the proposer’s risk assessment and risk management process is systematic and permits it to:
 - Capture (i.e. identify), understand, analyse and appropriately mitigate all reasonably foreseeable hazards which are associated to the vehicle under assessment; and
 - Identify systematically and exhaustively all the necessary safety related application conditions for the safe integration of the vehicle within the infrastructure and the safe operation and maintenance of the vehicle. Those safety related application conditions are to be included in the file accompanying the application for authorisation.
- › Form an expert judgement on the correct application of the risk assessment process of Commission Implementing Regulation (EU) 402/2013 and on the suitability of the results.

For this purpose, the Commission Implementing Regulation (EU) 402/2013 requires the assessment body (CSM RA) to:

- › Check the correct application by the proposer of the risk management process set out in Annex I of Commission Implementing Regulation (EU) 402/2013;
- › Check the suitability of the application of that process by the proposer and the appropriateness of the risk assessment results to fulfil safely the intended objectives; and
- › Deliver to the proposer a safety assessment report that contains the results of the check of compliance with the requirements of Commission Implementing Regulation (EU) 402/2013 and the assessment body (CSM RA) judgement and conclusions on the safety and suitability of the vehicle to fulfil its safety requirements.

The assessment body (CSM RA) independent assessment report is a transparent documentary evidence which supports the mutual recognition of the results from the proposer's risk assessment and risk management process. It avoids unnecessary additional risk assessments or duplication of work by other conformity assessment bodies.

It is not envisaged that the assessment body (CSM RA) performs an exhaustive check of all the evidence supporting the requirements capture and risk assessment performed by the applicant. Its role should be more systemic, focused on the process followed by the applicant to capture the requirements and ensure that all risks are covered and controlled; in order to do so, the assessment body (CSM RA) may need to check in detail some of the supporting evidence.

Cases where an assessment body (CSM RA) independent assessment is required

An independent assessment by an assessment body (CSM RA) is required in the following two cases:

- › **CASE 1:** when the relevant TSIs and/ or national rules requests the application of Commission Implementing Regulation (EU) 402/2013 (or specific parts of it), the NoBo(s) and/ or DeBo(s) is responsible for assessing the conformity of the vehicle with all the requirements of the relevant TSIs and/ or national rules, including the compliance with the requirements of Commission Implementing Regulation (EU) 402/2013.

In order to check the compliance with Commission Implementing Regulation (EU) 402/2013, and perform independent safety assessment, a NoBo must fulfil the same requirements as the assessment body (CSM RA):

- **Scenario 1:** If the NoBo and/ or DeBo fulfils the requirements and criteria in Annex II and is accredited or recognised according to Article 7 and Article 9 of Commission Implementing Regulation (EU) 402/2013, it can perform the independent assessment of the correct application of the risk assessment process set out in Commission Implementing Regulation (EU) 402/2013 and of the suitability of the results from that process.
- **Scenario 2:** If the NoBo and/ or DeBo does not fulfil the requirements and the criteria in Annex II of Commission Implementing Regulation (EU) 402/2013, it cannot deliver the independent assessment of the correct application of the risk assessment process set out in Commission Implementing Regulation (EU) 402/2013 and of the suitability of the results from that process. In that case, the NoBo and/ or DeBo can use the assessment work performed by an accredited or recognised assessment body (CSM RA) which meets all the necessary requirements. In such a case :
 - The assessment body (CSM RA) who performs the independent assessment work has to deliver its conclusions to the NoBo and/ or DeBo, or to the contracting entity, within an independent safety assessment report. This report will support the NoBo and/ or DeBo to provide its conclusions on the compliance with the relevant safety requirements of the considered TSIs and/ or national rules.
 - The NoBo and/ or DeBo can check (without repeating the work already performed) that an assessment body (CSM RA) has performed the independent assessment following the requirements in TSIs and/or national rules and the process described in

the Commission Implementing Regulation (EU) 402/2013, and has produced an assessment report according to Article 15 of Commission Implementing Regulation (EU) 402/2013. The report(s) issued by the assessment body (CSM RA) should be used by the NoBo and/or DeBo as valid evidence.

Independently of whether the NoBo and/ or DeBo will perform the independent safety assessment itself or whether it will use the outcomes of the work performed by an assessment body (CSM RA), duplication of work should be avoided. So, in practice, as the applicant (proposer) appoints both the NoBo and/ or DeBo and the assessment body (CSM RA), in order to avoid duplication of work between these conformity assessment bodies, the applicant (proposer) can request contractually that the NoBo and/ or DeBo and the assessment body (CSM RA) should find an agreement on *WHO* will do *WHAT* and *WHO* will *MUTUALLY RECOGNISE WHAT*.

If the requirements of the respective legislation are fulfilled, the same company can act as NoBo, DeBo and assessment body (CSM RA) for the project under assessment. Independence between these different roles is not required by the Union law.

- › **CASE 2:** When the change of the vehicle is significant, or the process in Annex I of Commission Implementing Regulation (EU) 402/2013 is applied, the assessment body (CSM RA) is responsible for the independent assessment.
- › **CASE 3:** For the requirements capture process of the essential requirement “safety” for the subsystems and the safe integration between subsystems for aspects not covered by the TSIs and the national rules.

How is the independent safety assessment done by an assessment body (CSM RA)?

The Commission Implementing Regulation (EU) 402/2013 does neither require that the assessment body (CSM RA) performs a complete independent safety assessment⁽³⁾, nor that it reviews thoroughly all the outputs of the risk management activities nor that it checks all details and all results from the risk assessment performed by the proposer. This would neither be cost effective nor necessary.

Compared to the conformity assessments for a TSI performed by a NoBo, which aims at checking that all the requirements of the considered TSIs are met (these are "standard based checks"), the independent safety assessment by an assessment body (CSM RA) is "more about making a judgement on safety", focusing the assessment on the areas with the highest risks. This is a distinct activity, with a different purpose and also with different competences. For the specific needs of the independent safety assessment, according to Article 6(2) of Commission Implementing Regulation (EU) 402/2013, the assessment body (CSM RA) needs to check the correct application by the applicant (proposer) of a full set of processes for the management of the quality and safety of the vehicle design.

To provide a judgement, based on evidence, of the suitability of the vehicle under assessment to fulfil its safety requirements⁽⁴⁾, the assessment body (CSM RA) needs to:

- › Have a thorough understanding of the significant change based on the documentation provided by the applicant (proposer);
- › Conduct an assessment of the organisation and processes used by the applicant (proposer) for managing the safety and quality (e.g. ISO 9001) during the design and implementation of the significant change, if the organisation and those processes are not already certified by a relevant conformity assessment body. If they are certified, the assessment body (CSM RA) should not reassess them but instead carry out the measures specified below;

(3) Commission Implementing Regulation (EU) 402/2013 specifies the assessments to be done by the assessment body (CSM RA) but it does not impose any specific working method. Section § 7.1 of the ISO/IEC 17020:2012 standard referred to in Annex II of that Regulation specifies general requirements on the inspection methods and procedures.

(4) Refer to the definition of "assessment body" in Article 3(14) of the Commission Implementing Regulation (EU) 402/2013.

- › Conduct an assessment of the organisation put in place for managing the change and an assessment of the application of those safety and quality processes for designing and implementing the significant change;
- › Conduct a representative vertical slice assessment⁽⁵⁾ on key risks to check whether the safety and quality processes are correctly applied by the applicant (proposer) and whether appropriate risk control measures are put in place following the risk assessment;
- › Have adequate assessment methods and sampling techniques, as well as sufficient knowledge of statistical techniques to ensure on the one side that the sampling method is representative of the whole process and statistically correct and on the other side that the assessment and interpretation of the risk assessment results is correct; and
- › When it uses methods or procedures which are not standardised, document them appropriately and fully, for reasons of transparency and to enable the mutual recognition of its safety assessment report.

The assessment body (CSM RA) should check that the application of the risk assessment process by the applicant (proposer) captures (i.e. identifies), understands, analyses and mitigates all reasonably foreseeable hazards associated with the significant change under assessment. The key tasks for the assessment body (CSM RA) independent safety assessment are therefore:

- › Getting an appreciation of the scope and context of the significant change and consequently of the necessary intensity of independent safety assessment or the size of the vertical slice to be assessed;
- › Selecting and planning a cost-effective assessment strategy based on risk, risk prioritisation and professional judgement;
- › Gathering relevant evidence by applying the selected assessment strategy;
- › Based on this evidence, forming a judgement on the compliance of the risk assessment and risk management with the requirements of Commission Implementing Regulation (EU) 402/2013 and on the suitability of the significant change to fulfil its safety requirements; and
- › Managing any outcomes, including the following:
 - A proactive and early identification of (potential) issues (within the scope of the assessment body);
 - A regular reporting of the identified issues to the applicant/ proposer to enable the later taking timely remedial actions; and
 - Tracking the issues raised to a resolution.

In any case, the applicant (proposer) can disagree with the assessment performed by the assessment body (CSM RA). In such a case, the applicant (proposer) should justify and document the parts for which it disagrees, see Article 15(1) of Commission Implementing Regulation (EU) 402/2013.

Relationship between entities performing an independent safety assessment (CENELEC standards) and assessment bodies (CSM RA)

The methodologies described in Commission Implementing Regulation (EU) 402/2013 and the CEN/CENELEC standards EN 50126/50128/50129 are not contradicting each other. One of the differences lies with the level of monitoring to which the entity performing and independent assessment is subject to: accreditation or recognition scheme according to Commission Implementing Regulation (EU) 402/2013 vs no monitoring in the framework of the CENELEC standards.

(5) The terms "vertical slice assessment" refer to a thorough end-to-end review of the application of the risk management process contained in the Appendix to Annex I of the of Commission Implementing Regulation (EU) 402/2013 for the key risks of the system under assessment. The purpose is to check a representative cross-sectional slice of the results from the risk assessment and to cover all the steps of the risk management process in Annex I of the of Commission Implementing Regulation (EU) 402/2013.

As described in the explanatory note “CSM for risk assessment and CENELEC standards” ref. 001SST1117, planned to be issued by the Agency, the Commission Implementing Regulation (EU) 402/2013 and the CENELEC standards should not be considered as two separate and consecutive tools; it is reasonable to use them in an integrated and complementary way. The compliance with the detailed requirements of the CENELEC standards can serve as “acceptable means of compliance” with the overall requirements of Commission Implementing Regulation (EU) 402/2013 provided that an independent assessment is either carried out by an accredited or recognised assessment body (CSM RA). If this is not the case, the assessment body (CSM RA) takes sole responsibility for accepting the work performed by the entity(ies) performing independent safety assessment(s).

However, the outcomes from an entity performing an independent safety assessment cannot be automatically recognised by an assessment body (CSM RA). Duplication of work must be avoided as far as possible. It is the responsibility of the applicant (proposer) to coordinate the work of the assessment bodies involved to avoid duplication of work and to ensure mutual recognition as far as reasonable. The more the entity performing an independent safety assessment meets requirements similar to those set out in Annex II of Commission Implementing Regulation (EU) 402/2013, the more the assessment body (CSM RA) would be able to accept the work performed by that entity.

3.5.2. Perform conformity assessment

Relevant references to Directive (EU) 2016/797:

- › Article 2
- › Article 15
- › Annex IV

When the relevant TSIs and/ or the national rules require the use of Commission Implementing Regulation (EU) 402/2013, they also specify the detailed assessment methodology (if needed, i.e. how to apply the Regulation) and the assessment criteria. In this case, the role of the NoBo and/ or the DeBo is to check whether this was applied, i.e. whether an assessment body (CSM RA) confirmed the correct application of Commission Implementing Regulation (EU) 402/2013 as required by the the relevant TSI or national rule. A NoBo or DeBo may not have the competency to carry out assessments described in the relevant TSI or national rule and/ or in Commission Implementing Regulation (EU) 402/2013 itself, but the same company may be accredited for more than one role and could therefore also execute more than one assessment role.

In any case, the final responsibility of the conformity assessment of the relevant TSIs and/ or national rules lies with the NoBo(s) and/ or DeBo(s). The assessment report issued by the assessment body (CSM RA), where the TSIs and/or the national rules requires the application of Commission Implementing Regulation (EU) 402/2013, should be treated by the NoBo(s) and/or DeBo(s) as any other evidence provided by the applicant in the framework of the EC verification procedure for other requirements (e.g. a test report where testing is required by TSIs and/or national rules).

3.5.3. Collect documentation from conformity assessment bodies.

The applicant collects the documentation from the conformity assessment bodies.

3.5.4. Article 26: Perform verifications and establish evidence

1. The applicant shall, as applicable per authorisation case, perform the necessary checks in order to establish the evidence referred to in Annex I.
2. The authorising entity and the concerned NSAs for the area of use shall not prescribe the requirements for the evidence to be included in the technical files accompanying the EC declarations of verification of the subsystems, but where there is a justified doubt, they may request the applicant to carry out additional verifications.

Relevant references to Directive (EU) 2016/797:

- › Article 2
- › Article 15
- › Article 21
- › Annex IV

The applicant for the purpose of Article 15 of Directive (EU) 2016/797 should:

- › Choose the EC verification modules to be used;
- › Identify the evidence to be delivered to demonstrate the compliance of the subsystem with the requirements;
- › Establish the technical documentation to be used to assess the conformity of the subsystem with the requirements of the relevant rules; and
- › Establish the relevant declarations for the subsystem(s) and the vehicle.

The NoBo(s) should :

- › Carry out the EC verification procedure;
- › Issue the EC certificates of verification; and
- › Compile the accompanying technical files.

The EC verification procedure described in Article 15 of Directive (EU) 2016/797 requires that the subsystem is to meet the requirements of the Union Law and any relevant national rules. Therefore, the conformity check should be performed against these requirements, NoBo for TSIs and DeBo for national rules. As a consequence, the responsibilities of the DeBo(s) should be the same as for the NoBo(s).

This item is under development and will be part of the Implementing Regulation on EC declaration of verification.

The responsibilities of the NoBo(s) apply mutatis mutandis for the DeBo(s).

The authorising entity and the concerned NSAs for the area of use should not prescribe the requirements for evidence, but when there is a justified doubt, they can request additional verifications to be carried out.

When the requirements for evidence are non-mandatory, but are giving presumption of conformity, the requirements for evidence should be defined in the relevant documents (such as guidelines).

Requirements for evidence, when they are mandatory, should be defined in the rules.

Requirements for evidence are covered by the TSIs and national rules that provide sufficient information on the assessment phases for each requirement (e.g. see chapter 6 and appendix H, table H.1 of Commission Regulation (EU) 1302/2014):

- › TSIs and national rules define for each requirement the mandatory demonstration (design review, type test etc.) to be carried out by the applicant.
- › Other means may define documents/ information that are non-mandatory and give a presumption of conformity such as:
 - TSI/ national rule guidelines;
 - Recommendation for use issued by NoBo; and
 - Acceptable means of compliance.

Declaration(s) made by applicant (EC declaration of verification, declaration of conformity to a type):

- › The EC declaration of verification of a subsystem is drawn up by the applicant and is transmitted with the technical file. The information to be provided on the EC declaration of verification is currently specified in Annex V of the Directive 2008/57/EC. However, the planned Implementing Regulation on EC declaration of verification will replace this annex and together with its guideline will provide more detailed provisions.
- › EC declarations of verification of subsystems are stored in ERADIS, see chapter 3.8.4.
- › Declaration of conformity to type is delivered by the applicant based on the EC verification procedure.
- › The information to be provided by the applicant is currently specified in Regulation 201/2011. However, the future Implementing Regulation on EC declaration of verification will replace it and provide updated provisions.

Certificates delivered by NoBo(s):

- › The content of the EC certificates are identified for each type of module used.

Certificates delivered by DeBo(s):

- › The provisions related to NoBo certificates should apply mutatis mutandis for DeBo Certificates.

The requirements capture process and the related evidence are the responsibility of the applicant. NoBo(s) and DeBo(s) do not have a formal role in this process, although the companies playing those roles may provide input to the applicant; in this case, those companies would not be acting as NoBo and/ or DeBo. The assessment body (CSM RA) does have the task to evaluate the process followed by the applicant and the related evidence where so requested by the Commission Implementing Regulation (EU) 2018/545, see chapter 3.3.1.

With regards to the conditions for use and other restrictions:

- › In the case of non-compliance the NoBo/ DeBo certificates can only contain conditions for use and other restrictions defined by the applicant. The technical file should provide detailed information related to “restrictions or limits and conditions of use”.
- › The authorising entity should approve the conditions for use and other restrictions.
- › A non-compliance that cannot be covered by conditions for use and other restrictions should not be allowed.
- › The authorisation delivered by the authorising entity can include additional conditions for use and other restrictions.
- › The monitoring of the DeBo is managed by the Member State.

3.5.5. Alternative method(s) for national rule(s)

Relevant references to Directive (EU) 2016/797:

- › Article 2
- › Article 13
- › Article 14

Alternative method(s) for national rule(s):

- › Can be proposed by the applicant;
- › Should give an alternative to the verification methodology, not to the requirement, for national rules; and
- › Are not binding.

An alternative method for a national rule could be: design demonstration (calculation), comparison with a similar authorised vehicle (“demonstration in use”), tests or a risk assessment.

There are two types of alternative method(s) for national rule(s):

1. Alternative method(s) for mandatory national rule(s).
2. Alternative method(s) for non-binding requirement(s) (e.g. EN standard, application guide) that give a presumption of conformity.

The type (1) alternative method (for mandatory national rules) should be managed as an “Acceptable national mean of compliance”, see chapter 3.3.3.

The type (2) alternative method (for a non-binding requirement that gives a presumption of conformity) should be evaluated by the DeBo and the concerned NSA may be involved. The applicant decides if there is a need to involve an assessment Body (CSM RA). The concerned Member State will assess if the alternative method proposed is acceptable. The concerned Member State informs the applicant about the accepted alternative method.

When an alternative method has been accepted as described above for type(1) and type (2) alternative methods:

- › The applicant provides the accepted alternative method to the DeBo;
- › The DeBo uses the accepted alternative method for the conformity assessment; and
- › The concerned Member State indicates if an accepted type (2) alternative method can become an “acceptable national means of compliance”.

Alternative method(s) for national rule(s) can be included in pre engagement, however it is possible for an applicant to only include an alternative method in its application but this poses a substantial risk that it will be refused. If no pre engagement has taken place, the alternative method would have not been discussed with the concerned NSA. Pre-engagement is voluntary for the applicant also in case where alternative method is used. In any case, the timeframe is in accordance with the applicable procedures (e.g. as defined in implementing acts).

Additional information for the description of the process:

- › The decision criteria for involving an assessment body (CSM RA) can be developed following return of experience.
- › The CSM on risk assessment methodology set out in Annex I of Commission Implementing Regulation (EU) 402/2013 can be used by the applicant to evaluate/ demonstrate that the alternative method is equivalent to the “original” method.

3.5.6. *Check if the verification and assessment results can be accepted*

The applicant checks if the verification and conformity assessment results can be accepted based on the evidence.

3.5.7. *Article 27: Correction of non-conformities*

1. The correction of non-conformities with TSIs and/or national rules requirements shall be carried out by the applicant, unless a non-application of TSI in accordance with Article 7 of Directive (EU) 2016/797 has been granted. That may apply mutatis mutandis for national rules when allowed by the Member State’s national legal framework.
2. In order to mitigate a situation of non-conformity the applicant may, alternatively, do one or more of the following:

- (a) change the design; in which case the process shall begin anew from the requirements capture set out in Article 13, for the modified elements only and those elements affected by the change;
 - (b) establish conditions for use of the vehicle and other restrictions in accordance with Article 20; in which case the conditions for use of the vehicle and other restrictions shall be defined by the applicant and checked by the relevant conformity assessment body.
3. The applicant's proposal for conditions for use of the vehicle and other restrictions as pursuant to Article 20 to correct a non-conformity shall be based on the necessary conformity assessments pursuant to Article 25.

Relevant references to Directive (EU) 2016/797:

- › Article 7

It is assumed that rules should be fully complied with unless a non-application of a TSI is granted and therefore the options for the applicant are limited to changing the design or changing the conditions of use and other restrictions. Remedial actions can be repeated until conformity is reached. Conditions for use and other restrictions should be avoided as much as possible. The possible conditions for use and other restrictions are described in chapter 3.3.6 "Identification of the conditions for use and other restrictions".

3.6. Chapter 5 - Stage 4: Submitting the application

For the application to be considered complete by the authorising entity and, when applicable, by the concerned NSAs for the area of use it should contain the information listed in Annex I. Compiling the application and the file accompanying the application covers all the activities related to the collection of the supporting documentation that is required for the application.

The certificates should contain the conditions for use and other restrictions, if any, as described in Directive (EU) 2016/797.

For description of the process, see Annex XVIII the flowchart for Stage 4.

3.6.1. Article 28: Establishment of evidence for the application

The applicant for a vehicle type authorisation and/or a vehicle authorisation for placing on the market shall establish the evidence for the application by:

- (a) putting together the EC declarations of verification for the subsystems composing the vehicle and providing the evidence, in the technical file accompanying the EC declarations, of the conclusions of the conformity assessments done following the identification carried out pursuant to Article 21;
- (b) ensuring that interfaces between subsystems that are not defined in TSIs and/or national rules, are covered by the requirements capture referred to in Article 13 and meet the essential requirements set out in Article 3.1 of Directive (EU) 2016/797.

Relevant references to Directive (EU) 2016/797:

- › Article 3
- › Article 4
- › Article 15
- › Article 21
- › Article 24
- › Annex III
- › Annex IV

The applicant that establishes the EC Declaration for Verification for subsystem(s) as specified in Article 15 of Directive (EU) 2016/797 (the applicant for placing on the market of a mobile subsystem) should:

- › Establish the EC declaration of verification for subsystem(s), including conditions for the interfaces with other subsystems; and
- › Take the full responsibility for the subsystem.

The EC declaration of verification is established at the level of the subsystem, therefore it is an intermediate document in the process leading to the vehicle type authorisation and/ or vehicle authorisation for placing on the market.

This approach will allow the mobile subsystem to be placed on the market without the need for any authorisation.

However, a mobile subsystem cannot be used until it is part of a vehicle/ vehicle type that is authorised. The subsystem verification of interfaces with other subsystems required under Article 15(3) of Directive (EU) 2016/797 requires a check only of items specified in the TSI. It follows that until the TSIs fully specify the interface on-board control-command and signalling (CCS) - rolling stock (RST) it is not an exhaustive check of technical compatibility and safe integration between the subsystems but simply a check of what is required by the TSIs (if anything).

A full check of technical compatibility and safe integration of the two sub-systems follows later when the subsystems are together and integrated to form a vehicle.

Although vehicle type authorisation and/ or vehicle authorisation for placing on the market is a stage that follows the EC declaration of verification for the mobile subsystem(s) the documentation for authorisation is mostly to be found in the technical files accompanying each EC declaration of verification.

The “Blue Guide⁽⁶⁾” (https://ec.europa.eu/growth/content/%E2%80%98blue-guide%E2%80%99-implementation-eu-product-rules-0_en) identifies, in its section 4.1.1, how a manufacturer may demonstrate conformity with the essential requirements, which by analogy applies to subsystems and vehicles. It complements the list of contents to be covered by the “technical file accompanying the EC declaration of verification for a sub-system” to be found in Article 15(4) of Directive (EU) 2016/797.

3.6.2. Article 29: The compilation of the file accompanying the application

1. The applicant shall prepare and compile in a structured way the content that is required for the file accompanying the application in accordance with Annex I.
2. For the authorisation referred to in Article 14(1)(b), (c), (d), and (e), the applicant shall check the validity of the existing vehicle type authorisation.
3. The applicant shall, for the authorisation referred to in Article 14(1)(c) and (d), submit the documentation necessary for the authorising entity to issue its decision, including where available any documentation accompanying the file for the previous authorisation.

Relevant references to Directive (EU) 2016/797:

- › Article 15
- › Article 21
- › Article 24
- › Article 54
- › Annex IV

⁶ Commission Notice 2016/C 272/01 *The ‘Blue Guide’ on the implementation of EU products rules 2016*

To compile the contents for the file accompanying the application for authorisation the applicant for vehicle authorisation for placing on the market as specified in Article 21 of Directive (EU) 2016/797 and/ or for vehicle type authorisation as specified in Article 24 of Directive (EU) 2016/797 should:

- › Produce documentary evidence of the requirements capture in relation to the essential requirements;
- › In the case of a renewed authorisation, check if the vehicle type authorisation is valid; and
- › Prepare and compile the content that is required for the authorisation file according to Annex I of Commission Implementing Regulation (EU) 2018/545, including the EC declarations of verification for all subsystems and the accompanying technical files, established by the applicant as specified in Article 15 of Directive (EU) 2016/797.

New authorisation or extension of area of use

The additional documentation expected in case of a new authorisation or an extension of the area of use is of the same nature as the content of the existing authorisation, but focused on the part where an update is necessary as regards to the changes related to the new authorisation or the extended area of use. In order to facilitate both the setting up and the assessment of the authorisation file, the applicant should keep the same structure as the existing authorisation file, to ensure consistency of the evidence provided.

In cases of new authorisation or extension of the area of use, the applicant should provide additional relevant documentation to the existing full accompanying file (decision issued in accordance with Article 46 and the full accompanying file for that decision, see also chapter 3.8.1). This should be seen as complementary documentation to the existing file and not that the applicant should provide all the documentation used for the previous authorisation process.

Wagon intended to transport dangerous goods

In accordance with section 2.4.d of Annex IV of Directive (EU) 2016/797, the technical file accompanying the EC Declaration of verification assembled by the applicant should contain the certificates of verification issued in accordance with other legal acts of the Union.

Article 21 of Directive (EU) 2016/797 states that the EC Declaration of verification is part of the documentation needed to obtain a vehicle type authorisation and/ or vehicle authorisation for placing on the market. It means that in the case of a freight tank-wagon, the applicant has to obtain the type approval according to RID prior to its application for a vehicle type authorisation and/ or vehicle authorisation for placing on the market.

The authorising entity should apply the vehicle authorisation process as described in Article 21 of Directive (EU) 2016/797 and check the presence of evidence that the type approval for the tank has been done according to RID and that it is still valid for the type of tank equipping the concerned wagon.

3.6.3. Article 30: Application content and completeness

1. For the application to be considered complete by the authorising entity and when relevant by the concerned NSAs for the area of use it shall contain the information set out in Annex I.
2. For the authorisation extended area of use referred to in Article 14(1)(c), the following points shall apply:
 - (a) the documentation to be added to the original full accompanying file for the decision issued in accordance with Article 46 by the applicant shall be limited to aspects concerning the relevant national rules and the technical compatibility between the vehicle and the network for the extended area of use;
 - (b) when the original vehicle type authorisation included non-applications of TSIs, the applicant shall add the relevant decisions for non-application of TSIs in accordance with Article 7 of

Directive (EU) 2016/797 covering the extended area of use to the original full accompanying file for the decision issued in accordance with Article 46;

- (c) in case of vehicles and/or vehicle types authorised under Directive 2008/57/EC or before, the information to be added by the applicant to the original file for the aspects covered by point (a) shall also include the applicable national rules.

Relevant references to Directive (EU) 2016/797:

- › Article 7
- › Article 13
- › Article 14
- › Article 21
- › Article 24
- › Article 54

The application form should contain documentary evidence covering at least the items specified in Annex I of Commission Implementing Regulation (EU) 2018/545.

Information to add to the original file (meaning existing file, or file from the previous authorisation) as applicable for the extended area of use should consist of providing evidence on:

- a) The placing on the market of the mobile subsystem(s) of which the vehicle is composed (the rolling stock subsystem and the on-board control-command and signalling subsystem) in accordance with Article 20 of Directive (EU) 2016/797, on the basis of the 'EC' declaration of verification;
- b) The technical compatibility of the subsystems referred to in point (a) within the vehicle, established on the basis of the relevant TSIs (specific cases), and where applicable, the relevant national rules for non-application of TSI(s) and open points;
- c) The safe integration of the subsystems referred to in point (a) within the vehicle, established on the basis of the relevant TSI(s), and where applicable, the relevant national rules for non-application of TSI(s) and open points, and the CSMs; and
- d) The technical compatibility of the vehicle with the network(s) included in the area of use referred to in paragraph 2, established on the basis of the relevant TSI(s) and, where applicable, the relevant national rules for non-application of TSI(s) and open points, registers of infrastructure and the CSM on risk assessment.

In the case of vehicle types authorised under Directive 2008/57/EC or before (no extension of the scope of the TSIs), the information to add to the original file for the aspects covered by points (b), (c) and (d) should also include the applicable national rules for all parameters.

The scope of the first set of TSIs applicable to vehicles was limited to the operation on the TEN network (from TSIs "2002" to TSIs "2011"). In this case, national rules are still applicable to cover the non-TEN network. It is however recommended to use as far as possible mutual recognition of national rules in order to limit unnecessary double checks.

Since 2014 and the entry into force of the new revised set of TSIs (under Directive 2008/57/EC), the TSIs applicable to vehicles cover not only the TEN network but also the rest of the Union rail network (as mentioned in Directive (EU) 2016/797 Annex I). This implies that the remaining national rules should cover:

- › Technical compatibility with the network for specificities linked to the existing network and not taken into account by the TSIs; and/ or
- › Open points or specific cases mentioned but not described in the TSIs.

