

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 II

**DEVELOPMENT AND MANAGEMENT OF RAILWAY SAFETY**

*Article 4*

**Role of actors in the Union rail system in developing and improving railway safety**

1 With the aim of developing and improving railway safety, Member States, within the limits of their competences, shall:

- a ensure that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Union law and international rules and of technical and scientific progress, and giving priority to the prevention of accidents;
- b ensure that all applicable legislation is enforced in an open and non-discriminatory manner, fostering the development of a single European rail transport system;
- c ensure that measures to develop and improve railway safety take account of the need for a system-based approach;
- d ensure that the responsibility for the safe operation of the Union rail system and the control of risks associated with it is laid upon the infrastructure managers and railway undertakings, each for its part of the system, obliging them to:
  - (i) implement necessary risk control measures as referred to in point (a) of Article 6(1), where appropriate in cooperation with each other;
  - (ii) apply Union and national rules;
  - (iii) establish safety management systems in accordance with this Directive;
- e without prejudice to civil liability in accordance with the legal requirements of the Member States, ensure that each infrastructure manager and each railway undertaking is made responsible for its part of the system and its safe operation, including supply of materials and contracting of services vis-à-vis users, customers, the workers concerned and other actors referred to in paragraph 4;
- f develop and publish annual safety plans setting out the measures envisaged to achieve the CSTs; and
- g where appropriate, support the Agency in its work to monitor the development of railway safety at Union level.

2 The Agency shall ensure, within the limits of its competences, that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Union law and of technical and scientific progress and giving priority to the prevention of serious accidents.

3 Railway undertakings and infrastructure managers shall:

- a implement the necessary risk control measures referred to in point (a) of Article 6(1), where appropriate in cooperation with each other and with other actors;

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- b take account in their safety management systems of the risks associated with the activities of other actors and third parties;
- c where appropriate, contractually oblige the other actors referred to in paragraph 4 having a potential impact on the safe operation of the Union rail system to implement risk control measures; and
- d ensure that their contractors implement risk control measures through the application of the CSMs for monitoring processes set out in the CSMs 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 of the national safety authority.

4 Without prejudice to the responsibilities of railway undertakings and infrastructure managers referred to in paragraph 3, entities in charge of maintenance and all other actors having a potential impact on the safe operation of the Union rail system, including manufacturers, maintenance suppliers, keepers, service providers, contracting entities, carriers, consignors, consignees, loaders, unloaders, fillers and unfillers, shall:

- a implement the necessary risk control measures, where appropriate in cooperation with other actors;
- b ensure that subsystems, accessories, equipment and services supplied by them comply with specified requirements and conditions for use so that they can be safely operated by the railway undertaking and/or the infrastructure manager concerned.

5 Railway undertakings, infrastructure managers and any actor referred to in paragraph 4 who identifies or is informed of a safety risk relating to defects and construction non-conformities or malfunctions of technical equipment, including those of structural subsystems, shall, within the limits of their respective competence:

- a take any necessary corrective measure to tackle the safety risk identified;
- b report those risks to the relevant parties involved, in order to enable them to take any necessary further corrective action to ensure continuous achievement of the safety performance of the Union rail system. The Agency may establish a tool that facilitates this exchange of information among the relevant actors, taking into account the privacy of the users involved, the results of a cost-benefit analysis as well as the IT applications and registers already set up by the Agency.

6 In the case of exchange of vehicles between railway undertakings, any involved actor shall exchange all information relevant to safe operation including, but not limited to, the status and history of the vehicle concerned, elements of the maintenance files for the purpose of traceability, traceability of loading operations and consignment notes.

#### *Article 5*

### **Common safety indicators ('CSIs')**

1 In order to facilitate assessment of the achievement of the CSTs and to provide for the monitoring of the general development of railway safety, Member States shall collect information on CSIs through the annual reports of the national safety authorities referred to in Article 19.

2 The CSIs are set out in Annex I.

## Article 6

### Common safety methods ('CSMs')

1 The CSMs shall describe how the safety levels, the achievement of safety targets and compliance with other safety requirements are assessed, including, where appropriate, through an independent assessment body, by elaborating and defining:

- a the risk evaluation and assessment methods;
- b the methods for assessing conformity with requirements in safety certificates and safety authorisations issued in accordance with Articles 10 and 12;
- c the methods for supervision to be applied by national safety authorities and the methods for monitoring to be applied by railway undertakings, infrastructure managers and entities in charge of maintenance;
- d the methods for assessing the safety level and the safety performance of railway operators at national and Union level;
- e the methods for assessing the achievement of safety targets at national and Union level; and
- f any other methods covering a process of the safety management system which need to be harmonised at Union level.

