

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 VI

CONFORMITY ASSESSMENT BODIES

Article 27

Notifying authorities

1 Member States shall appoint notifying authorities that shall be responsible for setting up and carrying out the necessary procedures for the assessment, notification and monitoring of conformity assessment bodies, including compliance with Article 34.

2 Member States shall ensure that those authorities notify the Commission and other Member States' bodies authorised to carry out third-party conformity assessment tasks as provided for in Articles 10(2) and 15(1). They shall also ensure that they inform the Commission and the other Member States of the designated bodies referred to in Article 15(8).

3 Member States may decide that the assessment and monitoring referred to in paragraph 1 are to be carried out by a national accreditation body within the meaning of, and in accordance with, Regulation (EC) No 765/2008.

4 Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body which is not a governmental entity, that body shall be a legal person and shall comply with the requirements laid down in Article 28. It shall put in place arrangements to cover liabilities arising out of its activities.

5 The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 28

Requirements relating to notifying authorities

A notifying authority shall:

- (a) be established in such a way as to avoid any conflict of interest with conformity assessment bodies;
- (b) be organised and operated in such a way as to safeguard the objectivity and impartiality of its activities;
- (c) be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment;
- (d) not offer or provide any activities that are performed by conformity assessment bodies or consultancy services on a commercial or competitive basis;

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- (e) safeguard the confidentiality of the information it obtains;
- (f) have at its disposal a sufficient number of competent personnel for the proper performance of its tasks.

Article 29

Obligation of notifying authorities to provide information

Member States shall inform the Commission of their procedures for the assessment, notification and monitoring of conformity assessment bodies, and of any changes to those procedures.

The Commission shall make that information publicly available.

Article 30

Conformity assessment bodies

1 For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 7 of this Article and in Articles 31 and 32.

2 A conformity assessment body shall be established under national law and shall have legal personality.

3 A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by the relevant TSI and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of product in relation to which it has been notified, a conformity assessment body shall have at its disposal:

- a the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- b the relevant descriptions of procedures in accordance with which conformity assessment is to be carried out, ensuring the transparency and the ability to apply those procedures. It shall have in place appropriate policies and procedures that distinguish between the tasks it carries out as a notified conformity assessment body and other activities;
- c the proper procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

It shall have the means necessary to perform in an appropriate manner the technical and administrative tasks connected with the conformity assessment activities and shall have access to all necessary equipment or facilities.

4 Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or unless the Member State itself is directly responsible for the conformity assessment.

5 The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under the relevant TSI or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

6 Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified conformity assessment bodies' coordination group established under the relevant Union law, and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

7 Conformity assessment bodies that are notified for trackside and/or on-board control-command and signalling subsystems shall participate in, or shall ensure that their assessment personnel are informed of, the activities of the ERTMS group referred to in Article 29 of Regulation (EU) 2016/796. They shall follow the guidelines produced as a result of the work of that group. In the event that they consider it inappropriate or impossible to apply them, the conformity assessment bodies concerned shall submit their observations for discussion to the ERTMS group for the continuous improvement of the guidelines.

Article 31

Impartiality of conformity assessment bodies

1 A conformity assessment body shall be a third-party body independent of the organisation or of the manufacturer of the product it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered to be such a body.

2 The impartiality of the conformity assessment bodies, of their top-level management and of the assessment personnel shall be guaranteed.

3 A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, or the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

4 A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This prohibition shall apply, in particular, to consultancy services.

5 Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

6 Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical

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competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

Article 32

Personnel of conformity assessment bodies

1 The personnel responsible for carrying out conformity assessment activities shall have the following skills:

- a sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- b satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- c appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of Union law;
- d the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

2 The remuneration of the top-level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

Article 33

Presumption of conformity of a conformity assessment body

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in *the Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Articles 30 to 32, in so far as the applicable harmonised standards cover those requirements.

Article 34

Subsidiaries of, and subcontracting by, notified bodies

1 Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Articles 30 to 32 and shall inform the notifying authority accordingly.

2 Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3 Activities of notified bodies may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4 Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under the relevant TSI.

Article 35

Accredited in-house bodies

1 Applicants may use an accredited in-house body to carry out conformity assessment activities for the purpose of implementing the procedures set out in modules A1, A2, C1 or C2 laid down in Annex II to Decision No 768/2008/EC and modules CA1 and CA2 laid down in Annex I to Decision 2010/713/EU. That body shall constitute a separate and distinct part of the applicant concerned and shall not participate in the design, production, supply, installation, use or maintenance of the products it assesses.

