

DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 11 May 2016
on railway safety
(recast)
(Text with EEA relevance)

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.

⁽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) 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 ⁽¹⁾ 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

⁽¹⁾ 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).

the Council ⁽¹⁾ 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 ⁽²⁾, 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.

⁽¹⁾ 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).

⁽²⁾ 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).

- (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 ⁽¹⁾.

- (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:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Directive lays down provisions to ensure the development and improvement of the safety of the Union rail system and improved access to the market for rail transport services by:

- (a) harmonising the regulatory structure in the Member States;
- (b) defining responsibilities between the actors in the Union rail system;
- (c) developing common safety targets ('CSTs') and common safety methods ('CSMs') with a view to gradually removing the need for national rules;
- (d) setting out the principles for issuing, renewing, amending and restricting or revoking safety certificates and authorisations;
- (e) requiring the establishment, for each Member State, of a national safety authority and an accident and incident investigating body; and
- (f) defining common principles for the management, regulation and supervision of railway safety.

⁽¹⁾ 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).

Article 2

Scope

1. This Directive applies to the rail system in the Member States, which may be broken down into subsystems for structural and functional areas. It covers safety requirements for the system as a whole, including the safe management of infrastructure and of traffic operation and the interaction between railway undertakings, infrastructure managers and other actors in the Union rail system.
2. This Directive shall not apply to:
 - (a) metros;
 - (b) trams and light rail vehicles, and infrastructure used exclusively by those vehicles; or
 - (c) networks that are functionally separate from the rest of the Union rail system and intended only for the operation of local, urban or suburban passenger services, as well as undertakings operating solely on those networks.
3. Member States may exclude from the scope of the measures implementing this Directive:
 - (a) privately owned railway infrastructure, including sidings, used by the owner or by an operator for the purpose of their respective freight activities or for the transport of persons for non-commercial purposes, and vehicles used exclusively on such infrastructure;
 - (b) infrastructure and vehicles reserved for strictly local, historical or tourist use;
 - (c) light rail infrastructure occasionally used by heavy rail vehicles under the operational conditions of the light rail system, where it is necessary for the purposes of connectivity of those vehicles only; and
 - (d) vehicles primarily used on light rail infrastructure but equipped with some heavy rail components necessary to enable transit to be effected on a confined and limited section of heavy rail infrastructure for connectivity purposes only.
4. Notwithstanding paragraph 2, Member States may decide to apply, where appropriate, provisions of this Directive to metros and other local systems in accordance with national law.

Article 3

Definitions

For the purposes of this Directive, the following definitions apply:

- (1) 'Union rail system' means the Union rail system as defined in point (1) of Article 2 of Directive (EU) 2016/797;
- (2) 'infrastructure manager' means an infrastructure manager as defined in point (2) of Article 3 of Directive 2012/34/EU of the European Parliament and of the Council ⁽¹⁾;
- (3) 'railway undertaking' means a railway undertaking as defined in point (1) of Article 3 of Directive 2012/34/EU, and any other public or private undertaking, the activity of which is to provide transport of goods and/or passengers by rail on the basis that the undertaking is to ensure traction, including undertakings which provide traction only;
- (4) 'technical specification for interoperability' (TSI) means a specification adopted in accordance with Directive (EU) 2016/797 by which each subsystem or part of a subsystem is covered in order to meet the essential requirements and ensure the interoperability of the Union rail system;
- (5) 'common safety targets' (CSTs) means the minimum safety levels that are to be reached by the system as a whole, and where feasible, by different parts of the Union rail system (such as the conventional rail system, the high-speed rail system, long railway tunnels or lines solely used for freight transport);

⁽¹⁾ Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area (OJ L 343, 14.12.2012, p. 32).

