

COMMISSION IMPLEMENTING REGULATION (EU) 2018/545**of 4 April 2018****establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) The practical arrangements for the vehicle authorisation process referred to in Directive (EU) 2016/797 should reduce the complexity, length and cost of the vehicle authorisation process, provide uniform conditions for harmonising the vehicle type authorisation and/or vehicle authorisation for placing on the market in the Union and foster collaboration among all the parties involved in the vehicle authorisation process. In order to reduce length and cost of the vehicle authorisation process, the time frames should practically be kept as short as possible.
- (2) Taking into account the experience gained by national safety authorities ('NSAs') in the authorisation process and in the preparation of the cooperation agreements referred to in Article 21(14) of Directive (EU) 2016/797, early contact with the applicant in the form of coordination ('pre-engagement') is recognised as good practice to facilitate the development of the relationship between the parties involved in the vehicle authorisation process. Such pre-engagement should be offered before an application for a vehicle type authorisation and/or vehicle authorisation for placing on the market is submitted, with the aim of enabling the authorising entity and the concerned NSAs for the area of use to become familiar with the project. In order for the applicant to be aware of what to expect, that pre-engagement should clarify to the applicant the applicable rules, provide the applicant with the details of the vehicle authorisation process, including the process of decision-making, and verify that the applicant has received sufficient information. The applicant is responsible for ensuring that all the requirements are met when submitting its application for vehicle type authorisation and/or vehicle authorisation for placing on the market. In performing its duties, it is assisted by other entities such as conformity assessment bodies, suppliers and service providers.
- (3) With a view to providing economies of scale and reducing administrative burden, vehicle type authorisation should enable the applicant to produce a number of vehicles of the same design and facilitate their authorisation. The vehicle type identifies the design that will be applied to all vehicles corresponding to that type. Every new vehicle type should follow the process of authorisation and a new type should only be created if it is authorised.
- (4) The concepts of variant and version of a vehicle type should be introduced in order to provide the possibility of identifying options for configuration or changes during the life cycle of the vehicle within an existing type, the difference between variants and versions being that variants require an authorisation while versions do not.
- (5) In order to ensure that the vehicle type continues to meet the requirements over time and that any changes to the design that affects the basic design characteristics are reflected as new variants and/or versions of the vehicle type, the process of configuration management of the vehicle type, should be used. The entity responsible for the configuration management of the vehicle type is the applicant that received the vehicle type authorisation.
- (6) As far as vehicles are concerned, it is necessary to have a configuration management process limited to changes that are not managed through the configuration management process of an authorised vehicle type.
- (7) The European Union Agency for Railways (the 'Agency') should set up guidelines describing, and where necessary, explaining the requirements set out in this Regulation. The guidelines should be updated, published and made

⁽¹⁾ 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) (OJ L 138, 26.5.2016, p. 44).

available to the public free of charge. With the aim of harmonising the approach to the exchange and recording of information through the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796 of the European Parliament and of the Council ⁽¹⁾, the guidelines should also include model templates set up by the Agency in cooperation with the NSAs.

