

Directive (EU) 2016/798 of the European Parliament and of the Council
of 11 May 2016 on railway safety (recast) (Text with EEA relevance)

CHAPTER III

SAFETY CERTIFICATION AND AUTHORISATION

Article 10

Single safety certificate

1 Without prejudice to paragraph 9, access to the railway infrastructure shall be granted only to railway undertakings which hold the single safety certificate issued by the Agency in accordance with paragraphs 5 to 7 or by a national safety authority in accordance with paragraph 8.

The purpose of the single safety certificate is to provide evidence that the railway undertaking concerned has established its safety management system and that it is able to operate safely in the intended area of operation.

2 In its application for a single safety certificate, the railway undertaking shall specify the type and extent of the railway operations covered and the intended area of operation.

3 The application for a single safety certificate shall be accompanied by a file including documentary evidence that:

- a the railway undertaking has established its safety management system in accordance with Article 9 and that it meets the requirements laid down in TSIs, CSMs and CSTs and in other relevant legislation in order to control risks and provide transport services safely on the network; and
- b the railway undertaking, where applicable, meets the requirements laid down in the relevant national rules notified in accordance with Article 8.

That application and information about all applications, the stages of the relevant procedures and their outcome, and, where applicable, the requests and decisions of the Board of Appeal, shall be submitted through the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796.

4 The Agency, or in the cases provided for by paragraph 8 the national safety authority, shall issue the single safety certificate, or inform the applicant of its negative decision, within a predetermined and reasonable time, and, in any case, not more than 4 months after all information required and any supplementary information requested have been submitted by the applicant. The Agency, or in the cases provided for by paragraph 8 the national safety authority, shall apply the practical arrangements on the certification procedure to be established in an implementing act, as referred to in paragraph 10.

5 The Agency shall issue a single safety certificate to railway undertakings having an area of operation in one or more Member States. In order to issue such a certificate, the Agency shall:

- a assess the elements set out in point (a) of paragraph 3; and

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- b immediately refer the railway undertaking's file in its entirety to the national safety authorities concerned by the intended area of operation for an assessment of the elements set out in point (b) of paragraph 3.

As part of the above assessments, the Agency or the national safety authorities shall be authorised to undertake visits and inspections on the sites of the railway undertaking and audits, and may request relevant supplementary information. The Agency and the national safety authorities shall coordinate the organisation of such visits, audits and inspections.

6 Within 1 month of receipt of an application for a single safety certificate, the Agency shall inform the railway undertaking that the file is complete or ask for relevant supplementary information, setting a reasonable deadline for the provision thereof. With regard to the completeness, relevance and consistency of the file, the Agency may also assess the elements set out in point (b) of paragraph 3.

The Agency shall take full account of the assessments under paragraph 5 before taking its decision on the issuing of the single safety certificate.

The Agency shall take full responsibility for any single safety certificates it issues.

7 Where the Agency disagrees with a negative assessment carried out by one or more national safety authorities pursuant to point (b) of paragraph 5, it shall inform that authority or authorities in question, giving reasons for its disagreement. The Agency and the national safety authority or authorities shall cooperate with a view to agreeing on a mutually acceptable assessment. Where necessary, the Agency and the national safety authority or authorities may decide to involve the railway undertaking. If no mutually acceptable assessment can be agreed on within 1 month after the Agency has informed the national safety authority or authorities of its disagreement, the Agency shall take its final decision unless the national safety authority or authorities have referred the matter for arbitration to the Board of Appeal established under Article 55 of Regulation (EU) 2016/796. The Board of Appeal shall decide whether to confirm the Agency's draft decision within 1 month of the request of the national safety authority or authorities.

Where the Board of Appeal agrees with the Agency, the Agency shall take a decision without delay.

Where the Board of Appeal agrees with the negative assessment of the national safety authority, the Agency shall grant a single safety certificate with an area of operations excluding the parts of the network which received a negative assessment.

Where the Agency disagrees with a positive assessment of one or more national safety authorities pursuant to point (b) of paragraph 5, it shall inform the authority or authorities in question, giving reasons for its disagreement. The Agency and the national safety authority or authorities shall cooperate with a view to agreeing on a mutually acceptable assessment. Where necessary, the Agency and the national safety authority or authorities may decide to involve the applicant. If no mutually acceptable assessment can be agreed on within 1 month after the Agency has informed the national safety authority or authorities of its disagreement, the Agency shall take its final decision.