- (6) 'common safety methods' (CSMs) means the methods describing the assessment of safety levels and achievement of safety targets and compliance with other safety requirements;
- (7) 'national safety authority' means the national body entrusted with the tasks regarding railway safety in accordance with this Directive or any body entrusted by several Member States with those tasks in order to ensure a unified safety regime;
- (8) 'national rules' means all binding rules adopted in a Member State, irrespective of the body issuing them, which contain railway safety or technical requirements, other than those laid down by Union or international rules, and which are applicable within that Member State to railway undertakings, infrastructure managers or third parties;
- (9) 'safety management system' means the organisation, arrangements and procedures established by an infrastructure manager or a railway undertaking to ensure the safe management of its operations;
- (10) 'investigator-in-charge' means a person responsible for the organisation, conduct and control of an investigation;
- (11) 'accident' means an unwanted or unintended sudden event or a specific chain of such events which have harmful consequences; accidents are divided into the following categories: collisions; derailments; level crossing accidents; accidents to persons involving rolling stock in motion; fires and others;
- (12) 'serious accident' means any train collision or derailment of trains resulting in the death of at least one person or serious injuries to five or more persons or extensive damage to rolling stock, the infrastructure or the environment, and any other accident with the same consequences which has an obvious impact on railway safety regulation or the management of safety; 'extensive damage' means damage that can be immediately assessed by the investigating body to cost at least EUR 2 million in total;
- (13) 'incident' means any occurrence, other than an accident or serious accident, affecting the safety of railway operations;
- (14) 'investigation' means a process conducted for the purpose of accident and incident prevention which includes the gathering and analysis of information, the drawing of conclusions, including the determination of causes and, when appropriate, the making of safety recommendations;
- (15) 'causes' means actions, omissions, events or conditions, or a combination thereof, which led to an accident or incident;
- (16) 'light rail' means an urban and/or suburban rail transport system with a crashworthiness of C-III or C-IV (in accordance with EN 15227:2011) and a maximum strength of vehicle of 800 kN (longitudinal compressive force in coupling area); light rail systems may have their own right of way or share it with road traffic and usually do not exchange vehicles with long-distance passenger or freight traffic;
- (17) 'conformity assessment body' means a body that has been notified or designated to be responsible for conformity assessment activities, including calibration, testing, certification and inspection; a conformity assessment body is classified as a 'notified body' following notification by a Member State; a conformity assessment body is classified as a 'designated body' following designation by a Member State;
- (18) 'interoperability constituents' means the interoperability constituents as defined in point (7) of Article 2 of Directive (EU) 2016/797;
- (19) 'keeper' means the natural or legal person that, being the owner of a vehicle or having the right to use it, exploits the vehicle as a means of transport and is registered as such in a vehicle register referred to in Article 47 of Directive (EU) 2016/797;
- (20) 'entity in charge of maintenance' ('ECM') means an entity in charge of the maintenance of a vehicle, and registered as such in a vehicle register referred to in Article 47 of Directive (EU) 2016/797;
- (21) 'vehicle' means a railway vehicle suitable for circulation on wheels on railway lines, with or without traction; a vehicle is composed of one or more structural and functional subsystems;

- (22) 'manufacturer' means the manufacturer as defined in point (36) of Article 2 of Directive (EU) 2016/797;
- (23) 'consignor' means an enterprise which consigns goods either on its own behalf or for a third party;
- (24) 'consignee' means any natural or legal person who receives goods pursuant to a contract of carriage; if the transport operation takes place without a contract of carriage, any natural or legal person that takes charge of the goods on arrivals shall be deemed to be the consignee;
- (25) 'loader' means an enterprise which loads packaged goods, small containers or portable tanks into or onto a wagon or a container, or which loads a container, bulk-container, multiple-element gas container, tank-container or portable tank onto a wagon;
- (26) 'unloader' means an enterprise which removes a container, bulk-container, multiple-element gas container, tank-container or portable tank from a wagon, or any enterprise which unloads packaged goods, small containers or portable tanks out of or from a wagon or a container, or any enterprise which discharges goods from a tank (tank-wagon, demountable tank, portable tank or tank-container), or from a battery-wagon or multiple-element gas container, or from a wagon, large container or small container for carriage in bulk or a bulk-container;
- (27) 'filler' means an enterprise that loads goods into a tank (including a tank-wagon, wagon with demountable tank, portable tank or tank-container), into a wagon, large container or small container for carriage in bulk, or into a battery-wagon or multiple-element gas container;
- (28) 'unfiller' means an enterprise that removes goods from a tank (including a tank-wagon, wagon with demountable tank, portable tank or tank-container), a wagon, a large container or small container for carriage in bulk, or from a battery-wagon or multiple-element gas container;
- (29) 'carrier' means an enterprise which carries out a transport operation pursuant to a contract of carriage;
- (30) 'contracting entity' means a public or private entity which orders the design and/or construction or the renewal or upgrading of a subsystem;
- (31) 'type of operation' means the type characterised by passenger transport, including or excluding high-speed services, freight transport, including or excluding dangerous goods services, and shunting services only;
- (32) 'extent of operation' means the extent characterised by the number of passengers and/or volume of goods and the estimated size of a railway undertaking in terms of number of employees working in the railway sector (i.e., as a micro, small, medium-sized or large enterprise);
- (33) 'area of operation' means a network or networks within one or more Member States where a railway undertaking intends to operate.

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;
- (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.

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.

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.

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 ⁽¹⁾.
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.

⁽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).

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 ⁽¹⁾.
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;

⁽¹⁾ 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).

- (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.

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⁽¹⁾, 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.

⁽¹⁾ 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).

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.

CHAPTER III

SAFETY CERTIFICATION AND AUTHORISATION

Article 10

Single safety certificate

1. Without prejudice to paragraph 9, access to the railway infrastructure shall be granted only to railway undertakings which hold the single safety certificate issued by the Agency in accordance with paragraphs 5 to 7 or by a national safety authority in accordance with paragraph 8.

The purpose of the single safety certificate is to provide evidence that the railway undertaking concerned has established its safety management system and that it is able to operate safely in the intended area of operation.

2. In its application for a single safety certificate, the railway undertaking shall specify the type and extent of the railway operations covered and the intended area of operation.

3. The application for a single safety certificate shall be accompanied by a file including documentary evidence that:

- (a) the railway undertaking has established its safety management system in accordance with Article 9 and that it meets the requirements laid down in TSIs, CSMs and CSTs and in other relevant legislation in order to control risks and provide transport services safely on the network; and
- (b) the railway undertaking, where applicable, meets the requirements laid down in the relevant national rules notified in accordance with Article 8.