- (8) The Agency and the NSAs should implement internal arrangements or procedures to ensure that the requirements of the vehicle authorisation process are fulfilled.
- (9) Considering that return of experience is recognised as a good practise, the NSAs and the Agency should be encouraged to share any related relevant information. With a view to provide such service, the Agency should establish a protocol and procedures for the recording and exchange of information among the Agency and NSAs.
- (10) To avoid any duplication of assessment and to reduce the administrative burden and cost for the applicant, the Agency and the NSAs should take into account the cooperation agreements and multilateral agreements concluded pursuant to Article 21(14) and (15) of Directive (EU) 2016/797, where relevant.
- (11) The Agency and the NSAs should register all relevant information and the documented reasons for the decision in the one-stop shop, in order to justify the decisions at each stage of the vehicle authorisation process. If the Agency and the NSAs have their own information management systems for the purposes of the assessment, they should ensure that all relevant information is transferred to the one-stop shop for the same reasons. In order to facilitate the communication between the interested parties, the guidelines of the Agency and the NSAs should provide practical arrangements for those communications which are not relevant for the decision-making process and which therefore do not need to be submitted through the one-stop shop.
- (12) Where the intended area of use for the vehicle type is limited to a network or networks within one Member State, the authorisation is valid without extension of the area of use for vehicles travelling to stations in neighbouring Member States with similar network characteristics, when those stations are close to the border. In such a case, the applicant may submit their application for a vehicle type authorisation and/or vehicle authorisation for placing on the market to the Agency or the NSA. Where the Agency acts as the authorising entity it is to consult the relevant NSAs in accordance with Article 21(8) of Directive (EU) 2016/797 and take into account the relevant cross-border agreements.
- (13) Where the Agency acts as the authorising entity, the applicant should, without prejudice to the provisions of point 2.6 of Annex IV to Directive (EU) 2016/797, have the right to submit its application to the Agency in one of the official languages of the Union. During the course of the assessment, the NSAs should have the right to address documents pertaining to the assessment to the Agency in a language of its Member State, without any obligation to translate them.
- (14) The Agency and the NSAs should develop internal arrangements or procedures for managing the issuing of vehicle type authorisations and/or vehicle authorisations for placing on the market with a view to reducing the administrative burden and costs for the applicant. In that respect, the applicant should have the possibility to submit copies of documents in the application file. The original documents should be available for verification by the Agency and the NSAs following the issuing of the vehicle type authorisation and/or vehicle authorisation for placing on the market.
- (15) It is necessary to harmonise the categorisation of issues in the assessment process to ensure that the applicant understands the severity of any issues raised by the Agency or by a NSA. That categorisation is particularly important when several NSAs are involved in the process. In order to facilitate the vehicle authorisation process and to reduce administrative burden in cases where there are no applicable national rules, the Agency's consultation with the concerned NSAs for the area of use should be limited to the check of the correct specification of the area use for the Member State concerned. In cases where the technical specifications for interoperability ('TSIs') contain specific provisions, the area of use should be able to cover the whole Union network and the checks performed by the Agency should be sufficient.
- (16) Vehicles and vehicle types are to remain authorised in accordance with Article 54(2) of Directive (EU) 2016/797 without prejudice to Article 21(12) and 24(3) of that Directive. In the case of renewal or upgrading of those vehicles, the provisions of this Regulation are to apply in accordance with Article 21(12) of Directive (EU) 2016/797.

⁽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 (OJ L 138, 26.5.2016, p. 1).

- (17) According to Article 54(4) of Directive (EU) 2016/797, the new vehicle authorisation regime is to start from 16 June 2019. However, Member States have the possibility to notify the Agency and the Commission pursuant to Article 57(2) of that Directive that they have extended the transposition period and may in consequence continue to issue vehicle type authorisation and/or vehicle authorisation for placing on the market in accordance with Directive 2008/57/EC of the European Parliament and of the Council ⁽¹⁾ until 16 June 2020. Between 16 June 2019 and 15 June 2020, two different legal regimes where the authorising entities are different could coexist. It is therefore necessary to clarify how the new regime should apply in addition to the old one where the intended area of use includes one or more of those Member States.
- (18) Where a NSA recognises that it will not be able to issue a vehicle type authorisation/vehicle authorisation for placing in service in accordance with Directive 2008/57/EC before either 16 June 2019, or 16 June 2020 in respect of those Member States that have notified the Agency and the Commission in accordance with Article 57(2) of Directive (EU) 2016/797, the Agency, when acting as authorising entity, should accept the results of the assessment of the NSA in order to avoid any duplication of assessment and additional burden and any delay for the applicant.
- (19) In order to facilitate the placing on the market of the vehicles and to reduce administrative burdens, a vehicle type authorisation and/or vehicle authorisation for placing on the market issued by the Agency should be recognised as equivalent to vehicle type authorisation referred to Article 26 of Directive 2008/57/EC and vehicle authorisation for placing in service referred to in Articles 22 and 24 of Directive 2008/57/EC.
- (20) TSIs in accordance with Article 4(3)(f) of Directive (EU) 2016/797, as well as national rules, should foresee a gradual transition, in particular taking into account projects at an advanced stage of development as defined in Article 2(23) of Directive (EU) 2016/797.
- (21) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 21 of Council Directive 96/48/EC ⁽²⁾,

HAS ADOPTED THIS REGULATION:

CHAPTER 1

GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Regulation lays down requirements to be complied with by:
 - (a) the applicant, when submitting, through the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796 of the European Parliament and of the Council, an application for vehicle type authorisation and/or vehicle authorisation for placing on the market;
 - (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.

⁽¹⁾ 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 (OJ L 191, 18.7.2008, p. 1).

⁽²⁾ Council 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).

