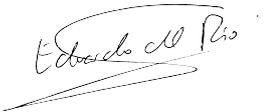


Making the railway system
work better for society.

Clarification note

Withdrawal of time limitations and/or conditions for use of the vehicle and other restrictions in an issued authorisation

	<i>Drafted by</i>	<i>Validated by</i>	<i>Approved by</i>
<i>Name</i>	DEL RIO Eduardo	DELSOIR Hugues	BREYNE Thierry
<i>Position</i>	Project Officer	VA team leader	Head of PAD unit
<i>Date</i>	08/04/2020	08/04/2020	08/04/2020
<i>Signature</i>		Po 	

Document History

<i>Version</i>	<i>Date</i>	<i>Comments</i>
1.0	26/03/2020	Initial version
1.1	08/04/2020	§2 wording improved to clarify the role of the Agency for authorisations issued by NSAs

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

Pursuant to Article 21(1) of Directive 2016/797, the applicant shall place a vehicle on the market only after having received an authorisation issued by the Agency pursuant to articles 21(5) or 21(7) or by the national safety authority pursuant to article 21(8).

The authorisation shall specify the conditions of use of the vehicle and other restrictions, according to article 21(10)(d) of the Directive and articles 48 and 49 of Regulation (EU) 2018/545. Authorisation for placing in service under on Directive 2008/57/EC may also contain conditions and other restrictions, pursuant to article 21(6) of the Directive.

It is also common to find temporary restrictions or time limitations in the validity of the authorisations, no matter the regime under which they were issued.

The procedure to follow in case of authorisations with time limitations that arrive to the expiry date or in case there is a need to remove or change the conditions for use of the vehicle and other restrictions is not explicitly described in the legal texts.

2. Line to take

Conditions for use of the vehicle and other restrictions (herein after referred to as CfU) are basic design characteristics, pursuant to articles 46(5) and 48(c)(iii) of the Regulation (EU) 2018/545. Therefore, changes in the CfU stated in the issued authorisation should be dealt with by the application of article 15 of Regulation (EU) 2018/545: a change in a basic design characteristic. The entity managing the change should decide the category of article 15(1) of the Regulation into which such change falls.

It should be noticed that time limited CfU are only allowed in certain cases, pursuant to article 46(6) of Regulation (EU) 2018/545.

Time limits and CfU can have a quite heterogeneous nature, and therefore it is not possible to cover all possible cases and scenarios. This clarification note covers the following cases:

1. **Temporary limitation in the issued authorisation caused by an administrative issue** (e.g. missing evidences), which does not require changes in the vehicle but maybe new evidences (e.g. test reports), maybe an update of the certificates of verification, the EC declarations of conformity and/or the technical file accompanying the declarations. CfU and other technical characteristics of the vehicle type are not impacted either.

In these cases, the authorising entity or the national safety authority (NSA) that issued the authorisation should withdraw the temporary limitation without the need to issue a new authorisation.

For the cases where a NSA issued the authorisation:

- › The NSA should withdraw the limitation, irrespectively of the legal regime in which the authorisation was issued and the current legal regime in the concerned Member State (e.g. authorisation issued under Directive 2008/57/EC, to be modified by a NSA of a Member State having already transposed the Directive (EU) 2016/797).
- › It may be an update of the existing authorisation, a letter overriding the limitation etc., depending on the possibilities allowed by the applicable national legal framework in each Member State. The applicant can send the missing documentation to the concerned NSA by any agreed means.
- › The Agency will not play any role, irrespectively of the area of use of the authorised vehicle type.

2. **Modification of the CfU in the issued authorisation that requires changes** in the design.

This is the general case, and should be dealt with by application of the Article 15 of Regulation (EU) 2018/545. Depending on the categorisation of the change according to article 15(1) of the Regulation, and depending whether the entity managing the change is also the holder of the vehicle type authorisation, there are several possibilities.

Where the entity managing the change is the holder of the vehicle type authorisation:

- (a) If the change is categorized as 15(1)(a) or (b), the concerned authorising entity or NSA can withdraw the temporary limitation without the need to issue a new authorisation through the OSS. It may be an update of the existing authorisation, a letter overriding the limitation etc.
- (b) If the change is categorized as 15(1)(c), in addition to the withdrawal of the limitation, there is a need to create a version of the vehicle type in ERATV, pursuant to article 15(3) of the Regulation. The entity that would be the authorising entity in case such change would require a new authorisation should take the responsibility of creating the version, based on the information provided by the entity managing the change and on the data available in ERATV for the vehicle type.
- (c) If the change is categorized as 15(1)(d), there shall be an application for a new authorization through the OSS. The entity managing the change can choose the authorising entity (Agency or concerned NSA) if the area of use covers one Member State; if the area of use covers more than one Member State, the Agency shall be the authorising entity.

If the entity managing the change is not the holder of the vehicle authorisation, all changes categorized as 15(1)(b), (c) or (d) of Regulation (EU) 2018/545 trigger a new authorisation.

3. Modification of the CfU without changes in the design.

This case should be also dealt with by the application of article 15 of the Regulation (EU) 2018/545, despite the fact that there are no changes in the design. This because CfU are basic design characteristics.

The entity managing the change shall analyze the effect of waiving the CfU and decide whether this can be allocated to article 15(1)(c) or 15(1)(d) of the Regulation. In the case where the entity managing the change is the holder of the vehicle type authorisation:

- (a) If the change is categorized as If 15(1)(c), point 2(b) above applies: the concerned authorising entity or NSA can withdraw the limitation without the need to issue a new authorisation, and a version of the vehicle type in ERATV needs to be created.
- (b) If the change is categorized as If 15(1)(d), 2(c) above applies: there shall be an application for a new authorization through the OSS.

If the entity managing the change is not the holder of the vehicle authorisation, all changes categorized as 15(1)(c) or (d) of Regulation (EU) 2018/545 trigger a new authorisation.

3. Legal background

a) Directive 2008/57/EC

› Article 21(6)

“All applications for an authorisation to place in service shall be the subject of a decision by the competent national safety authority, pursuant to Articles 22 and 23 or Articles 24 and 25. The authorisation to place in service may stipulate conditions of use and other restrictions.”

b) Directive (EU) 2016/797

› Article 21(10)

“Vehicle authorisations for placing on the market shall state:

- (a) the area(s) of use;*
- (b) the values of the parameters set out in the TSIs and, where applicable, in the national rules, for checking the technical compatibility between the vehicle and the area of use;*
- (c) the vehicle's compliance with the relevant TSIs and sets of national rules, relating to the parameters referred to in point (b);*
- (d) the conditions for use of the vehicle and other restrictions.”*

c) Regulation (EU) 2018/545

› 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 46(5). Decision for the authorisation or the refusal of the authorisation

“The conditions for use of the vehicle and other restrictions shall be defined according to the basic design characteristics of the vehicle type.”

› Article 46(6). Decision for the authorisation or the refusal of the authorisation

“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.”

- › Article 48. The information in the issued vehicle type authorisation

“The vehicle type authorisation issued by the authorising entity shall contain the following information:

[...]

(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;

[...]”