That application and information about all applications, the stages of the relevant procedures and their outcome, and, where applicable, the requests and decisions of the Board of Appeal, shall be submitted through the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796.

4. The Agency, or in the cases provided for by paragraph 8 the national safety authority, shall issue the single safety certificate, or inform the applicant of its negative decision, within a predetermined and reasonable time, and, in any case, not more than 4 months after all information required and any supplementary information requested have been submitted by the applicant. The Agency, or in the cases provided for by paragraph 8 the national safety authority, shall apply the practical arrangements on the certification procedure to be established in an implementing act, as referred to in paragraph 10.

5. The Agency shall issue a single safety certificate to railway undertakings having an area of operation in one or more Member States. In order to issue such a certificate, the Agency shall:

- (a) assess the elements set out in point (a) of paragraph 3; and
- (b) immediately refer the railway undertaking's file in its entirety to the national safety authorities concerned by the intended area of operation for an assessment of the elements set out in point (b) of paragraph 3.

As part of the above assessments, the Agency or the national safety authorities shall be authorised to undertake visits and inspections on the sites of the railway undertaking and audits, and may request relevant supplementary information. The Agency and the national safety authorities shall coordinate the organisation of such visits, audits and inspections.

6. Within 1 month of receipt of an application for a single safety certificate, the Agency shall inform the railway undertaking that the file is complete or ask for relevant supplementary information, setting a reasonable deadline for the provision thereof. With regard to the completeness, relevance and consistency of the file, the Agency may also assess the elements set out in point (b) of paragraph 3.

The Agency shall take full account of the assessments under paragraph 5 before taking its decision on the issuing of the single safety certificate.

The Agency shall take full responsibility for any single safety certificates it issues.

7. Where the Agency disagrees with a negative assessment carried out by one or more national safety authorities pursuant to point (b) of paragraph 5, it shall inform that authority or authorities in question, giving reasons for its disagreement. The Agency and the national safety authority or authorities shall cooperate with a view to agreeing on a mutually acceptable assessment. Where necessary, the Agency and the national safety authority or authorities may decide to involve the railway undertaking. If no mutually acceptable assessment can be agreed on within 1 month after the Agency has informed the national safety authority or authorities of its disagreement, the Agency shall take its final decision unless the national safety authority or authorities have referred the matter for arbitration to the Board of Appeal established under Article 55 of Regulation (EU) 2016/796. The Board of Appeal shall decide whether to confirm the Agency's draft decision within 1 month of the request of the national safety authority or authorities.

Where the Board of Appeal agrees with the Agency, the Agency shall take a decision without delay.

Where the Board of Appeal agrees with the negative assessment of the national safety authority, the Agency shall grant a single safety certificate with an area of operations excluding the parts of the network which received a negative assessment.

Where the Agency disagrees with a positive assessment of one or more national safety authorities pursuant to point (b) of paragraph 5, it shall inform the authority or authorities in question, giving reasons for its disagreement. The Agency and the national safety authority or authorities shall cooperate with a view to agreeing on a mutually acceptable assessment. Where necessary, the Agency and the national safety authority or authorities may decide to involve the applicant. If no mutually acceptable assessment can be agreed on within 1 month after the Agency has informed the national safety authority or authorities of its disagreement, the Agency shall take its final decision.

8. Where the area of operation is limited to one Member State, the national safety authority of that Member State may, under its own responsibility and when the applicant so requests, issue a single safety certificate. In order to issue such certificates, the national safety authority shall assess the file in relation to all the elements specified in paragraph 3 and shall apply the practical arrangements to be established in the implementing acts referred to in paragraph 10. As part of the above assessments, the national safety authority shall be authorised to undertake visits and inspections on the sites of the railway undertaking and audits. Within 1 month of receipt of the application, the national safety authority shall inform the applicant that the file is complete or ask for relevant supplementary information. The single safety certificate shall also be valid without an extension of the area of operations for railway undertakings travelling to stations in neighbouring Member States with similar network characteristics and similar operating rules, when those stations are close to the border, following consultation of the competent national safety authorities. This consultation may be carried out on a case-by-case basis or set out in a cross-border agreement between Member States or national safety authorities.

The national safety authority shall take full responsibility for any single safety certificates it issues.

9. A Member State may allow third-country operators to reach a station in its territory designated for cross-border operations and close to the border of that Member State without requiring a single safety certificate, provided that an appropriate level of safety is ensured through:

- (a) cross-border agreement between the Member State concerned and the neighbouring third country; or
- (b) contractual arrangements between the third-country operator and the railway undertaking or infrastructure manager that has a single safety certificate or safety authorisation to operate on that network, provided that the safety-related aspects of those arrangements have been duly reflected in their safety management system.

10. By 16 June 2018, the Commission shall adopt, by means of implementing acts, practical arrangements specifying:

- (a) how the requirements for the single safety certificate laid down in this Article shall be fulfilled by the applicant and listing the documents required;
- (b) the details of the certification process, such as procedural stages and timeframes for each stage of the process;
- (c) how the requirements laid down in this Article shall to be complied with by the Agency and the national safety authority through the different stages of the application and certification process, including in the assessment of applicants' files; and
- (d) the period of validity of single safety certificates issued by the Agency or by the national safety authorities, in particular in the case of updates of any single safety certificate resulting from changes to type, extent and area of operation.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3). They shall take into account the experience gained during the implementation of Commission Regulation (EC) No 653/2007 ⁽¹⁾ and of Commission Regulation (EU) No 1158/2010 ⁽²⁾ and the experience gained during the preparation of the cooperation agreements referred to in Article 11(1).