- 2 An accredited in-house body shall meet the following requirements:
- a it shall be accredited in accordance with Regulation (EC) No 765/2008;
 - b the body and its personnel shall, within the undertaking of which they form a part, be organisationally identifiable and have reporting methods which ensure their impartiality, and shall demonstrate it to the competent national accreditation body;
 - c neither the body nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the products they assess, nor shall they engage in any activity that might conflict with their independence of judgement or integrity in relation to their assessment activities;
 - d the body shall supply its services exclusively to the undertaking of which it forms a part.

3 An accredited in-house body shall not be notified to the Member States or the Commission, but information concerning its accreditation shall be given by the undertaking of which it forms a part or by the national accreditation body to the notifying authority at the request of that authority.

Article 36

Application for notification

1 A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2 That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Articles 30 to 32.

3 Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Articles 30 to 32.

Article 37

Notification procedure

1 Notifying authorities shall only notify conformity assessment bodies which comply with the requirements laid down in Articles 30 to 32.

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2 Notifying authorities shall notify the bodies referred to in paragraph 1 to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3 The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the product or products concerned, and the relevant accreditation certificate or other attestation of competence provided for in paragraph 4.

4 Where a notification is not based on an accreditation certificate as referred to in Article 36(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored periodically and will continue to satisfy the requirements laid down in Articles 30 to 32.

5 The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

6 The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 38

Identification numbers and lists of notified bodies

1 The Commission shall assign an identification number to a notified body.

A notified body shall be assigned a single identification number even where it is notified under several legal acts of the Union.

2 The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been allocated to them and the activities for which they have been notified.

The Commission shall ensure that that list is kept up to date.

Article 39

Changes to notifications

1 Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Articles 30 to 32, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2 In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 40

Challenges to the competence of notified bodies

1 The Commission shall investigate all cases where it has any doubt, or where a doubt is brought to its attention, regarding the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2 The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3 The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4 Where the Commission ascertains that a notified body does not meet, or no longer meets, the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including withdrawal of notification if necessary.

Article 41

Operational obligations of notified bodies

1 Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant TSI.

2 Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Notified bodies, when performing their activities, shall take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing, they shall nevertheless operate with the aim of assessing the compliance of the product with this Directive.

3 Where a notified body finds that requirements laid down in the relevant TSI or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

4 Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies with the relevant TSI or corresponding harmonised standards or technical specifications, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5 Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

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Article 42

Obligation of notified bodies to provide information

- 1 Notified bodies shall inform the notifying authority of the following:
 - a any refusal, restriction, suspension or withdrawal of a certificate;
 - b any circumstances affecting the scope of, and conditions for, notification;
 - c any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
 - d on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

The competent national safety authorities shall also be informed of any refusal, restriction, suspension or withdrawal of a certificate under point (a).

- 2 Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

- 3 Notified bodies shall provide the Agency with 'EC' certificates of verification of subsystems, 'EC' certificates of conformity of interoperability constituents and 'EC' certificates of suitability of use of interoperability constituents.

Article 43

Exchanges of best practice

The Commission shall provide for the organisation of exchanges of best practices between the Member States' national authorities responsible for notification policy.

Article 44

Coordination of notified bodies

The Commission shall ensure appropriate coordination and cooperation between bodies notified under this Directive through the establishment of a sectoral group of notified bodies. The Agency shall support the activities of notified bodies in accordance with Article 24 of Regulation (EU) 2016/796.

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

Article 45

Designated bodies

- 1 The requirements relating to conformity assessment bodies set out in Articles 30 to 34 shall also apply to bodies designated under Article 15(8), except:

- a in the case of skills required by its personnel under point (c) of Article 32(1), where the designated body shall have appropriate knowledge and understanding of national law;
- b in the case of documents to be kept at the disposal of the notifying authority under Article 34(4), where the designated body shall include documents relating to work carried out by subsidiaries or subcontractors under the relevant national rules.

2 The operational obligations laid down in Article 41 shall also apply to bodies designated under Article 15(8), except that those obligations refer to national rules instead of TSIs.

3 The information obligation laid down in Article 42(1) shall also apply to designated bodies, which shall inform Member States accordingly.