2 The Commission shall, by means of implementing acts, give a mandate to the Agency to draft CSMs and amendments thereto and to make the relevant recommendations to the Commission, on the basis of a clear justification of the need for a new or amended CSM and its impact on existing rules and on the level of safety of the Union rail system. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3). Where the committee referred to in Article 28 ('the committee') delivers no opinion, the Commission shall not adopt the draft implementing act, and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

The drafting, adoption and review of CSMs shall take account of the opinions of users, the national safety authorities and stakeholders, including social partners, where appropriate. The recommendations shall enclose a report on the results of that consultation and a report assessing the impact of the new or amended CSM to be adopted.

3 During the exercise of the mandate referred to in paragraph 2, the committee shall be kept systematically and regularly informed by the Agency or by the Commission of the preparatory work on the CSMs. During that work, the Commission may address to the Agency any useful recommendations concerning the CSMs and a cost-benefit analysis. In particular, the Commission may require that alternative solutions be examined by the Agency and that the assessment of the costs and benefits of those alternative solutions be set out in the report annexed to the draft CSMs.

The Commission shall be assisted by the committee for the tasks mentioned in the first subparagraph.

4 The Commission shall examine the recommendation issued by the Agency with a view to verifying that the mandate referred to in paragraph 2 is fulfilled. Where the mandate is not fulfilled, the Commission shall request the Agency to review its recommendation by indicating the points of the mandate which were not fulfilled. For justified reasons, the Commission may decide to modify the mandate given to the Agency in accordance with the procedure set out in paragraph 2.

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The Commission shall be assisted by the committee for the tasks mentioned in the first subparagraph.

5 The CSMs shall 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.

6 On the basis of the recommendation issued by the Agency and after the examination referred to in paragraph 4 of this Article, the Commission shall be empowered to adopt delegated acts in accordance with Article 27 concerning the content of CSMs, and of any amendments thereto.

7 Member States shall make any necessary amendments to their national rules in the light of the adoption of CSMs and amendments thereto without delay.

### *[<sup>F1</sup>Article 6a*

#### **Alignment of CSMs with revised deadlines**

The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to align the application dates of delegated acts adopted under Article 6(6) with the transposition deadline set out in Article 33(2a). The procedure provided for in Article 27a shall apply to delegated acts adopted pursuant to this Article.]

#### **Textual Amendments**

- F1** Inserted by [Directive \(EU\) 2020/700 of the European Parliament and of the Council of 25 May 2020 amending Directives \(EU\) 2016/797 and \(EU\) 2016/798, as regards the extension of their transposition periods \(Text with EEA relevance\).](#)

### *Article 7*

#### **Common safety targets ('CSTs')**

1 The CSTs shall establish the minimum safety levels to be reached by the system as a whole, and where feasible, by different parts of the rail system in each Member State and in the Union. The CSTs may be expressed in terms of risk acceptance criteria or target safety levels and shall take into consideration, in particular:

- a individual risks relating to passengers, staff including employees or contractors, level crossing users and others, and, without prejudice to existing national and international liability rules, individual risks relating to trespassers;
- b societal risks.

2 The Commission shall, by means of implementing acts, give a mandate to the Agency to draft CSTs and amendments thereto and to make the relevant recommendations to the Commission, on the basis of a clear justification of the need for a new or amended CST and its impact on existing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3). Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act, and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

3 During the exercise of the mandate referred to in paragraph 2, the committee shall be kept systematically and regularly informed by the Agency or by the Commission of the preparatory work on the CSTs. During that work, the Commission may address to the Agency any useful recommendations concerning the CSTs and a cost-benefit analysis. In particular, the Commission may require that alternative solutions be examined by the Agency and that the assessment of the cost and benefits of those alternative solutions be set out in the report annexed to the draft CSTs.

The Commission shall be assisted by the committee for the tasks mentioned in the first subparagraph.

4 The Commission shall examine the recommendation issued by the Agency with a view to verifying that the mandate referred to in paragraph 2 is fulfilled. Where the mandate is not fulfilled, the Commission shall request the Agency to review its recommendation by indicating the points of the mandate which were not fulfilled. For justified reasons, the Commission may decide to modify the mandate given to the Agency in accordance with the procedure set out in paragraph 2.

The Commission shall be assisted by the committee for the tasks mentioned in the first subparagraph.

5 The CSTs shall be revised at regular intervals, taking into account the global development of railway safety. The revised CSTs shall reflect any priority area where safety needs to be further improved.