11. Single safety certificates shall specify the type and extent of the railway operations covered and the area of operation. A single safety certificate may also cover sidings owned by the railway undertaking if these are included in its safety management system.

12. Any decision refusing the issuing of a single safety certificate or excluding part of the network in accordance with a negative assessment as referred to in paragraph 7 shall be duly substantiated. The applicant may, within 1 month of receipt of the decision, request that the Agency or the national safety authority, as appropriate, review the decision. The Agency or the national safety authority shall have 2 months from the date of receipt of the request for review in which to confirm or reverse its decision.

If the negative decision of the Agency is confirmed, the applicant may bring an appeal before the Board of Appeal designated under Article 55 of Regulation (EU) 2016/796.

If the negative decision of a national safety authority is confirmed, the applicant may bring an appeal before an appeal body in accordance with national law. Member States may designate the regulatory body referred to in Article 56 of Directive 2012/34/EU for the purpose of this appeal procedure. In that case, Article 18(3) of this Directive shall apply.

13. A single safety certificate issued either by the Agency or by a national safety authority under this Article shall be renewed upon application by the railway undertaking at intervals not exceeding 5 years. It shall be fully or partly updated whenever the type or extent of the operation is substantially altered.

14. Where an applicant already has a single safety certificate issued in accordance with paragraphs 5 to 7 and wishes to extend its area of operations, or where it already has a single safety certificate issued in accordance with paragraph 8 and wishes to extend its area of operations to another Member State, it shall supplement the file with the relevant documents referred to in paragraph 3 concerning the additional area of operation. The railway undertaking shall submit the file to the Agency, which shall, after following the procedures laid down in paragraphs 4 to 7, issue an updated single safety certificate covering the extended area of operation. In that case, only the national safety authorities concerned by the extension of operation shall be consulted for the purposes of assessing the file as provided for in point (b) of paragraph 3.

⁽¹⁾ Commission Regulation (EC) No 653/2007 of 13 June 2007 on the use of a common European format for safety certificates and application documents in accordance with Article 10 of Directive 2004/49/EC of the European Parliament and of the Council and on the validity of safety certificates delivered under Directive 2001/14/EC (OJ L 153, 14.6.2007, p. 9).

⁽²⁾ 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).

If the railway undertaking has a single safety certificate in accordance with paragraph 8 and wishes to extend the area of operation within that Member State, it shall supplement the file with the relevant documents referred to in paragraph 3 concerning the additional area of operation. It shall submit the file, through the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796, to the national safety authority, which shall, after following the procedures laid down in paragraph 8, issue an updated single safety certificate covering the extended area of operation.

15. The Agency and the competent national safety authorities may require the revision of single safety certificates issued by them following substantial changes to the safety regulatory framework.

16. The Agency shall inform the competent national safety authorities without delay, and in any case within 2 weeks, of the issue of a single safety certificate. The Agency shall inform the competent national safety authorities immediately in the case of renewal, amendment or revocation of a single safety certificate. It shall state the name and address of the railway undertaking, the issue date, the type, extent, validity and area of operation of the single safety certificate and, in the case of revocation, the reasons for its decision. In the case of single safety certificates issued by national safety authorities, the same information shall be provided by the competent national safety authority or authorities to the Agency within the same timeframe.

Article 11

Cooperation between the Agency and national safety authorities on issuing single safety certificates

1. For the purposes of Article 10(5) and (6) of this Directive, the Agency and the national safety authorities shall conclude cooperation agreements in accordance with Article 76 of Regulation (EU) 2016/796. The cooperation agreements shall be specific or framework agreements, and shall involve one or more national safety authorities. The cooperation agreements shall contain a detailed description of tasks and conditions for deliverables, the time limits applying to their delivery and an apportionment of the fees payable by the applicant.

2. The cooperation agreements may also include specific cooperation arrangements in the case of networks requiring specific expertise for geographical or historical reasons, with a view to reducing administrative burdens and costs to the applicant. Where such networks are isolated from the rest of the Union rail system, such specific cooperation arrangements may include the possibility of contracting tasks to the relevant national safety authorities when this is necessary in order to ensure efficient and proportionate allocation of resources for certification. Those cooperation agreements shall be in place before the Agency carries out the certification tasks in accordance with Article 31(3).

3. In the case of those Member States whose rail networks have a track gauge that is different from that of the main rail network within the Union and share identical technical and operational requirements with neighbouring third countries, in addition to the cooperation agreements referred to in paragraph 2 all the national safety authorities concerned in those Member States shall conclude with the Agency a multilateral agreement which shall include the conditions to facilitate the extension of the area of operation of safety certificates in the Member States concerned, where relevant.

Article 12

Safety authorisation of infrastructure managers

1. In order to be allowed to manage and operate a rail infrastructure, the infrastructure manager shall obtain a safety authorisation from the national safety authority in the Member State where the rail infrastructure is located.