*Article 2***Definitions**

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

- (1) 'authorising entity' means the entity that issues the vehicle type authorisation and/or vehicle authorisation for placing on the market;
- (2) 'basic design characteristics' means the parameters that are used to identify the vehicle type as specified in the issued vehicle type authorisation and recorded in the European Register of Authorised Vehicle Types ('ERATV').
- (3) 'configuration management' means a systematic organisational, technical and administrative process put in place throughout the lifecycle of a vehicle and/or vehicle type to ensure that the consistency of the documentation and the traceability of the changes are established and maintained so that:
 - (a) requirements from relevant Union law and national rules are met;
 - (b) changes are controlled and documented either in the technical files or in the file accompanying the issued authorisation;
 - (c) information and data is kept current and accurate;
 - (d) relevant parties are informed of changes, as required;
- (4) 'date of receipt of the application' means:
 - (a) where the Agency acts as the authorising entity, the first working day common to the Agency and to the NSAs concerned with the intended area of use following the acknowledgement of receipt of the application;
 - (b) where a NSA acts as the authorising entity, the first working day in the Member State concerned following the acknowledgement of receipt of the application;
- (5) 'entity managing the change' means the holder of the vehicle type authorisation, the keeper or the entity entrusted by them.
- (6) 'holder of the vehicle type authorisation' means the natural or legal person that has applied for and received the vehicle type authorisation, or its legal successor;
- (7) 'justified doubt' means an issue classified as 'type 4' according to Article 41(1)(d), with a justification and supporting evidence, raised by the authorising entity and/or the NSAs for the area of use concerning the information provided by the applicant in its application;
- (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;
- (9) 'pre-engagement' means a procedural stage preceding the submission of an application for authorisation performed upon request of the applicant;
- (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;
- (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;

- (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;
- (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;
- (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;
- (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;
- (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;
- (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.

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.

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.

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.

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 time frame 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.

*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.

*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.

*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.

*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.

*Article 11***Vehicle authorisation process for tram-trains in 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.

*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 time frames;
- (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.

CHAPTER 2

PREPARATION OF THE APPLICATION

Article 13

Requirements capture

1. In accordance with the overall objective of managing and mitigating 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; and
- (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 Commission Implementing Regulation (EU) No 402/2013 ⁽¹⁾ 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.

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 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

⁽¹⁾ Commission 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).

(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 time frames 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.

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).

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.

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.

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.

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.

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.

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.

CHAPTER 3

PRE-ENGAGEMENT

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 time frame 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 time frame 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.

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.

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.

CHAPTER 4

CONFORMITY ASSESSMENT

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.

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.

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.

CHAPTER 5

SUBMITTING THE APPLICATION*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.

*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.

*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.

*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.

CHAPTER 6

PROCESSING THE APPLICATION

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.

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.

Article 34

Time frame 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 time frame beyond what is set out in Article 21(4) of Directive (EU) 2016/797. The time frame for providing the supplementary information shall be proportionate to the difficulty for the applicant to provide the information requested. The assessment and the time frame 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.

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.

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.

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 time frame 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.

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.

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 file 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.

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 file 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.

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 (EU) 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.

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 time frame 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.

*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.

*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 time frames set out in Article 21(7) of Directive (EU) 2016/797. The Agency shall give the applicant reasons for the suspension.

*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.

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.

CHAPTER 7

FINAL DOCUMENTATION

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.

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) No 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) No 402/2013, covering the vehicle type;
- (d) an identification of:
 - (i) the vehicle type ID, in accordance with Annex II to Commission Implementing Decision 2011/665/EU ⁽¹⁾;
 - (ii) the vehicle type variants, where applicable;

⁽¹⁾ Commission 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).

- (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.

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.

*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.

*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.

*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.

CHAPTER 8

SUSPENSION OR REVOCATION OR AMENDMENT OF AN ISSUED AUTHORISATION

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.

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.

CHAPTER 9

FINAL PROVISIONS

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) No 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.

Article 56

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) 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.

Done at Brussels, 4 April 2018.

For the Commission
The President
Jean-Claude JUNCKER

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. Email (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. Email (M)
- 6.8. Languages to be used (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. Email (M)
- 7.8. Website (O)
- 7.9. VAT number (M)
- 7.10. Other relevant information (O)

8. 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) Email (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) Email (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) Email (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/EC (1) 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
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

(1) Commission 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).