6 On the basis of the recommendation issued by the Agency and after the examination referred to in paragraph 4 of this Article, the Commission shall be empowered to adopt delegated acts in accordance with Article 27 concerning the content of CSTs, and of any amendments thereto.

7 Member States shall make any necessary amendments to their national rules in order to achieve at least the CSTs, and any revised CSTs, in accordance with the implementation timetables attached to them. Those amendments shall be taken into account in the annual safety plans referred to in point (f) of Article 4(1). Member States shall notify those rules to the Commission in accordance with Article 8.

### *Article 8*

#### **National rules in the field of safety**

1 National rules notified by 15 June 2016 pursuant to Directive 2004/49/EC shall apply if they:

- a fall into one of the types identified under Annex II; and
- b comply with Union law, including in particular TSIs, CSTs and CSMs; and
- c would not result in arbitrary discrimination or a disguised restriction on rail transport operation between Member States.

2 By 16 June 2018, Member States shall review the national rules referred to in paragraph 1 and repeal:

- a any national rule which was not notified or which does not meet the criteria specified in paragraph 1;
- b any national rule which has been made redundant by Union law, including in particular TSIs, CSTs and CSMs.

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To that end, Member States may use the rule management tool referred to in Article 27(4) of Regulation (EU) 2016/796 and may request Agency to examine specific rules against the criteria specified in this paragraph.

3 Member States may lay down new national rules pursuant to this Directive only in the following cases:

- a where rules concerning existing safety methods are not covered by a CSM;
- b where operating rules of the railway network are not yet covered by TSIs;
- c as an urgent preventive measure, in particular following an accident or an incident;
- d where an already notified rule needs to be revised;
- e where rules concerning requirements in respect of staff executing safety-critical tasks, including selection criteria, physical and psychological fitness and vocational training are not yet covered by a TSI or by Directive 2007/59/EC of the European Parliament and of the Council<sup>(1)</sup>.

4 Member States shall submit the draft of a new national rule to the Agency and the Commission for consideration in due time and within the deadlines referred to in Article 25(1) of Regulation (EU) 2016/796, before the expected introduction into the national legal system of the proposed new rule, providing justification for its introduction, through the appropriate IT system in accordance with Article 27 of Regulation (EU) 2016/796. Member States shall ensure that the draft is sufficiently developed to allow the Agency to carry out its examination in accordance with Article 25(2) of Regulation (EU) 2016/796.

5 In the case of urgent preventive measures, Member States may adopt and apply a new rule immediately. That rule shall be notified in accordance with Article 27(2) of Regulation (EU) 2016/796 and subject to the assessment of the Agency in accordance with Article 26(1), (2) and (5) of Regulation (EU) 2016/796.

6 If the Agency becomes aware of any national rule, whether notified or not, which has become redundant or is in conflict with the CSMs or any other Union law adopted after the application of the national rule concerned, the procedure provided for in Article 26 of Regulation (EU) 2016/796 shall apply.

7 Member States shall notify to the Agency and to the Commission the national rules adopted. They shall use the appropriate IT system in accordance with Article 27 of Regulation (EU) 2016/796. Member States shall ensure that existing national rules are easily accessible, in the public domain and formulated in terminology that all interested parties can understand. Member States may be requested to provide additional information on their national rules.

8 Member States may decide not to notify rules and restrictions of a strictly local nature. In such cases, Member States shall mention those rules and restrictions in the registers of infrastructure referred to in Article 49 of Directive (EU) 2016/797 or indicate in the network statement referred to in Article 27 of Directive 2012/34/EU where those rules and restrictions are published.

9 National rules notified in accordance with this Article shall not be subject to the notification procedure provided for by Directive (EU) 2015/1535 of the European Parliament and the Council<sup>(2)</sup>.

10 Draft national rules and existing national rules shall be examined by the Agency in accordance with the procedures laid down in Articles 25 and 26 of Regulation (EU) 2016/796.

11 Without prejudice to paragraph 8, national rules not notified in accordance with this Article shall not apply for the purposes of this Directive.

## Article 9

### Safety management systems

1 Infrastructure managers and railway undertakings shall establish their respective safety management systems to ensure that the Union rail system can achieve at least the CSTs, that it is in conformity with the safety requirements laid down in TSIs, and that the relevant parts of CSMs and national rules notified in accordance with Article 8 are applied.