Specific cases in the TSIs are mostly related to technical compatibility with the network. For the extended area of use the relevant open points in the TSIs are those related to technical compatibility with the network. National rules covering open points that are not related to technical compatibility with the network should be mutually recognised.

3.6.4. Article 31: The submission of the application for authorisation through the one-stop shop

1. The application for a vehicle type authorisation and/or a vehicle authorisation for placing on the market shall be formally submitted by the applicant through the single entry point of the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796 and shall contain the information set out in Annex I.
2. When submitting its application for a vehicle type authorisation and/or a vehicle authorisation for placing on the market the applicant shall select the authorising entity in accordance with Article 21(5) and 21(8) of Directive (EU) 2016/797.
3. The selection of authorising entity made by the applicant shall be binding until the decision on the issuing of the vehicle type authorisation and/or the vehicle authorisation for placing on the market or the refusal of the application has been taken by the authorising entity or the application has been terminated by the applicant.
4. The applicant's file shall be referred through the one-stop shop to the concerned NSAs for the area of use.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Relevant references to Regulation (EU) 2016/796:

- › Article 12

All applications for vehicle authorisation should be submitted through the single entry point of the one-stop shop referred to in Regulation (EU) 2016/796 regardless of who will be the authorising entity. This also includes vehicles that are in the scope of Directive (EU) 2016/797 but that are not (and not intended to be) covered by TSIs (e.g. tram-trains, metric track gauges) with the exception only for those tram-trains for which Directive (EU) 2016/797 allows Member States to define a specific procedure.

The applicant should submit its application for a vehicle type authorisation/ vehicle authorisation for placing on the market through the single entry point of the one-stop shop, using the electronic application form and select the authorising entity when the area of use is limited to one Member State.

If a Member State has adopted national rules requiring a specific authorisation procedure to be followed for authorisation of tram-trains (where Directive (EU) 2016/797 allows for this), the Agency should not be involved in the authorisation process.

When the area of use is for more than one Member State, the one-stop shop will select the Agency as authorising entity by default. When the area of use is limited to one Member State, the applicant can choose the authorising entity responsible for the issuing of the vehicle type authorisation and/ or vehicle authorisation for placing on the market. In this latter case, only the Agency and the concerned NSA for the area of use will be proposed by the one-stop shop for selection by the applicant. Information already submitted by the applicant during any pre-engagement will be re-used to avoid any additional burden for the applicant.

If the Member State has not excluded from the scope of the Directive (EU) 2016/797 and thus has not adopted any particular national authorisation procedure for tram-trains, Article 21 of Directive (EU) 2016/797 should apply. The applicant can therefore choose either the Agency or the NSA in the case of

authorisation for an area of use limited to one Member State. However, in this case the TSIs do not apply, only national rules are applicable, so the part of the assessment by the authorising entity covering rules will be fully covered by the assessment by the concerned NSAs for the area of use.

When the authorisation process (starting at the pre-engagement stage if used) is triggered via the one-stop shop, the applicant should select the authorising entity in accordance with Article 21(5) and 21(8) of Directive (EU) 2016/797 (when the area of use is limited to a network or networks within one Member State whether it submits its application for vehicle type authorisation and/ or vehicle authorisation for placing on the market to the national safety authority of that Member State or to the Agency). From the moment this selection is made, the applicant will not be able to change its choice of authorising entity, unless the applicant terminates its initial application and triggers a new application to the other authorising entity. In such a case, the applicant should restart the whole authorisation process from the beginning.

It is only the applicant that can terminate an application. The authorising entity has to take a decision (either positive or negative) when an application has been submitted through the one-stop shop.

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, as it may be in a better position to perform some of the checks described in Annex II of Commission Implementing Regulation (EU) 2018/545 (e.g. non-application of TSIs linked to the type, validity of the existing type authorisation etc.).

The application should be made sufficiently in advance of when the applicant requires the vehicle type authorisation and/ or vehicle authorisation for placing on the market. The applicant should take into account that the maximum time frames specified in Article 34 of Commission Implementing Regulation (EU) 2018/545 may be extended if it is found during the check of completeness of the application that there is missing information or if a justified doubt is raised (and it is in duly recorded agreement with the applicant to extend the timeframe).

In its planning for its project the applicant for a vehicle type authorisation and/ or vehicle authorisation for placing on the market needs to take into account that the issued authorisation is only a milestone and that there are additional aspects that need to be considered before a vehicle can be used as intended. Factors to be considered by the applicant in its planning for when the application needs to be submitted should include:

- › The extent of pre-engagement, if any, that has been performed;
- › The timescale for submitting the application and the subsequent assessment by the authorising entity;
- › The complexity of and/ or uncertainties concerning the application; and
- › Any additional time required for the checks before the use of authorised vehicles (checks of authorisation, registration, route compatibility and integration into the composition of the train where it is intended to operate, see Article 23 of Directive (EU) 2016/797).

The one-stop shop will assign a unique identification number per application that can be added to all printed versions of documents related to individual cases.

3.7. Chapter 6 - Stage 5: Processing the application

For description of the process, see Annex XVIII the flowchart for Stage 5.

3.7.1. One-stop shop referral of the application to the authorising entity (the Agency/ NSA)

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Relevant references to Regulation (EU) 2016/796:

- › Article 12

3.7.2. Article 32: Application completeness check

1. The authorising entity shall check the completeness of the information and documentation provided by the applicant in the application in accordance with Article 30.
2. The concerned NSAs for the area of use shall :
 - (a) check that the area of use is correctly specified for its part;
 - (b) raise any issues concerning the completeness of the information and documentation provided for the assessment of the applicable national rules as specified in Annex III.
3. The completeness check referred to in paragraph 1 and 2 shall constitute a verification by the authorising entity, and the concerned NSAs for the area of use that:
 - (a) all the required information and documents referred to in Article 30 have been provided by the applicant in the application for vehicle type authorisation and/or vehicle authorisation for placing on the market;
 - (b) the provided information and documentation provided is considered relevant to allow the authorising entity and the concerned NSAs for the area of use to perform their assessments in accordance with Article 38 to Article 40.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

The authorising entity and the concerned NSAs for the area of use should evaluate the completeness of the application and the file accompanying the application in accordance with chapter 3.6.3 within one month following the date of receipt of the application and inform the applicant accordingly.

3.7.3. Article 33: Acknowledgement of application

1. The one-stop shop shall generate an automatic acknowledgment of the receipt of the application to the applicant.
2. The assessment of the application shall start on the date of receipt of the application.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Relevant references to Regulation (EU) 2016/796:

- › Article 12

The automatic acknowledgement of receipt of the application and the file accompanying the application will state that the date of receipt of the application is the first working day common to all concerned authorities. No checks will be performed at that stage.

The automatic acknowledgement of the receipt of the application will be sent by the one-stop shop to:

- › The Agency programme manager and the NSA contact point(s) of the area of use, if the area of use (selected by the applicant) covers more than one Member State or if the area of use covers one Member State and the Agency was selected as the authorising entity by the applicant; or

- › The NSA contact point if the area of use covers one Member State and the applicant has selected the NSA as the authorising entity.

The one-stop shop will automatically:

- › Update the directory of contact points of the application and the file accompanying the application with the details of the contact point of the applicant, of the contact points of the concerned NSAs for the area of use and of the Agency programme manager (if appropriate);
- › Provide access to the application and the file accompanying the application to the relevant users; and
- › Store the date of the submission of the application and the file accompanying the application (the date of the submission will be taken into account by the project manager to calculate the date of receipt of the application at a later stage).

The time frame, see chapter 3.7.4, starts on the date of receipt of the application. The project manager should calculate the date of receipt of the application based on the date of the submission of the application and the file accompanying the application (stored in the one-stop shop) and the first working day common for the concerned authorities.

The template for acknowledgement/ refusal of complete application and the file accompanying the application., see Annex VI, should be used to inform the applicant (within one month of the date of receipt of the application) of the result of the authorising entity's and the concerned NSAs for area of use evaluation of the completeness of the application and the file accompanying the application (according to chapter 3.6.2).

3.7.4. Article 34: Timeframe for the assessment of the application

1. The authorising entity and the concerned NSAs for the area of use shall evaluate, each for their own part, the completeness of the application as specified in Article 32 within one month following the date of receipt of the application. The authorising entity shall inform the applicant accordingly.
2. Where the applicant is informed that their file is complete, the final decision over the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market shall be taken no later than four months after the acknowledgement that the file is complete.
3. The decision of the authorising entity shall be issued within one month following the date of receipt of the application in case of authorisation in conformity to type in accordance with Article 14(1)(e).
4. If the applicant is informed that its file is not complete, the final decision over the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market shall be taken no later than four months following the submission of the missing information by the applicant, unless the application is fundamentally deficient, in which case it shall be rejected.
5. In the course of the assessment, even if the application is complete as referred to in paragraph 2, the authorising entity or the concerned NSAs for the area of use may, at any time, request supplementary information, setting a reasonable deadline for the provision thereof, without suspending the assessment unless the provisions of paragraph 6 apply.
6. When a justified doubt has been raised by the authorising entity or the concerned NSAs for the area of use and the applicant is required to provide supplementary information, the authorising entity may suspend the assessment and in duly recorded agreement with the applicant extend the timeframe beyond what is set out in Article 21(4) of Directive (EU) 2016/797. The timeframe for providing the supplementary information shall be proportionate to the difficulty for the applicant to provide the information requested. The assessment and the timeframe shall resume after the applicant provides the requested information. In the absence of agreement with the applicant, the authorising entity or the concerned NSAs for the area of use shall take its decision based on the available information.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Relevant references to Regulation (EU) 2016/796:

- › Article 58

The timeframes specified in Article 34 of Commission Implementing Regulation (EU) 2018/545 should be recognised as the maximum time frames for the tasks and not target times. The involved parties should strive to complete their tasks without unnecessary delay.

The automatic acknowledgement of the receipt of the application will be notified by the one-stop shop to the applicant, the authorising entity and the concerned NSAs for the area of use.

The notification will be sent to the applicant's contact person identified in the application form, with the authorising entity and the concerned NSAs for the area of use in copy. The one-stop shop will provide a link where the file accompanying the application file can be consulted.

The completeness check should take place within 1 month of the date of receipt of the application, according to the following timeframe:

- › Maximum one week for the authorising entity to identify the concerned NSAs for the area of use (if any) and refer the file to them;
- › Maximum two weeks for the concerned NSAs for the area of use (if any) to raise any issue concerning the completeness of the file and for the Agency to check completeness; and
- › Maximum one week for the authorising entity to confirm completeness or request supplementary information.

The authorising entity, in conjunction with the concerned NSAs for the area of use, can suspend the application if the information supplied is incomplete pursuant to Article 34(4) of Commission Implementing Regulation (EU) 2018/545. The assessment of the application (and the 4 month timeframe for the assessment) will start when the applicant has submitted all the missing information.

The assessment of the application should be carried out by the authorising entity and the concerned NSAs for the area of use to establish a reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their obligations and responsibilities in the design, manufacture, verification and validation stages of the vehicle and/ or vehicle type in order to ensure conformity with the essential requirements of all applicable legislation so that it may be placed on the market and may be used in the area of use of the vehicle type according to the conditions of use and other restrictions specified within the application.

The completion of the procedure will be monitored by the one-stop shop from the date of the automatic acknowledgement of the receipt of the application. The following time scales should be met by the authorising entity in all cases of authorisation except authorisation in conformity to type:

- › Assess whether the file accompanying the application and any requested documentary evidence are complete within one month following the date of receipt of the application. The applicant should be informed accordingly.
- › If the file accompanying the application is complete, take the final decision to issue the vehicle type authorisation/ vehicle authorisation for placing on the market within four months following the acknowledgement of the complete application.
- › If the file accompanying the application is not complete, take the final decision to issue the vehicle type authorisation/ vehicle authorisation for placing on the market within four months following the submission of the necessary information by the applicant.

For authorisation in conformity to type the decision should be issued within one month of the date of receipt of the application.

After completion of the acknowledgement/ refusal of the complete application and the file accompanying the application as described in chapter 3.7.3, the authorising entity, in coordination with the concerned NSAs for the area of use should, within 4 months of the acknowledgement of receipt of the complete application:

- › Define the scope of the assessment;
- › Carry out the assessment; and
- › Issue its recommendation for the final decision.

The authorising entity and the concerned NSAs for the area of use may ask, each for their respective part in the course of the assessment, for additional information and clarifications, including also any instances of non-compliance. Such requests should:

- › Always specify a timeframe for the response (appropriate to the complexity of the topic); and
- › Not suspend the timeframe for the assessment unless justified doubts are identified that prevent the assessment, or parts of it to continue.

This is a mechanism that allows the applicant to provide additional evidence (to resolve issues identified during the assessment) without any suspension of the timeframe of the assessment. This is different from justified doubts where the timeframe for the assessment can be suspended if there is a duly recorded agreement with the applicant.

The authorising entity and the concerned NSAs for the area of use should be as specific as possible, to assist the applicant in understanding the level of detail expected in the response, without imposing the action(s) to resolve it.

To be satisfactory, the applicant's written response should be sufficient to allay the concerns expressed and to show that its proposed arrangements will meet the requirements. It should include new text and/ or rephrasing to replace what was unsatisfactory in the application, with an explanation of how this deals with the identified deficiencies. The applicant may, in addition, supply relevant supporting information as well as amend/ add relevant text to the text contained in the application. If the authorising entity and/ or the concerned NSAs for the area of use does (do) not agree with the proposed measures and/ or timescales, it (they) should promptly contact the applicant to resolve the issue.

Due to that it is not possible to predict for the assessment when a justified doubt could be raised or the time needed to process a justified doubt there are no time frames specified. However, if the authorising entity and/ or the concerned NSAs for the area of use have a justified doubt they should without delay raise and process the justified doubt.

3.7.5. Article 35: Communication during the assessment of the application

1. The authorising entity, the concerned NSAs for the area of use and the applicant shall communicate through the one-stop shop as regards any issue referred to in Article 41.
2. The status of all stages of the vehicle authorisation process, the decision on the application and the documented reasons for that decision shall be communicated to the applicant through the one-stop shop.
3. The guidelines of the Agency and of the NSAs shall indicate arrangements for communicating between themselves and with the applicant.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Relevant references to Regulation (EU) 2016/796:

- › Article 12

The authorising entity and the concerned NSAs for the area of use should establish that the required competent staff are made available to allow the authorisation process to be completed within the defined timescale. It is recommended that the necessary competent staff are in place no later than 1 week from the date of receipt of the application. Information on the competent staff assigned to the procedure should be registered in the one-stop shop.

The information registered in the one-stop shop should cover the contact details of the experts from the authorising entity and the concerned NSAs for the area of use in order to facilitate the co-ordination work between the different parties or even within an organisation. A contact person should be appointed in each authority as appropriate. This information should be made visible to the applicant.

The applicant will be able to contact the authorisation team via a contact form. The contact form will direct the request to the relevant contact person. For that purpose, the contact form will distinguish queries on the parts concerning the TSIs from those on the relevant national rules of the application (based on the selected area of use).

For guidance on the use of the issues log, see chapter 3.7.11.

3.7.6. Article 36: Information management concerning the assessment of the application

1. The authorising entity and the concerned NSAs for the area of use shall register in the one-stop shop the outcomes of the stages of the vehicle authorisation process in which they are involved, each for their respective part of the assessment as applicable, including all the documents relating to the application concerning the following:
 - (a) receipt;
 - (b) handling;
 - (c) assessment;
 - (d) conclusions of the assessment of the application as specified in Article 45;
 - (e) final decision to issue or not the vehicle type authorisation or the vehicle authorisation for placing on the market;
 - (f) final documentation for the vehicle type authorisation and/or the vehicle authorisation for placing on the market in accordance to Article 47.
2. The final decision to issue or not the vehicle type authorisation and/or vehicle authorisation for placing on the market shall be communicated to the applicant through the one-stop shop.
3. For the documents listed in paragraph 1, the authorising entity and the concerned NSAs for area of use shall use the document control process provided by the one-stop shop.
4. Where the NSAs use an information management system for processing the applications addressed to them, they shall transfer all relevant information to the one-stop shop.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Relevant references to Regulation (EU) 2016/796:

- › Article 12

Information management

Any intermediate working documents, including informal correspondence with the applicant, can be archived in the one-stop shop.

The authorising entity and the concerned NSAs for the area of use are still free to establish their own information management systems consistent with the proposed process (e.g. by defining a storage policy, including retention time and storage location), in particular to manage intermediate working documents and informal correspondence.

3.7.7. Article 37: Coordination between the authorising entity and the concerned NSAs for the area of use for the assessment of the application

1. For the purpose of the assessment of the application, the concerned NSAs for the area of use shall plan, organise and agree on the necessary arrangements in order to take into account the classification of national rules and cross-acceptance referred to in Article 14(10) of Directive (EU) 2016/797. The agreed arrangements for the assessment of the application shall be communicated to the authorising entity and the applicant.
2. The authorising entity and the concerned NSAs for the area of use shall coordinate with each other in order to address any issues including any instances that may require an amendment of the application and/or request for supplementary information, where providing supplementary information has an impact on the timeframe of the assessment or has the potential to have an impact on their work, and agree on the way forward.
3. When concluding the coordination activities referred to in paragraph 2, the authorising entity and the concerned NSAs for the area of use shall take each for their own part the decision to inform the applicant through the OSS of any instances that may require an amendment of the application and/or request for supplementary information.
4. Before the authorising entity takes its final decision and before the concerned NSAs for the area of use submit their assessment files, the authorising entity and relevant NSAs for the area of use shall:
 - (a) discuss the outcome of their respective assessment; and
 - (b) agree on conditions for use and other restrictions and/or exclusions of area of use to be included in the vehicle type authorisation and/or in the vehicle authorisation for placing on the market.
5. On the basis of outcome of the coordination activities referred to in paragraph 4 of this Article, the authorising entity shall provide to the applicant its documented reasons for the decision. In so doing it shall take into account the assessment files of the concerned NSAs for the area of use, referred to in Article 40(6), regarding the issuing or refusal of the vehicle type authorisation and/or vehicle authorisation for placing on the market, including any conditions for use of the vehicle and other restrictions and/or exclusions of area of use to be included in the vehicle type authorisation and/or vehicle authorisation for placing on the market.
6. Records of the coordination activities shall be taken by the authorising entity and maintained in the one-stop shop in accordance with Article 36.

Relevant references to Directive (EU) 2016/797:

- › Article 14(10)
- › Article 21
- › Article 24

Relevant references to Regulation (EU) 2016/796:

- › Article 12

Coordination between the authorising entity and the concerned NSAs for the area of use

The concerned NSAs for the area of use should take into account the classification of national rules and cross-acceptance referred to in Article 14(10) of Directive (EU) 2016/797 (and the Implementing Act referred to in that article) and put in place the necessary arrangements in accordance with Article 37(1) of Commission Implementing Regulation (EU) 2018/545. This should be done with the aim of avoiding duplication of assessments for those national rules that are classified as equivalent for the concerned Member States and area of use. For equivalent national rules the NSAs for the concerned area of use should apply the principle of mutual recognition for the following aspects for assessment listed in Annex III of Commission Implementing Regulation (EU) 2018/545: point 5; point 6; point 7; point 9; point 10; point 12 and point 13. The arrangements should take into account:

- › Logical grouping of aspects and national rules to be assessed i.e. it can be helpful to assess a particular subject theme;
- › Language of the the documentation provided by the applicant in order to reduce the need for translation; and
- › Distribution of workload and other planning aspects.

The arrangements should at least describe:

- › In the case where the assessment of a parameter with equivalent national rules is shared by several NSAs for the area of use, which NSA for the area of use is responsible for the different aspects of the assessment ; and
- › The planning and coordination of the assessments.

The arrangements should be documented and agreed by the concerned NSAs for the area of use and then communicated to the applicant and the authorising entity through the one-stop shop.

The authorising entity can decide to coordinate with the concerned NSAs for the area of use, including the organisation of face-to-face meetings, depending on the maturity of the file accompanying the application.

If there are significant matters to be raised, the authorising entity and/ or the concerned NSAs for the area of use can request to meet the applicant to avoid multiple exchanges of correspondence to resolve outstanding matters.

The authorising entity and/ or the concerned NSAs for the area of use should confirm any pre-arranged date for this with the applicant or, otherwise arrange a date. In either case confirmation should be sent through the one-stop shop and an acknowledgement should be requested. This confirmation should be sent with details of the matters of concern.

Should such meeting be deemed necessary, the objectives should be set as follow:

- › Ensure that the applicant has understood clearly the identified areas of non-compliance;
- › Discuss what is required to remedy them; and
- › Agree the nature of the further information and any supporting evidence to be provided (action plan).

Any differences of opinion among experts (including those experts belonging to the same body) should be recorded in the assessment file.

The authorising entity and the concerned NSAs for the area of use should conclude no later than 1 week before the end of the 4 month assessment period, each for their own part, that either the application meets all requirements or that no further progress is likely with securing satisfactory responses to outstanding matters and they should then record the results of their respective assessment, including any differences of opinion amongst them and their recommendation for the issuing of the vehicle type authorisation/ vehicle authorisation for placing on the market, through the one-stop shop (see Annex IX-XI Model templates for assessment files).

3.7.8. Article 38: Assessment of the application

The assessment of the application shall be carried out by the authorising entity and the concerned NSAs for the area of use to establish a reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their obligations and responsibilities in the design, manufacture, verification and validation stages of the vehicle and/or vehicle type in order to ensure conformity with the essential requirements of the applicable legislation so that it may be placed on the market and may be used safely in the area of use of the vehicle type according to the conditions of use and other restrictions specified within the application.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

To have reasonable assurance, see chapter 3.2.2.12, that the applicant and the actors supporting the applicant have fulfilled their obligations and responsibilities, the authorising entity and the concerned NSAs for the area of use should satisfy themselves of the:

- › Efficacy of the process followed by the applicant and the supporting actors; and
- › Consistency, completeness and relevance of the documentation provided by the applicant.

The requirements for the assessment of the application to be carried out by the authorising entity and the concerned NSAs for the area of use are specified in Annexes II and III (in accordance with Articles 39 and 40 of Commission Implementing Regulation (EU) 2018/545). Different parts of the application require different approaches to checking, which can include:

- › Is the submission complete? Has the applicant included everything it has said it is including?
- › Have defined requirements been explicitly complied with? This includes requirements for signatories, and document structures in accordance with Union legal requirements, for items such as EC Declarations of Verification.
- › Are application elements within their period of validity? Many aspects of the application have limited periods of validity, such as the accreditation of conformity assessment bodies, the validity of EC certificates etc.
- › Is cross-referencing consistent? Applications are complex documents, and it is not unusual for items such as certificates to be updated in one part of the application but not another. If a pre-engagement baseline exists, is the application consistent with it?
- › Are selected rules and the choice of the case of authorisation valid? Consider whether the scope of the rule is compatible with the way it is being used in the application. Has it been superseded? Are non-conformities with the applicable mandatory rules dealt with in an appropriate way and are alternative solutions capable of comprehensively controlling any associated risks? Note that in case of a non-conformity with a rule, it is the responsibility of the authorising entity/ the concerned NSAs for the area of use to evaluate the alternative solutions (if any); the outcomes from an assessment body (CSM RA) should be taken into account, but the assessment body (CSM RA) cannot decide on the alternative solutions to be applied. See also chapter 3.5.7 of this guideline, related to Article 27 “Correction of non-conformities” of the Commission Implementing Regulation (EU) 2018/545.
- › Is an existing vehicle type, where used, still relevant and does it have a valid vehicle type authorisation? This can be affected by changes to the rules and standards applicable to the existing vehicle type, and by differences in the characteristics of the vehicle type for which an application is being made as compared to the vehicle type being used as a basis.

- › Have processes been correctly applied? This requires consideration of the defined elements of the processes and the participation of the correct actors. The assessor should acknowledge that the application of, for example, a risk assessment process can result in a range of reasonable outcomes and that the submission should not be rejected provided the proposed conclusions are justifiably in that range.
- › Is there evidence to support assertions? For example, where compliance with a rule/ standard has been declared the assessor may choose to review the completeness of the supporting evidence as an indicator of whether the assessment processes have been correctly applied.

The authorising entity and the concerned NSAs for the area of use should not:

- › Repeat or duplicate work carried out by other bodies (e.g. NoBo, DeBo, assessment body (CSM RA)); and
- › Use the authorisation process to check or evaluate the competence of conformity assessment bodies.

If a concerned NSA for the area of use becomes aware of what it considers sub-standard work by conformity assessment bodies it should:

- › Bring this to the attention of the authorising entity.

If the authorising entity becomes aware of what it considers sub-standard work by conformity assessment bodies it should:

- › Bring this to the attention of the concerned conformity assessment body;
- › Bring this to the attention of the body supervising/ accrediting/ overseeing the competence of the conformity assessment body;
- › Bring this to the attention of the concerned NSAs for the area of use; and
- › Decide if it is necessary to apply a higher level of scrutiny to parts of the verification and assessment process carried out by that conformity assessment body.

3.7.9. Article 39: The assessment of the application by the authorising entity

1. The authorising entity shall assess the aspects specified in Annex II.
2. Where a vehicle type authorisation and/or vehicle authorisation for placing on the market is to be issued for an area of use that is limited to the networks within one Member State and where the applicant has requested for the NSA to be the authorising entity in accordance with Article 21(8) of Directive (EU) 2016/797, the authorising entity shall, in addition to the assessments specified in paragraph 1, assess the aspects referred to in Annex III. In that case the authorising entity shall, in addition to those aspects listed in Annex III, also check whether there is any relevant information recorded pursuant to Article 8(2) and shall take it into account for the assessment of the application. Any issues raised shall be recorded in the issues log as specified in Article 41.
3. When a non-standardised methodology for the requirements capture has been used by the applicant, the authorising entity shall assess the methodology applying the criteria laid down in Annex II.
4. The authorising entity shall check the completeness, relevance and consistency of the evidence from the applied methodology for requirements capture irrespective of the method used. For a new authorisation as specified in Article 14(1)(d) the assessment performed by the authorising entity shall be limited to the parts of the vehicle that are changed and their impacts on the unchanged parts of the vehicle. The checks to be performed by the authorising entity for an "extended area of use" authorisation as specified in Article 14(1)(c) shall be limited to the applicable national rules and to the technical compatibility between the vehicle and the network for the extended area of use. Checks already carried out at the previous authorisation shall not be repeated by the authorising entity.

5. An assessment report shall be issued by the authorising entity and shall contain the following:
- (a) clear statement on whether the result of the assessment is negative or positive as per the applicant's request for the concerned area of use and, where appropriate, conditions for use or restrictions;
 - (b) summary of the assessments performed;
 - (c) report from the issues log for the concerned area of use;
 - (d) filled-in checklist giving evidence that all aspects specified in Annex II, and when applicable Annex III, have been assessed.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Check of the applied methodology for requirements capture (only applicable in case it is not a standardised methodology)

With regards to the methodology for requirements capture, the authorising entity should assess the methodology for requirements capture used by the applicant in case it is not a standardised methodology (examples of standardised methods for requirements capture are: Commission Implementing Regulation (EU) 402/2013, EN 50126). The check of the applied methodology for the requirements capture to be made by the authorising entity should follow the criteria laid down in Annex II of Commission Implementing Regulation (EU) 2018/545.

Check of the completeness, relevance and consistency of the evidence from the applied methodology for requirements capture

The authorising entity and the concerned NSAs for the area of use should perform a high-level check⁷ (meaning a completeness, relevance and consistency verification) of the evidence from the methodology used for the requirements capture which should be part of the file accompanying the application for authorisation for the authorisation cases: first, new and extended area of use.

It is not envisaged that the authorising entity and the concerned NSAs for the area of use should perform an exhaustive check of all the evidence supporting the requirements capture/ risk assessment performed by the applicant for non-safety related aspects, for which there is no independent assessment performed by an assessment body (CSM RA).

Its role should be more systemic, focused on the process followed by the applicant to capture and fulfil the requirements; in order to do so, the authorising entity may need to check in detail some supporting evidence. The depth and extent of the checks are described in Annex II and Annex III of Commission Implementing Regulation (EU) 2018/545.

When the risk management process set out in Annex I of Commission Implementing Regulation (EU) 402/2013, has been used as the methodology for requirements capture

When the risk management process described in Annex I of Commission Implementing Regulation (EU) 402/2013 is the methodology used for the requirements capture, the authorising entity should focus on checking to verify that the:

- › Declaration by the proposer (Article 16 of Commission Implementing Regulation (EU) 402/2013) is signed and supports that all identified hazards and associated risks are controlled; and

⁷ High-level and low-level are typically terms used to classify, describe and point to specific goals of a systematic operation. High-level checks refers to assessments that are more abstract in nature and related to overall goals and systemic features. Low-level checks involve more specific individual evaluations, focusing on the details.

- › Assessment report (Article 15 of Commission Implementing Regulation (EU) 402/2013) supports the declaration.

When another methodology than the risk management process set out in Annex I of Commission Implementing Regulation (EU) 402/2013, has been used as the methodology for requirements capture (when allowed)

The authorising entity and the concerned NSAs for the area of use should check the evidence of the application of the methodology following the criteria set out in Annex II and Annex III of Commission Implementing Regulation (EU) 2018/545, each for their part of the assessment (limited to national rules in the case of the concerned NSAs for the area of use):

- › System definition is complete and consistent with the design of the vehicle?
- › Hazard identification and classification is consistent and plausible?
- › All risks have been properly managed and mitigated?
- › Structured and consistent management of the hazards throughout the process?
- › etc.

