Commission Delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010 (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2018/762

of 8 March 2018

establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010

(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 6(6) thereof,

Having regard to Recommendation ERA-REC-115-REC from the European Union Agency for Railways delivered to the Commission on 9 March 2017, on the revision of the common safety methods for conformity assessment and the common safety methods for supervision,

Whereas:

(1) The common safety methods (CSMs) describe how the safety levels and the achievement of safety targets and compliance with other safety requirements are assessed.

(2) In accordance with Article 6(5) of Directive (EU) 2016/798, the CSMs are to be revised at regular intervals, taking into account the experience gained from their application and the global development of railway safety and with the objective of generally maintaining and, where reasonably practicable, continuously improving safety.

(3) By its Implementing Decision of 1 September 2016[(2)], the Commission issued a mandate to the European Union Agency for Railways (the 'Agency') in accordance with Article 6(2) of Directive (EU) 2016/798 to revise Commission Regulations (EU) No 1158/2010[(3)], (EU) No 1169/2010[(4)] and (EU) No 1077/2012[(5)]. On 9 March 2017, the Agency issued its recommendation, enclosing a report on the results of the consultation of national safety authorities, social partners and users and a report assessing the impact of the amended CSMs to be adopted, to address the mandate of the Commission. The Commission examined the recommendation issued by the Agency to verify that the mandate was fulfilled as referred to in Article 6(4) of Directive (EU) 2016/798.

(4) The purpose of the safety management system is to ensure that the railway undertakings and infrastructure managers achieve their business objectives in a safe manner. The

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2018/762. (See end of Document for details)*

safety management system is often integrated with other management systems to increase the overall performance of the organisation and reduce costs while mutualising the efforts at all levels of the organisation. To this end, the common framework of the ISO High Level Structure[(6)] is used to functionally cluster the requirements of the safety management system, as referred to in Article 9 of Directive (EU) 2016/798. This framework also facilitates the understanding and application of a process approach by the railway undertakings and infrastructure managers when developing, implementing, maintaining and continually improving their safety management system.

(5) Once issued with a single safety certificate or with a safety authorisation, the applicant should continue to use its safety management system as referred to in Article 9 of Directive (EU) 2016/798.

(6) The human behaviour plays a central role in the safe and efficient operation of the railway. Where that behaviour is considered to have contributed to an accident or incident, it may be that organisational factors, such as workload or job design, had an influence on that behaviour, and thus led to a lesser performance and aggravation of the consequences of that accident or incident. Therefore, it is essential that the railway undertakings and infrastructure managers take a systematic approach to supporting human performance and managing human and organisational factors within the safety management system.

(7) The way safety is perceived, valued and prioritised in an organisation reflects the real commitment to safety at all levels in the organisation. Therefore, it is also important for railway undertakings and infrastructure managers to identify the actions and behaviours that can shape a positive safety culture and to promote through their safety management system this culture of mutual trust, confidence and learning in which staff are encouraged to contribute to the development of safety by reporting dangerous occurrences and providing safety-related information.

(8) The safety management system should take into account the fact that Council Directive 89/391/EEC[(7)] and its relevant individual directives are fully applicable to the protection of the health and safety of workers engaged in railway construction, operation and maintenance. It does not create any additional responsibilities or tasks for the issuing authority other than to check if health and safety risks have been taken into account by the applicant for a single safety certificate or for a safety authorisation. Responsibility for checking the compliance with Directive 89/391/EEC may still be allocated on other competent authorities appointed by the Member States.

(9) The safety management system should where relevant take into consideration the potential additional risks generated by transporting dangerous goods by rail and thereby, should also take account of Directive 2008/68/EC of the European Parliament and of the Council[(8)].

(10) Regulations (EU) No 1158/2010 and (EU) No 1169/2010 will become obsolete and should therefore be replaced by this Regulation.

(11) As regards safety certificates, it follows from Article 10(15) of Directive (EU) 2016/798 that the national safety authority may require that the safety certificates be revised

following substantial changes to the safety regulatory framework. The changes brought about by Article 9 of Directive (EU) 2016/798 and by this Regulation, even though relevant and important, are not substantial. Therefore, Regulation (EU) No 1158/2010 should apply to safety certificates issued in accordance with Directive 2004/49/EC of the European Parliament and of the Council[9], until their expiry date. For the same reason, it is also necessary to postpone the repeal of Regulation (EU) No 1158/2010 until the end of the last day of the period during which it may still be applied by national safety authorities for the purposes of supervision. Moreover, in accordance with Directive (EU) 2016/798, existing safety certificates continue to be subject to Directive 2004/49/EC, on which Regulation (EU) No 1158/2010 was based.

(12) As regards safety authorisations, it follows from Article 12(2), second subparagraph of Directive (EU) 2016/798 that the national safety authority may require that the safety authorisations be revised following substantial changes to the safety regulatory framework. The changes brought about by Article 9 of Directive 2016/798/EC and by this Regulation, even though relevant and important, are not substantial. Therefore, Regulation (EU) No 1169/2010 should apply to safety authorisations issued in accordance with Directive 2004/49/EC, until their expiry date. For the same reason, it is also necessary to postpone the repeal of Regulation (EU) No 1169/2010 until the end of the last day of the period during which it may still be applied by national safety authorities for the purposes of supervision,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1 This Regulation establishes common safety methods (‘CSMs’) on safety management system requirements related to railway undertakings and infrastructure managers, as referred to in point (f) of Article 6(1) of Directive (EU) 2016/798.

2 This Regulation shall apply in respect of single safety certificates and safety authorisations issued pursuant to Directive (EU) 2016/798.

Article 2

Definition

For the purposes of this Regulation, ‘safety certification body’ means the body responsible for issuing a single safety certificate, either the Agency or a national safety authority.

Article 3

Safety management system requirements related to railway undertakings

Railway undertakings shall establish their safety management systems in accordance with the requirements set out in Annex I.

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2018/762. (See end of Document for details)*

Those safety management system requirements shall apply to the single safety certificates referred to in Article 10 of Directive (EU) 2016/798, for the purposes of the assessment of applications and of supervision.

Article 4

Safety management system requirements related to infrastructure managers

Infrastructure managers shall establish their safety management systems in accordance with the requirements set out in Annex II.

Those safety management system requirements shall apply to the safety authorisations referred to in Article 12 of Directive (EU) 2016/798, for the purposes of the assessment of applications and of supervision.

[*F1**Article 5*

Repeal

Regulations (EU) No 1158/2010 and (EU) No 1169/2010 are repealed with effect from 31 October 2025.**]**

Textual Amendments

F1 Substituted by Commission Delegated Regulation (EU) 2020/782 of 12 June 2020 amending Delegated Regulations (EU) 2018/761 and (EU) 2018/762 as regards their dates of application 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 6

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

[F1It shall apply from 16 June 2019 in the Member States that have not notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798.

It shall apply from 16 June 2020 in the 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 period for transposition of that Directive and that have not notified the Agency and the Commission in accordance with Article 33(2a) of Directive (EU) 2016/798 that they have further extended that transposition period.

It shall apply in all Member States from 31 October 2020.**]**

Textual Amendments

F1 Substituted by Commission Delegated Regulation (EU) 2020/782 of 12 June 2020 amending Delegated Regulations (EU) 2018/761 and (EU) 2018/762 as regards their dates of application

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.