2 The safety management system shall be documented in all relevant parts and shall in particular describe the distribution of responsibilities within the organisation of the infrastructure manager or the railway undertaking. It shall show how control is ensured by the management on different levels, how staff and their representatives on all levels are involved and how continuous improvement of the safety management system is ensured. There shall be a clear commitment to consistently apply human factors knowledge and methods. Through the safety management system, infrastructure managers and railway undertakings shall promote a culture of mutual trust, confidence and learning in which staff are encouraged to contribute to the development of safety while ensuring confidentiality.

- 3 The safety management system shall contain the following basic elements:
- a a safety policy approved by the organisation's chief executive and communicated to all staff;
  - b qualitative and quantitative targets of the organisation for the maintenance and enhancement of safety, and plans and procedures for reaching these targets;
  - c procedures to meet existing, new and altered technical and operational standards or other prescriptive conditions as laid down in TSIs, national rules referred to in Article 8 and Annex II, other relevant rules or authority decisions;
  - d procedures to assure compliance with the standards and other prescriptive conditions throughout the life cycle of equipment and operations;
  - e procedures and methods for identifying risks, carrying out risk evaluation and implementing risk-control measures whenever a change of operating conditions or the introduction of new material imposes new risks on the infrastructure or the man-machine-organisation interface;
  - f the provision of programmes for the training of staff and systems to ensure that the staff's competence is maintained and that tasks are carried out accordingly, including arrangements with regard to physical and psychological fitness;
  - g arrangements for the provision of sufficient information within the organisation and, where appropriate, between organisations of the railway system;
  - h procedures and formats for the documentation of safety information and designation of procedure for the configuration control of vital safety information;
  - i procedures to ensure that accidents, incidents, near misses and other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken;
  - j the provision of actions plans, alerts and information in the event of an emergency, agreed upon with the appropriate public authorities; and
  - k provisions for recurrent internal auditing of the safety management system.

Infrastructure managers and railway undertakings shall include any other element necessary to cover safety risks, in accordance with the assessment of risks arising from their own activity.

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4 The safety management system shall be adapted to the type, extent, area of operations and other conditions of the activity pursued. It shall ensure the control of all risks associated with the activity of the infrastructure manager or railway undertaking, including the supply of maintenance, without prejudice to Article 14, and material, and the use of contractors. Without prejudice to existing national and international liability rules, the safety management system shall also take into account, where appropriate and reasonable, the risks arising as a result of activities by other actors referred to in Article 4.

5 The safety management system of any infrastructure manager shall take into account the effects of operations by different railway undertakings on the network and shall provide for all railway undertakings to be able to operate in accordance with TSIs and national rules and with the conditions laid down in their safety certificate.

Safety management systems shall be developed with the aim of coordinating the emergency procedures of the infrastructure manager with all railway undertakings that operate on its infrastructure, and with the emergency services, so as to facilitate the rapid intervention of rescue services, and with any other party that could be involved in an emergency situation. For cross-border infrastructure, the cooperation between the relevant infrastructure managers shall facilitate the necessary coordination and preparedness of the competent emergency services on both sides of the border.

Following a serious accident, the railway undertaking shall provide assistance to victims helping them in complaints procedures under Union law, in particular Regulation (EC) No 1371/2007 of the European Parliament and of the Council<sup>(3)</sup>, without prejudice to the obligations of other parties. Such assistance shall use channels for communicating with victims' families and include psychological support for accident victims and their families.

6 Before 31 May of each year, all infrastructure managers and railway undertakings shall submit to the national safety authority an annual safety report concerning the preceding calendar year. The safety report shall contain:

- a information on how the organisation's corporate safety targets are met and the results of safety plans;
- b an account of the development of national safety indicators, and of the CSIs referred to in Article 5, in so far as it is relevant to the reporting organisation;
- c the results of internal safety auditing;
- d observations on deficiencies and malfunctions of railway operations and infrastructure management that might be relevant for the national safety authority, including a summary of information provided by the relevant actors in accordance with point (b) of Article 4(5); and
- e a report on the application of the relevant CSMs.

7 On the basis of the information provided by the national safety authorities in accordance with Articles 17 and 19, the Agency may address a recommendation to the Commission for a CSM covering elements of the safety management system which need to be harmonised at Union level, including through harmonised standards, as referred to in point (f) of Article 6(1). In such case, Article 6(2) shall apply.



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- (1) Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community ([OJ L 315, 3.12.2007, p. 51](#)).
- (2) Directive (EU) 2015/1535 of the European Parliament and the Council of 9 September 2015, laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services ([OJ L 241, 17.9.2015, p. 1](#)).
- (3) Regulation (EC) No 1371/2007 of the European Parliament and of the Council of 23 October 2007 on rail passengers' rights and obligations ([OJ L 315, 3.12.2007, p. 14](#)).