

Making the railway system work better for society.

Clarification note

Clarification on the authorisation case to be applied for a change in the area of use of an already authorised vehicle and/or vehicle type

	Drafted by	Validated by	Approved by
Name	E.DEL RIO N.BOUSSOUF	H.DELSOIR	T.BREYNE
Position	Project Officers	Team Leader	Head of Unit
Date	05/05/2020	05/05/2020	05/05/2020
Signature	Edurate M. Pro	pelson	

Document History

Version	Date	Comments	
1.0	25/09/2019	Final version	
1.1	01/10/2019	§1 & 2: typo correction (7.5.2.3 of LOC&PAS TSI) §2 2nd bullet point in 3rd paragraph: typo correction (MS B)	
1.2	05/05/2020	Update following publication of Regulation (EU) 2020/387	

The purpose of this document is to provide applicants and other external stakeholders of the vehicle authorisation business with information in regards to the specific topic referenced in the title. The clarifications contained in this document may be integrated in the next revision of the guidelines for the practical arrangements for the vehicle authorisation process, without prejudice of the formal process foreseen for updating the guideline.

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

1. Description of the issue

The article 21(13) of the Directive (EU) 2016/797 describes the process to follow for the extension of the area of use of a vehicle which has already been authorised. In particular, it specifies that there is a need to supplement the file with the relevant documents for the additional area of use. The process is further described in:

- Articles 14(1)(c), 30, 39 and 40 of the Regulation (EU) 2018/545;
- Clause 7.1.4 of the LOC&PAS TSI, and
- Clause 7.2.2.4 of the WAG TSI

However, in some cases an applicant does not want to extend the area of use, but to change it, meaning that there is no "additional" area of use as compared to the original one; instead, the vehicle will no longer operate in the original area of use, but only in the new area of use. In order to do so, it is often necessary to perform some changes in the vehicles, in order to make it compatible with the new area of use.

This case is not explicitly covered in the Directive (EU) 2016/797 nor in the Regulation (EU) 2018/545, and many applicants have doubts on what would be the correct application case, amongst the choices provided in article 14(1) of Regulation (EU) 2018/545.

2. Line to take

When an applicant wishes to change (rather than extend) the area of use of an already authorised vehicle from a Member State A to a Member State B, performing some changes in order to make the vehicle compatible with the area of use of Member State B, and the modified vehicle will not remain authorised in the Member State A, it should not be considered as an extension of the area of use.

The extension of the area of use pursuant to article 14(1)(c) of Regulation (EU) 2018/545 and to article 21(13) of Directive (EU) 2016/797 refers to extending the area of use of a vehicle that is already authorised. This is not the case in the described scenario: the modified vehicles are not authorised in Member State A, and in some cases, they cannot be authorised in Member State A, as after the changes necessary to make them compatible with the network in MS B they are no longer technically compatible with the network of Member State A.

The authorisation case should be a new authorisation following article 14(1)(d) of Regulation (E) 2018/545, although some of the concepts of the extension of the area of use pursuant to article 14(1)(c) of the Regulation are applicable as well:

- the technical compatibility with the network in Member State B needs to be assessed (as it would be the case of an extension of the area of use), and
- there is no need to apply for a new authorisation in Member State A (in case this would be technically possible), because the modified vehicles will not be operated there anymore.

Because the area of use of the modified vehicle will be limited to Member State B, the applicant can choose which entity can be the authorising entity: the Agency or the NSA.

If the new area of use covers more than 1 Member State, then the applicant should apply to the Agency for a new authorisation pursuant to article 14(1)(d) of Regulation (E) 2018/545 with an area of use covering more than 1 MS.

The assessments to be performed should be limited to:

- the changed parts (and the interfaces with the modified parts) and
- For rolling stock-locomotives and passenger: the requirements defined in the provisions 7.1.4(2), (3),
 (4) and (6) of commission implementing regulation (EU) 2020/387 amending regulation (EU) 1302/2014.
- For rolling stock freight wagons: the requirements defined in the provisions 7.2.2.4(2),(3),(4) and (6) of commission implementing regulation (EU) 2020/387 amending regulation (EU) 321/2013 WAG TSI.