8 Where the area of operation is limited to one Member State, the national safety authority of that Member State may, under its own responsibility and when the applicant so requests, issue a single safety certificate. In order to issue such certificates, the national safety authority shall assess the file in relation to all the elements specified in paragraph 3 and shall apply the practical arrangements to be established in the implementing acts referred to in paragraph 10. As part of the above assessments, the national safety authority shall be authorised

to undertake visits and inspections on the sites of the railway undertaking and audits. Within 1 month of receipt of the application, the national safety authority shall inform the applicant that the file is complete or ask for relevant supplementary information. The single safety certificate shall also be valid without an extension of the area of operations for railway undertakings travelling to stations in neighbouring Member States with similar network characteristics and similar operating rules, when those stations are close to the border, following consultation of the competent national safety authorities. This consultation may be carried out on a case-by-case basis or set out in a cross-border agreement between Member States or national safety authorities.

The national safety authority shall take full responsibility for any single safety certificates it issues.

9 A Member State may allow third-country operators to reach a station in its territory designated for cross-border operations and close to the border of that Member State without requiring a single safety certificate, provided that an appropriate level of safety is ensured through:

- a cross-border agreement between the Member State concerned and the neighbouring third country; or
- b contractual arrangements between the third-country operator and the railway undertaking or infrastructure manager that has a single safety certificate or safety authorisation to operate on that network, provided that the safety-related aspects of those arrangements have been duly reflected in their safety management system.

10 By 16 June 2018, the Commission shall adopt, by means of implementing acts, practical arrangements specifying:

- a how the requirements for the single safety certificate laid down in this Article shall be fulfilled by the applicant and listing the documents required;
- b the details of the certification process, such as procedural stages and timeframes for each stage of the process;
- c how the requirements laid down in this Article shall to be complied with by the Agency and the national safety authority through the different stages of the application and certification process, including in the assessment of applicants' files; and
- d the period of validity of single safety certificates issued by the Agency or by the national safety authorities, in particular in the case of updates of any single safety certificate resulting from changes to type, extent and area of operation.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3). They shall take into account the experience gained during the implementation of Commission Regulation (EC) No 653/2007⁽¹⁾ and of Commission Regulation (EU) No 1158/2010⁽²⁾ and the experience gained during the preparation of the cooperation agreements referred to in Article 11(1).

11 Single safety certificates shall specify the type and extent of the railway operations covered and the area of operation. A single safety certificate may also cover sidings owned by the railway undertaking if these are included in its safety management system.

12 Any decision refusing the issuing of a single safety certificate or excluding part of the network in accordance with a negative assessment as referred to in paragraph 7 shall be duly substantiated. The applicant may, within 1 month of receipt of the decision, request that the Agency or the national safety authority, as appropriate, review the decision. The Agency or the national safety authority shall have 2 months from the date of receipt of the request for review in which to confirm or reverse its decision.

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If the negative decision of the Agency is confirmed, the applicant may bring an appeal before the Board of Appeal designated under Article 55 of Regulation (EU) 2016/796.

If the negative decision of a national safety authority is confirmed, the applicant may bring an appeal before an appeal body in accordance with national law. Member States may designate the regulatory body referred to in Article 56 of Directive 2012/34/EU for the purpose of this appeal procedure. In that case, Article 18(3) of this Directive shall apply.

13 A single safety certificate issued either by the Agency or by a national safety authority under this Article shall be renewed upon application by the railway undertaking at intervals not exceeding 5 years. It shall be fully or partly updated whenever the type or extent of the operation is substantially altered.

14 Where an applicant already has a single safety certificate issued in accordance with paragraphs 5 to 7 and wishes to extend its area of operations, or where it already has a single safety certificate issued in accordance with paragraph 8 and wishes to extend its area of operations to another Member State, it shall supplement the file with the relevant documents referred to in paragraph 3 concerning the additional area of operation. The railway undertaking shall submit the file to the Agency, which shall, after following the procedures laid down in paragraphs 4 to 7, issue an updated single safety certificate covering the extended area of operation. In that case, only the national safety authorities concerned by the extension of operation shall be consulted for the purposes of assessing the file as provided for in point (b) of paragraph 3.

