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## Clarification note

# Mitigation of non-compliances with the applicable rules by means of conditions for use of the vehicle and other restrictions

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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 Regulation (EU) 2018/545 foresees the possibility to mitigate non-conformities with TSIs and national rules by means of establishing conditions for use of the vehicle and other restrictions. However, it has been found in several applications for authorisation that this is applied to solve every possible non-conformity, while this option should be limited to certain cases. After all, the TSIs and national rules are mandatory rules, and shall be complied with by a subsystem or an interoperability constituent in order for it to be placed on the market and integrated into a vehicle.

Similarly, requirements from other EU legislation shall also be complied with, unless the concerned legislation also includes the possibility to deviate from certain requirements in specific situations.

#### 2. Line to take

The TSIs, the national rules and other EU legislation are mandatory rules, and vehicles should comply with the technical requirements laid down in the mandatory rules. The following possibilities to deviate from a requirement established in a mandatory rule are foreseen in the legal framework:

- a) When the project benefits from a granted non-application request of the concerned requirement(s) of the TSI(s), pursuant to Article 7 of Directive (EU) 2016/797;
- b) In case of deficiencies in the applicable TSIs, pursuant to Article 6 of the Directive (EU) 2016/797; pending the amendment of the TSI, a Technical Opinion issued by the Agency, at the request of the Commission, shall constitute acceptable means of compliance and may therefore be used for the assessment of projects, pending the adoption of a revised TSI;
- c) In case of innovative solutions, pursuant to Article 10 of Regulation (EU) 2014/1302 and Article 10a of Regulation (EU) 2013/321: the positive opinion issued by the European Commission constitutes acceptable means of compliance;
- d) When it is possible to mitigate the non-conformity (e.g. bringing the vehicle in conformity to the TSIs and/or national rules) by applying some conditions for use and other restrictions, pursuant to Article 27(2)(b) of Regulation (EU) 2018/545;
- e) When the authorisation decision contains time limited conditions for use of the vehicle and other restrictions, as an exceptional temporary measure, where the conformity to the TSIs and/or national rules could not be completely proven before the issuing of the authorisation and/or national rules require that the applicant produces a plausible estimate of compliance , pursuant to Article 46(6) of Regulation (EU) 2018/545, or
- f) The TSIs allow deviations from certain technical requirements if certain conditions are met;:
  - For the upgrade/renewal of existing vehicles not covered by an EC Declaration of Verification placed in service before 1 January 2015, where the basic parameter is improved in the direction of the TSI defined performance and the entity managing the change demonstrates that the corresponding essential requirements are met and the safety level is maintained and, where reasonably practicable, improved (section 7.1.2.2a of Annex I of Regulations (EU) 2014/1302 and section 7.2.2.3 of Annex I of Regulation (EU) 2013/321);
  - Interoperability constituents not covered by an EC declaration of conformity or suitability for use, as described in Articles 8, 8a, 8b and 8c of Regulation (EU) 2013/321, and/or
  - Interoperability constituents and subsystems not implementing all functions, performance and interfaces, as described in sections 6.1.1.3 and 6.4.3 of Annex I of Regulation (EU) 2016/919.

The paragraphs below do not apply for this particular case, because the procedure to follow is already described in the TSIs.

Where a non-conformity is known by the manufacturer/applicant since the early stages of a project (e.g. derives from a contractual arrangement with its customer, or was identified in the design stage) and it is not covered by the cases described in paragraphs a, b or c above, the Agency, when acting as an authorising

entity and as a general rule, will not accept the use of conditions for use and other restrictions as a mitigation measure. The applicant should use any other of the possibilities provided by the legal framework, in particular the one envisaged in Article 27(2)(a) of Regulation (EU) 2018/545 (change the design) or request a non-application of the concerned requirements of the TSIs pursuant to Article 7 of Directive (EU) 2016/797, where allowed.

Only when the condition for use and other restrictions is of purely operational nature, as described in paragraph d (e.g. speed limitation, configurations not allowed, load restrictions etc.) this could be accepted, under the conditions described below.