Relevant information recorded pursuant to Article 8(2)

When the authorising entity is the Agency the concerned NSAs for the area of use will check if there is any relevant information recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545 and take it into account in their assessments.

Where the authorising entity is the NSA there are no NSAs for the area of use involved in the assessment. In this case the authorising entity (NSA) should check if there is any relevant information recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545 and take it into account in its assessment of the application.

Non-railway related legislation

Directive (EU) 2016/797 places an obligation on the applicant to ensure that all relevant Union law is met (see chapter 3.3.1 of this guideline to find a reference to an informative listing of the relevant Union law). This forms part of the requirements capture process to ensure that all risks are properly covered and traced to a relevant mitigation measure. Item 8.6 of Annex II “Aspects for assessment by the authorising entity” includes a check of this by the authorising entity. In order to establish a “reasonable assurance” that the applicant has fulfilled its responsibilities and obligations, the authorising entity should check that other EU legislation has been taken into account by reviewing the consistency between the outcomes of the requirements capture process and the EC Declaration(s) of Verification. There is no obligation on the authorising entity to ensure or assess that all relevant Union law has been identified and met, this is the responsibility of the applicant.

Under the "relevant Union law", there are some laws that are not applicable to railways. However, some other EU laws that are not railway specific must be respected in any case (e.g. REACH Regulation (EC) 1907/2006, EMC Directive 2014/30/EU, non-road mobile machinery emissions Regulation (EU) 2016/1628, etc.).

3.7.10. Article 40: The assessment of the application by the concerned NSAs for the area of use

1. The concerned NSAs for the area of use shall assess the aspects listed in Annex III. The assessments to be performed by the NSAs for the area of use shall only concern the relevant national rules for the area of use taking into account the agreed arrangements referred to in Article 37(1).
2. In the assessment of the requirements capture, the NSAs for the area of use shall check the completeness, relevance and consistency of the evidence produced by the applicant from the applied methodology for requirements capture.

3. For a new authorisation referred to in Article 14(1)(d), the assessment performed by the NSAs for the area of use shall be limited to the parts of the vehicle that are changed and their impacts on the unchanged parts of the vehicle.
4. The checks to be performed by the NSAs for the area of use for an extended area of use authorisation referred to in Article 14(1)(c) shall be limited to the applicable national rules and to the technical compatibility between the vehicle and the network for the extended area of use. Checks already carried out during the previous authorisation shall not be repeated by the NSAs for the area of use.
5. In accordance with Articles 6 and 14 of Directive (EU) 2016/797, the NSAs for the area of use shall, in addition to those aspects specified in Annex III, check if there is any relevant information recorded pursuant to Article 8(2) and shall take it into account for the assessment of the application. Any issues raised shall be recorded in the issues log as specified in Article 41.
6. An assessment files shall be issued by the NSAs for the area of use and shall contain the following:
 - (a) a clear statement on whether the result of the assessment is negative or positive as per the applicant's request for the concerned area of use and where appropriate conditions of use and restrictions;
 - (b) a summary of the assessments performed;
 - (c) a report based on the issues log for the concerned area of use;
 - (d) a filled-in checklist giving evidence that all aspects listed in Annex III have been assessed.

Relevant references to Directive (EU) 2016/797:

- › Article 6
- › Article 14
- › Article 21
- › Article 24

The role of the NSAs for the area of use

The NSAs for the area of use should:

- › For the relevant national rules, verify the completeness, relevance and consistency of the application in respect of the technical compatibility of the vehicle with the network in the area of use specified by the applicant.
- › Respond to consultations initiated by a NSA of a neighbouring state in respect of vehicles from the neighbouring state travelling to stations close to the border.
- › Issue temporary authorisations to use the vehicle for tests on the network where these are necessary. Take measures to ensure that the tests on the network take place.

Arrangements in order to take into account the classification of national rules and cross-acceptance

For those aspects not assessed due to the arrangements referred to in Article 37(1) of Commission Implementing Regulation (EU) 2018/545, see also guidance in chapter 3.7.7, it is sufficient in the assessment report issued by the concerned NSA for the area of use to make a reference to those arrangements.

Check of the completeness, relevance and consistency of the evidence from the applied methodology for requirements capture

The concerned NSAs for the area of use should perform a high-level check of the evidence from the methodology used for the requirements capture only when another methodology than the risk management process set out in Annex I of Commission Implementing Regulation (EU) 402/2013, has been used as the methodology for requirements capture and only for the national rules for the concerned area of use, as specified in Annex III of Commission Implementing Regulation (EU) 2018/545.

Return of experience

The concerned NSAs for the area of use in their assessment should in addition to those aspects specified in Annex III, check if there is any relevant information recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545 and to take it into account in their assessments. When there are issues raised concerning the return of experience that have been recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545 the issues should be recorded in the issues log, see chapter 3.7.11. This will ensure that the other members of the assessment team also have access to the information.

The return of experience that has been recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545 can provide information and knowledge concerning the performance of already authorised vehicle types and their component systems in order to guide the assessment of applications. There may be several different sources for the return of experience that has been recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545.

The supervisory activities conducted by NSAs may be one source of a relevant return of experience recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545 in respect of vehicle type authorisation/ vehicle authorisation for placing on the market. The use by NSAs of information and knowledge gained from supervisory activities provides a means for evaluating the effectiveness of the applicant's processes for the design, manufacture, verification and validation of the vehicle type/ vehicle.

Vehicle manufacturers, the principal applicants for vehicle type authorisation/ vehicle authorisation for placing on the market, are not a primary focus for NSA supervisory activities. However it is likely that supervisory activities relating to railway undertakings will provide the NSA with knowledge about the vehicles operated by the railway undertakings that is relevant to the assessment of applications for vehicle type authorisation/ vehicle authorisation for placing on the market. Of particular interest will be reactive activities arising from problems with vehicles, such as accidents, incidents or significant disruption to service.

The return of experience may relate to existing vehicles using the same design platform as that being used for the application being assessed, or it may relate to systems that are in use on existing vehicles. Although vehicles may be assembled by different manufacturers, many of the systems on them will be from the same supplier. Understanding common themes will provide grounds for prioritising the elements considered as part of the assessment of the application. These common themes may also concern the interaction of the vehicle with the infrastructure.

3.7.11. Article 41: Categorisation of issues

1. The authorising entity and, when applicable the concerned NSAs for the area of use, shall record issues identified during the course of their assessment of the application file in an issues log and categorise them as follows:
 - (a) 'type 1': issue that requires a response from the applicant for the understanding of the application file;
 - (b) 'type 2': issue that may lead to an amendment of the application file or minor action from the applicant; the action to be taken shall be left to the judgement of the applicant and shall not prevent the issuing of the vehicle type authorisation and/or the vehicle authorisation for placing on the market;
 - (c) 'type 3': issue that requires an amendment to the application file by the applicant but does not prevent the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market with additional and/or more restrictive conditions for use of the vehicle and other restrictions as compared to those specified by the applicant in its application, but the issue must be addressed in order to issue the vehicle type authorisation and/or vehicle authorisation for placing on the market; any action to be performed by the applicant to resolve the issue shall be proposed by the applicant and shall be agreed with the party that identified the issue;

(d) 'type 4': issue that requires an amendment of the application file by the applicant; the vehicle type authorisation and/or vehicle authorisation for placing on the market shall not be delivered unless the issue is resolved; any action to be performed by the applicant to resolve the issue shall be proposed by the applicant and shall be agreed with the party that identified the issue. Type 4 issue shall include in particular non-compliance pursuant to Article 26(2) of Directive 2016/797.

2. Following the response or the action taken by applicant according to the issue, the authorising entity or the concerned NSAs for the area of use shall re-evaluate the issues it identified, re-classify where relevant and assign one of the following status for each of the issues identified:

- (a) 'issue pending' when the evidence provided by the applicant is not satisfactory and additional information is still required;
- (b) 'issue closed out' when a suitable response has been provided by the applicant and no residual matter of concern remains.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Recording issues in the issues log

During the assessment of the application the authorising entity and the concerned NSAs for the area of use are likely to identify issues where the content of the application is unclear, there are questions arising from relevant information recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545 or it is lacking in evidence. These issues will require a response from the applicant.

All the aspects resulting from the assessment that are appropriate to take into account for the decision should be recorded in the issues log, not only those aspects that would prevent the authorising entity from taking the decision to issue the vehicle type authorisation and/ or vehicle authorisation for placing on the market.

Editorial or presentational concerns, or typographical errors, should not be taken as grounds for asserting that the applicant has not demonstrated compliance unless they affect the clarity of the evidence provided by the applicant.

The applicant can respond to an issue through the one-stop shop by, for example, uploading a document, providing additional information, etc..

It is likely, when the assessment team consists of several assessors, that the applicant would receive the same or similar requests concerning issues identified by the different assessors. The issues log in the one-stop shop can help to prevent that the same issue is raised several times by different assessors. Before raising an issue the assessor should consult the issues log and see if the issue already is recorded by another assessor.

Recording and categorising issues are an important part of the assessments performed by the authorising entity and the concerned NSAs for the area of use. In order to support the assessors in their work the one-stop shop provides the functionality to prefill their respective assessment files using the relevant information from the issues log. The assessors can edit the prefilled information in the assessment files.

Categorisation of issues

The issues will vary in significance, and categorisation is a useful tool to assist in resolving them appropriately. Each category of issue will require a different approach. The description of the issues reflects what would happen if the additional information is not provided by the applicant (e.g. a 'type 3' issue can be closed out in the end without conditions and restrictions for use).

When an issue is created and categorised, a preliminary assessment is performed by the authorising entity and/or the NSAs for the area of use.

‘type 1’ issue:

- › An aspect of the application is not clear. The applicant is invited to clarify it.
- › The applicant provides a response.
- › If the response successfully resolves the uncertainty the issue is ‘closed out’.
- › If the response does not resolve the situation, or there is no response, the issue is classified as ‘issue pending’. The applicant may be asked to clarify further.
- › A failure to close out a ‘type 1’ issue does not constitute grounds for rejecting an application. If the issue is not satisfactorily closed out the authorising entity will use its judgement to proceed with the assessment using the available information.

‘type 2’ issue:

- › An amendment of the application file or a minor action by the applicant is required. The applicant is advised of this.
- › The action is left to the applicant.
- › The applicant provides a response containing the amendment of the file or the result of the action taken by the applicant.
- › If the response contains a satisfactory resolution to the issue it is ‘closed out’.
- › If the response does not resolve the issue, or there is no response, the issue is classified as ‘issue pending’.
- › A failure to close out a ‘type 2’ issue does not constitute grounds for rejecting an application. If the issue is not satisfactorily closed out the authorising entity will use its judgement to proceed with the assessment using the available information.

‘type 3’ issue:

- › An amendment to the application file by the applicant is required (non-conformity). More restrictive conditions for use and other restrictions are required for taking the decision to issue of the vehicle type authorisation and/ or vehicle authorisation for placing on the market.
- › The applicant is invited to propose the actions to be taken (more restrictive conditions for use and other restrictions).
- › The applicant submits a written proposal for the more restrictive conditions for use and other restrictions to be applied.
- › The entity that raised the issue, either the authorising entity or the NSA for the area of use, assesses the proposal.
- › If satisfactory, the proposal for more restrictive conditions or restrictions forms part of the application. The issue is ‘closed out’; the assessment proceeds and the issue no longer prevents taking the decision to issue of the vehicle type authorisation and/ or vehicle authorisation for placing on the market.
- › If unsatisfactory, the proposal is rejected. The issue remains as ‘issue pending’ and the applicant is invited to make further proposals.
- › If no satisfactory proposal for more restrictive conditions for use and other restrictions can be found the application will be considered to be fundamentally deficient, and will be rejected.

‘type 4’ issue:

- › An amendment to the application file by the applicant is required (non-conformity). The issue has to be resolved before the decision to issue of the vehicle type authorisation and/ or vehicle authorisation for placing on the market can be taken. It can form the basis for a justified doubt, as specified in Article 42 of Commission Implementing Regulation (EU) 2018/545. For guidance on justified doubts see chapters 3.2.2.7 and 3.7.12.
- › The applicant is invited to the propose actions to be taken to resolve the issue.
- › The applicant submits a written proposal for the actions to be taken to resolve the issue and the timeframe needed to provide the amendment for the application file.
- › The entity that raised the issue, either the authorising entity or the NSA for the area of use, assesses the proposal.
- › If satisfactory, the entity that raised the issue informs the applicant and sets a timeframe for the applicant to provide the amendment of the application file.
- › If unsatisfactory, the entity that raised the issue informs the applicant of the reasons why the proposal is unsatisfactory and the issue is classified as ‘issue pending’. The applicant should provide an amended proposal taking into account the reasons given.
- › The applicant provides the amendment to the application file according to the accepted proposal.
- › If satisfactory, the amendment is included in the application file. The issue is ‘closed out’; the assessment proceeds and the issue no longer prevents from taking the decision to issue the vehicle type authorisation and/ or vehicle authorisation for placing on the market.
- › If unsatisfactory, the amendment is not included in the application file. The issue remains as ‘issue pending’ and the applicant is invited to make further amendments to the application file.
- › If the applicant has not provided an amendment within the timeframe set by the entity that raised the issue, the amendment will not be processed and the issue will remain as ‘issue pending’.

‘type 3’ issues may result in an authorisation with conditions and restrictions of use at the end of the assessment time if the relevant information is provided by the applicant; it can be possible that the additional information provided by the applicant closes the issue without any additional conditions for use and other restriction.

If ‘type 4’ issues cannot be closed out before the end of the defined timeframe for the assessment – or the extended timeframe when a justified doubt has been raised and in duly recorded agreement with the applicant the timeframe has been extended – the application will be considered to be fundamentally deficient and refused. For this category of issues, in principle it is not possible to define additional conditions for use and other restrictions that allow the issuing of the authorisation (otherwise, it would have been initially categorised as a ‘type 4’ issue). But after further analysis of the issue and discussion with the applicant, a ‘type 4’ issue maybe closed out with the application of conditions for use and other restrictions.

3.7.12. Article 42: Justified doubt

1. Where there is a justified doubt, the authorising entity and/or the concerned NSAs for the area of use may, alternatively, do one or more of the following:
 - (a) perform a more thorough and detailed check of the information provided in the application;
 - (b) request supplementary information from the applicant;
 - (c) request that the applicant conducts tests on the network.
2. The request from the authorising entity and/or the concerned NSAs for the area of use shall specify the matter that requires action from the applicant but shall not specify the nature or content of the corrective actions to be performed by the applicant. The applicant shall decide on what is the most suitable way for it to answer to the request from the authorising entity and/or the concerned NSAs for the area of use in.

3. The authorising entity shall coordinate with the concerned NSAs for the area of use regarding the actions proposed by the applicant.
4. The authorising entity and the concerned NSAs for the area of use shall, without prejudice to the provisions of Article 35, use the issues log referred to in Article 41 to manage any justified doubts. A justified doubt shall always:
 - (a) be classified as a type 4 issue pursuant to Article 41 (1)(d);
 - (b) be accompanied by a justification; and
 - (c) include a clear description of the matter that needs to be answered by the applicant.
5. Where the applicant agrees to provide supplementary information, pursuant to points (b) and (c) of paragraph 1 at the request of the authorising entity and/or the concerned NSAs for the area of use, the timeframe to provide that supplementary information shall be established in accordance with Article 34(5) and Article 34(6).
6. Where it is possible to remove a justified doubt by introducing additional and/or more restrictive conditions for use of the vehicle and other restrictions as compared to those specified by the applicant in its application and the applicant so agrees, a vehicle type authorisation and/or vehicle authorisation for placing on the market may be issued under such conditions for use of the vehicle and other restrictions.
7. Where the applicant does not agree to provide further information to remove the justified doubt raised by the authorising entity and/or the concerned NSAs for the area of use, the authorising entity shall take a decision on the basis of the available information.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Justified doubt

The definition of a justified doubt is described in chapter 3.2.2.7 (including a clarification of how ‘type 4 ‘ issues relate to justified doubts).

A justified doubt may be identified during the assessments performed by the authorising entity/ concerned NSA for the area of use and it can concern the following aspects:

- › Fulfilment of the essential requirements during the different stages of the process (design, manufacturing, verification and validation) by the applicant and by the supporting actors, in order to ensure conformity with all the relevant legislation;
- › Aspects of the design that could prevent the safe use of the vehicle in the area of use when used with the defined and intended conditions for use and other restrictions;
- › The process followed by the applicant and the supporting actors. For supporting actors this in particular refers to issues concerning the competencies of and the work performed by NoBo, DeBo and/ or Assessment body (CSM RA) and that can be grounds for restriction, suspension or withdrawal of their notification as specified in Article 39(1) of Directive (EU) 2016/797 or which justify measures according to Article 11(2) of Commission Implementing Regulation 402/2013/EU;
- › Consistency and relevance of the documentation provided;
- › Non-compliance pursuant to Article 26(2) of Directive 2016/797; and/ or
- › Relevant information recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545.

The raised justified doubt should be duly substantiated with details of the matters that, in the view of the authorising entity/ concerned NSA for the area of use, have not been properly considered in the application. These details should be specific and clearly identify the parts of the application file that are inadequate.

The means used for addressing the justified doubt is the responsibility of the applicant. The authorising entity/ concerned NSA for the area of use are required to describe the basis for the justified doubt so that it is clear to the applicant what is needed to remove the doubt, but not to impose a solution.

In the event that a justified doubt is raised by the authorising entity/ concerned NSAs for the area of use and where the applicant, in duly recorded agreement with the authorising entity, agrees that there is a need to provide further information, the applicant should propose the corrective actions and the timeframe (including an extension of the timeframe for the assessment, if needed). The authorising entity and the concerned NSA for the area of use will review the proposal and inform the applicant about the results of their assessment.

Depending on the nature of the justified doubt, the applicant may need additional time to provide the supplementary information (in particular, if tests on the network are necessary). In such a case, the authorising entity can, with the duly recorded agreement of the applicant, agree an extension of the timeframe for the assessment beyond the 4 months foreseen in Directive (EU) 2016/797 Article 21(4).

In the case of a disagreement with any decision of the authorising entity/ concerned NSA for the area of use (on the justified doubt itself, on the timeframe and/ or on the corrective actions) that results in a refusal of the authorisation request, the applicant can start the appeal procedure.

The authorising entity should not issue a vehicle type authorisation and/ or vehicle authorisation for placing on the market if the raised justified doubt(s) has not been resolved and the application and the file accompanying the application has not been amended accordingly by the applicant.

A 'type 4' issue, as specified in Article 41(1)(d) of Commission Implementing Regulation (EU) 2018/545, will not always be a justified doubt. If it is clear, (i.e. there is no doubt that evidence provided does not allow the issuing of the authorisation) that the issue, if not resolved with an amendment of the file, will lead to the direct rejection of the application, then a 'type 4' issue, not being considered as a justified doubt, should be raised. In such a case there will be no suspension of the assessment or extension of the timeframe.

3.7.13. Article 43: The checks to be performed by the authorising entity concerning the assessments performed by the concerned NSAs for the area of use

1. The authorising entity shall check whether the assessments from the NSAs for the area of use are consistent with each other as regards the results of the assessments referred to in Article 40(6)(a).
2. Where the result from the check referred to in paragraph 1 demonstrates that the assessments of the NSAs for the area of use are consistent, the authorising entity shall verify that:
 - (a) the checklists referred to in Article 40(6)(d) have been filled-in completely;
 - (b) all relevant issues have been closed.
3. Where the result from the check in paragraph 1 demonstrates that the assessments are not consistent, the authorising entity shall request the concerned NSAs for the area of use to further investigate the reasons. As a result of this investigation, alternatively, one or both of the following shall apply:
 - (a) the authorising entity may review its assessment as referred to in Article 39;
 - (b) the concerned NSAs for the area of use may review its assessment.
4. The outcomes of investigations of the NSAs for the area of use referred to in paragraph 3 shall be shared with all the NSAs for the area of use involved in the application for the vehicle type authorisation and/or the vehicle authorisation.

5. Where a checklist referred to in paragraph 2(a) is incomplete or where there are issues that have not been closed pursuant to paragraph 2(b), the authorising entity shall request the concerned NSAs for the area of use to further investigate the reasons.
6. The NSAs for the area of use shall provide replies to requests from the authorising entity with regard to inconsistencies in the assessments referred to in paragraph 3, incompleteness in the checklists referred to in paragraph 2(a) and/or issues that are not closed in accordance with paragraph 2(b). The authorising entity shall take full account of the assessments performed by the NSAs for the area of use concerning the applicable national rules. The extent of checks performed by the authorising entity shall be limited to the consistency of the assessments and the completeness of the assessments referred to in paragraphs 1 and 2.
7. In case of disagreement between the authorising entity and the concerned NSAs for the area of use, the arbitration procedure referred to in Article 21(7) of Directive (EU) 2016/797 shall be applied.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

The checks to be performed by the authorising entity concerning the assessments performed by the concerned NSAs for the area of use should only be a check of the completeness of the assessments performed (checklists complete and all issues closed) and the consistency between the assessments of the application performed by the NSAs for the area of use. It should not be a check of the detailed assessments performed by the NSAs for the area of use.

3.7.14. Article 44: Arbitration under Article 21(7) of Directive (EU) 2016/797 and Article 12(4)(b) of Regulation (EU) 2016/796

Where the Agency acts as the authorising entity, it may suspend the authorisation process, in consultation with the concerned NSAs for the area of use, during the cooperation needed to reach a mutually acceptable assessment and where applicable, until the Board of Appeal takes a decision, within the timeframes set out in Article 21(7) of Directive (EU) 2016/797. The Agency shall give the applicant reasons for the suspension.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Relevant references to Regulation (EU) 2016/796:

- › Article 55
- › Article 61

For description of the process of arbitration, review and appeal, see Annex XVIII the flowchart for Stage 5, including the flowcharts for Substage 5.1 and 5.2.

Arbitration under Article 21(7) of Directive (EU) 2016/797

The disagreement of the Agency with an assessment of one or more NSAs for area of use should be notified to the concerned NSAs for the area of use, through the one-stop-shop, together with the reasons for that disagreement.

In the case where the authorising entity disagrees with the recommendation of a NSA for the area of use or identifies any issue during its assurance process, it should review them together with the concerned NSAs for the area of use. Any such review should involve the applicant where necessary, to agree on a mutually acceptable assessment and if agreement cannot be achieved, the authorising entity should take appropriate actions.

The area of use should be identified in the application form by the applicant. However, in the case of arbitration between the Agency and the concerned NSAs for the area of use, there could be additional exclusions of part(s) of the network(s) concerned by the intended area of use, in accordance with Article 21(7) of Directive (EU) 2016/797.

Where no mutually acceptable agreement between the authorising entity and the concerned NSAs for the area of use can be reached, and the decision by the authorising entity includes networks of the area of use for which the concerned NSAs for the area of use have issued a negative assessment, the concerned NSAs for the area of use can refer the matter for arbitration to the Board of Appeal in accordance to the rules of procedure for the Board of Appeal.

The vehicle type authorisation and/ or vehicle authorisation for placing on the market process can be suspended during the duration of the arbitration, including the coordination to reach mutually acceptable assessment. The Agency should give the applicant reasons for the suspension.

Arbitration under Article 12(4)(b) of Regulation (EU) 2016/796

In cases where no consistency of the decisions can be ensured within one month of the beginning of the coordination process between the Agency and the concerned national safety authority (or authorities), the matter should be referred by the concerned national safety authority (or authorities) for arbitration to the Board of Appeal in accordance to the rules and procedures for the Board of Appeal.

The Board of Appeal should decide whether consistency of the decisions should be ensured or not.

The decision of the Board of Appeal taken within the arbitration process should be notified to the Agency and the concerned national safety authority (or authorities) in accordance to the rules and procedures for the Board of Appeal.

The Agency and the concerned national safety authority (or authorities) should take their final decisions in compliance with the findings of the Board of Appeal, acting within the framework of their internal procedures and should provide a statement of reasons for that decision.

The arbitration procedure only applies when the Agency is the authorising entity.

The arbitration procedure applies when there is a disagreement between the authorising entity and a NSA for the area of use concerning the results of the assessments made. As specified in Article 21(7) of Directive (EU) 2016/797 the arbitration procedure needs to be resolved within 1 month. During the time the arbitration procedure is applied the authorisation process can be suspended and the time frame specified in chapter 3.7.4 is then also suspended. The Agency should give the applicant reasons for the suspension.

The reviewing of the issue(s) with the concerned NSAs for the area of use could cause changes to the assessment report.

When the decision of the authorising entity results in the exclusion of networks from the area of use as compared to the application following a negative assessment by a NSA for the area of use, and satisfactory evidence can be provided at a later stage (after the issuing of the authorisation) by the applicant to the concerned NSAs for the area of use, the applicant can send a new application to the Agency requesting an extension of the area of use.

3.7.15. Article 45: Conclusion of the assessment of the application

1. The authorising entity shall ensure that the process for the assessment of the application has been carried out correctly by checking in an independent manner that:
 - (a) the different stages of the process for the assessment of the application have been correctly applied;
 - (b) there is sufficient evidence to show that all relevant aspects of the application have been assessed;
 - (c) written responses to type 3 and 4 issues and requests for supplementary information have been received from the applicant;
 - (d) type 3 and 4 issues were all resolved or where not resolved, together with clearly documented reasons;
 - (e) the assessments and decisions taken are documented, fair and consistent;
 - (f) the conclusions reached are based on the assessment files and reflect the assessment as a whole.
2. Where it is concluded that the process for the assessment of the application has been correctly applied, a confirmation of the correct application of paragraph 1, accompanied by any comments, shall suffice.
3. Where it is concluded that the process for the assessment of the application has not been correctly applied, then reasons for reaching that conclusion shall be clear and specific.
4. In conclusion of the assessment activities, the authorising entity shall complete an assessment file covering paragraphs 2 or 3 on the basis of the assessment files issued in accordance with Article 39(5) and Article 40(6).
5. The authorising entity shall provide documented reasons for its conclusion in the assessment file referred to in paragraph 4.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

In the context of the conclusion of the assessment activities to “check in an independent manner” means that a person within the organisation of the authorising entity that has not been directly involved in the assessment of the application performs the checks. It could be another assessor that has not been involved in the assessment that is to be checked or the decision maker.

The assessment file to be completed by the authorising entity in accordance with Article 40 of the Commission Implementing Regulation (EU) 2018/545 can be found in Annex X.

The assessment file for the conclusion of the assessment of the application to be completed by the authorising entity can be found in Annex XI.

3.7.16. Article 46: Decision for the authorisation or the refusal of the application

1. The authorising entity shall take a decision to issue the vehicle type authorisation and/or vehicle authorisation for placing on the market or to refuse the application within one week following the completion of the assessment without prejudice to the provisions of Article 34. That decision shall be taken on the grounds of the documented reasons referred to in Article 45(5).

2. The vehicle type authorisation and/or vehicle authorisation for placing on the market shall be issued by the authorising entity where the assessment of the aspects listed in Annex II and where applicable Annex III support a reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their responsibilities to the extent required, in accordance with Article 38.
3. Where, following the assessment of the aspects listed in Annex II and where applicable Annex III do not support a reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their obligations and responsibilities to the extent required, in accordance with Article 38, the authorising entity shall refuse the application.
4. The authorising entity shall state the following in its decision:
 - (a) any conditions for use of the vehicle and other restrictions;
 - (b) the reasons for the decision;
 - (c) the possibility and means of appealing the decision and the relevant time limits.
5. The conditions for use of the vehicle and other restrictions shall be defined according to the basic design characteristics of the vehicle type.
6. The authorisation decision shall not contain any time limited conditions for use of the vehicle and other restrictions, unless the following conditions are fulfilled:
 - (a) it is required because the conformity to the TSIs and/or national rules cannot be completely proven before the issuing of the authorisation; and/or
 - (b) the TSIs and/or national rules require that the applicant produces a plausible estimate of compliance.

The authorisation may then include a condition that real use demonstrates performance in line with the estimate within a specified period of time.
7. The final decision to issue the vehicle type authorisation and/or vehicle authorisation for placing on the market or to refuse the application shall be recorded in the one-stop shop and communicated together with the assessment files through the one-stop shop to the applicant and the concerned NSAs for the area of use.
8. Where the decision either refuses the application or issues the vehicle type authorisation and/or vehicle authorisation for placing on the market subject to different conditions for use of the vehicle and other restrictions when compared to those specified by the applicant in its application, the applicant may request that the authorising entity reviews its decision in accordance with Article 51 of this Regulation. Where the applicant is not satisfied with the reply of the authorising entity, it may bring an appeal before the competent authority in accordance with Article 21(11) of Directive (EU) 2016/797.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Relevant references to Regulation (EU) 2016/796:

- › Article 12
- › Article 55
- › Article 58
- › Article 59
- › Article 60

The authorising entity should take the decision to issue the vehicle type authorisation and/ or vehicle authorisation for placing on the market or to refuse the application within 1 week following the completion of the assessment.

