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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 8.3.2018 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

Delegations will find attached document C(2018) 1392 final.

Encl.: C(2018) 1392 final



EUROPEAN
COMMISSION

Brussels, 8.3.2018
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COMMISSION DELEGATED REGULATION (EU) .../...

of 8.3.2018

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

One of the purposes of Directive (EU) 2016/798 is to improve access to the market for rail transport services by defining common principles for the management, regulation and supervision of railway safety. In particular, Article 10(1) of Directive (EU) 2016/798 requires all railway undertakings to apply for a single safety certification before any operation. Article 12(1) set a similar requirement for the infrastructure managers to apply for a safety authorisation. To this aim, all railways undertakings and infrastructure managers should establishing their safety management system.

Point (f) of Article 6(1) of Directive (EU) 2016/798 provides a framework for establishing requirements on safety management system which need to be harmonised at Union level. The requirements provided in the present Regulation are built on the basis elements indicated in Article 9. The safety certification body and the national safety authority can use such requirements for assessing the quality of the safety management system before issuing a single safety certificate or a safety authorisation and for carrying out supervision activities.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with Article 6(2) of Directive (EU) 2016/798, on 1 September 2016 the Commission issued a mandate to the European Union Agency for Railways (the 'Agency') to revise the common safety method for assessing conformity with the requirements for obtaining railway safety certificates referred to in Commission Regulation (EU) No 1158/2010 of 9 December 2010¹, the common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation referred to in Commission Regulation (EU) No 1169/2010 of 10 December 2010² and the common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation referred to in Commission Regulation (EU) No 1077/2012 of 16 November 2012³. On 9 March 2017 the Agency submitted its recommendation on the revision of the CSMs to the Commission, supported by an impact assessment report to address the mandate of the Commission. The first version of this Regulation was based on the Agency's recommendation.

The Commission Expert Group on the Technical Pillar of the 4th Railway Package was consulted on the Recommendation of the Agency on 12 April 2017 and the draft Commission proposal was presented on 5 July 2017.

The consultation for public feedback was held from 24 August until 21 September 2017 (reference: Ares(2017)4156968). Several comments have been incorporated in the new version.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Regulation establishes CSM on safety management system requirements. The technical content is based on the requirement of Article 9 of Directive (EU) 2016/798 and the legal basis is provided by Point (f) of Article 6(1).

¹ OJ L 326, 10.12.2010, p. 11.

² OJ L 327, 11.12.2010, p.13.

³ OJ L 320, 17.11.2012, p. 3.

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(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 safety⁴, 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 2016⁵, 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 1158/2010⁶, (EU) No 1169/2010⁷ and (EU) No 1077/2012⁸. 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

⁴ OJ L 138, 26.05.2016, p. 102.

⁵ Commission Implementing Decision of 1 September 2016 on a mandate to the European Union Agency for Railways for the revision of the common safety methods for conformity assessment and the common safety method for supervision and repealing Implementing Decision C(2014) 1649 final (C(2016) 5504 final).

⁶ 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).

⁷ Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation (OJ L 327, 11.12.2010, p.13).

⁸ Commission Regulation (EU) No 1077/2012 of 16 November 2012 on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation (OJ L 320, 17.11.2012, p. 3).

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 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 Structure⁹ 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/EEC¹⁰ 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 ISO/IEC Directives, Part 1, consolidated supplement 2016, Annex SL Appendix 2.

¹⁰ Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p.1).

- (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/EC¹¹.
- (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 Council¹², 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 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.

¹¹ Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p.13).

¹² Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) (OJ L 164, 30.4.2004, p. 44).

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.

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.

Article 5

Repeal

Regulations (EU) No 1158/2010 and (EU) No 1169/2010 are repealed with effect from 16 June 2025.

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*.

It 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 in all Member States from 16 June 2020.

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

Done at Brussels, 8.3.2018

For the Commission
The President
Jean-Claude JUNCKER