When non-conformities are identified during the conformity assessment procedure, the applicant should, as a general rule, correct them and bring back the subsystem in conformity with the TSIs, pursuant to Articles 27(1) and 27(2)(a) of the Regulation (EU) 2018/545, or request a non-application of the concerned requirements of the TSIs. When it is not possible to:

- correct the identified non-conformities;
- request a non-application of the concerned requirements of the TSIs, or
- follow the procedure for deficiencies or innovative solutions because of the impact in the project (need to redesign the vehicle, delays and costs associated with the redesign and assessment of the changed design, time for approval of a request for non-application of a TSI, etc.),

then Article 27(2)(b) of Regulation (EU) 2018/545 allows to apply conditions for use of the vehicle and other restrictions to mitigate the non-conformity, where this is feasible (some non-conformities cannot be mitigated in this way) and duly justified.

This should be limited to cases where the non-conformity was not known and could not have been reasonably anticipated, and it's only discovered in the latest stages of the EC verification procedure and/or authorisation process. This is typically the case of non-conformities found during the on-track testing campaign, obliging to adopt some measures impacting the operational envelope of the vehicle (e.g. limitation in speed, limitation in cant-deficiency, limitation in the configuration for operation in multiple unit etc.).

When conditions for use of the vehicle and other restrictions are used to mitigate a non-conformity with the TSIs and/or national rules, the applicant should provide in the file accompanying the application through the one-stop shop a description of the requirements not complied with and/or the requirements whose compliance could not be completely proven, and the conditions for use of the vehicle and other restrictions identified as mitigating measures, including the relationships between them. In case of time limited conditions for use of the vehicle and other restrictions, the applicant should also provide the planning for providing the missing evidence.

The conformity assessment bodies shall assess the proposed conditions for use and other restrictions and confirm that the non-conformity and any associated risk are mitigated, which means that:

- The vehicle fulfils the requirements of the TSIs and/or national rules when the conditions for use of the vehicle and other restrictions are applied, and
- The conditions for use of the vehicle and other restrictions do not impact negatively the essential requirements.

The outcomes of their assessments shall be clearly included in the assessment reports, in particular, in the assessment report covering the process for requirements capture.

In case of time limited conditions for use and other restrictions, it is the responsibility of the applicant to provide the necessary evidence before the time limit in the vehicle type authorisation. The vehicle type authorisation issued will no longer be valid after its expiry date. Similarly, the authorisations for placing on the market of the vehicles issued in conformity to the vehicle type that had a time limit will also have the same time limit, and will no longer be valid after the expiry date of the vehicle type authorisation.

### 3. Legal background

#### a) Directive (EU) 2016/797

> Recital (34)

"The drawing-up of TSIs and their application to the Union rail system should not impede technological innovation, which should be directed towards improving economic performance."

> Article 4(2). Content of TSIs

"[...]

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.

[...]"

3. To the extent necessary to achieve the objectives of this Directive referred to in Article 1, each TSI shall:

[...]

c) establish the functional and technical specifications to be met by the subsystem and its interfaces in relation to other subsystems. If necessary, these specifications may vary according to the use of the subsystem, for example according to the categories of line, hub and/or vehicles provided for in Annex I;

[...]

- e) state, in each case under consideration, which procedures are to be used in order to assess the conformity or the suitability for use of the interoperability constituents, on the one hand, or the 'EC' verification of the subsystems, on the other. Those procedures shall be based on the modules defined in Commission Decision 2010/713/EU (1);
- f) indicate the strategy for the application of the TSI. In particular, it is necessary to specify the stages to be completed, taking into account the estimated costs and benefits and the expected repercussions for the stakeholders affected in order to make a gradual transition from the existing situation to the final situation in which compliance with the TSI shall be the norm. Where coordinated implementation of the TSI is necessary, such as along a corridor or between infrastructure managers and railway undertakings, the strategy may include proposals for staged completion;

[...]"

