

## ANNEX

## 6. ASSESSMENT OF CONFORMITY OF INTEROPERABILITY CONSTITUENTS AND EC VERIFICATION OF THE SUBSYSTEMS

Modules for the procedures for assessment of conformity and suitability for use and EC verification are defined in Article 8 of this Regulation.

6.1. **Interoperability Constituents**6.1.1. *Conformity assessment procedures*

- (1) The conformity assessment procedure of interoperability constituents as defined in section 5 of this TSI shall be carried out by application of the relevant modules.
- (2) Serviceable interoperability constituents that are suitable for reuse are not subject to the conformity assessment procedures.

6.1.2. *Application of modules*

- (1) The following modules for conformity assessment of interoperability constituents are used:
  - (a) CA ‘Internal production control’
  - (b) CB ‘EC type examination’
  - (c) CC ‘Conformity to type based on internal production control’
  - (d) CD ‘Conformity to type based on quality management system of the production process’
  - (e) CF ‘Conformity to type based on product verification’
  - (f) CH ‘Conformity based on full quality management system’
- (2) The modules for conformity assessment of interoperability constituents shall be chosen from those shown in Table 20.

TABLE 20

**Modules for conformity assessment to be applied for interoperability constituents**

Procedures	Rail	Rail fastening system	Track sleepers
Placed on the EU market before entry into force of relevant TSIs	CA or CH	CA or CH	
Placed on the EU market after entry into force of relevant TSIs	CB + CC or CB + CD or CB + CF or CH		

- (3) In the case of products placed on the market before the publication of relevant TSIs, the type is considered to have been approved and therefore EC type examination

(module CB) is not necessary, provided that the manufacturer demonstrates that tests and verification of interoperability constituents have been considered successful for previous applications under comparable conditions and are in conformity with the requirements of this TSI. In this case these assessments shall remain valid in the new application. If it is not possible to demonstrate that the solution is positively proven in the past, the procedure for interoperability constituents placed on the EU market after publication of this TSI applies.

- (4) The conformity assessment of interoperability constituents shall cover the phases and characteristics as indicated in Table 36 of Appendix A to this TSI.

6.1.3. *Innovative solutions for interoperability constituents*

If an innovative solution is proposed for an interoperability constituent, the procedure described in Article 10 shall apply.

6.1.4. *EC declaration of conformity for interoperability constituents*

6.1.4.1. *Interoperability constituents subject to other European Union Directives*

- (1) Article 13(3) of Directive 2008/57/EC, states ‘Where the interoperability constituents are the subject of other Community Directives covering other aspects, the EC declaration of conformity or suitability for use shall, in such instances, state that the interoperability constituents also meet the requirements of those other Directives.’
- (2) According to Annex IV (3) of Directive 2008/57/EC, the EC declaration of conformity shall be accompanied by the statement setting out the condition of use.

6.1.4.2. *EC declaration of conformity for rails*

No statement setting out the conditions of use is required.

6.1.4.3. *EC declaration of conformity for rail fastening systems*

The EC declaration of conformity shall be accompanied by statement setting out:

- (a) the combination of rail, rail inclination, rail pad and type of sleepers with which the fastening system may be used
- (b) the maximum axle load the rail fastening system is designed to accommodate.

6.1.4.4. *EC declaration of conformity for track sleepers*

The EC declaration of conformity shall be accompanied by statement setting out:

- (a) the combination of rail, rail inclination and type of rail fastening system with which the sleeper may be used,
- (b) the nominal and design track gauge,
- (c) the combinations of axle load and train speed the track sleeper is designed to accommodate.

6.1.5. *Particular assessment procedures for interoperability constituents*

6.1.5.1. *Assessment of rails*

Assessment of rail steel shall be done according to the following requirements:

- (a) Rail hardness shall be tested for position RS according to EN 13674-1:2011 paragraph 9.1.8, measured using one specimen (control sample out of production).
- (b) Tensile strength shall be tested according to EN 13674-1:2011 paragraph 9.1.9, measured using one specimen (control sample out of production).
- (c) Fatigue test shall be done according to EN 13674-1:2011 paragraph 8.1 and paragraph 8.4.

#### 6.1.5.2. *Assessment of sleepers*

- (1) Until 31 May 2021 a design track gauge for track sleepers below 1 437 mm shall be allowed.
- (2) For polyvalent gauge and multiple gauge track sleepers it is allowed not to assess the design track gauge for the nominal track gauge of 1 435 mm.

