Commission Implementing Regulation (EU) 2018/763 of 9 April 2018 establishing practical arrangements for issuing single safety certificates to railway undertakings pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council, and repealing Commission Regulation (EC) No 653/2007 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/763

of 9 April 2018

establishing practical arrangements for issuing single safety certificates to railway undertakings pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council, and repealing Commission Regulation (EC) No 653/2007

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety[(1)], and in particular Article 10(10) thereof,

Whereas:

(1) Provisions harmonising the approach to safety certification at Union level and fostering collaboration among all the parties involved in the safety assessment process are necessary, in order to reduce the complexity, length and cost of the certification procedure.

(2) Taking into account the experience gained in the preparation of the cooperation agreements referred to in Article 11(1) of Directive (EU) 2016/798, early contact with the applicant in the form of coordination (‘pre-engagement’) is recognised as good practice to facilitate the development of the relationship between the parties involved in the safety assessment process. Such pre-engagement should be offered before an application for a single safety certificate is submitted, with the aim of enabling the certification body to become familiar with the applicant's safety management system, clarifying how the safety assessment process will be conducted and how decisions will be made and verifying that the applicant has received sufficient information to know what is expected of it. Clarifications given in the context of pre-engagement should not affect the outcome of the assessment.

(3) The Agency should monitor the expiry dates of all valid single safety certificates with an area of operation in more than one Member State and should share that information with the relevant national safety authorities in order to facilitate the planning of their respective safety assessment activities.

(4) The Agency should publish and keep up to date an application guide, free of charge, describing and where necessary explaining the requirements set out in this Regulation. With the aim of harmonising the approach to the exchange and recording of information

through the one-stop shop, the application guide should also include model templates developed by the Agency in cooperation with the national safety authorities.

(5) The Agency and the national safety authorities should implement internal arrangements or procedures to ensure the requirements of the safety assessment are fulfilled.

(6) To avoid any duplication of assessment and to reduce the administrative burden and cost for the applicant, the Agency and the national safety authorities should take into account the cooperation agreements and multilateral agreements concluded pursuant to Article 11 of Directive (EU) 2016/798, where relevant.

(7) Where the intended area of operation is limited to one Member State, and the applicant intends to operate to one or more stations close to the border in neighbouring Member States with similar network characteristics and similar operating rules, it should be able to do so without an extension of its area of operation to those neighbouring Member States. When submitting its application for a single safety certificate, the applicant should select the safety certification body in accordance with Article 10(5) and (8) of Directive (EU) 2016/798. Where the Agency acts as the safety certification body it should consult the relevant national safety authorities and should take into account the relevant cross-border agreements.

(8) Where the Agency acts as the safety certification body, the applicant should have the right to submit its application file to the Agency in one of the official languages of the Union, without any obligation to translate it. This principle applies without prejudice to the possibility for the national safety authority to define a language policy concerning the part of the application referred to in point (b) of Article 10(3) of Directive (EU) 2016/798. During the course of the assessment, the national safety authority should have the right to address documents pertaining to the assessment to the Agency in a language of its Member State, without any obligation to translate them.

(9) Certification should be based on an assessment of the ability of the applicant to meet the safety management system requirements applicable to railway undertakings, including the relevant national rules and requirements of the applicable technical specification for interoperability relating to the operation and traffic management subsystem, and to apply them consistently. Once issued with a single safety certificate, the applicant should continue to use its safety management system as referred to in Article 9 of Directive (EU) 2016/798.

(10) The Agency and the national safety authorities should register all relevant information and the outcome of the assessment in the one-stop shop, to support and justify the decisions at each stage of the safety assessment process. If the Agency and the national safety authorities have their own information management systems for the purposes of safety assessment, they should ensure that all relevant information is transferred to the one-stop shop for the same reasons.

(11) The Agency and the national safety authorities should develop internal arrangements or procedures for managing the issuing of single safety certificates with a view to reducing administrative burdens and costs for the applicant. In that respect, the applicant should have the possibility to submit copies of documents in the application file. The original

documents should be available for verification by the Agency and the national safety authorities following the issuing of the single safety certificate.

(12) It is necessary to harmonise the categorisation of issues in the assessment process to ensure that the applicant understands the severity of any issues raised by the Agency or by a national safety authority. That categorisation is particularly important when several national safety authorities are involved in the process.

(13) In order to ensure that assessments are carried out effectively by the Agency and the national safety authorities and to reinforce mutual trust between them, the Agency and the national safety authorities should ensure that staff involved in assessments have the necessary competencies. To that end, those competencies should be identified.

(14) According to Article 31(3) of Directive (EU) 2016/798, the new safety certification regime will start from 16 June 2019. However, Member States have the possibility notifying the Agency and the Commission pursuant to Article 33(2) of that Directive that they have extended the transposition period and may in consequence continue to issue certificates in accordance with Directive 2004/49/EC of the European Parliament and of the Council[(2)] until 16 June 2020. It is therefore necessary to clarify how the new regime should apply in addition to the old one where the intended area of operation includes one or more of those Member States.