If the railway undertaking has a single safety certificate in accordance with paragraph 8 and wishes to extend the area of operation within that Member State, it shall supplement the file with the relevant documents referred to in paragraph 3 concerning the additional area of operation. It shall submit the file, through the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796, to the national safety authority, which shall, after following the procedures laid down in paragraph 8, issue an updated single safety certificate covering the extended area of operation.

15 The Agency and the competent national safety authorities may require the revision of single safety certificates issued by them following substantial changes to the safety regulatory framework.

16 The Agency shall inform the competent national safety authorities without delay, and in any case within 2 weeks, of the issue of a single safety certificate. The Agency shall inform the competent national safety authorities immediately in the case of renewal, amendment or revocation of a single safety certificate. It shall state the name and address of the railway undertaking, the issue date, the type, extent, validity and area of operation of the single safety certificate and, in the case of revocation, the reasons for its decision. In the case of single safety certificates issued by national safety authorities, the same information shall be provided by the competent national safety authority or authorities to the Agency within the same timeframe.

Article 11

Cooperation between the Agency and national safety authorities on issuing single safety certificates

1 For the purposes of Article 10(5) and (6) of this Directive, the Agency and the national safety authorities shall conclude cooperation agreements in accordance with Article 76 of Regulation (EU) 2016/796. The cooperation agreements shall be specific or framework

agreements, and shall involve one or more national safety authorities. The cooperation agreements shall contain a detailed description of tasks and conditions for deliverables, the time limits applying to their delivery and an apportionment of the fees payable by the applicant.

2 The cooperation agreements may also include specific cooperation arrangements in the case of networks requiring specific expertise for geographical or historical reasons, with a view to reducing administrative burdens and costs to the applicant. Where such networks are isolated from the rest of the Union rail system, such specific cooperation arrangements may include the possibility of contracting tasks to the relevant national safety authorities when this is necessary in order to ensure efficient and proportionate allocation of resources for certification. Those cooperation agreements shall be in place before the Agency carries out the certification tasks in accordance with Article 31(3).

3 In the case of those Member States whose rail networks have a track gauge that is different from that of the main rail network within the Union and share identical technical and operational requirements with neighbouring third countries, in addition to the cooperation agreements referred to in paragraph 2 all the national safety authorities concerned in those Member States shall conclude with the Agency a multilateral agreement which shall include the conditions to facilitate the extension of the area of operation of safety certificates in the Member States concerned, where relevant.

Article 12

Safety authorisation of infrastructure managers

1 In order to be allowed to manage and operate a rail infrastructure, the infrastructure manager shall obtain a safety authorisation from the national safety authority in the Member State where the rail infrastructure is located.

The safety authorisation shall comprise an authorisation confirming acceptance of the infrastructure manager's safety management system as provided for in Article 9, and shall include the procedures and provisions fulfilling the requirements necessary for the safe design, maintenance and operation of the railway infrastructure, including, where appropriate, the maintenance and operation of the traffic control and signalling system.

The national safety authority shall explain the requirements for the safety authorisations and the documents required, where appropriate in the form of an application guidance document.

2 The safety authorisation shall be valid for 5 years and may be renewed upon application by the infrastructure manager. It shall be wholly or partly revised whenever substantial changes are made to the infrastructure, signalling or energy subsystems or to the principles of their operation and maintenance. The infrastructure manager shall inform the national safety authority of all such changes without delay.

The national safety authority may require that the safety authorisation be revised following substantial changes to the safety regulatory framework.

3 The national safety authority shall take a decision on an application for safety authorisation without delay and in any event not more than 4 months after all the information required and any supplementary information requested has been submitted by the applicant.

4 The national safety authority shall inform the Agency without delay, and in any event within 2 weeks, of the safety authorisations that have been issued, renewed, amended or revoked.

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It shall state the name and address of the infrastructure manager, the issue date, scope and period of validity of the safety authorisation and, in the event of revocation, the reasons for its decision.

5 In the case of cross-border infrastructure, the competent national safety authorities shall cooperate in order to issue the safety authorisations.