See also the clarification note issued by the Agency with reference ERA1209/036 covering the applicability of the phase A as defined in the rolling stock TSIs in case of extension of the area of use of an already authorised vehicle.

3. Legal background

a) Directive (EU) 2016/797

Article 4. Content of TSIs "[...]

2. Fixed subsystems shall comply with the TSIs and national rules in force at the time of the request for authorisation of placing in service in accordance with this Directive and without prejudice to point (f) of paragraph 3.

Vehicles shall comply with TSIs and national rules in force at the time of the request for authorisation of placing on the market in accordance with this Directive and without prejudice to point (f) of paragraph 3.

The conformity and compliance of fixed subsystems and vehicles shall be permanently maintained while they are in use."

- > Article 21. Vehicle authorisation for placing on the market
 - "3. The application for a vehicle authorisation for placing on the market shall be accompanied by a file concerning the vehicle or vehicle type and including documentary evidence of:
 - (a) the placing on the market of the mobile subsystems of which the vehicle is composed in accordance with Article 20, on the basis of the 'EC' declaration of verification;
 - (b) the technical compatibility of the subsystems referred to in point (a) within the vehicle, established on the basis of the relevant TSIs, and where applicable, national rules;
 - (c) the safe integration of the subsystems referred to in point (a) within the vehicle, established on the basis of the relevant TSIs, and where applicable, national rules, and the CSMs referred to in Article 6 of Directive (EU) 2016/798;
 - (d) the technical compatibility of the vehicle with the network in the area of use referred to in paragraph 2, established on the basis of the relevant TSIs and, where applicable, national rules, registers of infrastructure and the CSM on risk assessment referred to in Article 6 of Directive (EU) 2016/798.

[...]

13. Where the applicant wishes to extend the area of use of a vehicle which has already been authorised, it shall supplement the file with the relevant documents referred to in paragraph 3 concerning the additional area of use. The applicant shall submit the file to the Agency, which shall, after following the procedures laid down in paragraphs 4 to 7, issue an updated authorisation covering the extended area of use.

If the applicant has received a vehicle authorisation in accordance with paragraph 8 and wishes to extend the area of use within that Member State, it shall supplement the file with the relevant documents referred to in paragraph 3 concerning the additional area of use. It shall submit the file to the national safety authority which shall, after following the procedures laid down in paragraph 8, issue an updated authorisation covering the extended area of use.

[...]"

b) Commission Implementing Regulation (EU) 2020/387 of 9 March 2020 (amendments to the annex of Regulation (EU) No 1302/2014 LOC&PAS TSI)

- "7.1.4. Rules for the extension of the area of use for existing rolling stock having an authorisation in accordance with Directive 2008/57/EC or in operation before 19 July 2010
 - (1) In the absence of full conformity with this TSI, point 2 applies to rolling stock that fulfils the following conditions when requesting the extension of its area of use in accordance with Article 21(13) of Directive (EU) 2016/797:
 - it has been authorised in accordance with Directive 2008/57/EC or put in operation before 19 July 2010;
 - b) it is registered with "Valid" registration code "00", in the National Vehicle Register in accordance with Commission Decision 2007/756/EC (*1) or in the European Vehicle Register in accordance with Commission Implementing Decision (EU) 2018/1614 (*2) and maintained in a safe state of running in accordance with Commission Implementing Regulation (EU) 2019/779 (*3).

The following provisions for extension of area of use apply also in combination with a new authorisation as defined in point (a) of Article 14(3) of Regulation (EU) 2018/545.

(2) Authorisation for an extended area of use of the rolling stock referred to in point 1 shall be based on the existing authorisation, if any, and on the technical compatibility between the rolling stock and the network in accordance with point (d) of Article 21(3) of Directive (EU) 2016/797 and compliance with the Basic Design Characteristics of Table 17a and 17b of this TSI, taking into account any restrictions or limitations.