### 6.2. **Infrastructure subsystem**

#### 6.2.1. *General provisions*

- (1) At the request of the applicant, the notified body carries out the EC verification of the infrastructure subsystem in accordance with Article 18 of Directive 2008/57/EC and in accordance with the provisions of the relevant modules.
- (2) If the applicant demonstrates that tests or assessments of an infrastructure subsystem or parts of the subsystem are the same as have been successful for previous applications of a design, the notified body shall consider the results of these tests and assessments for the EC verification.
- (3) The EC verification of the infrastructure subsystem shall cover the phases and characteristics indicated in Table 37 in Appendix B to this TSI.
- (4) Performance parameters as set out in point 4.2.1 of this TSI are not subject to the EC verification of the subsystem.
- (5) Particular assessment procedures for specific basic parameters of infrastructure subsystem are set out in point 6.2.4.
- (6) The applicant shall draw up the EC declaration of verification for the infrastructure subsystem in accordance with Article 18 and Annex V of Directive 2008/57/EC.

#### 6.2.2. *Application of modules*

For the EC verification procedure of the infrastructure subsystem, the applicant may choose either:

- (a) Module SG: EC verification based on unit verification, or
- (b) Module SH1: EC verification based on full quality management system plus design examination.

##### 6.2.2.1. *Application of module SG*

In the case where EC verification is most effectively undertaken by using information collected by the infrastructure manager, contracting entity or the main contractors involved (for example data obtained using track recording vehicle or other measuring devices), the notified body shall take this information into account to assess conformity.

#### 6.2.2.2. *Application of module SH1*

The SH1 module may be chosen only where the activities contributing to the proposed subsystem to be verified (design, manufacturing, assembling, installation) are subject to a quality management system for design, production, final product inspection and testing, approved and surveyed by a notified body.

#### 6.2.3. *Innovative solutions*

If an innovative solution is proposed for the infrastructure subsystem, the procedure described in Article 10 shall apply.

#### 6.2.4. *Particular assessment procedures for infrastructure subsystem*

##### 6.2.4.1. *Assessment of Structure gauge*

- (1) Assessment of structure gauge as a design review shall be done against characteristic cross sections using the results of calculations made by infrastructure manager or the contracting entity on the basis of sections 5, 7, 10, Annex C and point D.4.8 of Annex D of EN 15273-3:2013.
- (2) Characteristic cross sections are:
  - (a) track without cant,
  - (b) track with maximum cant,
  - (c) track with a civil engineering structure over the line
  - (d) any other location where the designed installation limit gauge is approached by less than 100 mm or the installation nominal gauge or uniform gauge is approached by less than 50 mm.
- (3) After assembly before putting into service clearances shall be verified at locations where the designed installation limit gauge is approached by less than 100 mm or the installation nominal gauge or uniform gauge is approached by less than 50 mm.
- (4) Instead of point (1), for the 1 520 mm track gauge system assessment of structure gauge as a design review is to be made against characteristic cross sections using the uniform structure gauge 'S' as defined in Appendix H to this TSI.
- (5) Instead of point (1), for the 1 600 mm track gauge system assessment of structure gauge as a design review is to be made against characteristic cross sections using the structure gauge 'IRL1' as defined in Appendix O to this TSI.

##### 6.2.4.2. *Assessment of distance between track centres*

- (1) A design review for assessment of the distance between track centres shall be done using the results of calculations made by the Infrastructure Manager or the contracting entity on the basis of chapter 9 of EN 15273-3:2013. The nominal distance between track centres shall be checked at the line layout where distances are given in parallel to the horizontal plane. The limit installation distance between track centres shall be checked with the radius and relevant cant.
- (2) After assembly before putting into service, distance between track centres shall be verified at critical locations where the limit installation distance between track centres as defined according chapter 9 of EN 15273-3:2013 is approached by less than 50 mm.

- (3) Instead of point (1), for the 1 520 mm track gauge system a design review for assessment of the distance between track centres is to be made using the results of calculations made by the infrastructure manager or the contracting entity. The nominal distance between track centres shall be checked at the line layout where distances are given in parallel to the horizontal plane. The limit installation distance between track centres shall be checked with the radius and relevant cant.
- (4) Instead of point (2), for the 1 520 mm track gauge system after assembly before putting into service, distance between track centres shall be verified at critical locations where the limit installation distance between track centres is approached by less than 50 mm.