(15) Where a national safety authority recognises that it will not be able to issue a safety certificate in accordance with Directive 2004/49/EC before either 16 June 2019, or 16 June 2020 in respect of those Member States that have notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798, the Agency, when acting as safety certification body, should take into account the results of the assessment of the national safety authority concerning the assessment of the corresponding elements set out in point (a) of Article 10(2) of Directive 2004/49/EC to avoid any duplication of assessment.

(16) A single safety certificate issued by the Agency should be recognised as equivalent to the part of the safety certificate referred to in point (a) of Article 10(2) of Directive 2004/49/EC. That certification is valid throughout the Union for equivalent rail transport operations. Therefore, Member States which have notified the Agency and the Commission pursuant to Article 33(2) of Directive (EU) 2016/798 should accept a single safety certificate issued by the Agency as equivalent to the part issued in accordance with point (a) of Article 10(2) of Directive 2004/49/EC.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 21 of Council Directive 96/48/EC[(3)],

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation sets out the practical arrangements to be applied by railway undertakings when submitting applications for single safety certificates or for the

renewal or update of such certificates through the one-stop shop facility referred to in Article 12 of Regulation (EU) 2016/796 of the European Parliament and of the Council[(4)] (‘one-stop shop’).

It also sets out the practical arrangements to be applied by safety certification bodies when assessing applications for single safety certificates, or for the renewal or update of such certificates as well as for coordinating with the national safety authorities concerned with the intended area of operation.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) ‘safety certification body’ means the body responsible for issuing a single safety certificate, either the Agency or a national safety authority;

(2) ‘date of receipt of the application’ means:

(a) where the Agency acts as the safety certification body, the first working day common to the Agency and to the national safety authorities concerned with the intended area of operation following the acknowledgement of receipt of the application file;

(b) where a national safety authority acts as the safety certification body, the first working day in the Member State concerned following the acknowledgement of receipt of the application file;

(3) ‘pre-engagement’ means a procedural stage preceding the submission of an application, in the course of which the applicant may request additional information on the following stages of the safety assessment process from the safety certification body and the national safety authorities concerned with the intended area of operation;

(4) ‘residual concern’ means a minor issue identified during the assessment of an application for a single safety certificate which does not prevent its issuing and can be deferred for later supervision;

(5) **[**[F1]‘relevant date’ means 16 June 2019 as regards those Member States that have not notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798 that they have extended the transposition period of that Directive. It means 16 June 2020 as regards those Member States that have notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798 that they have extended the transposition period of that Directive and that have not notified the Agency and the Commission in accordance with Article 33(2a) of Directive (EU) 2016/798. It means 31 October 2020 as regards those Member States that have notified the Agency and the Commission in accordance with Article 33(2a) of Directive (EU) 2016/798 that they have further extended the transposition period of that Directive.**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2020/777 of 12 June 2020 amending Implementing Regulation (EU) 2018/763 as regards the dates of application and certain transitional

provisions following the extension of the transposition deadline of Directive (EU) 2016/798 of the European Parliament and of the Council (Text with EEA relevance).

Article 3

Responsibilities of the Agency and the national safety authorities

1 In addition to the issuing of single safety certificates, the safety certification body shall be responsible for the following tasks:

a the planning, implementation and monitoring of the assessment work it carries out;

b the setting up of coordination arrangements between the relevant parties.

2 The safety certification body and the national safety authorities concerned with the intended area of operation shall accept pre-engagement at the request of the applicant and shall provide any clarifications requested by the applicant in the context of the pre-engagement.

3 For the purposes of issuing single safety certificates, the safety certification body and the national safety authorities concerned with the intended area of operation shall, each for their own part, compile the following information:

a all relevant information concerning the different stages of the assessment, including the reasons for the decisions taken during the assessment and the identification of any restriction or condition of use to be included in the single safety certificate;

b the outcome of the assessment, including summary conclusions and where appropriate, an opinion concerning the issuing of the single safety certificate.

4 Where the Agency acts as the safety certification body, it shall compile the information referred to in point (b) of paragraph 3 in the final outcome of the assessment.

5 The Agency shall monitor the expiry dates of all valid single safety certificates with an area of operation in more than one Member State and share that information with the relevant national safety authorities.

6 National safety authorities shall share with the Agency and other national safety authorities concerned with the intended area of operation all relevant information that may have an impact on the safety assessment process.

7 The Agency shall publish and keep up to date an application guide, free of charge, in all the official languages of the Union, describing and where necessary explaining the requirements set out in this Regulation. The application guide shall also include model templates developed by the Agency in cooperation with the national safety authorities.

8 The national safety authorities shall publish and keep up to date an application guide, free of charge, describing and where necessary explaining the national rules that apply in respect of the intended area of operation and the applicable national procedural rules.

9 The Agency and the national safety authority shall establish internal arrangements or procedures for managing the safety assessment process. Those arrangements or procedures shall take into account the agreements referred to in Article 11 of Directive (EU) 2016/798.

10 Each single safety certificate shall be given a unique European Identification Number (EIN). The Agency shall define the structure and content of EINs and make them available on its website.