The applicant shall provide an "EC declaration of verification" accompanied by technical files giving evidence of compliance with the requirements set out in this TSI, or with provisions having equivalent effect, for each basic parameter referred to in column 1 of Tables 17a and 17b and with the following clauses of this TSI:

- 4.2.4.2.2, 4.2.5.5.8, 4.2.5.5.9, 4.2.6.2.3, 4.2.6.2.4, 4.2.6.2.5, 4.2.8.2.7, 4.2.8.2.9.8
 (when running through phase or system separation sections is managed automatically), 4.2.9.3.1, 4.2.9.6, 4.2.12 and 4.2.12.6
- 4.2.5.3 in Italy
- 4.2.5.3.5 and 4.2.9.2.1 in Germany

through one or a combination of the following:

- a) compliance with requirements set out in this TSI as referred above;
- compliance with corresponding requirements set out in a previous TSI as referred above;
- c) compliance with alternative specifications deemed to have equivalent effect to the relevant requirements set out in this TSI as referred above;
- d) evidence that the requirements for technical compatibility with the network of the extended area of use are equivalent to the requirements for technical compatibility with the network for which the rolling stock is already authorised or in operation. Such evidence shall be provided by the applicant and may be based on the information of the register of railway infrastructure (RINF).
- (3) The equivalent effect of alternative specifications to the requirements of this TSI (point 2(c)) and the equivalence of requirements for technical compatibility with the network (point 2(d)) shall be justified and documented by the applicant by applying the risk management process set out in Annex I of Regulation (EU) No 402/2013. The justification has to be assessed and confirmed by an assessment body (CSM RA).

- (4) In addition to the requirements mentioned referred to in point 2 and where applicable, the applicant shall provide an "EC declaration of verification" accompanied by technical files giving evidence of compliance with the following:
 - a) specific cases relating to any part of the extended area of use, listed in this TSI, the TSI Noise (Regulation (EU) No 1304/2014), the TSI PRM (Regulation (EU) No 1300/2014) and CCS TSI (Regulation (EU) 2016/919);
 - b) the national rules referred to in points (a), (c) and (d) of Article 13(2) of Directive (EU) 2016/797 as notified in accordance with Article 14 of that Directive.
- (5) The authorising entity shall make publicly available through the Agency website details of the alternative specifications referred to in point 2(c) and of the requirements for technical compatibility with the network referred to in point 2(d) on the basis of which it granted authorisations for the extended area of use.
- (6) Where an authorised vehicle benefited from non-application of TSIs or part of them pursuant to Article 9 of Directive 2008/57/EC, the applicant shall seek derogation(s) in the Member States of the extended area of use in accordance to Article 7 of Directive (EU) 2016/797.
- (7) In accordance with Article 54(2) of Directive (EU) 2016/797, coaches used under Regolamento Internazionale Carrozze (RIC) shall be deemed authorised in accordance with the conditions under which they were used, including the area of use where they are operated. Following a change which requires a new authorisation for placing on the market in accordance with Article 21(12) of Directive (EU) 2016/797, coaches accepted under the latest RIC agreement shall conserve the area of use in which they were operating without further checks on the unchanged parts.
- c) Commission Implementing Regulation (EU) 2020/387 (amendments to the annex of Regulation (EU) No 321/2013 WAG TSI)
 - "7.2.2.4. Rules for the extension of the area of use for existing units having an authorisation in accordance with Directive 2008/57/EC or in operation before 19 July 2010
 - (1) In the absence of full conformity with this TSI, point 2 applies to units that fulfil the following conditions when requesting an extension of their area of use in accordance with Article 21(13) of Directive (EU) 2016/797:
 - 1. they have been authorised in accordance with Directive 2008/57/EC or put in operation before 19 July 2010;
 - 2. they are registered with "Valid" registration code "00", in the National Vehicle Register in accordance with Commission Decision 2007/756/EC (*1) or in the European Vehicle Register in accordance with Commission Implementing Decision (EU) 2018/1614 (*2) and maintained in a safe state of running in accordance with Commission Implementing Regulation (EU) 2019/779 (*3).

The following provisions for extension of area of use apply also in combination with a new authorisation as defined in point (a) of Article 14(3) of Regulation (EU) 2018/545.