> Article 6. Deficiencies in TSIs

"1. If, after its adoption, it appears that a TSI has a deficiency, that TSI shall be amended in accordance with Article 5(11). If appropriate, the Commission shall apply this procedure without delay. Such deficiencies shall include cases which could result in unsafe operations within a Member State.

2. Pending the review of a TSI, the Commission may request an opinion from the Agency. The Commission shall analyse the Agency's opinion and inform the committee of its conclusions.

3. At the request of the Commission, the Agency's opinion referred to in paragraph 2 shall constitute acceptable means of compliance and may therefore be used for the assessment of projects, pending the adoption of a revised TSI.

4. Any member of the network of representative bodies referred to in Article 38(4) of Regulation (EU) 2016/796 may make the Commission aware of possible TSI deficiencies."

> Article 7. Non-application of TSIs

*"1. Member States may allow the applicant not to apply one or more TSIs or parts of them in the following cases:* 

- a) for a proposed new subsystem or part of it, for the renewal or upgrading of an existing subsystem or part of it, or for any element referred to in Article 1(1) which is at an advanced stage of development or which is the subject of a contract in the course of performance on the date of application of the TSI(s) concerned;
- b) where, following an accident or a natural disaster, the conditions for the rapid restoration of the network do not economically or technically allow for partial or total application of the relevant TSIs, in which case the non-application of the TSIs shall be limited to the period before the restoration of the network;
- c) for any proposed renewal, extension or upgrading of an existing subsystem or part of it, when the application of the TSI(s) concerned would compromise the economic viability of the project and/or the compatibility of the rail system in the Member State concerned, for example in relation to the loading gauge, track gauge, space between tracks or electrification voltage;
- d) for vehicles arriving from or going to third countries the track gauge of which is different from that of the main rail network within the Union:
- e) for a proposed new subsystem or for the proposed renewal or upgrading of an existing subsystem in the territory of the Member State concerned when its rail network is separated or isolated by the sea or separated as a result of special geographical conditions from the rail network of the rest of the Union

[...]"

> Article 15. Procedure for establishing the 'EC' declaration of verification

"1. In order to establish the 'EC' declaration of verification necessary for placing on the market and placing in service referred to in Chapter V, the applicant shall request the conformity assessment body or bodies that it has selected for that purpose to apply the 'EC' verification procedure set out in Annex IV.

2. The applicant shall establish the 'EC' declaration of verification of a subsystem. The applicant shall declare on his sole responsibility that the subsystem concerned has been subject to the relevant verification procedures and that it satisfies the requirements of relevant Union law and any relevant national rule. The 'EC' declaration of verification and the accompanying documents shall be dated and signed by the applicant. [...]"

> Article 16. Non-compliance of subsystems with essential requirements

"1. Where a Member State finds that a structural subsystem covered by the 'EC' declaration of verification accompanied by the technical file does not fully comply with this Directive and, in particular, does not meet the essential requirements, it may request that additional checks be carried out.

2. The Member State making the request shall forthwith inform the Commission of any additional checks requested and set out the reasons therefor. The Commission shall consult the interested parties.

3. The Member State making the request shall state whether the failure to fully comply with this Directive is due to:

- a) non-compliance with the essential requirements or with a TSI, or incorrect application of a TSI, in which case the Commission shall forthwith inform the Member State where the person who drew up the 'EC' declaration of verification in error resides and shall request that Member State to take the appropriate measures;
- *b)* inadequacy of a TSI, in which case the procedure for amending the TSI as referred to in Article 6 shall apply"
- *b)* Regulation (EU) 2018/545
  - > 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 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 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."

> Article 46. Decision for the authorisation or the refusal of the application

#### "[...]

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.

[...]″

#### c) Regulation (EU) 2014/1302 (LOC&PAS TSI)

> Article 10

"1. In order to keep pace with technological progress, innovative solutions may be required, which do not comply with the specifications set out in the Annex and/or for which the assessment methods set out in the Annex cannot be applied. In that case, new specifications and/or new assessment methods associated with those innovative solutions shall be developed.