Article 13

Access to training facilities

1 Member States shall ensure that railway undertakings and infrastructure managers and their staff performing safety-critical tasks have fair and non-discriminatory access to training facilities for train drivers and staff accompanying trains, whenever such training is necessary for operating services on their network.

The training services shall include training on necessary route knowledge, operating rules and procedures, the signalling and control-command system and emergency procedures applied on the routes operated.

If the training services do not include examinations and granting of certificates, Member States shall ensure that staff of railway undertakings and infrastructure managers have access to such certificates.

The national safety authority shall ensure that the training services meet the requirements laid down respectively in Directive 2007/59/EC, in TSIs or in the national rules referred to in point (e) of Article 8(3) of this Directive.

2 If the training facilities are available only through a single railway undertaking or the infrastructure manager, Member States shall ensure that they are made available to other railway undertakings at a reasonable and non-discriminatory price which is cost-related and which may include a profit margin.

3 When recruiting new train drivers, staff on board trains and staff performing safety-critical tasks, railway undertakings may take into account any training, qualifications and experience acquired previously from other railway undertakings. For that purpose, such members of staff shall be entitled to have access to, obtain copies of, and communicate all documents attesting to their training, qualifications and experience.

4 Railway undertakings and infrastructure managers shall be responsible for the level of training and qualifications of their staff carrying out safety-critical work.

Article 14

Maintenance of vehicles

1 Each vehicle, before it is being used on the network, shall have an entity in charge of maintenance assigned to it and this entity shall be registered in the vehicle register in accordance with Article 47 of Directive (EU) 2016/797.

2 Without prejudice to the responsibility of the railway undertakings and infrastructure managers for the safe operation of a train as provided for in Article 4, the entity in charge of maintenance shall ensure that the vehicles for the maintenance of which it is in charge are in a safe state of running. To that end, the entity in charge of maintenance shall establish a maintenance system for those vehicles and shall by means of that system:

- a ensure that vehicles are maintained in accordance with the maintenance file of each vehicle and the requirements in force, including maintenance rules and relevant TSI provisions;
 - b implement the necessary risk evaluation and assessment methods established in the CSMs as referred to in point (a) of Article 6(1), where appropriate in cooperation with other actors;
 - c ensure that its contractors implement risk control measures through the application of the CSM on monitoring referred to in point (c) of Article 6(1) and that this is stipulated in contractual arrangements to be disclosed on request of the Agency or the national safety authority; and
 - d ensure the traceability of the maintenance activities.
- 3 The maintenance system shall be composed of the following functions:
- a a management function to supervise and coordinate the maintenance functions referred to in points (b) to (d) and to ensure the safe state of the vehicle in the railway system;
 - b a maintenance development function responsible to manage the maintenance documentation, including the configuration management, based on design and operational data as well as on performance and return on experience;
 - c a fleet-maintenance management function to manage the vehicle's removal for maintenance and its return to operation after maintenance;
 - d a maintenance delivery function to deliver the required technical maintenance of a vehicle or parts of it, including the release to service documentation.

The entity in charge of maintenance shall carry out the management function itself, but may outsource the maintenance functions referred to in points (b) to (d), or parts thereof, to other contracting parties such as maintenance workshops.

The entity in charge of maintenance shall ensure that all the functions set out in points (a) to (d) comply with the requirements and assessment criteria set out in Annex III.

Maintenance workshops shall apply relevant sections of Annex III as identified in the implementing acts adopted pursuant to point (a) of paragraph 8, which correspond to the functions and activities to be certified.

- 4 In the case of freight wagons, and after the adoption of the implementing acts referred to in point (b) of paragraph 8 in the case of other vehicles, each entity in charge of maintenance shall be certified and be awarded an entity in charge of maintenance certificate (ECM certificate) by an accredited or recognised body or by a national safety authority in accordance with the following conditions:
- a the accreditation and recognition processes of certification processes shall be based on criteria of independence, competence and impartiality;
 - b the system of certification shall provide evidence that an entity in charge of maintenance has established the maintenance system to ensure the safe state of running of any vehicle for which it is in charge of maintenance;
 - c the ECM certification shall be based on an assessment of the ability of the entity in charge of maintenance to meet the relevant requirements and assessment criteria set out in Annex III and to apply them consistently. It shall include a system of surveillance to ensure continuing compliance with those requirements and assessment criteria after award of the ECM certificate;
 - d the certification of maintenance workshops shall be based on the compliance with the relevant sections in Annex III applied to the corresponding functions and activities to be certified.