(2) Authorisation for an extended area of use of the units referred to in point 1 shall be based on the existing authorisation, if any, the technical compatibility between the unit and the network in accordance with point (d) of Article 21(3) of Directive (EU) 2016/797 and compliance with the Basic Design Characteristics of Table 11a of this TSI, taking into account any restrictions or limitations.

The applicant shall provide an "EC declaration of verification" accompanied by technical files giving evidence of compliance with the requirements set out in this TSI, or with provisions having equivalent effect, for each basic parameter referred to in column 1 of Table 11a of this TSI, through one or a combination of the following:

- a) compliance with requirements of this TSI as referred above;
- compliance with corresponding requirements set out in a previous TSI as referred above;
- c) compliance with alternative specifications deemed to have equivalent effect to the relevant requirements set out in this TSI as referred above;
- d) evidence that the requirements for technical compatibility with the network of the extended area of use are equivalent to the requirements for technical compatibility with the network for which the unit is already authorised or in operation. Such evidence shall be provided by the applicant and may be based on the information in the register of railway infrastructure (RINF).
- (3) The equivalent effect of alternative specifications to the requirements of this TSI (point 2(c)) and the equivalence of requirements for technical compatibility with the network (point 2(d)) shall be justified and documented by the Applicant by applying the risk management process set out in Annex I of Regulation (EU) No 402/2013. The applicant shall provide a positive assessment by an assessment body (CSM RA).
- (4) In addition to the requirements referred to in point 2 and where applicable, the applicant shall provide an "EC declaration of verification" accompanied by technical files giving evidence of compliance with the following:
 - a) specific cases relating to any part of the extended area of use, listed in this TSI, the TSI Noise (Regulation (EU) No 1304/2014) and CCS TSI (Regulation (EU) 2016/919);
 - b) the national rules referred to in points (a), (c) and (d) of Article 13(2) of Directive (EU) 2016/797 as notified in accordance with Article 14 of that Directive.
- (5) The authorising entity shall make publicly available through the Agency website details of the alternative specifications referred to in point 2(c) and of the requirements for technical compatibility with the network referred to in point 2(d) on the basis of which it granted authorisations for the extended area of use.
- (6) Where an authorised vehicle benefited from non-application of TSIs or part of them pursuant to Article 9 of Directive 2008/57/EC, the applicant shall seek derogation(s) in the Member States of the extended area of use in accordance to Article 7 of Directive (EU) 2016/797.
- (7) In accordance with Article 54(2) of Directive (EU) 2016/797, wagons used under Regolamento Internazionale Veicoli (RIV) shall be deemed authorised in accordance with the conditions under which they were used, including the area of use where they are operated. Following a change which requires a new authorisation for placing on the market in accordance with Article 21(12) of Directive (EU) 2016/797, wagons accepted under the latest RIV agreement shall conserve the area of use in which they were operating without further checks on the unchanged parts."

d) Regulation (EU) 2018/545

- > Article 14. Identification of the relevant authorisation
 - "1. The applicant shall identify and choose the relevant authorisation from the following cases: [...]
 - c) extended area of use: the vehicle type authorisation and/or the vehicle authorisation for placing on the market issued by the relevant authorising entity for an already authorised vehicle type and/or vehicle in order to extend the area of use without a change of the design, pursuant to in Article 21(13) of Directive (EU) 2016/797;
 - 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;

[...]

- 3. An applicant may combine:
 - a) a request for new authorisation with a request for an authorisation for an extended area of use; or
 - b) a request for a first authorisation with a request for authorisation in conformity to type.

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

Article 30. Application content and completeness

"[...

- 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;
 - 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 39. The assessment of the application by the authorising entity

"[...]

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.

[...][']

Article 40. The assessment of the application by the concerned NSAs for the area of use

"[...]

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.

[...]"

e) Guidelines for the practical arrangements for the vehicle authorisation process (ERA-PRG-005/02-361 V1.0)

> <u>chapter 3.3.2.1</u> Article 14: Identification of the relevant authorisation "[...]

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

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

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