2. Innovative solutions may be related to the rolling stock subsystem, its parts and its interoperability constituents.

3. If an innovative solution is proposed, the manufacturer or his authorised representative established within the Union shall declare how it deviates from or complements to the relevant provisions of this TSI and submit the deviations to the Commission for analysis. The Commission may request the opinion of the European Railway Agency (the Agency) on the proposed innovative solution.

4. The Commission delivers an opinion on the innovative solution proposed. If this opinion is positive, the appropriate functional and interface specifications and the assessment method, which need to be included in the TSI in order to allow the use of this innovative solution, shall be developed and subsequently integrated in the TSI during the revision process pursuant to Article 5 of Directive (EU) 2016/797. If the opinion is negative, the innovative solution proposed cannot be applied.

5. Pending the review of the TSI, the positive opinion delivered by the Commission shall be considered as acceptable means of compliance with the essential requirements of Directive (EU) 2016/797 and may therefore be used for the assessment of the subsystem."

> 7.1.2.2 Rules to manage changes in both rolling stock and rolling stock type

"[...]

(9) Without prejudice to clause 7.1.2.2a, all changes shall remain compliant with the applicable TSIs regardless their classification.

[...]"

> 7.1.2.2a. Particular rules for existing rolling stock not covered by an EC declaration of verification with a first authorisation for placing in service before 1 January 2015

(1) The following rules apply, in addition to clause 7.1.2.2, to existing rolling stock with a first authorisation for placing in service before 1 January 2015, where the scope of the change has an impact on basic parameters not covered by the EC declaration (if any).

(2) The compliance with technical requirements of this TSI is deemed established when a basic parameter is improved in the direction of the TSI defined performance and the entity managing the change demonstrates that the corresponding essential requirements are met and the safety level is maintained and, where reasonably practicable, improved. The entity managing the change shall in this case justify the reasons for which the TSI defined performance was not met, taking into account paragraph 3 of section 7.1.2.2. This justification shall be included in the technical file, if any, or in the original technical documentation of the vehicle.

(3) The particular rule set out in paragraph (2) above is not applicable to changes to basic parameters classified as 21(12)(a) in table 17c and 17d. For those changes, compliance with the TSI requirements is mandatory.

[...]″

#### d) Regulation (EU) 2013/321 (WAG TSI)

> Article 8

"1. An 'EC' certificate of verification for a subsystem that contains interoperability constituents which do not have an 'EC' declaration of conformity or suitability for use may be issued during a transitional period ending on 1 January 2024 provided the provisions laid down in Section 6.3 of the Annex are met.

2. The production or upgrade/renewal of the subsystem using non-certified interoperability constituents shall be completed within the transitional period set out in paragraph 1, including the placing on the market.

- 3. During the transitional period set out in paragraph 1:
  - a) the reasons for non-certification of any interoperability constituents shall be properly identified in the verification procedure referred to in paragraph 1;
  - b) the national safety authorities shall report on the use of non-certified interoperability constituents in the context of authorisation procedures in their annual report referred to in Article 19 of Directive (EU) 2016/798 of the European Parliament and of the Council.

4. After a transition period ending on 1 January 2015, newly produced interoperability constituents of 'rear-end signals', shall be covered by the required 'EC' declaration of conformity."

> Article 8a

"1. Notwithstanding the provisions in Section 6.3 of the Annex, an EC certificate of verification may be issued for a subsystem containing components corresponding to the 'friction element for wheel tread brakes' interoperability constituent that does not have an EC declaration of conformity during a transition period ending on 1 January 2024, if the following conditions are met:

- a) the component was manufactured before the date of application of this Regulation; and
- b) the interoperability constituent has been used in a subsystem that had been approved and placed on the market in at least one Member State before the date of application of this Regulation.

