

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) (Text with EEA relevance)

CHAPTER IV

SUBSYSTEMS

Article 12

Free movement of subsystems

Without prejudice to the provisions of Chapter V, Member States shall not, in their territory and on grounds relating to this Directive, prohibit, restrict or hinder the construction, placing in service and operation of structural subsystems constituting the rail system which meet the essential requirements. In particular, they shall not require checks which have already been carried out:

- (a) as part of the procedure leading to the ‘EC’ declaration of verification; or
- (b) in other Member States, before or after the entry into force of this Directive, with a view to verifying compliance with identical requirements under identical operational conditions.

Article 13

Conformity with TSIs and national rules

1 The Agency and the national safety authorities shall consider as meeting the essential requirements, those structural subsystems constituting the rail system which are covered, as appropriate, by the ‘EC’ declaration of verification established by reference to TSIs, in accordance with Article 15, or the declaration of verification established by reference to national rules in accordance with Article 15(8), or both.

2 National rules for implementing the essential requirements and, where relevant, acceptable national means of compliance, shall apply in the following cases:

- a where the TSIs do not cover, or do not fully cover, certain aspects corresponding to the essential requirements, including open points as referred to in Article 4(6);
- b where non-application of one or more TSIs or parts of them has been notified under Article 7;
- c where a specific case requires the application of technical rules not included in the relevant TSI;
- d national rules used to specify existing systems, limited to the aim of assessing technical compatibility of the vehicle with the network;
- e networks and vehicles not covered by TSIs;
- f as an urgent temporary preventive measure, in particular following an accident.

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Article 14

Notification of national rules

1 Member States shall notify to the Commission and to the Agency the existing national rules referred to in Article 13(2) in the following cases:

- a where the national rule(s) has/have not been notified by 15 June 2016. In that case, they shall be notified by 16 December 2016;
- b each time the rules are changed;
- c when a new request has been submitted in accordance with Article 7 for non-application of the TSI;
- d where national rules become redundant after publication or revision of the TSI concerned.

2 Member States shall notify the full text of national rules referred to in paragraph 1 through the appropriate IT system in accordance with Article 27 of Regulation (EU) 2016/796.

3 Member States shall ensure that national rules referred to in paragraph 1, including those covering the interfaces between vehicles and networks, are easily accessible, in the public domain and formulated in terminology that all interested parties can understand. Member States may be requested to provide additional information on those national rules.

4 Member States may lay down new national rules only in the following cases:

- a when a TSI does not fully meet the essential requirements;
- b as an urgent preventive measure, in particular following an accident.

5 Member States shall submit, through the appropriate IT system in accordance with Article 27 of Regulation (EU) 2016/796, the drafts of new national rules to the Agency and the Commission for consideration before the expected introduction of the proposed new rule into the national legal system, in due time and within the deadlines referred to in Article 25(1) of Regulation (EU) 2016/796 and provide justification for the introduction of that new national rule. Member States shall ensure that the draft is sufficiently developed to allow the Agency to carry out its examination in accordance with Article 25(2) of Regulation (EU) 2016/796.

6 When they adopt a new national rule, Member States shall notify it to the Agency and the Commission through the appropriate IT system in accordance with Article 27 of Regulation (EU) 2016/796.

7 In the case of urgent preventive measures, Member States may adopt and apply a new national rule immediately. That rule shall be notified in accordance with Article 27(2) of Regulation (EU) 2016/796 and subject to the assessment of the Agency in accordance with Article 26(1), (2) and (5) of that Regulation.

8 When notifying a national rule referred to in paragraph 1 or a new national rule, Member States shall provide justification of the need for that rule in order to fulfil an essential requirement not already covered by the relevant TSI.

9 Draft national rules and national rules referred to in paragraph 1 shall be examined by the Agency in accordance with the procedures laid down in Articles 25 and 26 of Regulation (EU) 2016/796.

10 The Commission shall establish, by means of implementing acts, the classification of the notified national rules in different groups with the aim of facilitating cross-acceptance

in different Member States and the placing on the market of vehicles, including compatibility between fixed and mobile equipment. Those implementing acts shall build on the progress achieved by the Agency in the field of cross-acceptance and shall be adopted in accordance with the examination procedure referred to in Article 51(3).

The Agency shall classify, in accordance with the implementing acts referred to in the first subparagraph, the national rules which are notified in accordance with this Article.

11 Member States may decide not to notify rules and restrictions of a strictly local nature. In such cases, Member States shall mention those rules and restrictions in the registers of infrastructure referred to in Article 49.

12 National rules notified under this Article are not subject to the notification procedure set out in Directive (EU) 2015/1535 of the European Parliament and of the Council⁽⁴⁾.

13 National rules not notified in accordance with this Article shall not apply for the purposes of this Directive.

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.

3 The task of the notified body responsible for the ‘EC’ verification of a subsystem shall begin at the design stage and cover the entire manufacturing period through to the acceptance stage before the subsystem is placed on the market or in service. It shall, in accordance with the relevant TSI, also cover verification of the interfaces of the subsystem in question with the system into which it is incorporated.

4 The applicant shall be responsible for compiling the technical file that is to accompany the ‘EC’ declaration of verification. That technical file shall contain all the necessary documents relating to the characteristics of the subsystem and, where appropriate, all the documents certifying conformity of the interoperability constituents. It shall also contain all the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance.

5 In the event of the renewal or upgrading of a subsystem resulting in an amendment to the technical file and affecting the validity of the verification procedures already carried out, the applicant shall assess the need for a new ‘EC’ declaration of verification.

6 The notified body may issue intermediate statement verifications to cover certain stages of the verification procedure or certain parts of the subsystem.

7 If the relevant TSIs allow, the notified body may issue certificates of verification for one or more subsystems or certain parts of those subsystems.

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8 Member States shall designate the bodies responsible for carrying out the verification procedure in respect of national rules. In that regard, designated bodies shall be responsible for the tasks involved. Without prejudice to Article 30, a Member State may appoint a notified body as a designated body, in which case the entire process may be carried out by a single conformity assessment body.

- 9 The Commission may specify, by means of implementing acts:
- a the details of the ‘EC’ verification procedures for subsystems, including the verification procedure in the case of national rules and the documents to be submitted by the applicant for the purposes of that procedure;
 - b the templates for the ‘EC’ declaration of verification, including in the case of a modification of the subsystem or in the case of additional verifications, the intermediate statement of verification, and templates for documents of the technical file that is to accompany those declarations as well as templates for the certificate of verification.

Those implementing acts shall be adopted in accordance with the examination procedure referred to Article 51(3).

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.

Article 17

Presumption of conformity

Interoperability constituents and subsystems which are in conformity with harmonised standards or parts thereof, the references of which have been published in *the Official Journal of the European Union*, shall be presumed to be in conformity with the essential requirements covered by those standards or parts thereof.

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- (1) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and rules on Information Society services ([OJ L 241, 17.9.2015, p. 1](#)).