

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

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PARLIAMENT AND OF THE COUNCIL

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on railway safety

(recast)

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

Having regard to the opinion of the Committee of the Regions⁽²⁾,

Acting in accordance with the ordinary legislative procedure⁽³⁾,

Whereas:

- (1) Directive 2004/49/EC of the European Parliament and of the Council⁽⁴⁾ has been substantially amended. Since further amendments are to be made, it should be recast in the interests of clarity.
- (2) Directive 2004/49/EC established a common regulatory framework for railway safety through harmonisation of the content of safety rules, the safety certification of railway undertakings, the tasks and roles of the national safety authorities and the investigation of accidents. Nevertheless, in order to pursue efforts to further develop a single European railway area, it is necessary to thoroughly revise Directive 2004/49/EC.
- (3) Metros, trams and other light rail systems are subject in many Member States to local technical requirements and are excluded from the scope of Directive (EU) 2016/797 of the European Parliament and of the Council⁽⁵⁾. In order to facilitate the implementation of this Directive and of Directive (EU) 2016/797, both Directives should have the same scope. Therefore, such local systems should be excluded from the scope of this Directive.
- (4) Insofar as some concepts referred to in this Directive may be usefully applied to metros and other local systems, Member States should be permitted to decide, without prejudice to the scope of this Directive, to apply certain provisions of this Directive that they

consider to be appropriate. In such cases, Member States should be allowed not to apply obligations such as the notification of national rules and reporting.

- (5) Safety levels in the Union rail system are generally high especially when compared to road transport. Railway safety should be generally maintained and, when practicable, continuously improved, taking into account technical and scientific progress, and the development of Union and international law. Priority should be given to the prevention of accidents. The impact of human factors should also be taken into consideration.
- (6) If a Member State introduces a higher level of safety, it should ensure that the rule adopted does not create a barrier to interoperability or result in discrimination.
- (7) The main actors in the Union rail system, infrastructure managers and railway undertakings should bear full responsibility for the safety of the system, each for their own part. Whenever appropriate, they should cooperate in implementing risk control measures.
- (8) Without prejudice to the responsibility of infrastructure managers and railway undertakings for developing and improving railway safety, the other actors, such as entities in charge of maintenance, manufacturers, carriers, consignors, consignees, fillers, unfillers, loaders, unloaders, maintenance suppliers, keepers, service providers and contracting entities, should not be precluded from assuming responsibility for their products, services and processes. Each actor in the Union rail system should be responsible, vis-à-vis the other actors, for complete and truthful communication of all relevant information to check whether vehicles are fit to run. This concerns, in particular, information on the status and history of a given vehicle, maintenance files, traceability of loading operations, and consignment notes.
- (9) Each railway undertaking, infrastructure manager and entity in charge of maintenance should ensure that its contractors and other parties implement risk control measures. To that end, each railway undertaking, infrastructure manager and entity in charge of maintenance should apply the methods for monitoring set out in the common safety methods ('CSMs'). Their contractors should apply this process through contractual arrangements. In view of the fact that such arrangements are an essential part of the safety management system of railway undertakings and infrastructure managers, railway undertakings and infrastructure managers should disclose their contractual arrangements on request of the European Union Agency for Railways ('the Agency') established by Regulation (EU) 2016/796 of the European Parliament and of the Council⁽⁶⁾ or the national safety authority in the context of supervision activities.
- (10) Member States should promote a culture of mutual trust, confidence and learning in which the staff of railway undertakings and infrastructure managers are encouraged to contribute to the development of safety while confidentiality is ensured.
- (11) Common safety targets ('CSTs') and CSMs have been gradually introduced to ensure that safety is maintained at a high level and, when necessary and where reasonably practicable, improved. They should provide tools for the assessment of the safety and performance of operators at Union level as well as in the Member States. Common

safety indicators ('CSIs') have been established in order to assess whether systems comply with the CSTs and to facilitate the monitoring of railway safety performance.