The authorisation should be issued by the authorising entity if the assessment of the aspects listed in Annex II and where applicable Annex III supports a reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their obligations and responsibilities to the extent required.

When the assessment of the aspects listed in Annex II and where applicable Annex III does not support a reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their responsibilities to the extent required, the authorising entity should refuse the application.

The authorising entity should state in its decision:

- › Any conditions for use and other restrictions (see chapter 3.3.6);
- › The justification for the decision; and
- › How the decision can be appealed.

The authorisation decision should not contain any time limited conditions for use and other restrictions unless:

- › This is required due to that the conformity to the TSIs and/ or national rules cannot be completely proven before the issuing of the authorisation; and/ or
- › There is a clear requirement in the TSIs and/ or national rules that the applicant should produce a plausible estimate of compliance.

The authorisation may then include a condition that real use demonstrates performance in line with the estimate within a specified period of time.

The final decision should be recorded in the one-stop shop and communicated together with the assessment file(s) through the one-stop shop to the applicant and the concerned NSAs for the area of use.

If the decision is a refusal of the application or the application is accepted subject to different conditions for use of the vehicle and other restrictions when compared to those specified by the applicant in its application, the applicant can request the authorising entity to review its decision and, if not satisfied, can bring an appeal before the competent authority in accordance with Article 21(11) of Directive (EU) 2016/797.

An authorisation should give applicants and railway undertakings legal certainty and therefore time-limited conditions for use and other restrictions should be avoided.

In the case where there are grounds for time limited condition for use and other restrictions, an authorisation may include a condition that real use demonstrates performance in line with the estimate within a specified period of time (e.g. that by time “t” reliability must be no less than 80% the estimated value).

The railway undertaking’s safety management system (that is supervised by the NSAs) should contain methods for monitoring performance, faults and failures. This should be applied so that:

- › It is verified that in real use the essential requirements are being met and conformity is being maintained with the values estimated at authorisation; and
- › Corrective action is taken when necessary (e.g. if design and endemic defects occur that prevent the original estimates from being achieved).

In addition if the return of experience found under the supervision by a NSA show that:

- › The estimates given for the authorisation are not being met by a vehicle, a series of vehicles and/ or a vehicle type; and
- › Satisfactory corrective action are not being taken.

The NSA can ask the authorising entity to suspend and revoke the authorisation of the vehicle, the series of vehicles and/ or the vehicle type.

3.8. Chapter 7 - Stage 6 Final documentation and authorisation

For description of the process, see Annex XVIII the flowchart for Stage 6.

3.8.1. Article 47: Final documentation for the vehicle type authorisation and/or vehicle authorisation for placing on the market

1. A vehicle type authorisation and/or vehicle authorisation for placing on the market shall take the form of a document containing the information referred to in Article 48 and/or Article 49.
2. The issued vehicle type authorisation and/or vehicle authorisation for placing on the market shall be assigned a unique European identification number ('EIN') of which the structure and content are defined and administrated by the Agency.
3. Different conditions for use of the vehicle and other restrictions when compared to those specified by the applicant in its application may be included in the vehicle type authorisation and/or vehicle authorisation for placing on the market.
4. The authorising entity shall date and duly sign the vehicle type authorisation and/or vehicle authorisation for placing on the market.
5. The authorising entity shall ensure that the decision issued in accordance with Article 46 and the full accompanying file for that decision are archived pursuant to Article 52.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

The full accompanying file for the decision issued in accordance with Article 46 of Commission Implementing Regulation (EU) 2018/545 is composed of the application and the file accompanying the application submitted by the applicant and all the documents used by the authorising entity to arrive at its decision, including the authorising entities decision.

The decision to issue the vehicle type authorisation and/ or vehicle authorisation for placing on the market should be based on the information provided for in the application and in the (final) assessment file.

The model templates for the standard formats for the vehicle type authorisation and vehicle authorisation for placing on the market can be found in Annex IV and V.

The authorising entity should complete the administrative closure by ensuring that all documentation and records are reviewed, organised and archived.

The authorising entity should co-ordinate with the concerned NSAs for the area of use to identify lessons learned to be used for future assessments.

This can include information on issues and risks as well as practices that worked well that can be applied to future assessments and possibly shared with (or even learned from) other bodies for continual improvement.

3.8.2. Article 48: The information in the issued vehicle type authorisation

The vehicle type authorisation issued by the authorising entity shall contain the following information:

- (a) the legal basis empowering the authorising entity to issue the vehicle type authorisation;
- (b) identification of:
 - (i) the authorising entity;
 - (ii) the application;

- (iii) authorisation case as specified in Article 14;
 - (iv) the applicant for the vehicle type authorisation;
 - (v) the EIN associated to the vehicle type authorisation.
- (c) an identification of the basic design characteristics of the vehicle type:
- (i) stated in the type and/or design examination certificates;
 - (ii) the area of use of the vehicle;
 - (iii) the conditions for use of the vehicle and other restrictions;
 - (iv) the reference, pursuant to the provisions of Article 16 of Regulation (EU) 402/2013, including the document identification and the version, to the written declaration by the proposer referred to in Article 3(11) of Regulation (EU) 402/2013, covering the vehicle type.
- (d) An identification of:
- (i) the vehicle type ID, in accordance with Annex II to Commission Decision 2011/665/EU¹ ;
 - (ii) the vehicle type variants, where applicable;
 - (iii) the vehicle type versions, where applicable;
 - (iv) values of the parameters set out in the TSIs and, where applicable, in the national rules, for checking the technical compatibility between the vehicle and the area of use;
 - (v) the vehicle type's compliance with the relevant TSIs and sets of national rules, relating to the parameters referred to in paragraph 1(d)(iv).
- (e) reference to the EC declarations of verification for the subsystems;
- (f) reference to other Union or national law with which the vehicle type is compliant;
- (g) reference to the documented reasons for the decision referred to in Article 45(5);
- (h) date and place of the decision to issue the vehicle type authorisation;
- (i) signatory of the decision to issue the vehicle type authorisation; and
- (j) the possibility and means of appealing the decision and the relevant time limits including information about the national appeal process.

¹Commission Implementing Decision 2011/665/EU of 4 October 2011 on the European register of authorised types of railway vehicles (OJ L 264, 8.10.2011, p. 32)

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24
- › Article 48

Conditions for use and other restrictions

The authorising entity and the concerned NSAs for the area of use can give further conditions for use and other restrictions as a result of its assessment. For further explanations to the 3 stage approach (intended conditions based on design, conditions derived from the conformity assessment, conditions imposed by the authorising entity and the concerned NSAs for the area of use), see chapter 3.3.6.

3.8.3. Article 49: The information in the issued vehicle authorisation for placing on the market

The vehicle authorisation for placing on the market issued by the authorising entity shall contain the following information:

- (a) the legal basis empowering the authorising entity to issue the vehicle authorisation for placing on the market;
- (b) identification of the:
 - (i) authorising entity;
 - (ii) application;
 - (iii) authorisation case as specified in Article 14;
 - (iv) applicant for the vehicle authorisation for placing on the market;
 - (v) EIN associated to the vehicle authorisation for placing on the market.
- (c) the reference to the vehicle type registration in ERATV, including the information on the vehicle type variant and/or vehicle type version, when applicable;
- (d) identification of the:
 - (i) vehicles;
 - (ii) areas of use;
 - (iii) conditions for use of the vehicle and other restrictions.
- (e) reference to the EC declarations of verification for the subsystems;
- (f) reference to other Union or national law with which the vehicle is compliant;
- (g) reference to the documented reasons for the decision referred to in Article 45(5);
- (h) in case of an authorisation in conformity to type pursuant to Article 14(1)(e), the reference to the declaration of conformity with an authorised vehicle type, including information on the vehicle type version and/or vehicle type variant when applicable;
- (i) the date and place of the decision to issue the vehicle authorisation for placing on the market;
- (j) the signatory of the decision to issue the vehicle authorisation for placing on the market; and
- (k) the possibility and means of appealing the decision and the relevant time limits, including information on the national appeal process.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24
- › Article 25
- › Article 46

Identification of the vehicles:

A vehicle that has been registered is identified by its European Vehicle Number, a numeric identification code as defined in Appendix 6 of Decision 2007/756/EC.

After a vehicle authorisation for placing on the market has been issued for a vehicle, the vehicle should be registered in the NVR. The registering entity, based on the request for registration of the keeper, should assign an EVN to the vehicle. The issuing of the vehicle authorisation for placing on the market and the registration of the vehicle may be combined, take place in parallel or be done in sequence (vehicle

authorisation for placing on the market issued before registration), depending on the internal procedures of the registering entity and the authorising entity. A common practice for the registration entity is to pre-reserve for the keeper a number that will become the EVN when the vehicle is registered.

Nevertheless, before the vehicle authorisation for placing on the market is issued the vehicle needs to be identified. In case the EVN is not yet reserved or assigned when the application for vehicle authorisation for placing on the market is submitted by the applicant the identification of the vehicle can be done by using the manufacturer's own system for identification of the vehicle or by identification of the product serial number.

3.8.4. Article 50: Registration in ERATV and ERADIS

1. The ERATV shall be completed by the authorising entity using the information provided by the applicant as part of the vehicle type authorisation application. The applicant shall be responsible for the integrity of the data provided to the authorising entity. The authorising entity shall be responsible for checking the consistency of the data provided by the applicant and making the ERATV entry available to the public.
2. The authorising entity shall ensure that the European Railway Agency Database of Interoperability and Safety ('ERADIS') has been updated as appropriate before delivering a vehicle type authorisation and/or vehicle authorisation for placing on the market.
3. For modifications pursuant to Article 15(1)(c) and 15(3), the authorising entity shall register in ERATV the new version of a vehicle type or the new version of a vehicle type variant, using the information provided by the holder of the vehicle type authorisation. The holder of the vehicle type authorisation is responsible for the integrity of the data provided to the authorising entity. The authorising entity shall be responsible for checking the consistency of the data provided by the holder of the vehicle type authorisation and making the ERATV entry available to the public.

Pending the registration of the new version of a vehicle type or the new version of a vehicle type variant, the vehicles modified to be conforming to the new version may already be operated without delay.

Relevant references to Directive (EU) 2016/797:

- › Article 42
- › Article 48

Relevant references to Regulation (EU) 2016/796:

- › Article 37

ERATV

The authorising entity should always issue a vehicle type authorisation even if the applicant has requested to have only a vehicle authorisation for placing on the market (except in the case of authorisation in conformity to type).

The decisions for vehicle authorisation for placing on the market and vehicle type authorisation will be stored in the one-stop shop. ERATV is the register of authorised vehicles types.

ERATV information should be part of the application for authorisation.

The responsibility of the data recorded in ERATV lies with the authorising entity. However, this does not prohibit that the applicant can fill-in part of the required data on behalf of the authorising entity.

It is envisaged that the Implementing Act on the register of authorised vehicle types, foreseen by Article 48(2) of the Directive (EU) 2016/797, should include the option to record vehicle type versions and/ or vehicle type variants.

ERADIS

The Regulation (EU) 2016/796 imposes the obligation to make publicly available the following documents:

- › ‘EC’ declarations of verification of subsystems;
- › ‘EC’ declarations of conformity of interoperability constituents; and
- › ‘EC’ declarations of suitability of use of interoperability constituents.

The Directive (EU) 2016/797 imposes on the NoBos the obligation to provide the Agency with:

- › ‘EC’ certificates of verification of subsystems;
- › ‘EC’ certificates of conformity of interoperability constituents; and
- › ‘EC’ certificates of suitability of use of interoperability constituents.

The Agency has set up the ERADIS register to store these certificates and declarations. This register should be used by:

- › Applicants to submit the EC declarations;
- › Manufacturers of interoperability constituents to submit the EC declarations; and
- › Notified Bodies to submit EC certificates.

There is no legal basis to impose on the DeBos the obligation to provide their certificates for national rules to the Agency. However, the principle of “mutatis mutandis” could be applied; therefore DeBos should upload the certificates in ERADIS when the relevant feature in ERADIS has been developed and is available.

Vehicle registration in NVR

Each vehicle should be registered in the NVR specifying the vehicle type and, where applicable, the specific combination of vehicle type version and/ or vehicle type variant the vehicle or the series of vehicles belongs to. Vehicle registration is done upon the keepers request and is not part of the vehicle authorisation process.

For ECVVR/ NVR:

- › The keeper provides the data, it is responsible for the integrity of the data.
- › The registering entity checks the global consistency and updates NVR.

When the area of use is limited to one Member State, every vehicle should be registered in only that Member State’s National Vehicle Register (NVR). Any future changes to the area of use should only be recorded in the NVR where the authorisation was initially registered.

Where the area of use for a vehicle covers more than one Member State then it should be registered in only one of the Member States concerned and the keeper should decide in which of the concerned Member States it wants to register its vehicle.

When the area of use of the vehicle is extended:

- › The vehicle should be registered only in the NVR of the Member State where the vehicle was initially authorised.
- › The keeper should request the registration entity to update the registration with the details on the reference to the vehicle type authorisation covering the extended area of use.

For wagons compliant with paragraph 7.1.2 of the Annex of the WAG TSI Regulation (EU) 321/2013, the vehicle keeper should decide in which Member State the vehicle should be registered. When the keeper registers its vehicle, it should also indicate all Member States in which the vehicle is authorised and the area of use covered by the authorisation.

The vehicle registers of all EU Member States and non-EU OTIF Contracting States should be connected to ECVVR, which therefore may provide information on all registered vehicles.

Responsibility of the integrity of the data to be included in the registers

The entity keeping the register (i.e. the registering entity for the vehicle register, the Agency for ERATV and ERADIS) should perform the basic check against the specifications (e.g. format of data, mandatory/ optional fields, etc.) and/ or the reference data.

The applicant is responsible for providing technical data for ERATV and for the integrity of the data they provide. The applicant may introduce the technical data in ERATV (requesting access first), although the authorising entity is responsible to validate and check the consistency of the data (namely, to verify that the data introduced by the applicant is consistent with the technical documentation of the vehicle).

Regarding ECVVR/ NVR, the keeper provides the data, they are responsible for the integrity of the data. The registering entity checks the global consistency and updates NVR.

The planned International Registry of Mobile Assets – Railway equipment

The Luxembourg Protocol to the Cape Town Convention on International Interests in Mobile Equipment on Matters specific to Rail Rolling Stock (the Rail Protocol) is a global treaty that focuses on facilitating financing of railway vehicles by providing an international recognition and registration of financial security interests of such assets. There is already a similar regime in place for aircraft (www.internationalregistry.aero/ir-web/).

The Rail Protocol was adopted in 2007. It needs 4 ratifications and a certificate of readiness from OTIF, as secretary to the Supervisory authority to enter into force. The status (27th June 2017) was that there were 3 ratifications (European Union, Gabon and Luxembourg), 7 signatures (France, Germany, Italy, Mozambique, Sweden, Switzerland and United Kingdom) and ongoing discussions with 19 Governments.

The Rail Protocol will provide a system for rights of creditors whose interests will be registered, and searchable at an international registry to be based in Luxembourg and operated by Regulis SA (same as for the International Registry of Mobile Assets – Aircraft). It applies to financing of railway vehicles operated domestically as well as internationally and it will also introduce a new global unique and permanent numbering system for railway vehicles (URVIS).

The identification number (URVIS) will be:

- › Affixed to the vehicle;
- › Associated in the International Registry with the manufacturer's name and the manufacturer's identification number for the vehicle; or
- › Associated in the International Registry with a national or regional identification.

The vehicle can be registered in the international registry and the vehicle assigned with the URVIS number before, during or after the vehicle authorisation for placing on the market has been issued. Also existing vehicles authorised under another regime can be registered.

The applicant will be able to use the URVIS number to identify the vehicle in its application for vehicle authorisation for placing on the market.

For more information on the Rail Protocol and the associated International Registry:

- › www.unidroit.org
- › www.railworkinggroup.org

3.8.5. Article 51: Review under Article 21(11) of Directive (EU) 2016/797

1. Where the decision of the authorising entity contains a refusal or different conditions for use of the vehicle and other restrictions when compared to those specified by the applicant in its application, the applicant may request the review of the decision within one month from the date of its receipt. That request shall be submitted by the applicant through the one-stop shop.

2. The request for review shall include a list of issues that, in the view of the applicant, have not been properly taken into consideration during the vehicle authorisation process.
3. Any supplementary information which has been developed and filed through the one-stop shop after the date of issuing of the authorisation decision shall not be admissible as evidence.
4. The authorising entity, where applicable in coordination with relevant NSAs for the area of use, shall ensure impartiality of the review process.
5. The review process shall address the issues justifying the negative decision of the authorising entity in accordance with the applicant's request.
6. Where the Agency acts as the authorising entity, a decision to reverse or not its decision shall be subject to review in coordination with the relevant NSAs for the area of use, where applicable.
7. The authorising entity shall confirm or reverse its first decision within two months from the date of receipt of the request for review. That decision shall be communicated to the relevant parties through the one-stop shop.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Relevant references to Regulation (EU) 2016/796:

- › Article 12
- › Articles 58 to 62

For description of the process see Annex XVIII the flowchart for Substage 5.2.

Review

The applicant can request a review under Article 21(11) of Directive (EU) 2016/797 for two cases; where the decision contains:

- › A refusal (no authorisation is issued); or
- › Different conditions for use of the vehicle and other restrictions as compared to those specified by the applicant in its application.

Where the negative decision is reversed within the review process, the authorising entity should issue the vehicle type authorisation and/ or vehicle authorisation for placing on the market without delay.

If the negative decision of the authorising entity is confirmed, the applicant may bring an appeal before the Board of Appeal (for applications for which the Agency has been selected as an authorising entity) or before the national appeal body (for applications for which the relevant NSA has been selected as the authorising entity), in accordance with the national procedure.

Appeal

Any appeal against a decision of the Agency should be brought before the Board of Appeal in accordance to the rules of procedure for the Board of Appeal.

Where the Board of Appeal finds that the grounds for appeal are founded, the Agency in coordination with the concerned NSAs for the area of use should take its final decision in compliance with the findings of the Board of Appeal and should provide a statement of reasons for that decision.

Where the decision subject to an appeal, either to the Board of Appeal or to the national appeal body, is reversed, the authorising entity should issue the vehicle type authorisation and/ or vehicle authorisation for placing on the market without delay and in any case, not later than one month following the notification of findings by the Board of Appeal.

The decision of the Board to refuse the appeal should be recorded in the one-stop shop and reflected in the file accompanying the application. After the completion of the appeal process, the final decision of the authorising entity, including the findings notified by the Board of Appeal, should be notified to the applicant and the concerned NSAs for the area of use, through the one-stop shop.

3.8.6. Article 52: Archiving of a decision and the full accompanying file for the decision issued in accordance with Article 46

1. The decision and the full accompanying file for the decision issued in accordance with Article 46 shall be retained in the one stop shop for at least 15 years.
2. The full accompanying file for the decision of the authorisation entity issued in accordance with Article 46 shall include all documents used by the authorising entity and the assessment files of the concerned NSAs for the area of use.
3. After the expiry of the retention time set out in paragraph 1, the decision given in accordance with Article 46 for the issue of a vehicle type authorisation and/or a vehicle authorisation for placing on the market, and its full accompanying file shall be moved to a historical archive and kept for a period of five years after the termination of the service life of the vehicle, as recorded in the register referred to in Article 47 of Directive (EU) 2016/797.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24

Relevant references to Regulation (EU) 2016/796:

- › Article 12
- › Article 77

It is possible to re-import the file into the one-stop shop (and export to NSA systems) from the historical archive.

The archived file should include all documents used by the authorising entity to take the authorisation decision, such as:

- › The application and the file accompanying the application (as submitted by the applicant).
- › Additional documents submitted by the applicant on request of the authorising entity and added to the original file (by the authorising entity).
- › Issues log (including content.), etc.

It should also include:

- › Documents produced by the authorising entity;
- › Documents produced by the concerned NSAs for the area of use; and
- › Authorising decision.

The end of the service life of a vehicle

The provisions for the end of the service life of the vehicle are laid down in the Annex of the NVR Decision:

- › The provisions for withdrawal of registration; and
- › The codes for “withdrawal” of an authorisation. This contains, for example, the date of official scrapping and/ or other disposal arrangement and the code of withdrawal mode.

3.9. Chapter 8 - Suspension or revocation or amendment of an issued authorisation

3.9.1. Article 53: Suspension, revocation or amendment of an issued authorisation

1. Temporary safety measures in the form of suspension of a vehicle type authorisation may be applied by the authorising entity in accordance with Article 26(3) of Directive (EU) 2016/797.
2. In the cases referred to in Article 26(3) of Directive (EU) 2016/797 and following a review of the measures taken to address the serious safety risk, the authorising entity that issued the authorisation may decide to revoke or amend the authorisation in accordance with Article 26(4) of Directive (EU) 2016/797.
3. The applicant may launch an appeal against the decision to revoke or amend an authorisation in accordance with Article 26(5) of Directive (EU) 2016/797.
4. The authorising entity shall inform the Agency where there is a decision to revoke or amend an authorisation and give the reasons for its decision. The Agency shall inform all NSAs of the decision to revoke or amend an authorisation and the reasons for the decision.

Relevant references to Directive (EU) 2016/797:

- › Article 26

Relevant references to Regulation (EU) 2016/796:

- › Article 55
- › Article 58
- › Article 59
- › Article 60

The conditions for when a vehicle type authorisation and/ or vehicle authorisation for placing on the market can be suspended, revoked or amended are defined in Article 26 of Directive (EU) 2016/797.

The criteria 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 (ECM) (e.g. a safety management system that does not properly control maintenance leading to vehicles no longer meeting the essential requirements).

In the 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 conforming to that type. However, the concerned vehicles should be withdrawn, meaning that they can no longer be used, pursuant to article 26(8) of Directive (EU) 2016/797.

3.9.2. Article 54: The effect of suspension or revocation or amendment of an issued authorisation on the registration in ERATV, ERADIS and Vehicle registers

1. When the authorising entity takes a decision to revoke, suspend or amend a vehicle type authorisation it shall update the ERATV accordingly, subject to the provisions of Article 26(4) of Directive (EU) 2016/797, and ensure that ERADIS is updated accordingly.
2. The Member State where the vehicle is registered shall ensure that any decision to revoke or amend a vehicle type authorisation and/or a vehicle authorisation for placing on the market is reflected in the register referred to in Article 47 of Directive (EU) 2016/797.

Relevant references to Directive (EU) 2016/797:

- › Article 26
- › Article 42
- › Article 47
- › Article 48

Relevant references to Regulation (EU) 2016/796:

- › Article 37

3.10. Chapter 9 - Final provisions

3.10.1. Article 55: Transitional provisions

1. Where a NSA recognises that it will not be able to issue a vehicle authorisation in accordance with Directive 2008/57/EC before the relevant date in the Member State concerned, it shall inform the applicant and the Agency immediately.
2. In the case referred to in Article 21(8) of Directive (EU) 2016/797, the applicant shall decide whether to continue to be assessed by the NSA or to submit an application to the Agency. The applicant shall inform both of them and the following shall apply:
 - (a) in cases where the applicant has decided to submit an application to the Agency, the NSA shall transfer the application file and the results of its assessment to the Agency. The Agency shall accept the assessment carried out by the NSA;
 - (b) in cases where the applicant has decided to continue with the NSA, the NSA shall finalise the assessment of the application and decide on the issue of the vehicle type authorisation and/or vehicle authorisation for placing on the market in accordance with Article 21 of Directive (EU) 2016/797 and this Regulation.
3. Where the area of use is not limited to one Member State, the authorising entity shall be the Agency and the procedure set out in point (a) of paragraph 2 applies.
4. In cases referred to in paragraphs 2 and 3, the applicant shall submit a revised application for a vehicle type authorisation and/or a vehicle authorisation for placing on the market by means of the one-stop shop, in accordance with this Regulation. The applicant may request assistance for supplementing the file from the authorising entities involved.
5. A vehicle authorisation and/or vehicle type authorisation issued by the Agency between 16 June 2019 and 16 June 2020 shall exclude the network or networks in any of the Member States that have notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797 and that have not yet transposed that Directive and not brought into force its national transposition measures. The NSAs of the Member States that have made such a notification shall:

- (a) treat a vehicle type authorisation issued by the Agency as equivalent to the authorisation for types of vehicles issued in accordance with Article 26 of Directive 2008/57/EC and apply paragraph 3 of Article 26 of Directive 2008/57/EC as regards this vehicle type;
 - (b) accept a vehicle authorisation issued by the Agency as equivalent to the first authorisation issued in accordance with Article 22 or 24 of Directive 2008/57/EC and issue an additional authorisation in accordance with article 23 or 25 of Directive 2008/57/EC.
6. In cases referred to in point (a) of paragraph 2 and in paragraph 5, the NSA shall cooperate and coordinate with the Agency to undertake the assessment of the elements set out in point (a) of Article 21(5) of Directive (EU) 2016/797.
7. Freight wagons compliant with paragraph 7.1.2. of the Annex of WAG TSI Regulation (EU) 321/2013 and with a vehicle authorisation for placing on the market shall be treated between 16 June 2019 and 16 June 2020 as vehicle with an authorisation for placing into service for the purpose of Directive 2008/57/EC by Member States that have notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797 and that have not yet transposed that Directive and not brought into force its national transposition measures.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24
- › Article 54
- › Article 55
- › Article 57
- › Article 58
- › Article 59

Relevant references to Regulation (EU) 2016/796:

- › Article 12

In the transition to the new regime, and for cases where the Agency will be the authorising entity:

- › When the applicant wants to engage with the Agency before the submission of an application for authorisation, the applicant should contact the Agency sufficiently in advance of the entry into force of the Regulation (EU) 2018/545.

For the cases where the NSAs will be the authorising entity:

- › In those cases where there is a pre-engagement it is necessary to take into account the new legal framework and the practical arrangements to be applied.

For cases where the Agency will be the authorising entity but one or several Member State(s) in the area of use has (have) notified the Agency or the Commission in accordance with Article 57(2) of Directive (EU) 2016/797:

- › Those Member States who have not yet transposed Directive (EU) 2016/797 should apply as far as possible the cross-acceptance principles and the simultaneous authorisation procedure as described in the Reference Document application guide.

Vehicles authorised under previous regimes

Where it is not possible to find documentary evidence of the issued authorisation and/ or the file accompanying the authorisation for vehicles authorised under previous regimes (in particular, before Directive 2008/57/EC), the authorising entity should consider that the vehicle has been authorised as long as this is reflected in the NVR registration (see Annex I point 18.6).

In the case of a first authorisation issued according to Directive 2008/57/EC, for which there is an application for extension of its area of use under Directive (EU) 2016/797, the Agency should be the authorising entity, pursuant to Articles 21(5), 21(8) and 54 of Directive (EU) 2016/797: the area of use covers two or more Member States. As this would be an extension of the area of use, the authorisation extends the existing authorisation to the new Member State(s).

3.10.2. Article 59: Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

It shall apply from 16 June 2019 in the Member States that have not notified the Agency or the Commission in accordance with Article 57(2) of Directive (EU) 2016/797. It shall apply in all Member States from 16 June 2020.

However, Article 55(1) shall apply from 16 February 2019 in all Member States. The facilitation measures provided in Article 55(2), (3), (4) and (6) shall be made available from 16 February 2019. Article 55(5) of this Regulation shall apply from 16 June 2019 in all Member States.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Relevant references to Directive (EU) 2016/797:

- › Article 21
- › Article 24
- › Article 57
- › Article 58
- › Article 59

3.11. Annexes

Annex I of Commission Implementing Regulation (EU) 2018/545 describes the information that should be included in the application and the file accompanying the application for authorisation. It does not relate to specific documents or evidences. The applicant can decide how to structure the file accompanying the application for authorisation as long as all the required information is included.

Annex II and III describe the assessments to be performed by the authorising entity and the concerned NSAs for the area of use for the information in the application and the file accompanying the application for authorisation. When a NSA acts as an authorising entity, it should check the elements in both Annex II and Annex III. When the Agency acts as an authorising entity, it should assess the elements set out in Annex II, whereas the concerned NSAs for the area of use should assess the elements set out in Annex III for their respective part.

Annex I Content of the application

(M) means required information to be submitted by the applicant.

(O) means optional information that may still be submitted by the applicant.