The safety authorisation shall comprise an authorisation confirming acceptance of the infrastructure manager's safety management system as provided for in Article 9, and shall include the procedures and provisions fulfilling the requirements necessary for the safe design, maintenance and operation of the railway infrastructure, including, where appropriate, the maintenance and operation of the traffic control and signalling system.

The national safety authority shall explain the requirements for the safety authorisations and the documents required, where appropriate in the form of an application guidance document.

2. The safety authorisation shall be valid for 5 years and may be renewed upon application by the infrastructure manager. It shall be wholly or partly revised whenever substantial changes are made to the infrastructure, signalling or energy subsystems or to the principles of their operation and maintenance. The infrastructure manager shall inform the national safety authority of all such changes without delay.

The national safety authority may require that the safety authorisation be revised following substantial changes to the safety regulatory framework.

3. The national safety authority shall take a decision on an application for safety authorisation without delay and in any event not more than 4 months after all the information required and any supplementary information requested has been submitted by the applicant.

4. The national safety authority shall inform the Agency without delay, and in any event within 2 weeks, of the safety authorisations that have been issued, renewed, amended or revoked. It shall state the name and address of the infrastructure manager, the issue date, scope and period of validity of the safety authorisation and, in the event of revocation, the reasons for its decision.

5. In the case of cross-border infrastructure, the competent national safety authorities shall cooperate in order to issue the safety authorisations.

Article 13

Access to training facilities

1. Member States shall ensure that railway undertakings and infrastructure managers and their staff performing safety-critical tasks have fair and non-discriminatory access to training facilities for train drivers and staff accompanying trains, whenever such training is necessary for operating services on their network.

The training services shall include training on necessary route knowledge, operating rules and procedures, the signalling and control-command system and emergency procedures applied on the routes operated.

If the training services do not include examinations and granting of certificates, Member States shall ensure that staff of railway undertakings and infrastructure managers have access to such certificates.

The national safety authority shall ensure that the training services meet the requirements laid down respectively in Directive 2007/59/EC, in TSIs or in the national rules referred to in point (e) of Article 8(3) of this Directive.

2. If the training facilities are available only through a single railway undertaking or the infrastructure manager, Member States shall ensure that they are made available to other railway undertakings at a reasonable and non-discriminatory price which is cost-related and which may include a profit margin.

3. When recruiting new train drivers, staff on board trains and staff performing safety-critical tasks, railway undertakings may take into account any training, qualifications and experience acquired previously from other railway undertakings. For that purpose, such members of staff shall be entitled to have access to, obtain copies of, and communicate all documents attesting to their training, qualifications and experience.

4. Railway undertakings and infrastructure managers shall be responsible for the level of training and qualifications of their staff carrying out safety-critical work.

Article 14

Maintenance of vehicles

1. Each vehicle, before it is being used on the network, shall have an entity in charge of maintenance assigned to it and this entity shall be registered in the vehicle register in accordance with Article 47 of Directive (EU) 2016/797.

2. Without prejudice to the responsibility of the railway undertakings and infrastructure managers for the safe operation of a train as provided for in Article 4, the entity in charge of maintenance shall ensure that the vehicles for the maintenance of which it is in charge are in a safe state of running. To that end, the entity in charge of maintenance shall establish a maintenance system for those vehicles and shall by means of that system:

- (a) ensure that vehicles are maintained in accordance with the maintenance file of each vehicle and the requirements in force, including maintenance rules and relevant TSI provisions;
- (b) implement the necessary risk evaluation and assessment methods established in the CSMS as referred to in point (a) of Article 6(1), where appropriate in cooperation with other actors;
- (c) ensure that its contractors implement risk control measures through the application of the CSM 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 the national safety authority; and
- (d) ensure the traceability of the maintenance activities.

3. The maintenance system shall be composed of the following functions:

- (a) a management function to supervise and coordinate the maintenance functions referred to in points (b) to (d) and to ensure the safe state of the vehicle in the railway system;
- (b) a maintenance development function responsible to manage the maintenance documentation, including the configuration management, based on design and operational data as well as on performance and return on experience;
- (c) a fleet-maintenance management function to manage the vehicle's removal for maintenance and its return to operation after maintenance;
- (d) a maintenance delivery function to deliver the required technical maintenance of a vehicle or parts of it, including the release to service documentation.

The entity in charge of maintenance shall carry out the management function itself, but may outsource the maintenance functions referred to in points (b) to (d), or parts thereof, to other contracting parties such as maintenance workshops.

The entity in charge of maintenance shall ensure that all the functions set out in points (a) to (d) comply with the requirements and assessment criteria set out in Annex III.

Maintenance workshops shall apply relevant sections of Annex III as identified in the implementing acts adopted pursuant to point (a) of paragraph 8, which correspond to the functions and activities to be certified.