2. The production, upgrade or renewal of any subsystem using non-certified interoperability constituents shall be completed, including granting authorisation for placing on the market, before the transition period set out in paragraph 1 expires

- 3. During the transition period set out in paragraph 1:
  - a) the reasons for non-certification of any interoperability constituents shall be properly identified in the verification procedure for the subsystem referred to in paragraph 1; and
  - b) national safety authorities shall report in their annual report, as referred to in Article 19 of Directive (EU) 2016/798, on the use of non-certified 'friction element for wheel tread brakes' interoperability constituents in the context of authorisation procedures."
- > Article 8b

*"*1. Until the expiry of their current approval period, *'*friction element for wheel tread brakes' interoperability constituents listed in Appendix G of the Annex do not need to be covered by an EC

declaration of conformity. During this period, 'friction elements for wheel tread brakes' listed in Appendix G of the Annex shall be deemed to be compliant with this Regulation.

2. After their current approval period expires, 'friction element for wheel tread brakes' interoperability constituents listed in Appendix G of the Annex shall be covered by EC declaration of conformity."

> Article 8c

1. Notwithstanding the provisions in Section 6.3 of the Annex, an EC certificate of verification may be issued for a subsystem containing components corresponding to the 'friction element for wheel tread brakes' interoperability constituent that does not have an EC declaration of conformity during a transition period of 10 years after the expiry of the approval period of the interoperability constituent, if the following conditions are met:

- a) the component was manufactured before the expiry of the approval period of the interoperability constituent; and
- b) the interoperability constituent has been used in a subsystem that had been approved and placed on the market in at least one Member State before the expiry of its approval period.

2. The production, upgrade or renewal of any subsystem using non-certified interoperability constituents shall be completed, including granting authorisation for placing on the market, before the transition period set out in paragraph 1 expires.

- 3. During the transition period set out in paragraph 1.
  - a) the reasons for non-certification of any interoperability constituents shall be properly identified in the verification procedure for the subsystem referred to in paragraph 1; and
  - b) the national safety authorities shall report in their annual report, as referred to in Article 19 of Directive (EU) 2016/798, on the use of non-certified 'friction element for wheel tread brakes' interoperability constituents in the context of authorisation procedures.
- > Article 10a

"1. In order to keep pace with technological progress, innovative solutions may be required that do not comply with the specifications set out in the Annex and/or for which the assessment methods set out in the Annex cannot be applied. In that case, new specifications and/or new assessment methods associated with those innovative solutions shall be developed.

2. Innovative solutions may be related to the 'rolling stock – freight wagon' subsystem, its parts and its interoperability constituents.

3. If an innovative solution is proposed, the manufacturer or his authorised representative established within the Union shall declare how it deviates from or complements to the relevant provisions of this TSI and submit the deviations to the Commission for analysis.

4. The Commission shall deliver an opinion on the innovative solution proposed. If this opinion is positive, the appropriate functional and interface specifications and the assessment method, which must be included in the TSI in order to allow the use of this innovative solution, shall be developed and subsequently integrated in the TSI during the revision process carried out pursuant to Article 5 of Directive (EU) 2016/797. If the opinion is negative, the innovative solution proposed shall not be applied.

5. Pending the review of the TSI, the positive opinion delivered by the Commission shall be considered as acceptable means of compliance with the essential requirements of Directive (EU) 2016/797 and may therefore be used for the assessment of the subsystem."

> 7.2.2.2 Rules to manage changes in both a unit or a unit type

"[...]

Without prejudice to clause 7.2.2.3, all changes shall remain compliant with the applicable TSIs regardless their classification.

[...]"

 7.2.2.3 Particular rules for existing units not covered by an EC declaration of verification with a first authorisation for placing in service before 1 January 2015

"The following rules apply, in addition to clause 7.2.2.2, to existing units with a first authorisation for placing in service before 1 January 2015, where the scope of the change has an impact on basic parameters not covered by the EC declaration.

The compliance with technical requirements of this TSI is deemed established when a basic parameter is improved in the direction of the TSI defined performance and the entity managing the change demonstrates that the corresponding essential requirements are met and the safety level is maintained and, where reasonably practicable, improved. The entity managing the change shall in this case justify the reasons for which the TSI defined performance was not met, taking into account migration strategies of other TSIs as stated in section 7.2.2.2. This justification shall be in the technical file, if any, or in the original technical documentation of the unit.