#### 6.2.4.3. *Assessment of nominal track gauge*

- (1) Assessment of the nominal track gauge at design review shall be done by checking the self-declaration of the applicant.
- (2) Assessment of the nominal track gauge at assembly before putting into service shall be done by checking the interoperability constituent sleeper's certificate. For non-certified interoperability constituents assessment of the nominal track gauge shall be done by checking the self-declaration of the applicant.

#### 6.2.4.4. *Assessment of track layout*

- (1) At design review the curvature, cant, cant deficiency and abrupt change of cant deficiency shall be assessed against the local design speed.
- (2) Assessment of switches and crossings layout is not required.

#### 6.2.4.5. *Assessment of cant deficiency for trains designed to travel with higher cant deficiency*

Point 4.2.4.3(2) states that 'It is permissible for trains specifically designed to travel with higher cant deficiency (for example multiple units with lower axle loads; vehicles with special equipment for the negotiation of curves) to run with higher cant deficiency values, subject to a demonstration that this can be achieved safely'. This demonstration is outside the scope of this TSI and thus not subject to a notified body verification of the infrastructure subsystem. The demonstration shall be undertaken by the RU, if necessary in cooperation with the IM.

#### 6.2.4.6. *Assessment of design values for equivalent conicity*

Assessment of design values for equivalent conicity shall be done using the results of calculations made by the infrastructure manager or the contracting entity on the basis of EN 15302:2008+A1:2010.

#### 6.2.4.7. *Assessment of railhead profile*

- (1) The design profile of new rails shall be checked against point 4.2.4.6.
- (2) Reused serviceable rails shall not be subject to the requirements for railhead profile as set out in point 4.2.4.6.

#### 6.2.4.8. *Assessment of switches and crossings*

Assessment of switches and crossings related to points 4.2.5.1 to 4.2.5.3 shall be done by checking that a self-declaration of the infrastructure manager or contracting entity exists.

#### 6.2.4.9. *Assessment of new structures, earthworks and earth pressure effects*

- (1) Assessment of new structures shall be done by checking the traffic loads and the track twist limit used for design against the minimum requirements of points 4.2.7.1

and 4.2.7.3. The notified body is not required to review the design nor carry out any calculations. When reviewing the value of factor alpha used in the design according to point 4.2.7.1 it is only necessary to check that the value of factor alpha satisfies Table 11.

- (2) Assessment of new earthworks and earth pressure effects shall be done by checking the vertical loads used for design according to requirements of point 4.2.7.2. When reviewing the value of factor alpha used in the design according to point 4.2.7.2 it is only necessary to check that the value of factor alpha satisfies Table 11. The notified body is not required to review the design nor carry out any calculations.

#### 6.2.4.10. *Assessment of existing structures*

- (1) Assessment of existing structures against the requirements of point 4.2.7.4(3) (b) and (c) shall be done by one of the following methods:
  - (a) check that the values of EN line categories, in combination with the allowed speed published or intended to be published for the lines containing the structures, is in line with the requirements of Appendix E of this TSI,
  - (b) check that the values of EN line categories, in combination with the allowed speed specified for the structures or for the design, is in line with the requirements of Appendix E of this TSI,
  - (c) check the traffic loads specified for the structures or for the design against the minimum requirements of points 4.2.7.1.1 and 4.2.7.1.2. When reviewing the value of factor alpha according to point 4.2.7.1.1 it is only necessary to check that the value of factor alpha is in line with the value of factor alpha mentioned in Table 11.
- (2) It is not required to review the design nor carry out any calculations.
- (3) For existing structures assessment point 4.2.7.4(4) applies respectively.

#### 6.2.4.11. *Assessment of platform offset*

- (1) Assessment of the distance between the track centre and the platform edge as a design review shall be done using the results of calculations made by the Infrastructure Manager or the contracting entity on the basis of chapter 13 of EN 15273-3:2013.
- (2) After assembly before putting into service clearances shall be verified. The offset is checked at the ends of the platform and every 30 m in straight track and every 10 m in curved track.
- (3) Instead of point (1), for the 1 520 mm track gauge system assessment of the distance between the track centre and the platform edge as a design review shall be done against requirements of point 4.2.9.3. Point (2) applies accordingly.
- (4) Instead of point (1), for the 1 600 mm track gauge system assessment of the distance between the track centre and the platform edge as a design review shall be done against requirements of point 4.2.9.3(4). Point (2) applies accordingly.