4. In the case of freight wagons, and after the adoption of the implementing acts referred to in point (b) of paragraph 8 in the case of other vehicles, each entity in charge of maintenance shall be certified and be awarded an entity in charge of maintenance certificate (ECM certificate) by an accredited or recognised body or by a national safety authority in accordance with the following conditions:

- (a) the accreditation and recognition processes of certification processes shall be based on criteria of independence, competence and impartiality;
- (b) the system of certification shall provide evidence that an entity in charge of maintenance has established the maintenance system to ensure the safe state of running of any vehicle for which it is in charge of maintenance;
- (c) the ECM certification shall be based on an assessment of the ability of the entity in charge of maintenance to meet the relevant requirements and assessment criteria set out in Annex III and to apply them consistently. It shall include a system of surveillance to ensure continuing compliance with those requirements and assessment criteria after award of the ECM certificate;
- (d) the certification of maintenance workshops shall be based on the compliance with the relevant sections in Annex III applied to the corresponding functions and activities to be certified.

Where the entity in charge of maintenance is a railway undertaking or an infrastructure manager, compliance with the conditions set out in the first subparagraph may be checked by the national safety authority pursuant to the procedures referred to in Article 10 or 12 and may be confirmed on the certificates issued in accordance with those procedures.

5. The certificates issued in accordance with paragraph 4 shall be valid throughout the Union.
6. On the basis of the recommendation of the Agency, the Commission shall, by means of implementing acts, adopt detailed provisions on the certification conditions referred to in the first subparagraph of paragraph 4 for the entity in charge of maintenance of freight wagons, including the requirements set out in Annex III in compliance with the relevant CSM and TSIs, and, when necessary, shall amend those provisions.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3).

The certification system applicable to freight wagons adopted by Commission Regulation (EU) No 445/2011 ⁽¹⁾ shall continue to apply until the implementing acts referred to in this paragraph apply.

7. By 16 June 2018, the Agency shall evaluate the system of certification of the entity in charge of maintenance for freight wagons, consider the expediency of extending that system to all vehicles and the mandatory certification of maintenance workshops and submit its report to the Commission.

8. On the basis of the evaluation carried out by the Agency pursuant to paragraph 7, the Commission shall, by means of implementing acts, adopt, if appropriate, and, when necessary, subsequently amend detailed provisions identifying which of the requirements set out in Annex III shall apply for the purpose of:

- (a) maintenance functions carried out by maintenance workshops, including detailed provisions to ensure the uniform implementation of the certification of maintenance workshops, in compliance with the relevant CSM and TSIs;
- (b) the certification of entities in charge of maintenance of vehicles other than freight wagons, on the basis of the technical characteristics of such vehicles, including detailed provisions to ensure the uniform implementation of the certification conditions by the entity in charge of maintenance for vehicles other than freight wagons, in compliance with the relevant CSM and TSIs.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3).

Article 15

Derogations from the system of certification of entities in charge of maintenance

1. Member States may fulfil the obligation to identify the entity in charge of maintenance through alternative measures with respect to the maintenance system established in Article 14, in the following cases:

- (a) vehicles registered in a third country and maintained in accordance with the law of that country;
- (b) vehicles used on networks or lines the track gauge of which is different from that of the main rail network within the Union and in respect of which fulfilment of the requirements laid down in Article 14(2) is ensured by international agreements with third countries;
- (c) freight wagons and passenger coaches which are in shared use with third countries the track gauge of which is different from that of the main rail network within the Union;
- (d) vehicles used on the networks referred to in Article 2(3), and military equipment and special transport requiring an ad hoc national safety authority permit to be delivered prior to their entry into service. In this case derogations shall be granted for periods not longer than 5 years.

⁽¹⁾ Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 (OJ L 122, 11.5.2011, p. 22).

2. The alternative measures referred to in paragraph 1 shall be implemented through derogations to be granted by the relevant national safety authority or by the Agency when:
 - (a) registering vehicles pursuant to Article 47 of Directive (EU) 2016/797, as far as the identification of the entity in charge of maintenance is concerned;
 - (b) delivering single safety certificates and safety authorisations to railway undertakings and infrastructure managers pursuant to Articles 10 and 12 of this Directive, as far as the identification or certification of the entity in charge of maintenance is concerned.
3. Derogations shall be identified and justified in the annual report referred to in Article 19. Where it appears that undue safety risks are being taken on the Union rail system, the Agency shall immediately inform the Commission thereof. The Commission shall make contact with the parties concerned and, where appropriate, request the Member State concerned to withdraw its derogation decision.