- (12) National rules, which are often based on national technical standards, are being gradually replaced by rules based on common standards, established by CSTs, CSMs and technical specifications for interoperability ('TSIs'). In order to eliminate the obstacles to interoperability, the volume of national rules, including operating rules, should be reduced as a consequence of extending the scope of the TSIs to the whole of the Union rail system and of closing open points in the TSIs. For that purpose, Member States should keep their system of national rules updated, delete obsolete rules and inform the Commission and the Agency thereof without delay.
- (13) National rules should be drafted and published in such a way that any potential user of a national network can understand them. However, such rules often refer to other documents such as national standards, European standards, international standards or other technical specifications which might be partly or fully protected by intellectual property rights. It is appropriate, therefore, that the obligation of publication should not apply to any documents referred to directly or indirectly in the national rule.
- (14) National rules often include requirements which are partly relevant for both interoperability and safety purposes. Safety being an essential requirement of Directive (EU) 2016/797, a national rule may be relevant for Directive (EU) 2016/797 and for this Directive. The distinction between the terms 'national safety rules' and 'national technical rules' as defined in Directive 2004/49/EC and Directive 2008/57/EC of the European Parliament and of the Council⁽⁷⁾ respectively should therefore be removed and replaced by the concept of 'national rules' which are to be notified under Directive (EU) 2016/797 and/or this Directive. National rules are to be notified under Directive (EU) 2016/797 mainly when they relate to the placing on the market or placing in service of structural subsystems. They should be notified under this Directive when they relate to the operation of the Union rail system, or to the specific subjects of this Directive, including the role of the actors, safety certification, safety authorisation and accident investigation.
- (15) In view of the gradual approach to eliminating obstacles to the interoperability of the Union rail system and of the time consequently required for the adoption of TSIs, steps should be taken to avoid a situation where Member States adopt new national rules or undertake projects that increase the diversity of the present system except in the specific situations as provided for in this Directive. The safety management system is the recognised tool for controlling risks, whereas infrastructure managers and railway undertakings are responsible for taking immediate corrective action to prevent recurrence of accidents. Member States should avoid establishing new national rules immediately after an accident, unless such new rules are required as an urgent preventive measure.
- (16) Train control and signalling systems play a critical role in ensuring railway safety. In this regard, the deployment of the European Rail Traffic Management System (ERTMS) on the Union railway network constitutes an important contribution to improving safety levels.

- (17) In carrying out their duties and fulfilling their responsibilities, infrastructure managers and railway undertakings should implement a safety management system meeting Union requirements and containing common elements. Information on safety and on the implementation of the safety management system should be submitted to the Agency and to the national safety authority in the Member State concerned.
- (18) Through its processes, the safety management system should ensure that human capabilities and limitations and the influences on human performance are addressed by applying human factors knowledge and using recognised methods.
- (19) Rail freight services should also encompass the transport of dangerous goods. However, a distinction should be made between the objective of this Directive, which is to maintain and, where possible, improve the safety of the Union rail system, and that of Directive 2008/68/EC of the European Parliament and of the Council⁽⁸⁾, which is, mainly, to regulate the classification of substances and the specification of their containments, including the safe loading, unloading and use of the containments within the existing railway system. Consequently, without prejudice to Directive 2008/68/EC, the safety management system of the railway undertakings and of the infrastructure managers should duly take into consideration the potential additional risks generated by carrying dangerous goods containments.
- (20) All railway undertakings should be subject to the same safety requirements in order to ensure a high level of railway safety and equal conditions. A railway undertaking should hold a safety certificate as a condition of being allowed to obtain access to the railway infrastructure. The safety certificate should provide evidence that the railway undertaking has established its safety management system and that it is able to comply with the relevant safety standards and rules for the relevant area of operation. When the Agency issues a single safety certificate to a railway undertaking having an area of operation in one or more Member States, it should be the only authority to assess whether the railway undertaking has correctly established its safety management system. The national safety authorities concerned by the intended area of operation should be involved in assessing the requirements laid down in the relevant national rules.
- (21) Harmonised methods based on Directive 2004/49/EC have been established, to be applied to the actors in the Union rail system and the national safety authorities, on monitoring, conformity assessment, supervision and risk evaluation and assessment. That regulatory framework is sufficiently mature to move progressively towards a 'single safety certificate' valid within the area of operation of the railway undertaking concerned.
- (22) In order to make the procedures for issuing single safety certificates to railway undertakings more efficient and coherent, it is necessary to assign the Agency a central role in the issuing of such certificates. Where the area of operation is limited to one Member State, the applicant should have the possibility of choosing whether to submit its application for a single safety certificate, through the one-stop shop referred to in Regulation (EU) 2016/796, to the national safety authority of that Member State or to the Agency. The choice made by the applicant should be binding until the application