1. Type of application (M):

- 1.1. Type authorisation
 - (a) Vehicle type variants (when applicable)
 - (b) Vehicle type versions (when applicable)
- 1.2. Authorisation for placing on the market
 - (a) Single vehicle; or
 - (b) Series of vehicles

2. Authorisation case (M):

- 2.1. First authorisation
- 2.2. New authorisation
- 2.3. Extended area of use
- 2.4. Renewed type authorisation
- 2.5. Authorisation in conformity to type

3. Area of use (M):

- 3.1. Member States
- 3.2. Networks (per Member State)
- 3.3. Stations with similar network characteristics in neighbouring Member States when those stations are close to the border as specified in Article 21.8 of Directive (EU) 2016/797 (when applicable)
- 3.4. Definition of the extended area of use (only applicable for the authorisation case "Extended area of use")
- 3.5. Whole EU network

4. Issuing authority (M):

- 4.1. The Agency; or
- 4.2. The national safety authority of the Member State (only applicable in case of an area of use limited to one Member State and requested by the applicant as specified in Article 21(8) of Directive (EU) 2016/797)

5. Applicant's information:

- 5.1. Legal denomination (M)
- 5.2. Applicant's name (M)
- 5.3. Acronym (O)
- 5.4. Complete postal address (M)
- 5.5. Phone (M)
- 5.6. Fax (O)
- 5.7. E-mail (M)
- 5.8. Website (O)
- 5.9. VAT number (O)
- 5.10. Other relevant information (O)

6. Contact person information:

- 6.1. First name (M)
- 6.2. Surname (M)
- 6.3. Title or function (M)
- 6.4. Complete postal address (M)
- 6.5. Phone (M)
- 6.6. Fax (O)
- 6.7. E-mail (M)
- 6.8. Languages spoken (M)

7. Current vehicle type authorisation holder (Not applicable in case of first authorisation) (M):

- 7.1. Legal denomination (M)
- 7.2. Type authorisation holder's name (M)
- 7.3. Acronym (O)
- 7.4. Complete postal address (M)
- 7.5. Phone (M)
- 7.6. Fax (O)
- 7.7. E-mail (M)
- 7.8. Website (O)

7.9. VAT number (M)

7.10. Other relevant information (O)

8. Conformity assessment bodies information (M):

8.1. Notified body(ies):

- (a) Legal denomination (M)
- (b) Notified body name (M)
- (c) Notified body ID number (M)
- (d) Acronym (O)
- (e) Complete postal address (M)
- (f) Phone (M)
- (g) Fax (O)
- (h) E-mail (M)
- (i) Website (O)
- (j) VAT number (M)
- (k) Other relevant information (O)

8.2. Designated body(ies):

- (a) Legal denomination (M)
- (b) Designated body name (M)
- (c) Acronym (O)
- (d) Complete postal address (M)
- (e) Phone (M)
- (f) Fax (O)
- (g) E-mail (M)
- (h) Website (O)
- (i) VAT number (M)
- (j) Other relevant information (O)

8.3. Assessment body (CSM RA), not applicable for authorisation in conformity to type:

- (a) Legal denomination (M)
- (b) Assessment body (CSM RA) name (M)
- (c) Acronym (O)
- (d) Complete postal address (M)
- (e) Phone (M)
- (f) Fax (O)
- (g) E-mail (M)
- (h) Website (O)
- (i) VAT number (M)
- (j) Other relevant information (O)

9. Pre-engagement:

9.1. Reference to pre-engagement baseline (O)

9.2. Other relevant project information (O)

10. Description of the vehicle type (*to be specified according to decision 2011/665/EU Annex II) (M):

10.1. Type ID*:

10.2. Vehicle type versions (when applicable)

10.3. Vehicle type variants (when applicable):

10.4. Date of record in ERATV* (not applicable for first authorisation)

10.5. Type name*

10.6. Alternative type name* (when applicable)

10.7. Category*

10.8. Subcategory*

11. Information on the vehicles (to be specified according to decision 2007/756/EU¹ when available) (M)

11.1. EVN numbers or pre-reserved vehicle numbers

11.2. Other specification of the vehicles when EVN numbers or pre-reserved vehicle numbers are not available

¹Commission Decision 2007/756/EC of 9 November 2007 adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC (notified under document number C(2007) 5357) (OJ L 305, 23.11.2007, p. 30)

12. Reference to existing vehicle type authorisation (not applicable in case of first authorisation) (M)

- 13. Description of the changes as compared to the authorised vehicle type (only applicable in case of a new authorisation) (M)**
- 14. Conditions for use of the vehicle and other restrictions (to be specified according to decision 2011/665/EU Annex II) (M):**
 14.1. Coded restrictions
 14.2. Non-coded restrictions
- 15. CCS additional functions (M)**
- 16. Applicable rules (M):**
 16.1. TSIs, including the the legal reference in the Official Journal of the European Union
 16.2. Specific TSIs clauses for an area of use covering the whole EU network (when applicable)
 16.3. Specification of the selection of requirements from a newer version of a TSI as compared to the TSI applicable for the assessment (including withdrawn requirements) (when applicable)
 16.4. National rules (when applicable)
 16.5. Non-applications of TSIs according to the provisions of Article 7 of Directive (EU) 2016/797 (when applicable)
 16.6. Applicable rules for the extended area of use.
 16.7. Updated TSIs and/or national rules (only applicable for renewed type authorisation)
- 17. Applicant's confirmation and signature (M)**
- 18. Annexes (M):**

The information that shall be included in the application is specified per authorisation case. An (x) in the column for the applicable authorisation case indicates that the information is mandatory (M) for this authorisation case.

		First authorisation	Renewed type authorisation	Extended area of use	New authorisation	Authorisation in conformity to type
18.1	The supporting evidence for the requirements capture in accordance with Article 13(1). If the applicant uses the methodology set out in Annex I of Regulation (EU) 402/2013, the supporting evidence consists of the declaration by the proposer referred to in Article 16 of Regulation (EU) 402/2013 and the safety assessment report referred to in Article 15 of Regulation (EU) 402/2013. If another methodology is used, the evidence required is that necessary to demonstrate that it provides the same level of assurance as the methodology set out in Annex I of Regulation (EU) 402/2013.	X		X	X	
18.2	Mapping table indicating where the information needed for the aspects to be assessed according to Annex II and III can be found	X	X	X	X	
18.3	The relevant decisions for non-application of TSIs according to Article 7 of Directive (EU) 2016/797 (when applicable)	X	X	X	X	X
18.4	Declaration of conformity to the type and associated documentation (Article 24 Directive (EU) 2016/797)					X

18.5	EC Declarations of Verification for the mobile subsystems, including accompanying technical files (Article 15 Directive (EU) 2016/797).	X	X	X	X	
18.6	The file accompanying the application and the decision from the previous authorisation or when applicable the reference to the decision issued according to Article 46 and to the full accompanying file for the decision archived in the one-stop shop.		X	X	X	
18.7	Specification of and where applicable ⁸ a description of the methodology used for the requirements capture for the: a) essential requirements for subsystems as specified in Article 3 and Annex III of Directive (EU) 2016/797; b) technical compatibility of the subsystems within the vehicle; c) safe integration of the subsystems within the vehicle; and d) technical compatibility of the vehicle with the network in the area of use.	X		X	X	
18.8	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) covering the requirements capture for the essential requirements "safety" for the subsystems and safe integration between subsystems..	X		X	X	
18.9	When not fully covered by TSIs and/or national rules, the documentary evidence of the technical compatibility of the vehicle with the network in the area of use.	X		X	X	
18.10	Risk declaration (Article 16 Regulation (EU) 402/2013) covering the requirements capture for the essential requirements "safety" for the subsystems and safe integration between subsystems for aspects not covered by the TSIs and the national rules.	X		X	X	
18.11	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) covering the potential modification of the overall safety level for the vehicle			X	X	
18.12	Risk declaration (Article 16 Regulation (EU) 402/2013) covering the potential modification of the overall safety level for the vehicle			X	X	

⁸Non standardised methodology

18.13	Information required for ERATV (according to Annex II of decision 2011/665/EU)	X		X	X	
18.14	Maintenance & operation documentation (including rescue), when not included in 18.4 and/or 18.5.	X		X	X	

Optional information

Manufacturer's/ Contracting entity information (only in cases when it is not the applicant):

1. Legal denomination
2. Manufacturer's/ Contracting entity name
3. Acronym
4. Complete postal address
5. Phone
6. Fax
7. E-mail
8. Website
9. VAT number
10. Other relevant information

Guidance for Annex I

Point 10.1 – Type ID

A code is assigned to the vehicle type/ vehicle type variant/ vehicle type version by ERATV pursuant to Article 48 of Directive (EU) 2016/797. A vehicle type type/ vehicle type variant/ vehicle type version number may be reserved and the applicant can prefill the relevant data in ERATV.

A single application form can cover both the vehicle type authorisation and the authorisation of the first vehicle of that vehicle type.

Point 18.1 - The supporting evidence for the requirements capture in accordance with Article 13(1).

For the essential requirement "safety" for the subsystems and for the safe integration between subsystems for aspects not covered by the TSIs and the national rules, the supporting evidence for the requirements capture process includes the safety assessment report (Article 15 of Commission Implementing Regulation (EU) 402/2013) issued by the assessment body (CSM RA). The declaration by the proposer (Article 16 of Commission Implementing Regulation (EU) 402/2013) is covered in point 18.10.

Where the applicant applies another methodology, the evidence to be provided by the applicant should allow the authorising entity to be confident that it provides the same level of assurance as the methodology set out in Annex I of Regulation (EU) 402/2013 (see the criteria laid down in Annex II, point 7.2 Commission Implementing Regulation (EU) 2018/545).

Point 18.2 - Mapping table indicating where the information needed for the aspects to be assessed according to Annex II and III can be found

The "Mapping table " is intended to be used for the assessment of the application to facilitate the understanding of the links between the documents provided by the applicant and the aspects to be checked by the authorising entity and/ or the concerned NSAs for the area of use.

It is advisable for the applicant to consult Annex II and Annex III in order to have a better understanding of what will be assessed and to better understand what documentation and the level of detail that is needed.

Point 18.5 – EC Declarations of Verification for the mobile subsystems, including accompanying technical files (Article 15 Directive (EU) 2016/797).

The EC Declaration of Verification of a subsystem is accompanied by a technical file. This technical file is assembled by the applicant and should include at least:

- › A list of interoperability constituents incorporated into the subsystem; and
- › The files submitted by the conformity assessment bodies.

Point 18.6 - The file accompanying the application and the decision from the previous authorisation or when applicable the reference to the decision issued according to Article 46 and to the full accompanying file for the decision archived in the one-stop shop.

For vehicles and/ or vehicle types that have not received an authorisation pursuant to Directive (EU) 2016/797 the following documents are considered as equivalent:

- › When the vehicle/ vehicle type has received an authorisation pursuant to Directive 2008/57/EC:
 - The vehicle type authorisation decision issued pursuant to Article 26(1) or 26(2) of Directive 2008/57/EC and the decision(s) issued pursuant to Article 22 and 23 of Directive 2008/57/EC for a TSI conform vehicle, including the supporting files for the decisions.
 - The vehicle type authorisation decision issued pursuant to Article 26(1) or 26(2) of Directive 2008/57/EC and the decision(s) issued pursuant to Article 24 and 25 of Directive 2008/57/EC for a non-TSI conform vehicle, including the supporting files for the decisions.
 - The vehicle type authorisation issued pursuant to Article 26(1) or 26(2) of Directive 2008/57/EC and decision for the subsequent authorisation of vehicle(s) in conformity with the vehicle type pursuant to Article 26(3) of Directive 2008/57/EC.
- › When the vehicle/ vehicle type has received an authorisation before Directive 2008/57/EC was in force:
 - The decision(s) for the initial authorisation(s), including any supporting file(s). There should be a clear indication of the scope and the legal base for the decision; or
 - If no authorisation was required at the time the vehicle was placed in service it is sufficient to provide evidence supporting that:
 - No authorisation was required; and
 - That the vehicle was placed in service and has remained in service (i.e. registration).

Point 18.7 - Specification of and where applicable⁹ a description of the methodology used for the requirements capture

The requirements capture process covers all the relevant requirements for the vehicle and/ or the vehicle type concerned. In case of a first authorisation, the whole vehicle type and/ or vehicle should be covered by the requirements capture process. In case of a new authorisation, the requirements capture process should cover the changed parts and the interfaces between the changed and the unchanged parts. Finally, for an extension of the area of use, the requirements capture process should cover the aspects related to national rules applicable for the extended area of use that do not require a change of the design of the vehicle (such a change should be covered by a new authorisation in the original area of use).

The description of the methodology used for the requirements capture can refer to or re-use existing documents generated in the framework of other processes already established by the manufacturer/ supplier (namely quality management, change management or requirement management processes).

⁹ Non standardised methodology

Point 18.9 - When not fully covered by TSIs and/ or national rules, the documentary evidence of the technical compatibility of the vehicle with the network

The documentation referred to in point 18.7 refers to the description of the methodology used for the requirements capture process. The documentation referred to in point 18.1 relates to the evidence from the application of the methodology for the requirements capture process. Finally, the documentation referred to in point 18.9 refers to the demonstration (evidence) of the technical compatibility of the vehicle with the network, where those aspects are not covered by the relevant TSIs and/ or national rules.

Points 18.8; 18.10; 18.11 and 18.12 - CSM on risk assessment report and declaration by the proposer (Article 16 of Commission Implementing Regulation (EU) 402/2013)

In the case of a change to an existing vehicle and/ or vehicle type, the application of Commission Implementing Regulation (EU) 402/2013 is always required. If the change is considered significant, the safety assessment report referred to in Article 15 of Commission Implementing Regulation (EU) 402/2013 should be included in the file accompanying the application for authorisation (point 18.11) , together with the declaration by the proposer (applicant) referred to in Article 16 of Commission Implementing Regulation (EU) 402/2013 (point 18.12).

Pursuant to Article 4 of Commission Implementing Regulation (EU) 402/2013, if the applicant considers that the change is not significant, there is no need to apply the risk management process of Commission Implementing Regulation (EU) 402/2013, and therefore it is not necessary to involve an assessment body (CSM RA). Therefore, if there is still a need to apply for an authorisation pursuant to Article 21(12) of Directive (EU) 2016/797, and concerning the modification (not the requirements capture process), it is not necessary to include the documents containing the information referred to in points 18.11 and 18.12 in the file accompanying the application for authorisation.

However, it is always required to perform a requirements capture process. If the applicant needs to obtain an authorisation pursuant to Article 21(12) of Directive (EU) 2016/797, the requirements capture process for the essential requirement “safety” within subsystems and safe integration between subsystems, the risk assessment process described in Annex I of Commission Implementing Regulation (EU) 402/2013 applies. The process check of the safety related aspects of the requirements capture should be performed by an assessment body (CSM RA), and there is a need to include in the file accompanying the application for authorisation the safety assessment report and the declaration by the proposer referred to in Articles 15 and 16 of Commission Implementing Regulation (EU) 402/2013 for the requirements capture process and the documents containing the information referred to in point 18.8 and 18.10.

The information referred to in points 18.8, 18.10, 18.11 and 18.12 can be contained in one or more documents; it may even be possible that different assessment bodies (CSM RA) are responsible for different parts of the assessments. This is left up to the applicant (proposer) to decide.

If there are no safety related aspects and/ or aspects related to safe integration between subsystems in the requirements capture process, and the change is not significant, there is still the need for the applicant to involve an assessment body (CSM RA), and to include in the file accompanying the application for authorisation the documents containing the information referred to in points 18.8, 18.10, 18.11 and 18.12. These documents are the evidence that an assessment body (CSM RA) has checked the process followed by the applicant to conclude that indeed there are no safety related aspects or aspects related to the safe integration between subsystems.

Point 18.13 - Information required for ERATV (according to Annex II of decision 2011/665/EU)

Section 3 of Annex II of the ERATV Decision 2011/665/EU will be updated in order to include the area of use of a vehicle type.

Signatures

All the documents that need to be signed by the applicant, the Agency and NSAs will have an electronic signature through the one-stop shop.

Annex II Aspects for assessment by the authorising entity

The information that shall be assessed by the authorising entity is specified per authorisation case. An (x) in the column for the applicable authorisation case indicates that this aspect is mandatory to assess for this authorisation case.

		First authorisation	Renewed type authorisation	Extended area of use	New authorisation	Authorisation in conformity to type
1	Application consistent with the pre-engagement baseline (when applicable)	X	X	X	X	X
2	Authorisation case selected by the applicant is adequate	X	X	X	X	X
3	The TSIs and other applicable Union law identified by the applicant are correct	X	X	X	X	
4	Selected conformity assessment bodies (notified body(ies), assessment body (CSM RA)) have the proper accreditation or recognition as applicable	X	X	X	X	
5	Non-applications of TSIs according to the provisions of Article 7 of Directive (EU) 2016/797: 5.1 Validity (time and area of use); 5.2 Applicable to the project; and 5.3 Consistent with the identified and applied rules.	X	X	X	X	X
6	6.1 Is the applied methodology used for the requirements capture fit for purpose concerning the following aspects: (a) Has a standardised/accepted methodology been used?; and (b) Is the method intended for and suitable for the essential requirements it covers? 6.2 When the methodology applied is not standardised or covers other essential requirements than it is intended for, the following aspects shall be checked to evaluate if they are sufficiently considered and covered by the methodology: (a) Degree of independent assessment applied (b) System definition (c) Hazard identification and classification (d) Risk acceptance principles (e) Risk evaluation (f) Requirements established (g) Demonstration of compliance with the requirements (h) Hazard management (log)	X		X	X	
7	Sufficient evidence from the methodology used for the requirements capture:	X		X	X	

	<p>7.1 When the risk management process set out in Annex I of Regulation (EU) 402/2013, has been used as the methodology for requirements capture the following shall be checked:</p> <ul style="list-style-type: none"> (a) CSM on risk assessment, declaration by the proposer (Article 16 Regulation (EU) 402/2013) is signed by the proposer and supports that all identified hazards and associated risks are controlled to an acceptable level. (b) CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) supports the declaration by the proposer for the specified scope according to Article 13 and at least the essential requirement safety for subsystems and safe integration between subsystems within the vehicle. <p>7.2 When another methodology than the risk management process set out in Annex I of Regulation (EU) 402/2013, has been used as the methodology for requirements capture the following shall be checked:</p> <ul style="list-style-type: none"> (a) System definition is complete and consistent with the design of the vehicle? (b) Hazard identification and classification is consistent and plausible? (c) All risks have been properly managed and mitigated? (d) Requirements derived from the risk management are properly traced to the risk and to the evidence of compliance with the requirement? (e) Structured and consistent management of the hazards throughout the process? (f) Is there a positive opinion from the independent assessment? 					
<p>8</p>	<p>EC Declarations of Verification and EC certificates (Article 15 Directive (EU) 2016/797), check:</p> <ul style="list-style-type: none"> 8.1 Signatures 8.2 Validity 8.3 Scope 8.4 Conditions for use of the vehicle and other restrictions, non-compliances 8.5 Non-application of TSIs (when applicable) 8.6 All applicable legislation is covered, including other non-railway related legislation 8.7 Interoperability constituents (validity, scope, conditions for use of the vehicle and other restrictions): <ul style="list-style-type: none"> (a) EC certificates of conformity (b) EC certificates of suitability of use 	<p>X</p>	<p>X</p>	<p>X</p>	<p>X</p>	
<p>9</p>	<p>Reports from Conformity assessment bodies (Article 15 Directive (EU) 2016/797), check:</p>	<p>X</p>	<p>X</p>	<p>X</p>	<p>X</p>	

	<p>9.1 Consistency with EC Declarations of Verification and EC certificates</p> <p>9.2 All applicable rules are covered</p> <p>9.3 Deviations & non-conformities (when applicable) are identified and match the non-application requests</p> <p>9.4 Combination of modules used is allowed</p> <p>9.5 Conditions for use of the vehicle and other restrictions are properly identified and are consistent with the conditions in the application for authorisation</p> <p>9.6 The supporting evidences used by the conformity assessment bodies are matching the applicable assessment phases described in TSIs (design review, type test, etc.).</p>					
10	Check of assessments from NSAs for the area of use, as specified in Article 43	X	X	X	X	
11	Validity of the original vehicle type authorisation		X	X	X	X
12	Original vehicle type authorisation is valid for the concerned area of use		X		X	X
13	Existing conditions for use of the vehicle and other restrictions		X	X	X	
14	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) covering the requirements capture for the essential requirements "safety" for the subsystems and safe integration between subsystems positive opinion.	X		X	X	
15	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) covering the potential modification of the overall safety level for the vehicle (significant change) positive opinion			X	X	
16	Changes as compared to the authorised vehicle type are sufficiently described and match the CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013)				X	
17	EC Declarations of Verification and EC certificates are properly updated in relation to the changed and/or updated rules		X			
18	<p>Reports from conformity assessment bodies are properly updated in relation to the changed and/or updated rules:</p> <p>18.1 Changed and/or updated rules are covered</p> <p>18.2 There is evidence that the vehicle type still fulfils the requirements</p>		X			
19	Evidence that the design of the vehicle type has not changed		X	X		
20	Identification of the vehicle or series of vehicles covered by the declaration of conformity to the vehicle type					X

21	Declaration of conformity to the type and supporting documents (Article 24 Directive (EU) 2016/797)						X
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Guidance for Annex II

Point 6 - Assessment of the methodology for requirements capture

Chapter 3.7.8, 3.7.9 and 3.7.10 provides further guidance on the assessments to be performed by the authorising entity and/ or by the concerned NSAs for the area of use regarding the methodology for the requirements capture.

The authorising entity is expected to check different aspects when assessing a methodology that is not standardised, as specified in point 6.2. The objective is to get the assurance that the process followed by the applicant to capture the applicable requirements and to demonstrate that essential requirements other than safety are also met is suitable and provides a similar level of trust as the methodology described in the Commission Implementing Regulation (EU) 402/2013 concerning the capture and achievement of the essential requirement safety. In such a case, the authorising entity would be performing the task that an assessment body (CSM RA) would have done in the framework of the Regulation; the extent and depth of the checks depend on the methodology applied and on the degree of independent assessment that the methodology require.

With regards to the degree of independent assessment, it should be noted that the risk management process described in Annex I of Commission Implementing Regulation (EU) 402/2013 requires the involvement of an assessment body (CSM RA), it also defines the competences that an entity must demonstrate in order to act as an assessment body (CSM RA) and establishes an accreditation/recognition scheme for assessment bodies (CSM RA).

However, other methodologies do not require an independent assessment, or if it is required, there are differences regarding the approach and/ or criteria that an entity should meet in order to perform this activity (namely accreditation/ recognition scheme). Some methodologies may be close to that of the Commission Implementing Regulation (EU) 402/2013, and some others may have different criteria and no accreditation/ recognition/ supervision scheme at all.

In order to determine to which extent the outcomes of an independent assessment not performed under the umbrella of the Commission Implementing Regulation (EU) 402/2013 (where allowed) can be taken into account when assessing the evidence provided in the file accompanying the application for authorisation, the authorising entity should examine the methodology applied for the requirements capture, as described in points 18.1 of Annex I and 7.2 of Annex II of Commission Implementing Regulation (EU) 2018/545. In particular, the authorising entity should check what the requirements are related to in the independent assessment (if any) and whether it provides the same level of assurance.

Point 8 - EC Declarations of Verification and EC certificates (Article 15 Directive (EU) 2016/797)

In the Guidelines for the Commission Implementing Regulation on the EC Declarations of Verification more details are given concerning the EC declaration of verification of a subsystem and on EC certificates. Amongst other items, the handling of the declaration of conformity of an interoperability constituent when there is no notified body involved (according to modules CA, CA1 and CA2 of the Decision 2010/713/EC) is addressed.

Point 8.6 All applicable legislation is covered, including other non-railway related legislation

According to the Directive (EU) 2016/797, there is a clear obligation for the applicant to ensure that all relevant Union law is met. The requirements capture process is the right tool for the applicant to ensure that all risks are properly covered and traced to a relevant mitigation measure. These mitigation measures may well be the provisions of the applicable Union law (for some risks).

Annex II (and in particular, point 8.6) describes the aspects that are to be verified by the authorising entity in order to establish a “reasonable assurance” that the applicant has fulfilled its responsibilities. From this point of view, the authorising entity should check that the applicant has taken into account other EU legislation. It does not impose an obligation for the authorising entity to ensure or assess that the legislation is actually met (see chapter 3.7.9).

The check to be performed by the authorising entity is a consistency check between the outcomes of the requirements capture process and the EC declaration(s) of verification.

Point 10 - Check of assessments from the concerned NSAs for the area of use, as specified in Article 43

The details of the checks to be performed by the authorising entity are specified in Article 43 of the Commission Implementing Regulation (EU) 2018/545.

The task of the authorising entity is not to check, recheck or overcheck the assessment carried on by other parties involved in the authorisation process, but to check the consistency of this assessment.

Point 20 - Evidence that the design of the vehicle type has not changed

A renewed authorisation is limited to the case where, after assessment against the changed rule(s), it is proven that the vehicle type conforms without any design change.

A new authorisation is the authorisation issued after the upgrading/ renewal (change of the design) of an existing vehicle and/ or vehicle type that is already authorised.

Annex III Aspects for assessment by the concerned NSAs for the area of use

This Annex is not applicable when the area of use covers the whole EU network and the TSIs contain specific conditions for this.

The information that shall be assessed by the concerned NSAs for the area of use in relation to the relevant national rules is specified per authorisation case. An (x) in the column for the applicable authorisation case indicates that this aspect is mandatory to assess for this authorisation case

		First authorisation	New authorisation	Extended area of use	Renewed type authorisation
1	Application consistent with the pre-engagement baseline (when applicable)	X	X	X	X
2	The area of use for the concerned Member State is correctly specified	X	X	X	X
3	The national rules and requirements for the concerned area of use identified by the applicant are correct.	X	X	X	
4	Selected conformity assessment bodies relevant for the concerned area of use (designated body(ies), assessment body (CSM RA)) have the proper accreditation or recognition as applicable.	X	X	X	X
5	Sufficient evidence from the methodology used for the requirements capture only for the national rules for the concerned area of use: 5.1 When another methodology than the risk management process set out in Annex I of Regulation (EU) 402/2013, has been used as the methodology for requirements capture the following shall be checked: (a) System definition is complete and consistent with the design of the vehicle? (b) Hazard identification and classification is consistent and plausible? (c) All risks have been properly managed and mitigated? (d) Requirements derived from the risk management are properly traced to the risk and to the evidence of compliance with the requirement?	X	X	X	
6	EC Declarations of Verification and Certificates (national rules) (Article 15 Directive (EU) 2016/797), check: 6.1 Signatures 6.2 Validity 6.3 Scope 6.4 Conditions for use of the vehicle, other restrictions, non-compliances	X	X	X	X
7	Reports from conformity assessment bodies (Article 15 Directive (EU) 2016/797), check: 7.1 Consistency with EC Declarations of Verification and certificates. 7.2 Deviations & non-conformities (when applicable) are identified	X	X	X	X

	7.3 Conditions for use and other restrictions are properly identified and are consistent with the conditions in the application for authorisation. 7.4 The supporting evidences used by conformity assessment bodies are matching the applicable assessment phases described in national rules.				
8	Existing conditions for use of the vehicle and other restrictions		X	X	X
9	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) covering the requirements capture for the essential requirements "safety" for the subsystems and safe integration between subsystems positive opinion.	X	X	X	
10	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013) covering the potential modification of the overall safety level for the vehicle (significant change) positive opinion		X	X	
11	Changes as compared to the authorised vehicle type are sufficiently described and match the CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) 402/2013)		X		
12	EC Declarations of Verification and EC certificates are properly updated in relation to the changed/updated national rules				X
13	Reports from conformity assessment bodies are properly updated in relation to the changed/updated rules: 13.1 Changed/updated national rules are covered 13.2 There are evidence that the vehicle type still fulfils the requirements				X

Guidance for Annex III

Point 5 - Sufficient evidence from the methodology used for the requirements capture only for the national rules for the concerned area of use

The NSAs for the area of use, in relation to national rules, will also have a role in checking the evidence of the application of a non-standard methodology for the requirements capture. The checks should be systemic, focused on the process and on the relevance of the national rules used as mitigation measures in the risk assessment process. In order to do so, the NSAs for the area of use may need to check in detail some supporting evidence.