CHAPTER IV

NATIONAL SAFETY AUTHORITIES

Article 16

Tasks

1. Each Member State shall establish a national safety authority. Member States shall ensure that the national safety authority has the necessary internal and external organisational capacity in terms of human and material resources. That authority shall be independent in its organisation, legal structure and decision-making from any railway undertaking, infrastructure manager, applicant or contracting entity and from any entity awarding public service contracts. Provided that such independence is guaranteed, that authority may be a department within the national ministry responsible for transport matters.
2. The national safety authority shall be entrusted with at least the following tasks:
 - (a) authorising the placing in service of the trackside control-command and signalling, energy and infrastructure subsystems constituting the Union rail system in accordance with Article 18(2) of Directive (EU) 2016/797;
 - (b) issuing, renewing, amending and revoking vehicle authorisations for placing on the market in accordance with Article 21(8) of Directive (EU) 2016/797;
 - (c) supporting the Agency in the issuing, renewal, amendment and revocation of vehicle authorisations for placing on the market in accordance with Article 21(5) of Directive (EU) 2016/797 and type authorisations of vehicle in accordance with Article 24 of Directive (EU) 2016/797;
 - (d) supervising, in its territory, that interoperability constituents are in compliance with the essential requirements as required by Article 8 of Directive (EU) 2016/797;
 - (e) ensuring that a vehicle number has been assigned in accordance with Article 46 of Directive (EU) 2016/797, without prejudice to Article 47(4) of that Directive;
 - (f) supporting the Agency in the issuing, renewal, amendment and revocation of single safety certificates granted in accordance with Article 10(5);
 - (g) issuing, renewing, amending and revoking single safety certificates granted in accordance with Article 10(8);
 - (h) issuing, renewing, amending and revoking safety authorisations granted in accordance with Article 12;
 - (i) monitoring, promoting, and, where appropriate, enforcing and updating the safety regulatory framework including the system of national rules;
 - (j) supervising railway undertakings and infrastructure managers in accordance with Article 17;
 - (k) where relevant, and in accordance with national law, issuing, renewing, amending and revoking train driving licences in accordance with Directive 2007/59/EC;
 - (l) where relevant, and in accordance with national law, issuing, renewing, amending and revoking certificates granted to entities in charge of maintenance.

3. The tasks referred to in paragraph 2 may not be transferred or subcontracted to any infrastructure manager, railway undertaking or contracting entity.

Article 17

Supervision

1. National safety authorities shall oversee continued compliance with the legal obligation incumbent on railway undertakings and infrastructure managers to use a safety management system as referred to in Article 9.

For that purpose, the national safety authorities shall apply the principles set out in the relevant CSMs for supervision referred to in point (c) of Article 6(1), ensuring that supervision activities include, in particular, checking the application by railway undertakings and infrastructure managers of:

- (a) the safety management system to monitor its effectiveness;
- (b) the individual or partial elements of the safety management system, including operational activities, the supply of maintenance and material and the use of contractors to monitor their effectiveness; and
- (c) the relevant CSMs referred to in Article 6. The supervision activities relating to this point shall also apply to entities in charge of maintenance, where appropriate.

2. Railway undertakings shall inform the relevant national safety authorities at least 2 months before starting any new rail transport operation, in order to allow the latter to plan the supervision activities. Railway undertakings shall also provide a breakdown of the categories of staff and the types of vehicles.

3. The holder of a single safety certificate shall inform the competent national safety authorities without delay of any major changes to the information referred to in paragraph 2.

4. The monitoring of compliance with applicable working, driving and rest-time rules for train drivers shall be ensured by competent authorities designated by Member States. Where the monitoring of compliance is not ensured by national safety authorities, the competent authorities shall cooperate with the national safety authorities with a view to allowing the national safety authorities to fulfil their role of supervision of railway safety.

5. If a national safety authority finds that a holder of a single safety certificate no longer satisfies the conditions for certification, it shall ask the Agency to restrict or revoke that certificate. The Agency shall immediately inform all the competent national safety authorities. If the Agency decides to restrict or revoke the single safety certificate, it shall give reasons for its decision.

In the event of disagreement between the Agency and the national safety authority, the arbitration procedure indicated in Article 10(7) shall apply. If the result of that arbitration procedure is that the single safety certificate is to be neither restricted nor revoked, the temporary safety measures referred to in paragraph 6 of this Article shall be suspended.

Where the national safety authority has itself issued the single safety certificate in accordance with Article 10(8), it may restrict or revoke the certificate, giving reasons for its decision, and shall inform the Agency.

The holder of a single safety certificate whose certificate has been restricted or revoked either by the Agency or by the national safety authority shall have the right to appeal in accordance with Article 10(12).

6. If, during supervision, a national safety authority identifies a serious safety risk, it may at any time apply temporary safety measures, including immediately restricting or suspending the relevant operations. If the single safety certificate was issued by the Agency, the national safety authority shall immediately inform the Agency thereof and provide supporting evidence for its decision.

If the Agency finds that the holder of a single safety certificate no longer satisfies the conditions for certification, it shall immediately restrict or revoke that certificate.

If the Agency finds that the measures applied by the national safety authority are disproportionate, it may ask the national safety authority to withdraw or adapt those measures. The Agency and the national safety authority shall cooperate with a view to reaching a mutually acceptable solution. Where necessary, this process shall also involve the railway undertaking. If the latter procedure fails, the decision of the national safety authority to apply temporary measures shall remain in force.

The decision of the national safety authority relating to temporary safety measures shall be subject to national judicial review as referred to in Article 18(3). In such a case, the temporary safety measures may apply until the end of the judicial review, without prejudice to paragraph 5.

If the duration of a temporary measure is longer than 3 months, the national safety authority shall ask the Agency to restrict or revoke the single safety certificate and the procedure set out in paragraph 5 shall apply.

7. The national safety authority shall supervise the trackside, control-command and signalling, energy and infrastructure subsystems and ensure that they are in compliance with the essential requirements. In the case of cross-border infrastructures, it will perform its activities of supervision in cooperation with other relevant national safety authorities. If the national safety authority finds that an infrastructure manager no longer satisfies the conditions for its safety authorisation, it shall restrict or revoke that authorisation, giving reasons for its decision.