is completed or terminated. This new regime should make the Union rail system more effective and efficient by reducing administrative burdens for railway undertakings.

- (23) The Agency and the national safety authorities should cooperate and share competences as appropriate for the issuing of single safety certificates. Clear procedural and arbitration provisions should be established to address situations where the Agency and the national safety authorities disagree on assessments made in relation to the issuing of single safety certificates.
- (24) The new allocation of functions and tasks between national safety authorities and the Agency concerning the issuing of safety certificates should be done efficiently. To that end, cooperation agreements between the Agency and the national safety authorities should be established.
- (25) In particular, cooperation agreements are required to take account of the specific geographical and historical situation of certain Member States, while ensuring the proper functioning of the internal market. Where operation is limited to networks requiring specific expertise for geographical or historical reasons, and where such networks are isolated from the rest of the Union rail system, it should be possible for the applicant to fulfil the necessary formalities locally by interacting with the relevant national safety authorities. To that end, for the purposes of reducing administrative burdens and costs, it should be possible for the cooperation agreements to be concluded between the Agency and the relevant national safety authorities to provide for an appropriate allocation of tasks, without prejudice to the ultimate responsibility of the Agency in issuing the single safety certificate.
- (26) The railway networks located in the Baltic States (Estonia, Latvia and Lithuania) have 1520 mm track gauge, which is the same as in neighbouring third countries, but different from that of the main rail network within the Union. These Baltic networks have inherited common technical and operational requirements which provide de facto interoperability between them, and, in this respect, the safety certificate issued in one of these Member States might be extended to the rest of these networks. To facilitate the efficient and proportionate allocation of resources for safety certification, and to reduce the financial and administrative burden for the applicant in such cases, the specific cooperation arrangements between the Agency and relevant national safety authorities should include, where necessary, the possibility of contracting tasks to these national safety authorities.
- (27) This Directive should not lead to a reduced level of safety and should not increase costs in the Union's railway sector. To that end, the Agency and the national safety authorities should take full responsibility for the single safety certificates they issue, assuming in particular contractual and non-contractual liabilities in that regard. In the event of a judicial inquiry involving the Agency or its staff, the Agency should cooperate fully with the competent authorities of the Member State or States concerned.
- (28) A clear distinction should be drawn between, on the one hand, the immediate responsibility of the Agency and the national safety authorities for safety deriving from the issuing of the safety certificates and safety authorisations and, on the other, the national safety authorities' task of providing a national regulatory framework and

supervising the performance of all parties concerned on a continuous basis. Each national safety authority should oversee continued compliance with the legal obligation imposed on a railway undertaking or infrastructure manager to establish a safety management system. Establishing evidence of such compliance may require not only on-site inspections of the railway undertaking or infrastructure manager concerned, but also supervision tasks to be carried out by the national safety authorities in order to assess that the railway undertaking or infrastructure manager continue to duly apply their safety management system after having been granted a safety certificate or a safety authorisation. National safety authorities should coordinate their supervision activities in relation to railway undertakings established in different Member States, and should share information among themselves and, where appropriate, with the Agency. The Agency should assist the national safety authorities in their cooperation. In that context, necessary arrangements should be established by the Agency and the national safety authorities to facilitate the exchange of information between them.