Annex IV Model template for the vehicle type authorisation

VEHICLE TYPE AUTHORISATION	
Vehicle type authorisation in conformity with Directive (EU) 2016/797 and Commission Implementing Regulation (EU) 2018/545	
1. AUTHORISATION INFORMATION	
Application ID:	
EU identification number (EIN):	
Authorising entity:	
Legal base empowering the authorising entity to issue this vehicle type authorisation:	Article 24(1) of Directive (EU) 2016/797 and Regulation (EU) 2016/796 Article 21/ reference to relevant national law when the vehicle type authorisation is issued by a NSA
Authorisation case as specified in Article 14 of Commission Implementing Regulation (EU) 2018/545:	
2. APPLICANT	
Legal denomination:	
Applicant name:	
3. VEHICLE TYPE	
Category:	
Subcategory	
3.1 VEHICLE TYPE VARIANT 1 AND VERSION 1 [FURTHER VEHICLE TYPE VARIANT/VERSION COMBINATIONS CAN BE ADDED]	
Name:	
Alternative name:	
Vehicle type ID (reference of the vehicle type registration in ERATV):	
Basic design characteristics:	See Annex 1
Values of the parameters for checking technical compatibility between the vehicle and the area of use:	See Annex 2
Identification of the vehicle type variant and version's compliance with TSIs and sets of national rules:	
Reference to the EC Declaration(s) of verification for the subsystem(s):	
Reference to other Union or national law with which the vehicle type variant and version is compliant	
4. ANNEXES	

Annex 1	Basic design characteristics
Annex 2	Values of the parameters for checking technical compatibility between the vehicle and the area of use
Annex 3	Appeal process
Annex 4	
Annex 5	
Annex 6	
Annex 7	

5. DOCUMENTED REASONS FOR THE DECISION

Reference to the documented reasons for the decision:	
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6. APPEAL

Possibility and means for appealing the decision:	Annex 3
Relevant time limits:	Annex 3

Date and place of the decision to issue the vehicle type authorisation:

Authorised signatory of the authorising entity:

Annex V Model template for the vehicle authorisation for placing on the market

VEHICLE AUTHORISATION FOR PLACING ON THE MARKET	
Vehicle authorisation for placing on the market in conformity with Directive (EU) 2016/797 and Commission Implementing Regulation (EU) 2018/545.	
1. AUTHORISATION INFORMATION	
Application ID:	
EU identification number (EIN):	
Authorising entity:	
Legal base empowering the authorising entity to issue this vehicle authorisation for placing on the market:	Article 21(4) of Directive (EU) 2016/797 and Regulation (EU) 2016/796 Article 20/ reference to relevant national law when the vehicle authorisation for placing on the market is issued by a NSA
Authorisation case as specified in Article 14 of Commission Implementing Regulation (EU) 2018/545:	
2. APPLICANT	
Legal denomination:	
Applicant name:	
3. VEHICLE	
3.1 VEHICLE	
Vehicle type ID (reference of the vehicle type registration in ERATV)	
Identification of the vehicle:	
Identification of the area of use:	
Identification of the conditions for use of the vehicle and other restrictions:	
Reference to the EC declaration(s) of verification for the subsystem(s):	
Reference to other Union or national law with which the vehicle is compliant:	
In case of an authorisation in conformity to type, the reference to the declaration of conformity with an authorised vehicle type:	
3.2 SERIES OF VEHICLES	
Vehicle type ID (reference of the vehicle type registration in ERATV):	
Identification of the vehicles of the series :	
Identification of the area of use:	
Identification of the conditions for use of the vehicle and other restrictions:	
Reference to the EC declaration(s) of verification for the subsystem(s):	

Reference to other Union or national law with which the vehicle is compliant:	
In case of an authorisation in conformity to type, the reference to the declaration of conformity with an authorised vehicle type:	
4. ANNEXES	
Annex 1	Appeal process
Annex 2	
5. DOCUMENTED REASONS FOR THE DECISION	
Reference to the documented reasons for the decision:	
6. APPEAL	
Possibility and means for appealing the decision:	Annex 1
Relevant time limits:	Annex 1
Date and place of the decision to issue the vehicle authorisation for placing on the market:	
Authorised signatory of the authorising entity:	

Annex VI Model template for the acknowledgement/ refusal of receipt of complete application file

ACKNOWLEDGEMENT/ REFUSAL OF RECEIPT OF COMPLETE APPLICATION FILE	
Acknowledgement/ refusal of receipt of complete application as specified in Article 34 of Commission Implementing Regulation (EU) 2018/545 for a vehicle type authorisation and / or vehicle authorisation for placing on the market in conformity with Directive (EU) 2016/797 and Commission Implementing Regulation (EU) 2018/545	
1. APPLICATION INFORMATION	
Application ID:	
Reference to pre-engagement baseline (when applicable):	
Date of acknowledgement of application (Article 33 of Commission Implementing Regulation (EU) 2018/545):	
Date of receipt of the application (Article 2(4) of Commission Implementing Regulation (EU) 2018/545):	
Authorising entity:	
Concerned NSAs for the area of use (when applicable):	
Type of application:	
Vehicle type authorisation:	
Vehicle type variants (when applicable):	
Vehicle type versions (when applicable):	
Vehicle authorisation for placing on the market:	
Single vehicle:	
Series of vehicles:	
Authorisation case(s) as specified in Article 14 of Commission Implementing Regulation (EU) 2018/545:	
Combined application for new authorisation and extended area of use as specified in Article 14(3)(a) of Commission Implementing Regulation (EU) 2018/545:	
Combined application for first authorisation and authorisation in conformity with type as specified in Article 14(3)(b) of Commission Implementing Regulation (EU) 2018/545:	
2. APPLICANT	
Legal denomination:	
Applicant name:	
3. THE APPLICATION IS (Article 34 of Commission Implementing Regulation (EU) 2018/545):	
COMPLETE	

	<p>The final decision on authorisation shall be taken no more than four months after the date of this acknowledgement of the receipt of the complete application.</p> <p>Please note that supplementary information may be requested in the course of the assessment.</p>
INCOMPLETE	
	<p>The following information is missing and must be submitted for the assessment to proceed: <<details>></p> <p>The final decision on authorisation shall be taken no more than four months after the date of submission of the missing information.</p> <p>Please note that supplementary information may be requested in the course of the assessment.</p>
FUNDAMENTALLY DEFICIENT	
	<p><<reasons>></p> <p>The application is rejected.</p>
<p>Date:</p> <p style="text-align: right;"> Authorised signatory of the authorising entity <i>EU Agency for Railways / National Safety Authority</i> </p> <p style="text-align: right;"> Authorised signatory of the National Safety Authority for the area of use (where applicable) <i>Area of use</i> </p> <p style="text-align: right;"> Authorised signatory of the National Safety Authority for the area of use (where applicable) <i>Area of use</i> </p>	

Annex VII Model template for the pre-engagement application

PRE-ENGAGEMENT APPLICATION	
Application for pre-engagement before submitting an application for a vehicle type authorisation and / or vehicle authorisation for placing on the market in conformity with Directive (EU) 2016/797 and Commission Implementing Regulation (EU) 2018/545	
1. PRE-ENGAGEMENT APPLICATION INFORMATION	
Type of application:	
Vehicle type authorisation:	
Vehicle type variants (when applicable):	
Vehicle type versions (when applicable):	
Vehicle authorisation for placing on the market:	
Single vehicle:	
Series of vehicles:	
2. APPLICANT	
Legal denomination:	
Applicant name:	
Acronym (optional):	
Complete postal address:	
Phone:	
Fax (optional):	
E-mail:	
Website (optional):	
VAT number (optional):	
Other relevant information (optional):	
Contact person:	
First name:	
Surname:	
Title or function:	
Complete postal address:	
Phone:	
Fax (optional):	
E-mail:	
Languages to be used:	
3. PRE-ENGAGEMENT FILE	
Description of the intended vehicle type and/or vehicle to be authorised:	
Intended variants and/or versions	
Description of the tasks and activities to develop it	
Choice of authorising entity:	

Authorisation case(s) as specified in Article 14 of Commission Implementing Regulation (EU) 2018/545:	
Combined application for new authorisation and extended area of use as specified in Article 14(3)(a) of Commission Implementing Regulation (EU) 2018/545:	
Combined application for first authorisation and authorisation in conformity with type as specified in Article 14(3)(b) of Commission Implementing Regulation (EU) 2018/545:	
Specification of the intended area of use:	
Specification of the anticipated conditions for use of the vehicle and other restrictions identified pursuant to Article 20 of Commission Implementing Regulation (EU) 2018/545:	
The applicant’s planning for its part of the vehicle authorisation process, including the planning that covers tests on the network (when applicable):	
Identification of the methodology for the process for the requirements capture in accordance with Article 13 of Commission Implementing Regulation (EU) 2018/545:	
List of the rules and requirements identified as those that are to be applied in accordance with Article 17 and 18 of Commission Implementing Regulation (EU) 2018/545:	
List of the identified conformity assessments pursuant to Article 21 of Commission Implementing Regulation (EU) 2018/545 (including the modules to be applied and the use of Intermediate Statements of Verification ('ISV') (when applicable)):	
Description of the practical arrangements to use the vehicle for tests on the network (when applicable):	
List of the content of the documentation anticipated by the applicant to be submitted to the authorising entity and the concerned NSAs for the area of use for the vehicle type authorisation and/or vehicle authorisation for placing on the market:	
Proposal concerning the languages to be used for the vehicle authorisation process pursuant to Article 10 of Commission Implementing Regulation (EU) 2018/545:	
Description of the applicant’s organisation for its part of the vehicle authorisation process including but not limited to the applicant’s contact information, contact persons information, requests for setting up coordination and meetings with the authorising entity and the concerned NSAs for the area of use:	
4. ANNEXES	

Annex 1	
Annex 2	
Annex 3	
Annex 4	
Annex 5	
Annex 6	
Annex 7	
Date:	
Authorised signatory of the applicant	

Annex VIII Model template for the pre-engagement baseline

PRE-ENGAGEMENT BASELINE	
Opinion on the approach proposed by the applicant in the pre-engagement application in respect of an application for a vehicle type authorisation and / or vehicle authorisation for placing on the market in conformity with Directive (EU) 2016/797 and Commission Implementing Regulation (EU) 2018/545	
1. PRE-ENGAGEMENT BASELINE INFORMATION	
Pre-engagement baseline ID:	
2. PRE-ENGAGEMENT APPLICATION INFORMATION	
Application ID:	
Date of receipt of the pre-engagement application:	
Date of acknowledgement of complete pre-engagement application:	
Authorising entity:	
Concerned NSAs for the area of use (when applicable):	
Type of application:	
Vehicle type authorisation:	
Vehicle type variants (when applicable):	
Vehicle type versions (when applicable):	
Vehicle authorisation for placing on the market:	
Single vehicle:	
Series of vehicles:	
Description of the intended vehicle type and/or vehicle to be authorised:	
Intended variants and/or versions	
3. APPLICANT	
Legal denomination:	
Applicant name:	
4. PRE-ENGAGEMENT BASELINE	
Item of pre-engagement application	Authorising entity and concerned NSAs for the area of use (when applicable) opinion concerning applicant's proposal
Description of the intended vehicle type and/or vehicle to be authorised:	
Intended variants and/or versions	
Description of the tasks and activities to develop it	
Choice of authorising entity:	
Authorisation case(s) as specified in Article 14 of Commission Implementing Regulation (EU) 2018/545:	

Combined application for new authorisation and extended area of use as specified in Article 14(3)(a) of Commission Implementing Regulation (EU) 2018/545:	
Combined application for first authorisation and authorisation in conformity with type as specified in Article 14(3)(b) of Commission Implementing Regulation (EU) 2018/545:	
Specification of the intended area of use:	
Specification of the anticipated conditions for use of the vehicle and other restrictions identified pursuant to Article 20 of Commission Implementing Regulation (EU) 2018/545:	
The applicant's planning for its part of the vehicle authorisation process, including the planning that covers tests on the network (when applicable):	
Identification of the methodology for the process for the requirements capture in accordance with Article 13 of Commission Implementing Regulation (EU) 2018/545:	
List of the rules and requirements identified as those that are to be applied in accordance with Article 17 and 18 of Commission Implementing Regulation (EU) 2018/545:	
List of the identified conformity assessments pursuant to Article 21 of Commission Implementing Regulation (EU) 2018/545 (including the modules to be applied and the use of Intermediate Statements of Verification ('ISV') (when applicable)):	
Description of the practical arrangements to use the vehicle for tests on the network (when applicable):	
List of the content of the documentation anticipated by the applicant to be submitted to the authorising entity and the concerned NSAs for the area of use for the vehicle type authorisation and/or vehicle authorisation for placing on the market:	
Proposal concerning the languages to be used for the vehicle authorisation process pursuant to Article 10 of Commission Implementing Regulation (EU) 2018/545:	
Description of the applicant's organisation for its part of the vehicle authorisation process including but not limited to the applicant's contact information, contact persons, requests for setting up coordination and meetings with the authorising entity and the concerned NSAs for the area of use:	
5. ANNEXES	
Annex 1	

Annex 2	
Annex 3	
Annex 4	
Annex 5	
Annex 6	
Annex 7	

For the reasons stated above in the opinion of the signatory organisations the pre-engagement application submitted by the applicant proposes a satisfactory/ unsatisfactory approach for an application for vehicle type authorisation and/ or vehicle authorisation for placing on the market.

Information:

1. As specified in Article 22(2) of Commission Implementing Regulation (EU) 2018/545: *“The timeframe from the issuing of the opinion referred to in Article 24(2) to the applicant’s submission of the application for vehicle type authorisation and/or vehicle authorisation for placing on the market shall not exceed 84 months.”*
2. Pursuant to Article 24(4) of Commission Implementing Regulation (EU) 2018/545 *“In case of changes affecting the pre-engagement file which are relevant for the pre-engagement baseline, the applicant shall send an amended and updated pre-engagement application only considering the changes and the interfaces with the unchanged parts.”*

Date:

Authorised signatory of the authorising entity

EU Agency for Railways / National Safety Authority

Authorised signatory of the National Safety Authority for the area of use (where applicable)

Area of use

Authorised signatory of the National Safety Authority for the area of use (where applicable)

Area of use

Annex IX Model template for the assessment file as specified in Article 39(5) of Commission Implementing Regulation (EU) 2018/545 and the check to be performed by the authorising entity concerning the assessments performed by the concerned NSAs for the area of use, as specified in Article 43 of Commission Implementing Regulation (EU) 2018/545

THE AUTHORISING ENTITY ASSESSMENT FILE AS SPECIFIED IN ARTICLE 39(5) OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/545 AND THE CHECK TO BE PERFORMED BY THE AUTHORISING ENTITY CONCERNING THE ASSESSMENTS PERFORMED BY THE CONCERNED NSAs FOR THE AREA OF USE, AS SPECIFIED IN ARTICLE 43 OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/545	
Assessment of application for a vehicle type authorisation and / or vehicle authorisation for placing on the market in conformity with Directive (EU) 2016/797 and Commission Implementing Regulation (EU) 2018/545	
1. APPLICATION INFORMATION	
Application ID:	
Reference to pre-engagement baseline (when applicable):	
Date of acknowledgement of application (Article 33 of Commission Implementing Regulation (EU) 2018/545):	
Date of receipt of the application (Article 2(4) of Commission Implementing Regulation (EU) 2018/545):	
Date for acknowledgement of complete application:	
Date for submission of missing information by the applicant in case of incomplete application:	
Authorising entity:	
Concerned NSAs for the area of use (when applicable):	
Type of application:	
Vehicle type authorisation:	
Vehicle type variants (when applicable):	
Vehicle type versions (when applicable):	
Vehicle authorisation for placing on the market:	
Single vehicle:	
Series of vehicles:	
Authorisation case(s) as specified in Article 14 of Commission Implementing Regulation (EU) 2018/545:	
Combined application for new authorisation and extended area of use as specified in Article 14(3)(a) of Commission Implementing Regulation (EU) 2018/545:	
Combined application for first authorisation and authorisation in conformity with type as specified in	

Article 14(3)(b) of Commission Implementing Regulation (EU) 2018/545:	
2. APPLICANT	
Legal denomination:	
Applicant name:	
3. ASSESSMENT PERFORMED AS SPECIFIED IN ARTICLE 39(5) OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/545	
Statement concerning the result of the assessment for the concerned area of use (negative or positive result):	
Conditions for use and other restrictions (when applicable):	
Summary of the assessments performed:	
Report from the issues log for the concerned area of use:	Annex 1
Filled in checklist giving evidence for assessment of the aspects specified in Annex II of Commission Implementing Regulation (EU) 2018/545:	Annex 2
Filled in checklist giving evidence for assessment of aspects specified in Annex III of Commission Implementing Regulation (EU) 2018/545 (when applicable):	
Record of check for any relevant information recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545 (when applicable):	
4. THE CHECK TO BE PERFORMED BY THE AUTHORISING ENTITY CONCERNING THE ASSESSMENTS PERFORMED BY THE CONCERNED NSAs FOR THE AREA OF USE, AS SPECIFIED IN ARTICLE 43 OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/545 (WHEN APPLICABLE)	
Check that the assessments from the NSAs for the area of use are consistent with each other as regards the results of the assessments referred to in Article 40(6)(a):	
In the case of inconsistent assessments from the NSAs for the area of use, the result of the investigation specified in Article 45(3) of Commission Implementing Regulation (EU) 2018/545:	
The checklists referred to in Article 40(6)(d) have been filled-in completely:	
All relevant issues have been closed:	
In the case of incomplete checklist(s) and/ or issues that have not been closed, the result of the investigation specified in Article 45(5) of	

Commission Implementing Regulation (EU) 2018/545:	
In case of disagreement between the authorising entity and concerned NSAs for the area of use, the result from the arbitration procedure referred to in Article 21(7) of Directive (EU) 2016/797:	
5. ANNEXES	
Annex 1	Report from the issues log for the concerned area of use
Annex 2	Filled in checklist giving evidence for assessment of the aspects specified in Annex II of Commission Implementing Regulation (EU) 2018/545
Annex 3	
Annex 4	
Annex 5	
Annex 6	
Annex 7	
Date:	Authorised signatory of the authorising entity <i>EU Agency for Railways / National Safety Authority</i>

Annex X Model template for the assessment file as specified in Article 40(6) of Commission Implementing Regulation (EU) 2018/545

THE NSAs FOR THE AREA OF USE ASSESSMENT FILE AS SPECIFIED IN ARTICLE 40(6) OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/545	
Assessment of application for a vehicle type authorisation and / or vehicle authorisation for placing on the market in conformity with Directive (EU) 2016/797 and Commission Implementing Regulation (EU) 2018/545	
1. APPLICATION INFORMATION	
Application ID:	
Reference to pre-engagement baseline (when applicable):	
Date of acknowledgement of application (Article 33 of Commission Implementing Regulation (EU) 2018/545):	
Date of receipt of the application (Article 2(4) of Commission Implementing Regulation (EU) 2018/545):	
Date for acknowledgement of complete application:	
Date for submission of missing information by the applicant in case of incomplete application:	
Authorising entity:	
Concerned NSAs for the area of use (when applicable):	
Type of application:	
Vehicle type authorisation:	
Vehicle type variants (when applicable):	
Vehicle type versions (when applicable):	
Vehicle authorisation for placing on the market:	
Single vehicle:	
Series of vehicles:	
Authorisation case(s) as specified in Article 14 of Commission Implementing Regulation (EU) 2018/545:	
Combined application for new authorisation and extended area of use as specified in Article 14(3)(a) of Commission Implementing Regulation (EU) 2018/545:	
Combined application for first authorisation and authorisation in conformity with type as specified in Article 14(3)(b) of Commission Implementing Regulation (EU) 2018/545:	
2. APPLICANT	
Legal denomination:	
Applicant name:	

3. ASSESSMENT	
Statement concerning the result of the assessment for the concerned area of use (negative or positive result):	
Conditions for use and other restrictions (when applicable):	
Summary of the assessments performed:	
Report from the issues log for the concerned area of use:	Annex 1
Filled in checklist giving evidence for assessment of aspects specified in Annex III of Commission Implementing Regulation (EU) 2018/545:	Annex 2
Record of check for any relevant information recorded pursuant to Article 8(2) of Commission Implementing Regulation (EU) 2018/545:	
4. ANNEXES	
Annex 1	Report from the issues log for the concerned area of use
Annex 2	Filled in checklist giving evidence for assessment of the aspects specified in Annex III of Commission Implementing Regulation (EU) 2018/545
Annex 3	
Annex 4	
Annex 5	
Annex 6	
Annex 7	
Date:	
Authorised signatory of the NSA for the area of use <i>Area of use</i>	

Annex XI Model template for the assessment file for the conclusion of the assessment of the application as specified in Article 45(4) of Commission Implementing Regulation (EU) 2018/545

ASSESSMENT FILE FOR THE CONCLUSION OF THE ASSESSMENT OF THE APPLICATION AS SPECIFIED IN ARTICLE 45(4) OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/545	
<p>The authorising entity’s conclusion of the assessment of the application for a vehicle type authorisation and / or vehicle authorisation for placing on the market in conformity with Directive (EU) 2016/797 and Commission Implementing Regulation (EU) 2018/545</p>	
<p>1. APPLICATION INFORMATION</p>	
Application ID:	
Reference to pre-engagement baseline (when applicable):	
Date of acknowledgement of application (Article 33 of Commission Implementing Regulation (EU) 2018/545):	
Date of receipt of the application (Article 2(4) of Commission Implementing Regulation (EU) 2018/545):	
Date for acknowledgement of complete application:	
Date for submission of missing information by the applicant in case of incomplete application:	
Authorising entity:	
Concerned NSAs for the area of use (when applicable):	
Type of application:	
Vehicle type authorisation:	
Vehicle type variants (when applicable):	
Vehicle type versions (when applicable):	
Vehicle authorisation for placing on the market:	
Single vehicle:	
Series of vehicles:	
Authorisation case(s) as specified in Article 14 of Commission Implementing Regulation (EU) 2018/545:	
Combined application for new authorisation and extended area of use as specified in Article 14(3)(a) of Commission Implementing Regulation (EU) 2018/545:	
Combined application for first authorisation and authorisation in conformity with type as specified in Article 14(3)(b) of Commission Implementing Regulation (EU) 2018/545:	
<p>2. APPLICANT</p>	
Legal denomination:	
Applicant name:	

3. CHECK OF THE PROCESS FOR THE ASSESSMENT OF THE APPLICATION AS SPECIFIED IN ARTICLE 45(1) OF COMMISSION IMPLEMENTING REGULATION .../...

The different stages of the process for the assessment of the application have been correctly applied:	
There is sufficient evidence to show that all relevant aspects of the application have been assessed:	
Written responses to type 3 and 4 issues and requests for supplementary information have been received from the applicant:	
Type 3 and 4 issues were all resolved or where not resolved, together with clearly documented reasons:	
The assessments and decisions taken are documented, fair and consistent:	
The conclusions reached are based on the assessment files and reflect the assessment as a whole:	

4. DOCUMENTED REASONS FOR THE CONCLUSION

Confirmation of the correct application of Article 45(1) of Commission Implementing Regulation (EU) 2018/545, accompanied by any comments:	
Conclusion that the process for the assessment of the application has not been correctly applied, including clear and specific reasons for reaching that conclusion:	

5. ANNEXES

Annex 1	
Annex 2	
Annex 3	

Date:

Authorised signatory of the authorising entity
 EU Agency for Railways / National Safety Authority

Annex XII Model template for the decision for the authorisation or the refusal of the application as specified in Article 46 of Commission Implementing Regulation (EU) 2018/545

THE DECISION FOR THE AUTHORISATION OR THE REFUSAL OF THE APPLICATION AS SPECIFIED IN ARTICLE 46 OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/545	
<p>The authorising entity’s decision for the authorisation or the refusal of the application for a vehicle type authorisation and / or vehicle authorisation for placing on the market in conformity with Directive (EU) 2016/797 and Commission Implementing Regulation (EU) 2018/545</p>	
1. APPLICATION INFORMATION	
Application ID:	
Date of acknowledgement of application (Article 33 of Commission Implementing Regulation (EU) 2018/545):	
Date of receipt of the application (Article 2(4) of Commission Implementing Regulation (EU) 2018/545):	
Date for acknowledgement of complete application:	
Date for submission of missing information by the applicant in case of incomplete application:	
Date for the completion of the assessment:	
Authorising entity:	
Concerned NSAs for the area of use (when applicable):	
Type of application:	
Vehicle type authorisation:	
Vehicle type variants (when applicable):	
Vehicle type versions (when applicable):	
Vehicle authorisation for placing on the market:	
Single vehicle:	
Series of vehicles:	
Authorisation case(s) as specified in Article 14 of Commission Implementing Regulation (EU) 2018/545:	
Combined application for new authorisation and extended area of use as specified in Article 14(3)(a) of Commission Implementing Regulation (EU) 2018/545:	
Combined application for first authorisation and authorisation in conformity with type as specified in Article 14(3)(b) of Commission Implementing Regulation (EU) 2018/545:	
2. APPLICANT	
Legal denomination:	
Applicant name:	

3. DECISION FOR THE AUTHORISATION OR THE REFUSAL OF THE APPLICATION AS SPECIFIED IN ARTICLE 46 OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/545	
Documented reasons for the decision as referred to in Article 45(5) of Commission Implementing Regulation (EU) 2018/545:	Annex 1
The assessment of the aspects listed in Annex II and where applicable Annex III support a reasonable assurance that the applicant and the actors supporting the applicant have fulfilled their responsibilities to the extent required, in accordance with Article 38 of Commission Implementing Regulation (EU) 2018/545?:	
Any conditions for use of the vehicle and other restrictions:	
Statement concerning the reasons for the decision:	
The possibility and means of appealing the decision and the relevant time limits:	Annex 2
4. CONCLUSION	
Decision to issue the authorisation:	
Decision to refuse the application:	
5. ANNEXES	
Annex 1	The assessment file for the conclusion of the assessment of the application as specified in Article 45(4) of Commission Implementing Regulation (EU) 2018/545
Annex 2	Appeal process
Annex 3	
Date:	
Authorised signatory of the authorising entity EU Agency for Railways / National Safety Authority	

Annex XIII List of content for the notification as specified in Article 16(4) of Commission Implementing Regulation (EU) 2018/545

(R) means recommended information to be submitted by the entity managing the change.

(O) means other information that can still be submitted by the entity managing the change.

(2) Type of notification (R):

- (a) Single vehicle; or
- (b) Series of vehicles

(3) Area of use (R):

- (a) Member States
- (b) Networks (per Member State)
- (c) Stations with similar network characteristics in neighbouring Member States when those stations are close to the border as specified in Article 21.8 of Directive (EU) 2016/797 (when applicable)
- (d) Whole EU network

(4) Authorising entity to be notified (R):

- (a) The Agency; or
- (b) The national safety authority of the Member State (only applicable in case of an area of use limited to one Member State and requested by the applicant as specified in Article 21(8) of Directive (EU) 2016/797)

(5) Information about the entity managing the change (R):

- (a) Legal denomination (R)
- (b) Name (R)
- (c) Acronym (O)
- (d) Complete postal address (R)
- (e) Phone (R)
- (f) Fax (O)
- (g) E-mail (R)
- (h) Website (O)
- (i) VAT number (O)
- (j) Other relevant information (O)

(6) Contact person information (R):

- (a) First name (R)
- (b) Surname (R)
- (c) Title or function (R)
- (d) Complete postal address (R)
- (e) Phone (R)
- (f) Fax (O)
- (g) E-mail (R)
- (h) Languages to be used: (R)

(7) Current vehicle type authorisation holder (when applicable) (R):

- (a) Legal denomination (R)
- (b) Type authorisation holder's name (R)
- (c) Acronym (O)
- (d) Complete postal address (R)
- (e) Phone (R)
- (f) Fax (O)
- (g) E-mail (R)
- (h) Website (O)
- (i) VAT number (O)
- (j) Other relevant information (O)

(8) Assessment bodies information (R):

- (a) Notified body(ies):
 - (1) Legal denomination (R)
 - (2) Notified body name (R)
 - (3) Notified body ID number (R)
 - (4) Acronym (O)
 - (5) Complete postal address (R)
 - (6) Phone (R)
 - (7) Fax (O)
 - (8) E-mail (R)
 - (9) Website (O)
 - (10) VAT number (O)
 - (11) Other relevant information (O)
- (b) Designated body(ies):
 - (1) Legal denomination (R)
 - (2) Designated body name (R)
 - (3) Acronym (O)
 - (4) Complete postal address (R)
 - (5) Phone (R)
 - (6) Fax (O)
 - (7) E-mail (R)
 - (8) Website (O)
 - (9) VAT number (O)
 - (10) Other relevant information (O)
- (c) Assessment body(CSM RA):
 - (1) Legal denomination (R)
 - (2) Assessment body (CSM RA) name (R)
 - (3) Acronym (O)
 - (4) Complete postal address (R)
 - (5) Phone (R)
 - (6) Fax (O)
 - (7) E-mail (R)
 - (8) Website (O)
 - (9) VAT number (O)
 - (10) Other relevant information (O)

(9) Description of the vehicle type (when applicable; *to be specified according to decision 2011/665/EU Annex II) (R):

- (a) Type ID*:
- (b) Vehicle type version (when applicable):
- (c) Vehicle type variant (when applicable):
- (d) Date of record in ERATV*:
- (e) Type name*
- (f) Alternative type name* (when applicable)
- (g) Category*
- (h) Subcategory*

(10) Information on the vehicle(s) (to be specified according to decision 2007/756/EU) (R)

- (a) EVN number(s)

(11) Description of the changes as compared to the authorised vehicle and vehicle type (R)

(12) Conditions for use of the vehicle and other restrictions (to be specified according to decision 2011/665/EU Annex II) (R):

- (a) Coded restrictions
- (b) Non-coded restrictions

(13) Applicable rules (R):

- (a) TSIs, including the legal reference in the Official Journal of the European Union
- (b) Specific TSIs clauses for an area of use covering the whole EU network (when applicable)
- (c) Specification of the selection of requirements from a newer version of a TSI as compared to the TSI applicable for the assessment (including withdrawn requirements) (when applicable)
- (d) National rules (when applicable)
- (e) Non-applications of TSIs according to the provisions of Article 7 of Directive (EU) 2016/797 (when applicable)

(14) Confirmation and signature by the entity managing the change (R)**(15) Annexes (R):**

- 14.1 The supporting evidence for the requirements capture in accordance with Article 13(1) of Commission Implementing Regulation (EU) 2018/545.

If the entity managing the change uses the methodology set out in Annex I of Regulation (EU) 402/2013, the supporting evidence consists of the declaration by the proposer (entity managing the change) referred to in Article 16 of Regulation (EU) 402/2013 and an assessment report referred to in Article 15 of Regulation (EU) 402/2013. If another methodology is used, the evidence required is that necessary to demonstrate that it provides the same level of assurance as the methodology set out in Annex I of Regulation (EU) 402/2013.