#### 6.2.4.12. *Assessment of maximum pressure variations in tunnels*

- (1) Assessment of maximum pressure variation in the tunnel (10 kPa criterion) shall be done using the results of numerical simulations according to chapters 4 and 6 of EN 14067-5:2006+A1:2010 made by the infrastructure manager or the contracting entity on the basis of all expected operational conditions with the trains complying with the

Locomotives and Passengers TSI and intended to run at speeds greater than or equal to 200 km/h in the specific tunnel to be assessed.

- (2) The input parameters to be used are to be such that the reference characteristic pressure signature of the trains set out in the locomotives and passenger rolling stock TSI is fulfilled.
- (3) The reference cross section areas of the interoperable trains (constant along a train) to be considered is to be, independently to each motor or trailer vehicle:
  - (a) 12 m<sup>2</sup> for vehicles designed for GC and DE3 reference kinematic profile,
  - (b) 11 m<sup>2</sup> for vehicles designed for GA and GB reference kinematic profile,
  - (c) 10 m<sup>2</sup> for vehicles designed for G1 reference kinematic profiles.

The vehicle gauge to be considered shall be set on the basis of the gauges selected according to point 4.2.1.

- (4) The assessment may take into account construction features which reduce the pressure variation if any, as well as the tunnel length.
- (5) The pressure variations due to atmospheric or geographical conditions can be neglected.

#### 6.2.4.13. *Assessment of effect of crosswinds*

This demonstration of the safety is outside the scope of this TSI and thus not subject to a notified body verification. The demonstration shall be undertaken by the infrastructure manager, if necessary in cooperation with the railway undertaking.

#### 6.2.4.14. *Assessment of fixed installations for servicing trains*

Assessment of fixed installations for servicing trains is in the responsibility of the Member State concerned.

#### 6.2.5. *Technical solutions giving presumption of conformity at design stage*

Presumption of conformity at design stage for technical solutions may be assessed prior and independent from a specific project.

##### 6.2.5.1. *Assessment of track resistance for plain line*

- (1) The demonstration of conformity of the track to the requirements of point 4.2.6 may be done by reference to an existing track design which meets the operating conditions intended for the subsystem concerned.
- (2) A track design shall be defined by the technical characteristics as set out in Appendix C.1 to this TSI and by its operating conditions as set out in Appendix D.1 to this TSI.
- (3) A track design is considered to be existing, if both of the following conditions are met:
  - (a) the track design has been in normal operation for at least one year and
  - (b) the total tonnage over the track was at least 20 million gross tons for the period of normal operation.
- (4) The operating conditions for an existing track design refer to conditions which have been applied in normal operation.

- (5) The assessment to confirm an existing track design shall be performed by checking that the technical characteristics as set out in Appendix C.1 to this TSI and conditions of use as set out in Appendix D.1 to this TSI are specified and that the reference to the previous use of the track design is available.
- (6) When a previously assessed existing track design is used in a project, the notified body shall only assess that the conditions of use are respected.
- (7) For new track designs that are based on existing track designs, a new assessment can be performed by verifying the differences and evaluating their impact on the track resistance. This assessment may be supported for example by computer simulation or by laboratory or in situ testing.
- (8) A track design is considered to be new, if at least one of the technical characteristics set out in Appendix C to this TSI or one of conditions of use set out in Appendix D to this TSI is changed.

#### 6.2.5.2. *Assessment for switches and crossing*

- (1) The provisions as set out in point 6.2.5.1 are applicable for the assessment of track resistance for switches and crossings. Appendix C.2 sets out the technical characteristics of switches and crossings design and Appendix D.2 sets out the conditions of use of switches and crossings design.
- (2) Assessment of design geometry of switches and crossings shall be done according to point 6.2.4.8 of this TSI.
- (3) Assessment of maximum unguided length of fixed obtuse crossings shall be done according to point 6.2.4.8 of this TSI.

#### 6.3. **EC Verification when speed is used as a migration criterion**

- (1) Point 7.5 allows a line to be put into service at a lower speed than the ultimate intended speed. This point sets out requirements for EC verification in this case.
- (2) Some limiting values set out in section 4 depend on the intended speed of the route. Conformity should be assessed at the intended ultimate speed; however it is permissible to assess speed dependant characteristics at the lower speed at the time of placing in service.
- (3) The conformity of the other characteristics for the intended speed of the route remains valid.
- (4) To declare the interoperability at this intended speed, it is only necessary to assess the conformity of the characteristics temporarily not respected, when they are brought up to the required level.

#### 6.4. **Assessment of maintenance file**

- (1) Point 4.5 requires the infrastructure manager to have for each interoperable line a maintenance file for the infrastructure subsystem.
- (2) The notified body shall confirm that the maintenance file exists and contains the items listed in point 4.5.1. The notified body is not responsible for assessing the suitability of the detailed requirements set out in the maintenance file.