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Where the entity in charge of maintenance is a railway undertaking or an infrastructure manager, compliance with the conditions set out in the first subparagraph may be checked by the national safety authority pursuant to the procedures referred to in Article 10 or 12 and may be confirmed on the certificates issued in accordance with those procedures.

5 The certificates issued in accordance with paragraph 4 shall be valid throughout the Union.

6 On the basis of the recommendation of the Agency, the Commission shall, by means of implementing acts, adopt detailed provisions on the certification conditions referred to in the first subparagraph of paragraph 4 for the entity in charge of maintenance of freight wagons, including the requirements set out in Annex III in compliance with the relevant CSM and TSIs, and, when necessary, shall amend those provisions.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3).

The certification system applicable to freight wagons adopted by Commission Regulation (EU) No 445/2011⁽³⁾ shall continue to apply until the implementing acts referred to in this paragraph apply.

7 By 16 June 2018, the Agency shall evaluate the system of certification of the entity in charge of maintenance for freight wagons, consider the expediency of extending that system to all vehicles and the mandatory certification of maintenance workshops and submit its report to the Commission.

8 On the basis of the evaluation carried out by the Agency pursuant to paragraph 7, the Commission shall, by means of implementing acts, adopt, if appropriate, and, when necessary, subsequently amend detailed provisions identifying which of the requirements set out in Annex III shall apply for the purpose of:

- a maintenance functions carried out by maintenance workshops, including detailed provisions to ensure the uniform implementation of the certification of maintenance workshops, in compliance with the relevant CSM and TSIs;
- b the certification of entities in charge of maintenance of vehicles other than freight wagons, on the basis of the technical characteristics of such vehicles, including detailed provisions to ensure the uniform implementation of the certification conditions by the entity in charge of maintenance for vehicles other than freight wagons, in compliance with the relevant CSM and TSIs.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3).

Article 15

Derogations from the system of certification of entities in charge of maintenance

1 Member States may fulfil the obligation to identify the entity in charge of maintenance through alternative measures with respect to the maintenance system established in Article 14, in the following cases:

- a vehicles registered in a third country and maintained in accordance with the law of that country;
- b vehicles used on networks or lines the track gauge of which is different from that of the main rail network within the Union and in respect of which fulfilment of the

- requirements laid down in Article 14(2) is ensured by international agreements with third countries;
- c freight wagons and passenger coaches which are in shared use with third countries the track gauge of which is different from that of the main rail network within the Union;
 - d vehicles used on the networks referred to in Article 2(3), and military equipment and special transport requiring an ad hoc national safety authority permit to be delivered prior to their entry into service. In this case derogations shall be granted for periods not longer than 5 years.
- 2 The alternative measures referred to in paragraph 1 shall be implemented through derogations to be granted by the relevant national safety authority or by the Agency when:
- a registering vehicles pursuant to Article 47 of Directive (EU) 2016/797, as far as the identification of the entity in charge of maintenance is concerned;
 - b delivering single safety certificates and safety authorisations to railway undertakings and infrastructure managers pursuant to Articles 10 and 12 of this Directive, as far as the identification or certification of the entity in charge of maintenance is concerned.
- 3 Derogations shall be identified and justified in the annual report referred to in Article 19. Where it appears that undue safety risks are being taken on the Union rail system, the Agency shall immediately inform the Commission thereof. The Commission shall make contact with the parties concerned and, where appropriate, request the Member State concerned to withdraw its derogation decision.

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- (1) Commission Regulation (EC) No 653/2007 of 13 June 2007 on the use of a common European format for safety certificates and application documents in accordance with Article 10 of Directive 2004/49/EC of the European Parliament and of the Council and on the validity of safety certificates delivered under Directive 2001/14/EC ([OJ L 153, 14.6.2007, p. 9](#)).
- (2) Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates ([OJ L 326, 10.12.2010, p. 11](#)).
- (3) Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 ([OJ L 122, 11.5.2011, p. 22](#)).