15. **CCS additional functions (M)**16. **Applicable rules (M):**16.1. TSIs, including 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	<p>The supporting evidence for the requirements capture in accordance with Article 13(1).</p> <p>If the applicant uses the methodology set out in Annex I of Regulation (EU) No 402/2013, the supporting evidence consists of the declaration by the proposer referred to in Article 16 of Regulation (EU) No 402/2013 and the safety assessment report referred to in Article 15 of Regulation (EU) No 402/2013.</p> <p>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) No 402/2013.</p>	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

		First authorisation	Renewed type authorisation	Extended area of use	New authorisation	Authorisation in conformity to type
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 ⁽¹⁾ a description of the methodology used for the requirements capture for the: <ul style="list-style-type: none"> (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) No 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) No 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	

		First authorisation	Renewed type authorisation	Extended area of use	New authorisation	Authorisation in conformity to type
18.11	CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) No 402/2013) covering the potential modification of the overall safety level for the vehicle			X	X	
18.12	Risk declaration (Article 16 Regulation (EU) No 402/2013) covering the potential modification of the overall safety level for the vehicle			X	X	
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	

(¹) Non standardised methodology

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	X		X	X	

		First authorisation	Renewed type authorisation	Extended area of use	New authorisation	Authorisation in conformity to type
	(f) Requirements established (g) Demonstration of compliance with the requirements (h) Hazard management (log)					
7	<p>Sufficient evidence from the methodology used for the requirements capture:</p> <p>7.1. When the risk management process set out in Annex I of Regulation (EU) No 402/2013, has been used as the methodology for requirements capture the following shall be checked:</p> <p>(a) CSM on risk assessment, declaration by the proposer (Article 16 Regulation (EU) No 402/2013) is signed by the proposer and supports that all identified hazards and associated risks are controlled to an acceptable level.</p> <p>(b) CSM on risk assessment, safety assessment report (Article 15 Regulation (EU) No 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> <p>7.2. When another methodology than the risk management process set out in Annex I of Regulation (EU) No 402/2013, has been used as the methodology for requirements capture the following shall be checked:</p> <p>(a) System definition is complete and consistent with the design of the vehicle?</p> <p>(b) Hazard identification and classification is consistent and plausible?</p> <p>(c) All risks have been properly managed and mitigated?</p> <p>(d) Requirements derived from the risk management are properly traced to the risk and to the evidence of compliance with the requirement?</p> <p>(e) Structured and consistent management of the hazards throughout the process?</p> <p>(f) Is there a positive opinion from the independent assessment?</p>	X		X	X	

		First authorisation	Renewed type authorisation	Extended area of use	New authorisation	Authorisation in conformity to type
8	<p>EC Declarations of Verification and EC certificates (Article 15 Directive (EU) 2016/797), check:</p> <p>8.1. Signatures</p> <p>8.2. Validity</p> <p>8.3. Scope</p> <p>8.4. Conditions for use of the vehicle and other restrictions, non-compliances</p> <p>8.5. Non-application of TSIs (when applicable)</p> <p>8.6. All applicable legislation is covered, including other non-railway related legislation</p> <p>8.7. Interoperability constituents (validity, scope, conditions for use and other restrictions):</p> <p>(a) EC certificates of conformity</p> <p>(b) EC certificates of suitability of use</p>	X	X	X	X	
9	<p>Reports from Conformity assessment bodies (Article 15 Directive (EU) 2016/797), check:</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>	X	X	X	X	
10	Check of assessments from NSAs for the area of use, as specified in Article 43	X	X	X	X	

		First authorisation	Renewed type authorisation	Extended area of use	New authorisation	Authorisation in conformity to type
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) No 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) No 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) No 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	Reports from conformity assessment bodies are properly updated in relation to the changed and/or updated rules: 18.1 Changed and/or updated rules are covered 18.2 There is evidence that the vehicle type still fulfils the requirements		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

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) No 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

		First authorisation	New authorisation	Extended area of use	Renewed type authorisation
7	<p>Reports from conformity assessment bodies (Article 15 Directive (EU) 2016/797), check:</p> <p>7.1. Consistency with EC Declarations of Verification and certificates.</p> <p>7.2. Deviations & non-conformities (when applicable) are identified</p> <p>7.3. Conditions for use and other restrictions are properly identified and are consistent with the conditions in the application for authorisation.</p> <p>7.4. The supporting evidences used by conformity assessment bodies are matching the applicable assessment phases described in national rules.</p>	X	X	X	X
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) No 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) No 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) No 402/2013)		X		
12	EC Declarations of Verification and EC certificates are properly updated in relation to the changed/updated national rules				X
13	<p>Reports from conformity assessment bodies are properly updated in relation to the changed/updated rules:</p> <p>13.1. Changed/updated national rules are covered</p> <p>13.2. There is evidence that the vehicle type still fulfils the requirements</p>				X