- (29) The Agency and the national safety authorities should cooperate closely in cases where a national safety authority concludes that a holder of a single safety certificate issued by the Agency no longer satisfies the conditions for certification. In such a case, it should ask the Agency to restrict or revoke that certificate. An arbitration procedure should be established to deal with cases of disagreement between the Agency and the national safety authority. If a national safety authority identifies a serious safety risk during supervision, it should inform the Agency and any other national safety authority concerned in the area of operation of the railway undertaking. The national safety authorities concerned should be allowed to apply temporary safety measures, including immediately restricting or suspending the relevant operations. A serious safety risk in this context should be understood as being a serious instance of non-compliance with legal obligations or safety requirements that may in itself, or in a series of consequential events, cause an accident or a serious accident.
- (30) The Agency should be able to establish a tool that facilitates the exchange of information among the relevant actors who identify or are informed of a safety risk relating to defects and construction non-conformities or malfunctions of technical equipment.
- (31) The single safety certificate should be issued on the basis of evidence that a railway undertaking has established its safety management system.
- (32) Infrastructure managers should have a key responsibility for the safe design, maintenance and operation of their rail network. Infrastructure managers should be subject to a safety authorisation by the national safety authority concerning their safety management system and to other provisions so as to meet safety requirements.
- (33) The certification of train staff might create difficulties for new entrants. Member States should ensure that facilities for the training and certification of train staff necessary to meet requirements under national rules are available to railway undertakings intending to operate on the relevant network.
- (34) The entity in charge of maintenance should be certified for freight wagons. Where the entity in charge of maintenance is an infrastructure manager, this certification should be included in the procedure for safety authorisation. The certificate issued to such an

entity should guarantee that the maintenance requirements of this Directive are met for any freight wagon for which it is responsible. That certificate should be valid throughout the Union and should be issued by a body able to audit the maintenance system established by the entity. As freight wagons are frequently used in international traffic, and as the entity in charge of maintenance may want to use workshops established in more than one Member State, the certification body should be able to implement its controls throughout the Union. The Agency should evaluate the system of certification of the entity in charge of maintenance for freight wagons and should, if appropriate, recommend its extension to all rail vehicles.

- (35) The national safety authorities should be fully independent in their organisation, legal structure and decision-making from any railway undertaking, infrastructure manager, applicant, contracting entity or entity which awards public service contracts. They should carry out their tasks in an open and non-discriminatory way and should cooperate with the Agency to create a single European railway area and coordinate their decision-making criteria. It should be possible, where necessary, for Member States to decide to include their national safety authority within the national ministry responsible for transport matters, provided that the independence of the national safety authority is respected. In order to fulfil their tasks, the national safety authorities should have the necessary internal and external organisational capacity in terms of human and material resources.
- (36) The national investigating bodies play a core role in the safety investigation process. Their work is of the utmost importance in determining the causes of an accident or incident. It is therefore essential that they should possess the financial and human resources required to conduct effective and efficient investigations. The national investigating bodies should cooperate with a view to exchanging information and best practices. They should establish a programme of peer reviews in order to monitor the effectiveness of their investigations. The peer-review reports should be provided to the Agency in order to allow it to monitor the overall safety performance of the Union rail system.
- (37) Serious accidents on the railways are rare. However, they can have disastrous consequences and raise concern among the public about the safety performance of the Union rail system. All such accidents should therefore be investigated from a safety perspective to avoid recurrence with the results of the investigations being made publicly available. Other accidents and incidents should also be subject to safety investigations when they involve significant precursors to a serious accident.
- (38) A safety investigation should be kept separate from any judicial inquiry into the same incident, and those conducting it should be granted access to evidence and witnesses. It should be carried out by a permanent body that is independent of the actors in the Union rail system. The body should function in a way which avoids any conflict of interest and any possible involvement in the causes of the occurrences that are investigated. In particular, its functional independence should not be affected if it is closely linked, for organisational and legal structure purposes, to the national safety authority, the Agency or the regulator of railways. Its investigations should be carried out with as

much openness as possible. For each occurrence, the investigating body should establish the relevant investigation group possessing the expertise needed to find the immediate and underlying causes.