- 14.2 Mapping table indicating where the information needed for the aspects to be assessed according to Annex XIV can be found.
- 14.3 EC Declaration(s) of Verification for the mobile subsystem(s), including accompanying technical file(s) (Article 15 Directive (EU) 2016/797).
- 14.4 The file accompanying the application and the decision from the previous authorisation or when applicable the reference to the decision issued according to Article 46 and to the full accompanying file for the decision archived in the one-stop shop.
- 14.5 Specification of and where applicable a description of the methodology used for the requirements capture.
- 14.6 Declaration by the entity managing the change that the criteria set-up in article 21(12) of Directive (EU) 2016/797 are not triggered and that the categorisation by the entity managing the change pursuant to articles 15(1)(b) or 15(1)(c) of Commission Implementing Regulation (EU) 2018/545 is correct.
- 14.7 Evidence that the criteria set-up in article 21(12) are not triggered and that the categorisation by the entity managing the change pursuant to articles 15(1)(b) or 15(1)(c) of Commission Implementing Regulation (EU) 2018/545 is correct.
- 14.8 The relevant decisions for non-application of TSIs according to Article 7 of Directive (EU) 2016/797 (when applicable).
- 14.9 When not fully covered by TSIs and/or national rules, the documentary evidence of the technical compatibility of the vehicle with the network in the area of use.
- 14.10 Maintenance & operation documentation (including rescue), when not included in point 14.3.

Further guidance can be found in the Annex I (guidance to Annex I “Content of the application” of the Commission Implementing Regulation (EU) 2018/545).

Annex XIV Aspects to assess for the notification as specified in Article 16(4) of Commission Implementing Regulation (EU) 2018/545

1. The TSIs and other applicable Union law identified by the entity managing the change are correct.
2. Selected conformity assessment bodies have the proper accreditation or recognition as applicable.
3. Non-applications of TSIs according to the provisions of Article 7 of Directive (EU) 2016/797:
 - 3.1. Validity (time and area of use);
 - 3.2. Applicable to the vehicle(s); and
 - 3.3. Consistent with the identified and applied rules.
4. Methodology for the requirements capture
 - 4.1. Is the applied methodology used for the requirements capture fit for purpose concerning the following aspects:
 - (a) Has a standardised/accepted methodology been used?; and
 - (b) Is the method intended for and suitable for the essential requirements it covers?
 - 4.2. When the methodology applied is not, the following aspects shall be checked to evaluate if they are sufficiently considered and covered by the methodology:
 - (a) Degree of independent assessment applied.
 - (b) System definition.
 - (c) Hazard identification and classification.
 - (d) Risk acceptance principles.
 - (e) Risk evaluation.
 - (f) Requirements established.
 - (g) Demonstration of compliance with the requirements.
 - (h) Hazard management (log).
5. Sufficient evidence from the methodology used for the requirements capture:
 - 5.1. When the risk management process set out in Annex I of Regulation (EU) 402/2013 has been used as the methodology for requirements capture the following shall be checked:
 - (a) CSM on risk assessment, declaration by the proposer (entity managing the change; Article 16 Regulation (EU) 402/2013) is signed by the proposer and supports that all identified hazards and associated risks are controlled to an acceptable level.
 - (b) CSM on risk assessment, assessment report (Article 15 Regulation (EU) 402/2013) supports the declaration by the proposer (entity managing the change) for the specified scope according to Article 13.
 - 5.2. When another methodology than the risk management process set out in Annex I of Regulation (EU) 402/2013, has been used as the methodology for requirements capture the following shall be checked:
 - (a) System definition is complete and consistent with the design of the vehicle?
 - (b) Hazard identification and classification is consistent and plausible?
 - (c) All risks have been properly managed and mitigated?
 - (d) Requirements derived from the risk management are properly traced to the risk and to the evidence of compliance with the requirement?
 - (e) Structured and consistent management of the hazards throughout the process?
 - (f) Is there a positive opinion from the independent assessment (where applicable)?
6. EC Declarations of Verification and EC certificates (Article 15 Directive (EU) 2016/797), check:
 - 6.1. Signatures.
 - 6.2. Validity.
 - 6.3. Scope.
 - 6.4. Conditions for use and other restrictions, non-compliances.

- 6.5. Non-application of TSIs (when applicable).
- 6.6. All applicable legislation is covered, including other non-railway related legislation.
- 6.7. Interoperability constituents (validity, scope, conditions for use of the vehicle and other restrictions):
 - (a) EC certificates of conformity.
 - (b) EC certificates of suitability of use.
7. Reports from Conformity assessment bodies (Article 15 Directive (EU) 2016/797), check:
 - 7.1. Consistency with EC Declarations of Verification and EC certificates.
 - 7.2. All applicable rules are covered.
 - 7.3. Deviations and non-conformities (when applicable) are identified and match the non-application requests.
 - 7.4. Combination of modules used is allowed.
 - 7.5. Conditions for use and other restrictions are properly identified and are consistent with the conditions in the notification.
 - 7.6. The supporting evidences used by the conformity assessment bodies are matching the applicable assessment phases described in TSIs (design review, type test, etc.).
8. Check of the analysis of the notification concerning the parameters related to the national rules by the NSAs for the area of use:
 - 8.1. The area of use for the concerned Member State is correctly specified.
 - 8.2. The national rules and requirements for the concerned area of use identified by the entity managing the change are correct.
 - 8.3. Selected conformity assessment bodies have the proper accreditation or recognition as applicable.
 - 8.4. Sufficient evidence from the methodology used for the requirements capture only for the national rules for the concerned area of use (see point 5.2).
 - 8.5. EC Declaration(s) of Verification and Certificates for the national rules for the concerned area of use (see point 6).
 - 8.6. Reports from conformity assessment bodies related to the the national rules for the concerned area of use (see point 7).
 - 8.7. Conditions for use and other restrictions (see point 11).
 - 8.8. Consistency of the changes with the evidence of the application of the methodology for requirements capture, the declaration by the entity managing the change concerning the criteria in article 21(12) of Directive (EU) 2016/797 and the evidence of the correct categorisation of the change (see point 12).
9. Validity of the original vehicle authorisation and vehicle type authorisation.
10. Original vehicle authorisation and vehicle type authorisation is valid for the concerned area of use.
11. The conditions for use of the vehicle and other restrictions stated in the notification are compatible with the changes introduced in the vehicle, the existing conditions for use and other restrictions, the conditions for use and other restrictions described in the EC declaration(s) of verification and EC certificate(s), and the evidence of the requirements capture.
12. The changes as compared to the authorised vehicle and vehicle type are sufficiently described and are consistent with:
 - 12.1. The evidence of the application of the methodology for requirements capture.
 - 12.2. The declaration by the entity managing the change that the criteria set-up in article 21(12) of Directive (EU) 2016/797 are not triggered and that the categorisation by the entity managing the change pursuant to articles 15(1)(b) or 15(1)(c) of Commission Implementing Regulation (EU) 2018/545 is correct.

- 12.3. The evidence that the criteria set-up in article 21(12) of Directive (EU) 2016/797 are not triggered and that the categorisation by the entity managing the change pursuant to articles 15(1)(b) or 15(1)(c) of Commission Implementing Regulation (EU) 2018/545 is correct.
13. The entity managing the change is not the holder of the vehicle type authorisation.
14. The categorisation pursuant to articles 15(1)(b) or 15(1)(c) made by the entity managing the change is correct (the change does not trigger the criteria in article 21(12) of Directive (EU) 2016/797 and therefore does not require a new authorisation, see Annex XVIII flowchart for Substage 1.1).

Annex XV Model template for submitting the notification as specified in Article 16(4) of Commission Implementing Regulation (EU) 2018/545

NOTIFICATION OF CHANGES AS SPECIFIED IN ARTICLE 16(4) OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/545	
Notification of changes to an already authorised vehicle as specified in Article 16(4) of Commission Implementing Regulation (EU) 2018/545.	
(R) means recommended information to be submitted by the entity managing the change. (O) means other information that can still be submitted by the entity managing the change.	
1. NOTIFICATION INFORMATION	
Type of notification (R):	
Single vehicle	
Series of vehicles	
Area of use (R):	
Authorising entity to be notified (R):	
2. ENTITY MANAGING THE CHANGE	
Legal denomination (R):	
Name (R):	
Acronym (O):	
Complete postal address (R):	
Phone (R):	
Fax (O):	
E-mail (R):	
Website (O):	
VAT number (O):	
Other relevant information (O):	
Contact person:	
First name (R):	
Surname (R):	
Title or function (R):	
Complete postal address (R):	
Phone (R):	
Fax (O):	
E-mail (R):	
Languages to be used (R):	
3. CURRENT VEHICLE TYPE AUTHORISATION HOLDER (WHEN APPLICABLE)	
Legal denomination (R):	
Type authorisation holder's name (R):	
Acronym (O):	
Complete postal address (R):	

Phone (R):	
Fax (O):	
E-mail (R):	
Website (O):	
VAT number (O):	
Other relevant information (O):	
4. ASSESSMENT BODY(IES) (R):	
4.1 NOTIFIED BODY(IES):	
Legal denomination (R):	
Notified body name (R):	
Notified body ID number (R):	
Acronym (O):	
Complete postal address (R):	
Phone (R):	
Fax (O):	
E-mail (R):	
Website (O):	
VAT number (O):	
Other relevant information (O):	
4.2 DESIGNATED BODY(IES):	
Legal denomination (R):	
Designated body name (R):	
Acronym (O):	
Complete postal address (R):	
Phone (R):	
Fax (O):	
E-mail (R):	
Website (O):	
VAT number (O):	
Other relevant information (O):	
4.3 ASSESSMENT BODY(CSM RA):	
Legal denomination (R):	
Assessment body (CSM RA) name (R):	
Acronym (O):	
Complete postal address (R):	
Phone (R):	
Fax (O):	
E-mail (R):	
Website (O):	
VAT number (O):	

Other relevant information (O):	
5. NOTIFICATION FILE	
Description of the vehicle type (when applicable;*to be specified according to decision 2011/665/EU Annex II) (R):	
Type ID*:	
Vehicle type version (when applicable):	
Vehicle type variant (when applicable):	
Date of record in ERATV*:	
Type name*:	
Alternative type name* (when applicable):	
Category*:	
Subcategory*:	
Information on the vehicle(s) (to be specified according to decision 2007/756/) (R):	
EVN number(s):	
Description of the changes as compared to the authorised vehicle and vehicle type (R):	
Conditions for use of the vehicle and other restrictions (to be specified according to decision 2011/665/EU Annex II) (R):	
Coded restrictions:	
Non-coded restrictions:	
Applicable rules (R):	
TSIs, including the legal reference in the Official Journal of the European Union	
Specific TSIs clauses for an area of use covering the whole EU network (when applicable)	
Specification of the selection of requirements from a newer version of a TSI as compared to the TSI applicable for the assessment (including withdrawn requirements) (when applicable)	
National rules (when applicable)	
Non-applications of TSIs according to the provisions of Article 7 of Directive (EU) 2016/797 (when applicable)	
Annexes (R):	Annex 1 - 10
6. ANNEXES	
Annex 1	The supporting evidence for the requirements capture in accordance with Article 13(1) of Commission Implementing Regulation (EU) 2018/545
Annex 2	Mapping table indicating where the information needed for the aspects to be assessed according to Annex XIV can be found.

Annex 3	EC Declaration(s) of Verification for the mobile subsystem(s), including accompanying technical file(s) (Article 15 Directive (EU) 2016/797).
Annex 4	The file accompanying the application and the decision from the previous authorisation or when applicable the reference to the decision issued according to Article 46 and to the full accompanying file for the decision archived in the one-stop shop.
Annex 5	Specification of and where applicable a description of the methodology used for the requirements capture.
Annex 6	Declaration by the entity managing the change that the criteria set-up in article 21(12) of Directive (EU) 2016/797 are not triggered and that the categorisation by the entity managing the change pursuant to articles 15(1)(b) or 15(1)(c) of Commission Implementing Regulation (EU) 2018/545 is correct.
Annex 7	Evidence that the criteria set-up in article 21(12) are not triggered and that the categorisation by the entity managing the change pursuant to articles 15(1)(b) or 15(1)(c) of Commission Implementing Regulation (EU) 2018/545 is correct.
Annex 8	The relevant decisions for non-application of TSIs according to Article 7 of Directive (EU) 2016/797 (when applicable).
Annex 9	When not fully covered by TSIs and/or national rules, the documentary evidence of the technical compatibility of the vehicle with the network in the area of use.
Annex 10	Maintenance & operation documentation (including rescue), when not included in Annex 3.
Annex 11	
Annex 12	
Date:	
Authorised signatory of the entity managing the change	

Annex XVI Model template for the decision as specified in Article 16(4) of Commission Implementing Regulation (EU) 2018/545

THE REASONED DECISION FOR THE REQUEST FOR AN APPLICATION FOR AUTHORISATION FOLLOWING THE NOTIFICATION BY THE ENTITY MANAGING THE CHANGE AS SPECIFIED IN ARTICLE 16(4) OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/545	
1. NOTIFICATION INFORMATION	
Notification ID:	
Date of receipt of the notification:	
Authorising entity:	
Concerned NSAs for the area of use (when applicable):	
Type of notification:	
Single vehicle:	
Series of vehicles:	
Area of use:	
Description of the vehicle type (when applicable;*to be specified according to decision 2011/665/EU Annex II) (R):	
Type ID*:	
Vehicle type version (when applicable):	
Vehicle type variant (when applicable):	
Date of record in ERATV*:	
Type name*:	
Alternative type name* (when applicable):	
Category*:	
Subcategory*:	
Information on the vehicle(s) (to be specified according to decision 2007/756/) (R):	
EVN number(s):	
2. ENTITY MANAGING THE CHANGE	
Legal denomination:	
Applicant name:	
3. REASONED DECISION FOR THE THE REQUEST FOR AN APPLICATION FOR AUTHORISATION FOLLOWING THE NOTIFICATION BY THE ENTITY MANAGING THE CHANGE AS SPECIFIED IN ARTICLE 16(4) OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/545	
Documented reasons for the decision as referred to in Article 16(4) of Commission Implementing Regulation (EU) 2018/545:	Annex 1
The assessment of the aspects listed in Annex 1 support that the entity managing the change has submitted insufficiently substantiated information as specified in Article 16(4) of	

Commission Implementing Regulation (EU) 2018/545?:	
The assessment of the aspects listed in Annex 1 support that the entity managing the change has made a wrong categorisation as specified in Article 16(4) of Commission Implementing Regulation (EU) 2018/545?:	
Statement concerning the reasons for the decision:	
4. CONCLUSION	
Decision to request an application for authorisation:	
5. ANNEXES	
Annex 1	Documented reasons for the decision as referred to in Article 16(4) of Commission Implementing Regulation (EU) 2018/545:
Annex 2	
Annex 3	
Annex 4	
Annex 5	
Annex 6	
Annex 7	
Date:	
Authorised signatory of the authorising entity EU Agency for Railways / National Safety Authority	

Annex XVII Model template for submitting the application as specified in Article 31(1) of Commission Implementing Regulation (EU) 2018/545

APPLICATION AS SPECIFIED IN ARTICLE 31(1) OF COMMISSION IMPLEMENTING REGULATION (EU) 2018/545	
Application for vehicle type authorisation and/or vehicle authorisation for placing on the market as specified in Article 31(1) of Commission Implementing Regulation (EU) 2018/545	
(M) means mandatory information to be submitted by the applicant. (O) means optional information that may still be submitted by the applicant.	
1. APPLICATION INFORMATION	
Type of application (M):	
Vehicle type authorisation:	
Vehicle type variants (when applicable):	
Vehicle type versions (when applicable):	
Vehicle authorisation for placing on the market:	
Single vehicle:	
Series of vehicles:	
Authorisation case (as specified in Article 14(1) of Commission Implementing Regulation (EU) 2018/545 (M):	
Area of use (M):	
Issuing authority (M):	
Reference to pre-engagement baseline (O):	
Other relevant project information (O):	
2. APPLICANT	
Legal denomination (M):	
Name (M):	
Acronym (O):	
Complete postal address (M):	
Phone (M):	
Fax (O):	
E-mail (M):	
Website (O):	
VAT number (O):	
Other relevant information (O):	
Contact person:	
First name (M):	
Surname (M):	
Title or function (M):	
Complete postal address (M):	
Phone (M):	
Fax (O):	

E-mail (M):	
Languages to be used (M):	
3. CURRENT VEHICLE TYPE AUTHORISATION HOLDER (NOT APPLICABLE IN CASE OF FIRST AUTHORISATION)	
Legal denomination (M):	
Type authorisation holder's name (M):	
Acronym (O):	
Complete postal address (M):	
Phone (M):	
Fax (O):	
E-mail (M):	
Website (O):	
VAT number (O):	
Other relevant information (O):	
4. ASSESSMENT BODY(IES) (M):	
4.1 NOTIFIED BODY(IES):	
Legal denomination (M):	
Notified body name (M):	
Notified body ID number (M):	
Acronym (O):	
Complete postal address (M):	
Phone (M):	
Fax (O):	
E-mail (M):	
Website (O):	
VAT number (O):	
Other relevant information (O):	
4.2 DESIGNATED BODY(IES):	
Legal denomination (M):	
Designated body name (M):	
Acronym (O):	
Complete postal address (M):	
Phone (M):	
Fax (O):	
E-mail (M):	
Website (O):	
VAT number (O):	
Other relevant information (O):	
4.3 ASSESSMENT BODY (CSM RA) (NOT APPLICABLE FOR AUTHORISATION IN CONFORMITY WITH TYPE):	
Legal denomination (M):	

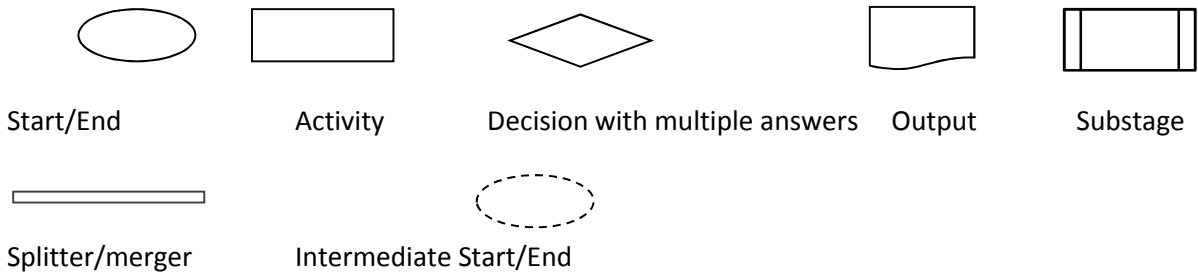
Assessment body (CSM RA) name (M):	
Acronym (O):	
Complete postal address (M):	
Phone (M):	
Fax (O):	
E-mail (M):	
Website (O):	
VAT number (O):	
Other relevant information (O):	
5. APPLICATION FILE	
Description of the vehicle type (when applicable;*to be specified according to decision 2011/665/EU Annex II) (M):	
Type ID*:	
Vehicle type version (when applicable):	
Vehicle type variant (when applicable):	
Date of record in ERATV* (not applicable for first authorisation):	
Type name*:	
Alternative type name* (when applicable):	
Category*:	
Subcategory*:	
Information on the vehicle(s) (to be specified according to decision 2007/756/) (M):	
EVN number(s) or pre-reserved vehicle numbers:	
Other specification of the vehicles when EVN numbers or pre-reserved numbers are not available:	
Reference to the existing vehicle type authorisation (not applicable in case of first authorisation) (M):	
Description of the changes as compared to the authorised vehicle type (only applicable in case of new authorisation) (M):	
Conditions for use of the vehicle and other restrictions (to be specified according to decision 2011/665/EU Annex II) (R):	
Coded restrictions:	
Non-coded restrictions:	
CCS additional functions (M):	
Applicable rules (M):	
TSIs, including the legal reference in the Official Journal of the European Union:	

Specific TSIs clauses for an area of use covering the whole EU network (when applicable):	
Specification of the selection of requirements from a newer version of a TSI as compared to the TSI applicable for the assessment (including withdrawn requirements) (when applicable):	
National rules (when applicable):	
Non-applications of TSIs according to the provisions of Article 7 of Directive (EU) 2016/797 (when applicable):	
Applicable rules for the extended area of use:	
Updated TSIs and/ or national rules (only applicable for renewed type authorisation):	
Annexes (M):	Annex -
6. ANNEXES	
Annex 1	
Annex 2	
Annex 3	
Annex 4	
Annex 5	
Annex 6	
Annex 7	
Annex 8	
Annex 9	
Annex 10	
Annex 11	
Annex 12	
Annex 13	
Date:	
Authorised signatory of the applicant	

Annex XVIII Flowcharts

How to read the flowcharts**Symbols**

Standard flowchart that describes the authorisation process, using 6 Unified Modelling Language symbols:

**Principles**

- › The symbols are linked with directed arrows.
- › It is indicated on the merger symbol if parallel arrows are considered as “And” or “Or”.
- › Splitter symbol is always considered as “And”.
- › The flowchart starts and ends with the same symbol.
- › An activity is an action that requires the use of a verb, e.g. Request, Provide, Modify.
- › A decision is often an answer to a question. The answer is often binary Yes/ No but may be also multiple alternatives.
- › An output is the result of an action and is often a document either paper based or electronic based.
- › Outputs are placed with the recipient.
- › The role indicated in the flowchart is to be understood as the role responsible for the activity. Other actors might be supporting but are not specified in the flowchart.
- › If there is a time frame defined in the legislation this is indicated where it starts in the activity/ decision/ output by a: (*).
- › The activities/ decisions/ outputs have been colour coded to indicate if it is:
 - Green = Recommended practice; and
 - Purple = Mandatory according to EU legislation.
- › References to legislation are placed next to the relevant activity/ decision/ output in a yellow box.
- › The following abbreviations are used for the legal references:
 - ID – Interoperability Directive (EU) 2016/797
 - IR – Commission Implementing Regulation (EU) 2018/545
 - AR – Commission Regulation (EU) 2016/796
 - IRD – Commission Implementing Regulation (EU) yyyy/nnn (on EC declaration of verification)
 - CSM – Commission Implementing Regulation (EU) 402/2013
 - REG – Commission Regulation (EU) 201/2011

List of flowcharts

Stage 1 – Preparation of the application

Stage 1 – Substage 1.1 – Identification of the relevant authorisation

Stage 1 – Substage 1.2 – Processing of the notification

Stage 2 – Pre-engagement

Stage 3 – Conformity assessment

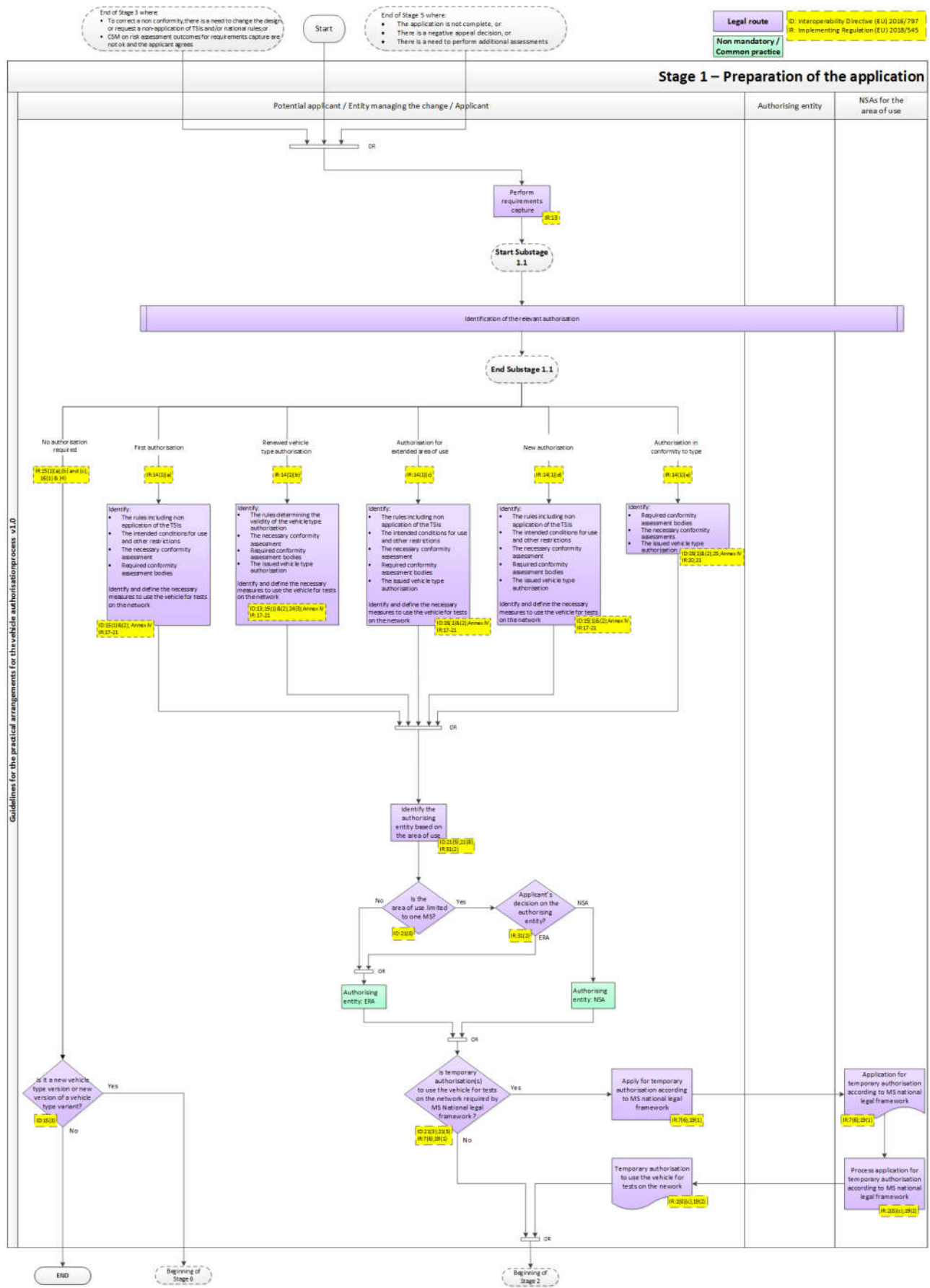
Stage 4 – Submitting the application

Stage 5 – Processing the application

Stage 5 – Substage 5.1 – Arbitration

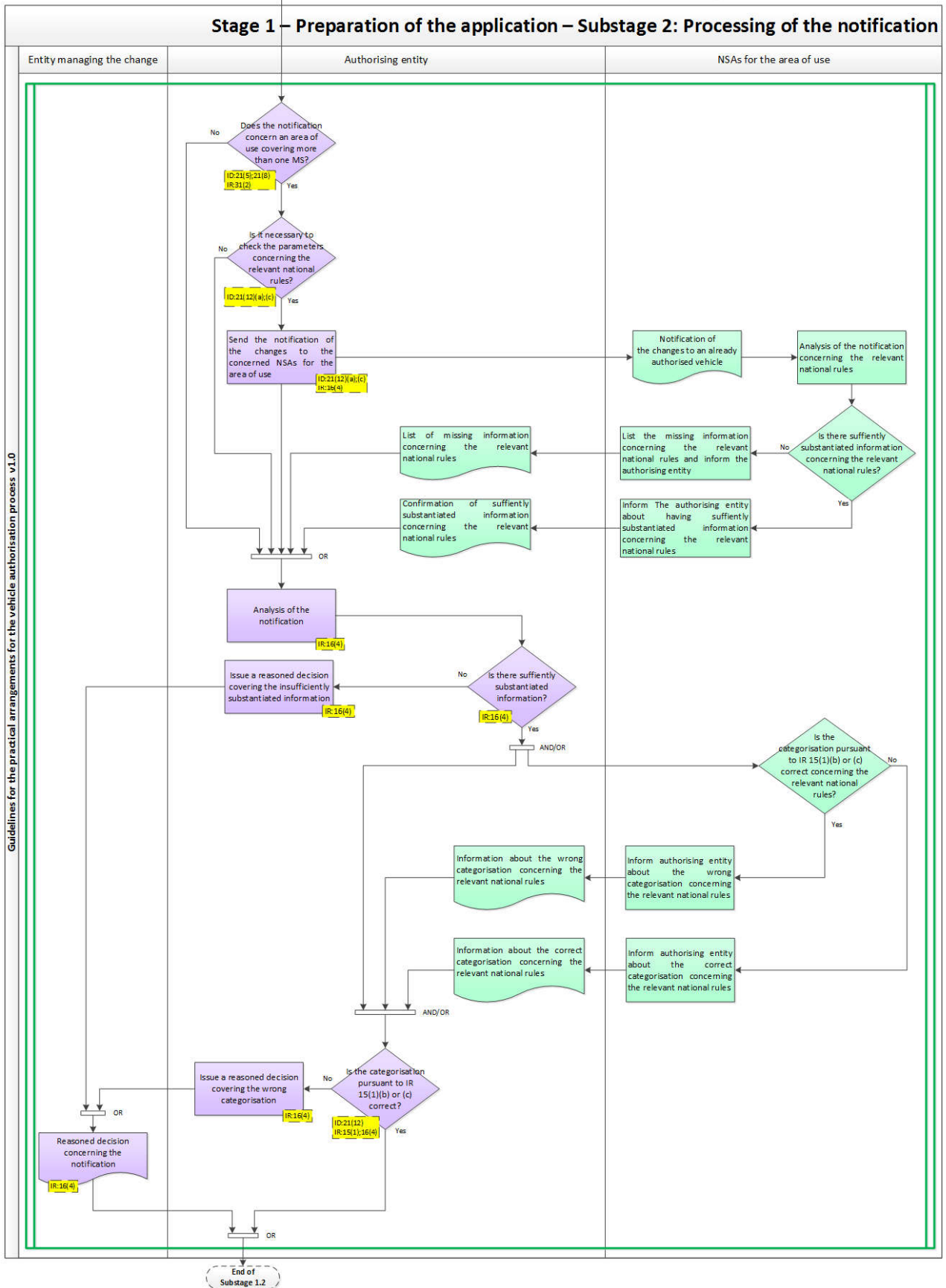
Stage 5 – Substage 5.2 – Review and appeal