The particular rule set out in the above paragraph is not applicable in changes impacting the basic parameters and classified as 21(12)a set out in table 11b. For those changes, compliance with the TSI requirements is mandatory."

### e) Regulation (EU) 2016/919 (CCS 7SI)

> 6.1.1.3 Partial fulfilment of TSI requirements

"With regard to checking if essential requirements are fulfilled through compliance with the basic parameters, and without prejudice to the obligations set out in Chapter 7 of this TSI, controlcommand and signalling interoperability constituents and subsystems that do not implement all functions, performance and interfaces as specified in Chapter 4 (including the specifications referred to in Annex A), can obtain EC certificates of conformity or, respectively, certificates of verification, under the following conditions for issuing and using the certificates:

- (1) The applicant for EC verification of a trackside control-command and signalling subsystem is responsible for deciding which functions, performance and interfaces need to be implemented to meet the objectives for the service and to ensure that no requirements contradicting or exceeding the TSIs are exported to the on-board control-command and signalling subsystems.
- (2) The operation of an on-board control-command and signalling subsystem, that does not implement all functions, performance and interfaces specified in this TSI, may be subject to conditions and limits of use due to compatibility and/or safe integration with trackside control-command and signalling subsystems. Without prejudice to the tasks of a Notified Body described in respective Union legislation and related documents the applicant for EC verification is responsible for ensuring that the technical file provides all the information<sup>(1)</sup> that an operator needs to identify such conditions and limits of use.

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<sup>&</sup>lt;sup>(1)</sup> The template to be used to provide this information will be defined in the Application Guide.

(3) The authorising entity may refuse for duly justified reasons the authorisation for placing in service or on the market, or place conditions and limits of use on the operation, of control-command and signalling subsystems that do not implement all functions, performance and interfaces specified in this TSI.

If a control-command and signalling interoperability constituent or subsystem does not implement all functions, performance and interfaces specified in this TSI, the provisions of point 6.4.3 shall apply."

- > 6.4.3 Partial fulfilment of the requirements due to limited application of the TSI
- > 6.4.3.1 Interoperability constituents

"If an interoperability constituent does not implement all functions, performance and interfaces specified in this TSI, an EC certificate of conformity may only be issued if the unimplemented functions, interfaces or performance are not required to integrate the interoperability constituent into a subsystem for the use indicated by the applicant, for example<sup>(2)</sup>,

- (1) the on-board ETCS interface to STM if the interoperability constituent is intended for installation on vehicles in which no external STM is needed;
- (2) the RBC interface to other RBCs, if the RBC is intended for use in an application for which no neighbouring RBCs are planned.

The EC certificate of conformity (or accompanying documents) for the interoperability constituent shall fulfil all the following requirements:

- (1) it indicates which functions, interfaces or performance are not implemented;
- (2) it provides enough information to make it possible to identify the conditions under which the interoperability constituent can be used;
- (3) it provides enough information to make it possible to identify the conditions of and restriction on the use that will apply to the interoperability of a subsystem incorporating it."
- > 6.4.3.2 Subsystems

"If a control-command and signalling subsystem does not implement all functions, performance and interfaces of this TSI (e.g. because they are not implemented by an interoperability constituent integrated into it), the certificate of verification shall indicate which requirements have been assessed and the corresponding conditions and restrictions on the use of the subsystem and its compatibility with other subsystems."

> 6.4.3.3 Content of certificates

"In any event, notified bodies shall coordinate with the Agency the way in which conditions and restrictions of use of interoperability constituents and subsystems are managed in the relevant certificates and technical files in the working group set up under Article 24 of Regulation (EU) 2016/796 of the European Parliament and of the Council<sup>(3)</sup>."

<sup>&</sup>lt;sup>(2)</sup> The procedures described in this Chapter do not prejudice the possibility of grouping constituents together.

<sup>&</sup>lt;sup>(3)</sup> 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)