- (39) An investigation after a serious accident should be carried out in such a way that all parties are given the possibility to be heard and to share the results. In particular, during the investigation, the investigating body should update the parties whom it judges as having safety-related responsibility on the progress of the investigation, and should take account of their views and opinions. This will allow the investigating body to receive any additional relevant information and to be aware of different opinions on its work so that it can complete its investigation in the most appropriate manner. Such consultation should in no case lead to apportioning blame or liability but, rather, to collecting factual evidence and learning lessons for the future improvement of safety. The investigating body should, however, be free to choose the information it intends to share with such parties in order to avoid any undue pressure, except when this is requested by those conducting the judicial procedure. The investigating body should also take account of the reasonable information needs of any victims and of their relatives.
- (40) In order to improve the efficiency of their activities and to facilitate the discharge of their duties, investigating bodies should have timely access to the site of an accident, where necessary in good cooperation with any judicial authority involved in the matter. The reports on investigations and any findings and recommendations provide crucial information for the further improvement of railway safety and should be made publicly available at Union level. Safety recommendations should be acted upon by the addressees and actions reported back to the investigating body.
- (41) In the event that the direct cause of an accident or incident seems to be related to human actions, attention should be paid to the particular circumstances and the manner in which routine activities are performed by staff during normal operations, including the design of the man-machine interface, the suitability of procedures, conflicting objectives, workload and any other circumstances which may have influence on the occurrence, including physical and work-related stress, fatigue or psychological fitness.
- (42) Efforts should be made to ensure that a high level of training and advanced qualifications is available across the Union.
- (43) In order to supplement and amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of CSMs and CSTs, and their revision. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (44) Implementing powers should be conferred on the Commission in order to ensure uniform conditions for the implementation of this Directive with regard to the mandate of the Agency to draft CSMs and CSTs and their amendments and to make the relevant recommendations to the Commission; practical arrangements for the purpose of safety

certification; detailed provisions identifying which of the requirements set out in Annex III are to apply for the purpose of maintenance functions carried out by maintenance workshops, including detailed provisions to ensure the uniform implementation of certification of maintenance workshops, in compliance with the relevant CSM and TSIs; detailed provisions identifying which of the requirements set out in Annex III are to apply for the purpose of certification of entities in charge of maintenance of the vehicles other than freight wagons, on the basis of the technical characteristics of such vehicles, including detailed provisions to ensure uniform implementation of certification conditions for the entity in charge of maintenance for vehicles other than freight wagons, in compliance with the relevant CSM and TSIs and the reporting structure of the accident and incident investigation report. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽⁹⁾.

- (45) The Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.
- (46) Since the objectives of this Directive, namely coordinating activities in the Member States in order to regulate and supervise safety, investigating accidents and establishing CSTs, CSMs, CSIs and common requirements for single safety certificates, cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.
- (47) The obligation to transpose this Directive into national law should be confined to those provisions representing a substantive amendment as compared to Directive 2004/49/EC. The obligation to transpose the provisions that are unchanged arises under that Directive.
- (48) This Directive should be without prejudice to the obligation of the Member States relating to the time limits for transposition into national law of the Directives set out in Part B of Annex IV,

HAVE ADOPTED THIS DIRECTIVE:

- (1) [OJ C 327, 12.11.2013, p. 122.](#)
- (2) [OJ C 356, 5.12.2013, p. 92.](#)
- (3) Position of the European Parliament of 26 February 2014 (not yet published in the Official Journal) and position of the Council at first reading of 10 December 2015 ([OJ C 57, 12.2.2016, p. 64](#)). Position of the European Parliament of 28 April 2016 (not yet published in the Official Journal).
- (4) 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 ([OJ L 164, 30.4.2004, p. 44](#)).
- (5) Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (see page 44 of this Official Journal).
- (6) Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (see page 1 of this Official Journal).
- (7) Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community ([OJ L 191, 18.7.2008, p. 1](#)).
- (8) 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](#)).
- (9) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([OJ L 55, 28.2.2011, p. 13](#)).