- (3) The notified body shall include a reference to the maintenance file required by point 4.5.1 of this TSI in the technical file referred to in Article 18(3) of Directive 2008/57/EC.

## 6.5. Subsystems containing Interoperability constituents not holding an EC declaration

### 6.5.1. Conditions

- (1) Until 31 May 2021, a notified body is allowed to issue an EC certificate of verification for a subsystem even if some of the interoperability constituents incorporated within the subsystem are not covered by the relevant EC declarations of conformity and/or suitability for use according to this TSI, if the following criteria are complied with:
- (a) the conformity of the subsystem has been checked against the requirements of section 4 and in relation to sections 6.2 to 7 (except point 7.7 ‘Specific Cases’) of this TSI by the notified body. Furthermore the conformity of the ICs to section 5 and 6.1 does not apply, and
  - (b) the interoperability constituents, which are not covered by the relevant EC declaration of conformity and/or suitability for use, have been used in a subsystem already approved and put in service in at least one of the Member State before the entry in force of this TSI.
- (2) EC declarations of conformity and/or suitability for use shall not be drawn up for the interoperability constituents assessed in this manner.

### 6.5.2. Documentation

- (1) The EC certificate of verification of the subsystem shall indicate clearly which interoperability constituents have been assessed by the notified body as part of the subsystem verification.
- (2) The EC declaration of verification of the subsystem shall indicate clearly:
- (a) Which interoperability constituents have been assessed as part of the subsystem;
  - (b) Confirmation that the subsystem contains the interoperability constituents identical to those verified as part of the subsystem;
  - (c) For those interoperability constituents, the reason(s) why the manufacturer did not provide an EC Declaration of conformity and/or suitability for use before its incorporation into the subsystem, including the application of national rules notified under Article 17 of Directive 2008/57/EC.

### 6.5.3. Maintenance of the subsystems certified according to 6.5.1.

- (1) During and after the transition period and until the subsystem is upgraded or renewed (taking into account the decision of Member State on application of TSIs), the interoperability constituents which do not hold an EC Declaration of conformity and/or suitability for use and are of the same type are allowed to be used as maintenance related replacements (spare parts) for the subsystem, under the responsibility of the body responsible for maintenance.
- (2) In any case the body responsible for maintenance must ensure that the components for maintenance related replacements are suitable for their applications, are used within their area of use and enable interoperability to be achieved within the rail system

while at the same time meeting the essential requirements. Such components must be traceable and certified in accordance with any national or international rule or any code of practice widely acknowledged in the railway domain.

#### **6.6. Subsystem containing serviceable interoperability constituents that are suitable for reuse**

##### *6.6.1. Conditions*

- (1) A notified body is allowed to issue an EC certificate of verification for a subsystem even if some of the interoperability constituents incorporated within the subsystem are serviceable interoperability constituents that are suitable for reuse, if the following criteria are complied with:
  - (a) the conformity of the subsystem has been checked against the requirements of section 4 and in relation to sections 6.2 to 7 (except point 7.7 ‘Specific Cases’) of this TSI by the notified body. Furthermore the conformity of the ICs to 6.1 does not apply, and
  - (b) the interoperability constituents are not covered by the relevant EC declaration of conformity and/or suitability for use.
- (2) EC declarations of conformity and/or suitability for use shall not be drawn up for the interoperability constituents assessed in this manner.

##### *6.6.2. Documentation*

- (1) The EC certificate of verification of the subsystem shall indicate clearly which interoperability constituents have been assessed by the notified body as part of the subsystem verification.
- (2) The EC declaration of verification of the subsystem shall indicate clearly:
  - (a) Which interoperability constituents are serviceable interoperability constituents that are suitable for reuse;
  - (b) Confirmation that the subsystem contains the interoperability constituents identical to those verified as part of the subsystem.

##### *6.6.3. Use of serviceable interoperability constituents in maintenance*

- (1) Serviceable interoperability constituents that are suitable for reuse are allowed to be used as maintenance related replacements (spare parts) for the subsystem, under the responsibility of the body responsible for maintenance.
- (2) In any case the body responsible for maintenance must ensure that the components for maintenance related replacements are suitable for their applications, are used within their area of use, and enable interoperability to be achieved within the rail system while at the same time meeting the essential requirements. Such components must be traceable and certified in accordance with any national or international rule, or any code of practice widely acknowledged in the railway domain.