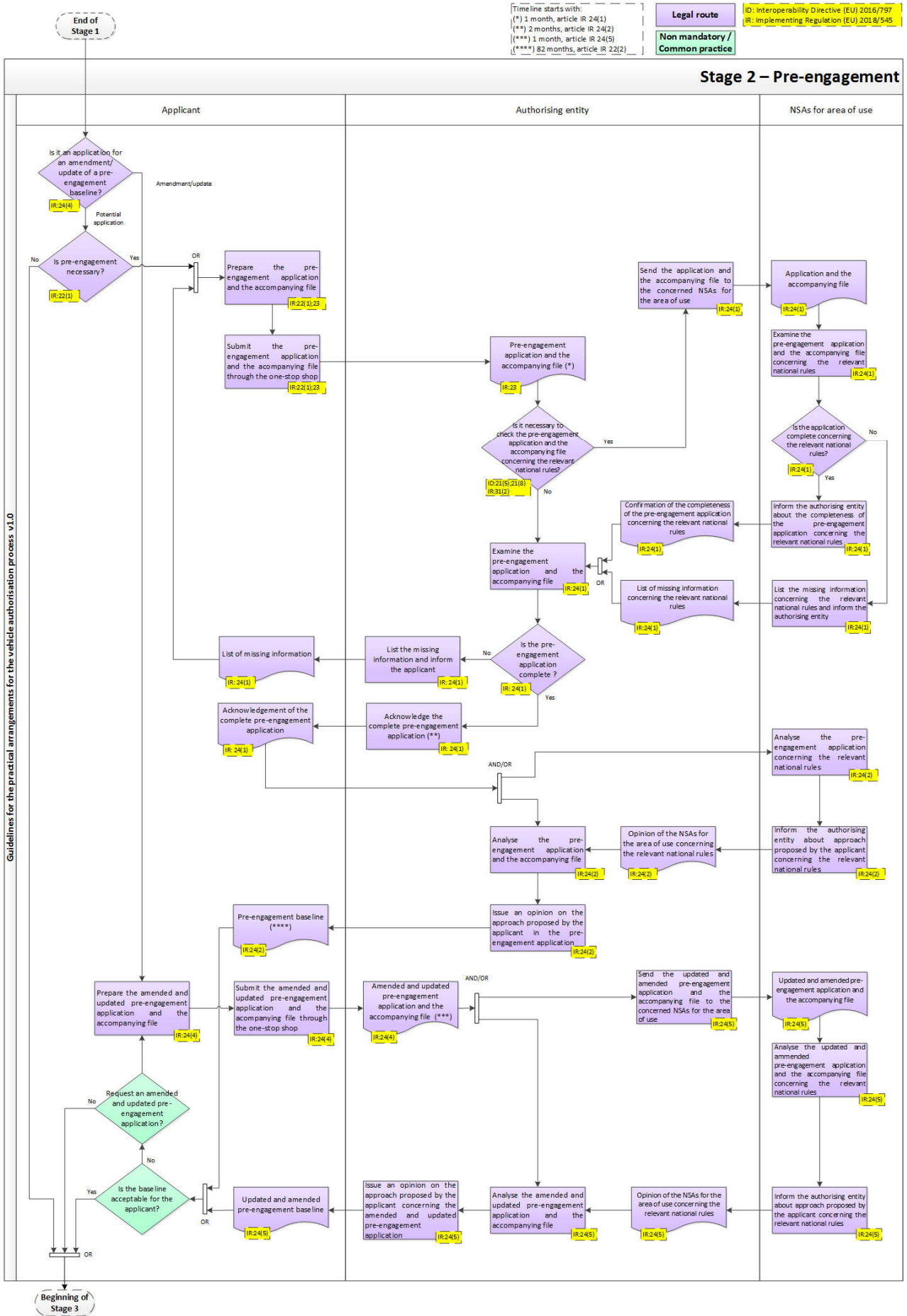
Stage 6 - Final documentation



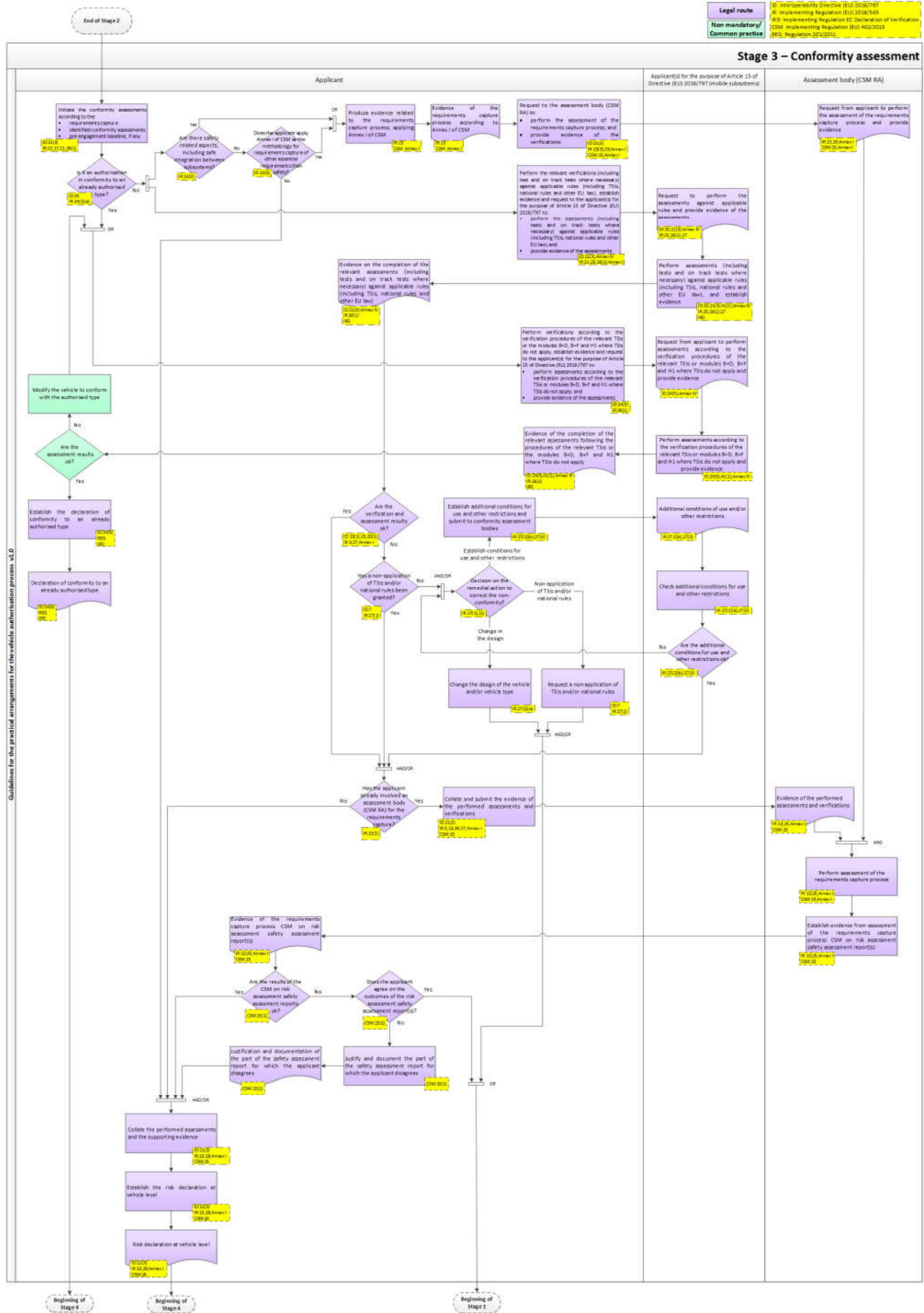
**Non mandatory/
Common practice** ID: Interoperability Directive (EU) 2016/797
IR: Implementing Regulation (EU) 2018/545

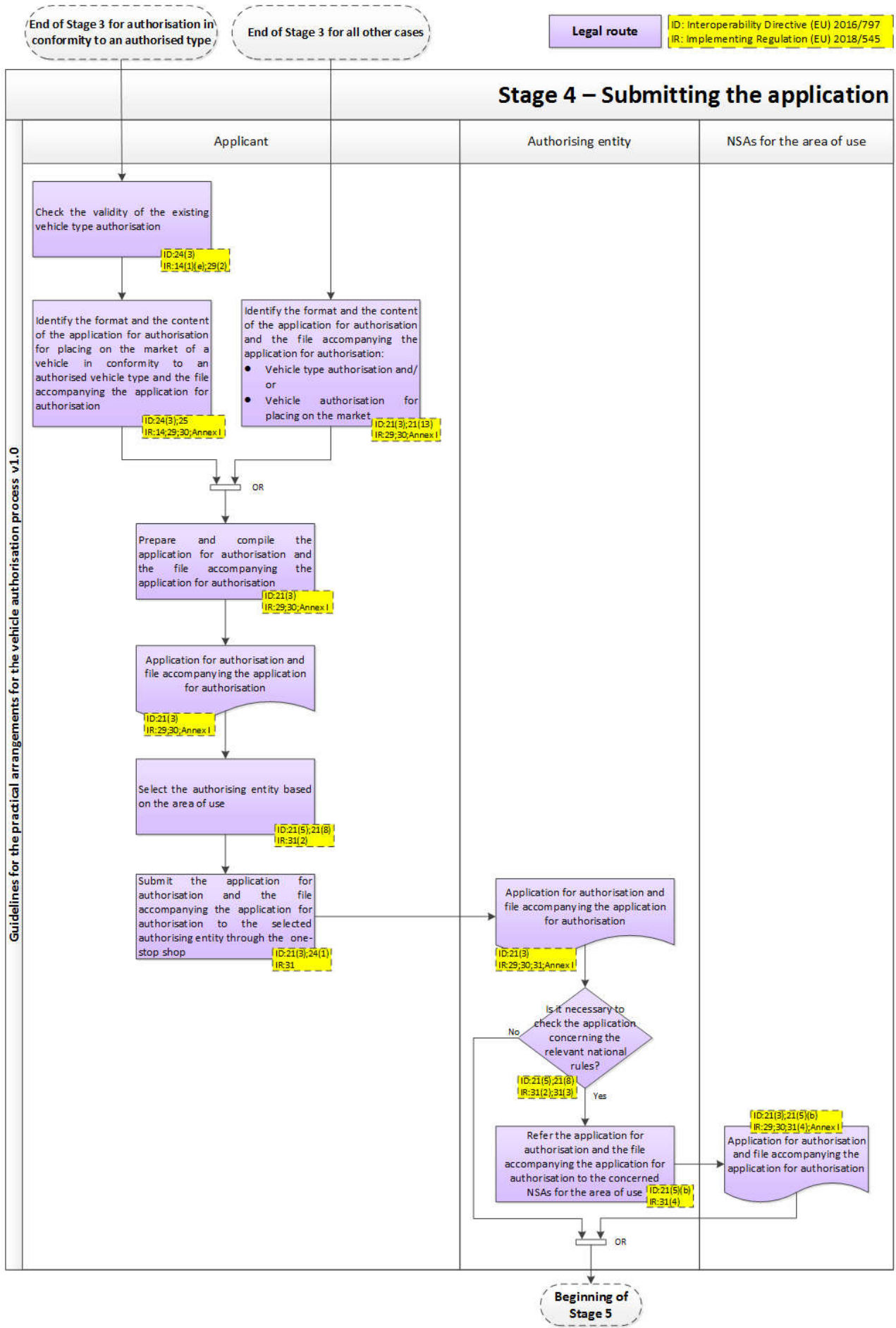
Legal route





Legal route	EU interoperability Directive (EU) 2016/797 EU implementing Regulation (EU) 2018/858 EU Implementing Regulation (EU) 402/2013 EU Regulation 2016/251
Non mandatory/ Common practice	

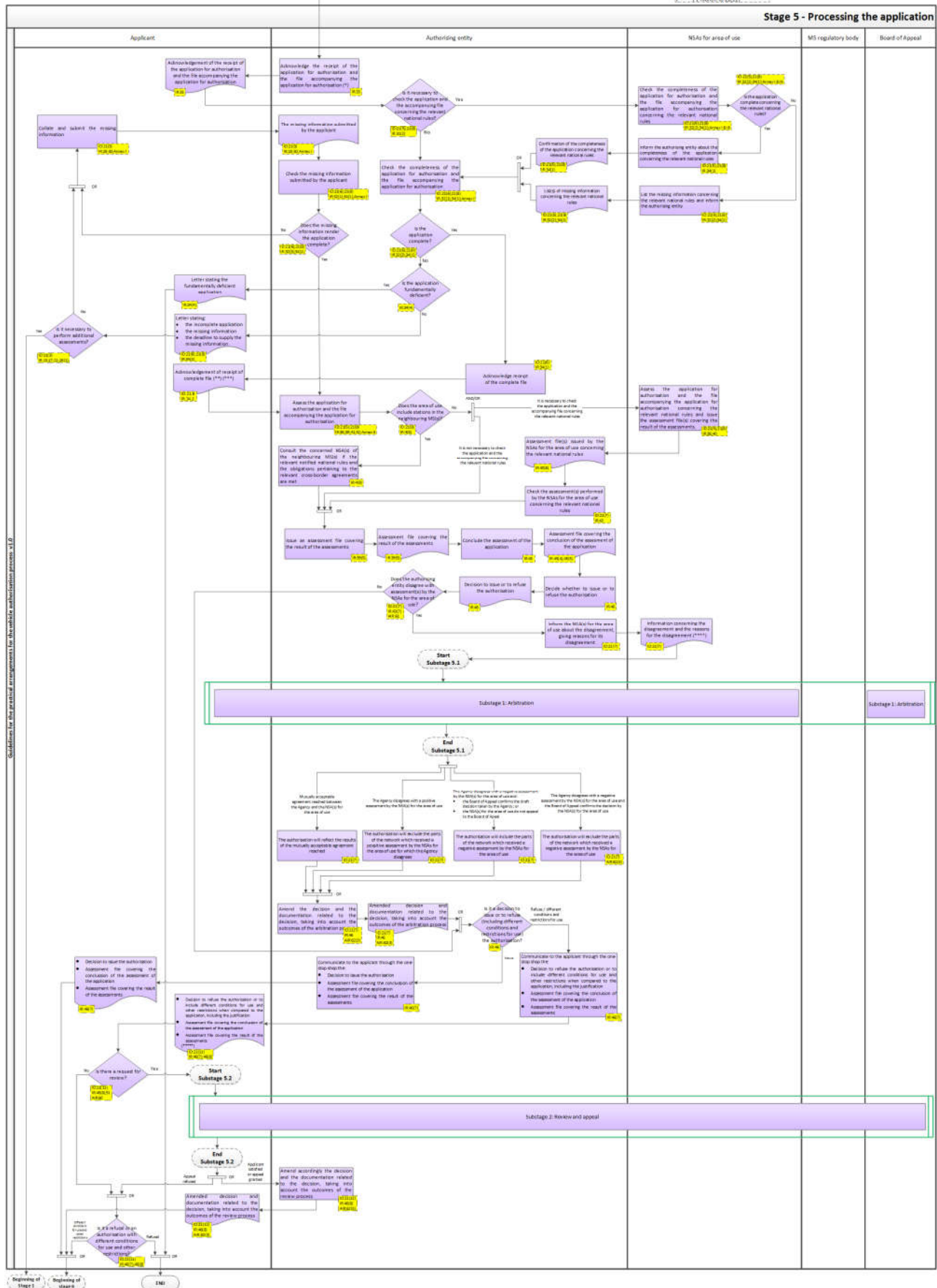


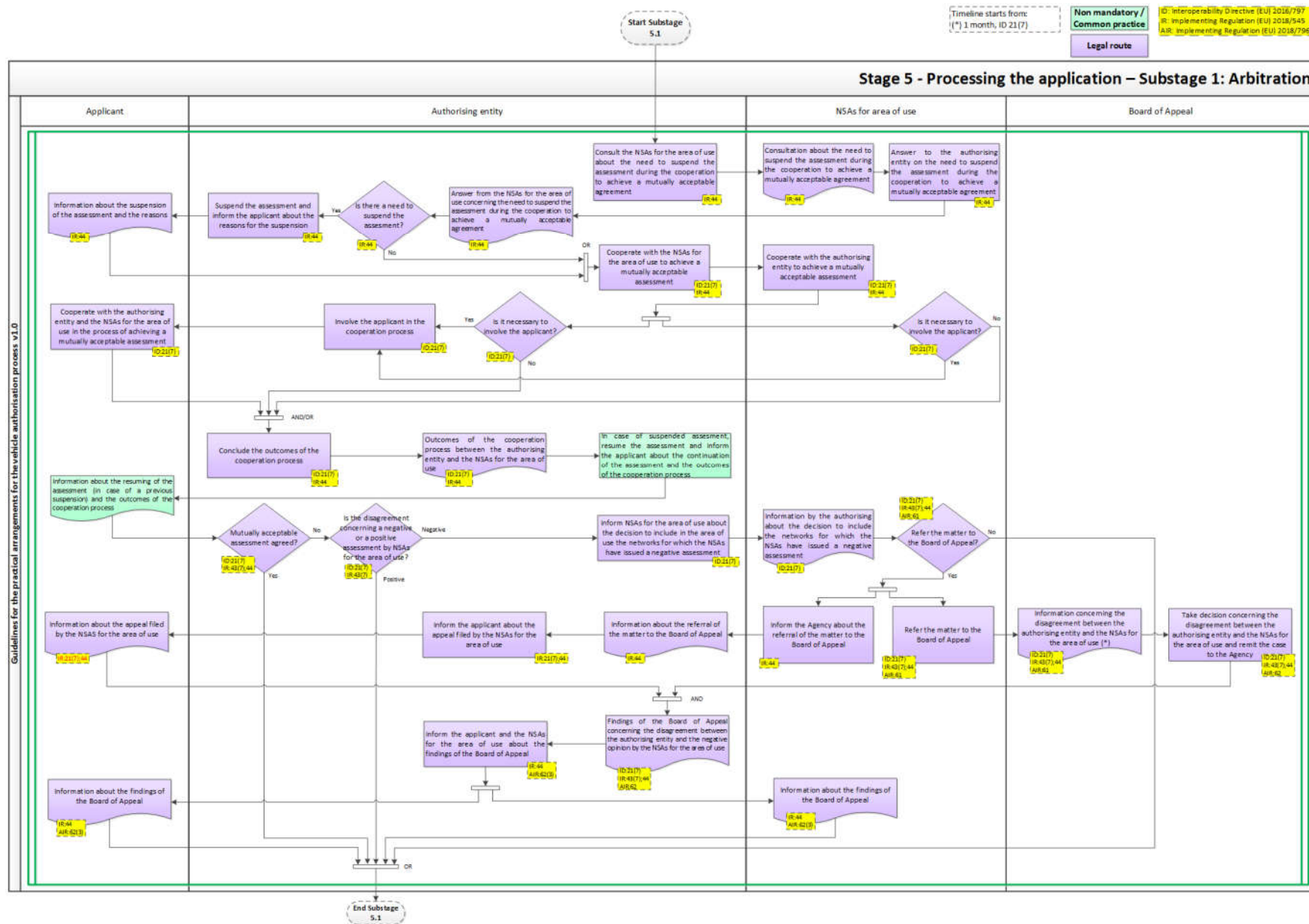


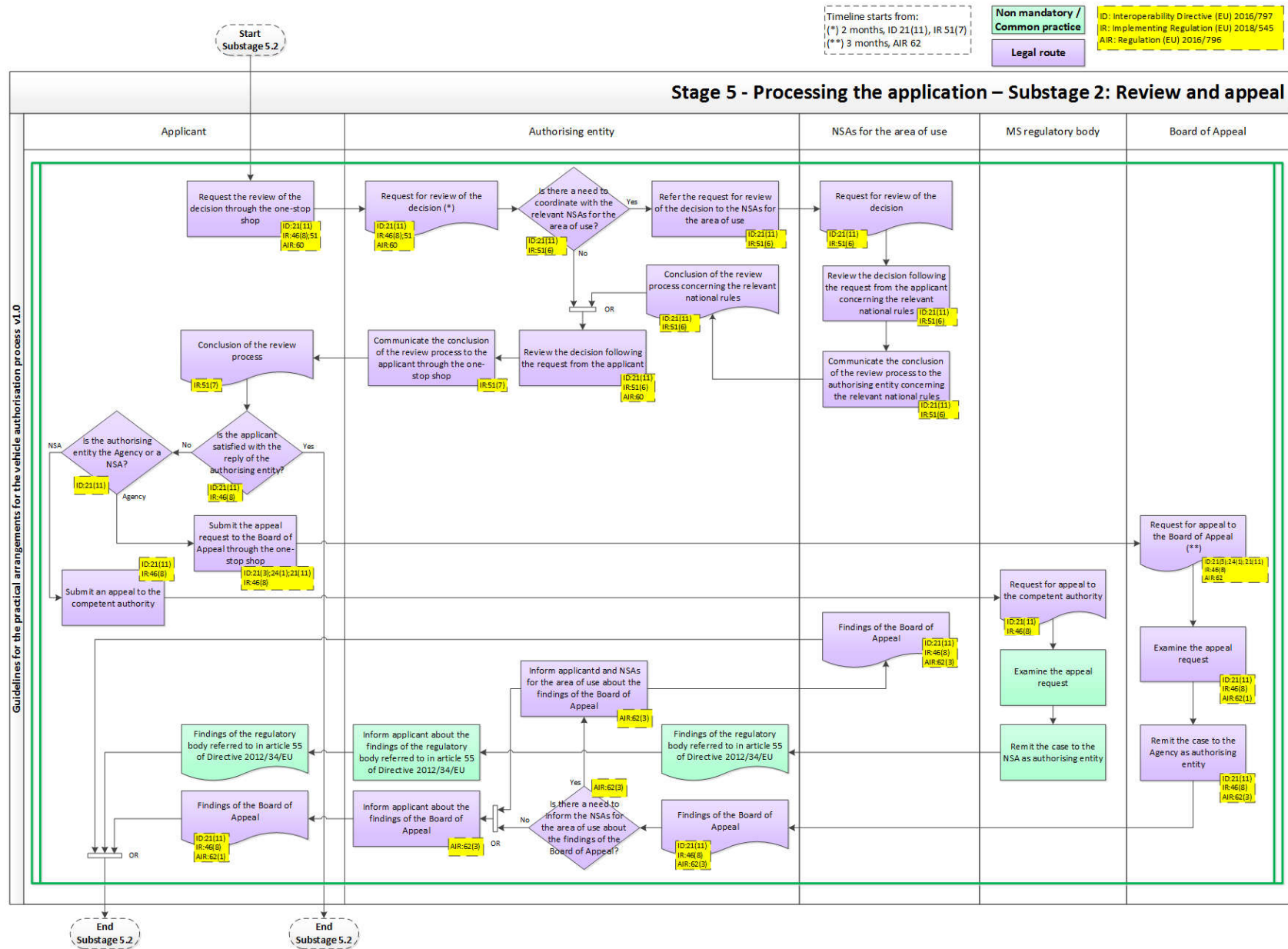
Timeline starts with:
 [**] 1 month, ID 21(06) & 21(0)(R 34(1))
 [***] 1 month, ID 21(06) & 21(0)(R 34(1))
 [****] 1 month, ID 21(07)
 [*****] 1 month, ID 21(11)

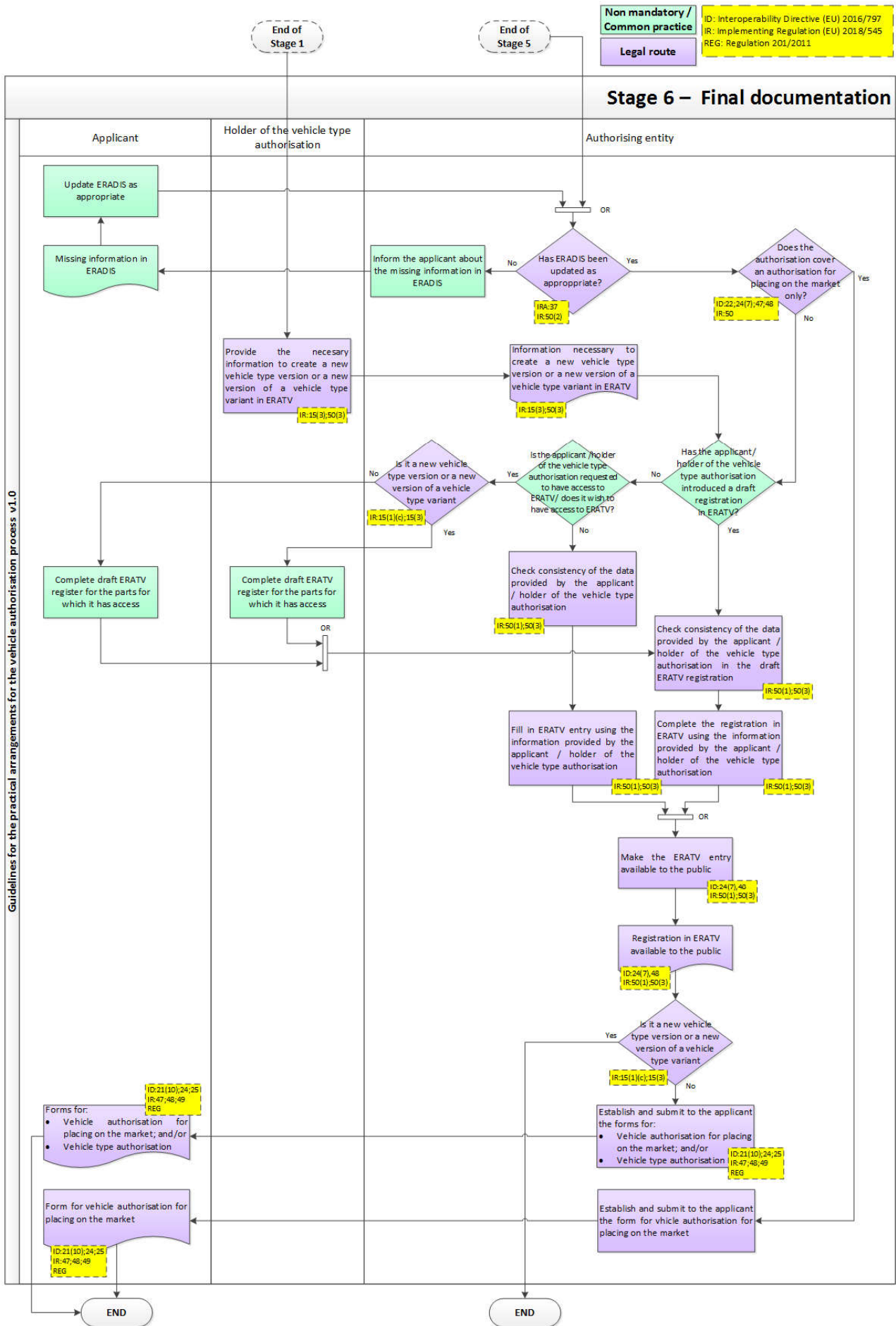
Non mandatory / Common practice
 [**] 1 month, ID 21(06) & 21(0)(R 34(1))
 [***] 1 month, ID 21(06) & 21(0)(R 34(1))
 [****] 1 month, ID 21(07)
 [*****] 1 month, ID 21(11)

Legal route









Annex XIX Comment sheet

Document Review – Comment Sheet

*Document commented: “Guidelines for the practical arrangements for the vehicle authorisation process”
v1.0 (ERA-PRG-005/02-361)*

<i>Requestor:</i>	The Agency
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	<i>Reviewer 1</i>	<i>Reviewer 2</i>	<i>Reviewer 3</i>	<i>Reviewer 4</i>	<i>Reviewer 5</i>
<i>Date:</i>					
<i>Name:</i>					
<i>Organisation:</i>					
<i>Email:</i>					

Document History

<i>Version</i>	<i>Date</i>	<i>Comments</i>
1.0		

Conventions:

<i>Type of Comment</i>		<i>Reply by requestor</i>	
<i>G</i>	General	<i>R</i>	Rejected
<i>M</i>	Mistake	<i>A</i>	Accepted
<i>U</i>	Understanding	<i>D</i>	Discussion necessary
<i>P</i>	Proposal	<i>NWC</i>	Noted without need to change

Review Comments <if necessary add extra lines in the table>

<i>N°</i>	<i>Reference (e.g.Art, §)</i>	<i>Type</i>	<i>Reviewer</i>	<i>Reviewer's Comments, Questions, Proposals</i>	<i>Reply</i>	<i>Proposal for the correction or justification for the rejection</i>
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
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