8. When supervising the effectiveness of the safety management systems of infrastructure managers and railway undertakings, the national safety authorities may take into account the safety performance of actors as referred to in Article 4(4) of this Directive, and, where appropriate, the training centres referred to in Directive 2007/59/EC as long as their activities have an impact on railway safety. This paragraph applies without prejudice to the responsibility of the railway undertakings and infrastructure managers referred to in Article 4(3) of this Directive.

9. The national safety authorities of Member States where a railway undertaking operates shall cooperate in coordinating their supervision activities concerning that railway undertaking to ensure that any key information on the specific railway undertaking is shared, particularly on known risks and its safety performance. The national safety authority shall also share information with other relevant national safety authorities and the Agency if it finds that the railway undertaking is not taking the necessary risk control measures.

That cooperation shall ensure that the supervision has sufficient coverage and that the duplication of inspections and audits is avoided. The national safety authorities may develop a common supervision plan in order to ensure that audits and other inspections are carried out periodically, taking into account the type and extent of transport operations in each of the Member States concerned.

The Agency shall assist such coordination activities by developing guidelines.

10. National safety authorities may address notices to warn infrastructure managers and railway undertakings in cases of non-compliance with their obligations set out in paragraph 1.

11. National safety authorities shall use information gathered by the Agency during the assessment of the file referred to in point (a) of Article 10(5) for the purposes of supervision of a railway undertaking after issuing its single safety certificate. They shall use the information gathered during the process of safety authorisation in accordance with Article 12 for the purposes of supervision of the infrastructure manager.

12. For the purpose of renewing single safety certificates, the Agency, or the competent national safety authorities in the case of a safety certificate issued in accordance with Article 10(8), shall use information gathered during the supervision activities. For the purpose of renewing safety authorisations, the national safety authority shall also use information gathered during its supervision activities.

13. The Agency and the national safety authorities shall make the necessary arrangements to coordinate and ensure the full exchange of information referred to in paragraphs 10, 11 and 12.

*Article 18***Decision-making principles**

1. The Agency, when considering applications for a single safety certificate in accordance with Article 10(1), and the national safety authorities shall carry out their tasks in an open, non-discriminatory and transparent way. In particular, they shall allow all interested parties to be heard and give reasons for their decisions.

They shall promptly respond to requests and applications and communicate their requests for information without delay and adopt all their decisions within 4 months after all relevant information has been provided by the applicant. They may at any time request the technical assistance of infrastructure managers and railway undertakings or other qualified bodies when they are carrying out the tasks referred to in Article 16.

In the process of developing the national regulatory framework, the national safety authorities shall consult all actors and interested parties, including infrastructure managers, railway undertakings, manufacturers and maintenance providers, users and staff representatives.

2. The national safety authorities shall be free to carry out all inspections, audits and investigations that are needed for the accomplishment of their tasks, and they shall be granted access to all relevant documents and to premises, installations and equipment of infrastructure managers and railway undertakings and, where necessary, of any actor referred to in Article 4. The Agency shall have the same rights in relation to railway undertakings when it carries out its safety certification tasks in accordance with Article 10(5).

3. Member States shall take the measures necessary to ensure that decisions taken by the national safety authorities are subject to judicial review.

4. The national safety authorities shall conduct an active exchange of views and experience, in particular within the network established by the Agency in order to harmonise their decision-making criteria across the Union.

*Article 19***Annual report**

National safety authorities shall publish an annual report concerning their activities in the preceding year and send them to the Agency by 30 September. The report shall contain information on:

- (a) the development of railway safety, including an aggregation at Member State level of the CSIs, in accordance with Article 5(1);
- (b) important changes in legislation and regulation concerning railway safety;
- (c) the development of safety certification and safety authorisation;
- (d) the results of, and experience relating to, the supervision of infrastructure managers and railway undertakings, including the number and outcome of inspections and audits;
- (e) the derogations decided in accordance with Article 15; and
- (f) the experience of the railway undertakings and infrastructure managers on the application of the relevant CSMs.

CHAPTER V

ACCIDENT AND INCIDENT INVESTIGATION

*Article 20***Obligation to investigate**

1. Member States shall ensure that an investigation is carried out by the investigating body referred to in Article 22 after any serious accident on the Union rail system. The objective of the investigation shall be to improve, where possible, railway safety and the prevention of accidents.

2. The investigating body referred to in Article 22 may also investigate those accidents and incidents which under slightly different conditions might have led to serious accidents, including technical failures of the structural subsystems or of interoperability constituents of the Union rail system.

The investigating body may decide whether or not an investigation of such an accident or incident is to be undertaken. In making its decision it shall take into account:

- (a) the seriousness of the accident or incident;
- (b) whether it forms part of a series of accidents or incidents relevant to the system as a whole;
- (c) its impact on railway safety; and
- (d) requests from infrastructure managers, railway undertakings, the national safety authority or the Member States.

3. The extent of investigations and the procedure to be followed in carrying out investigations shall be determined by the investigating body, taking into account Articles 21 and 23 and depending on the lessons it expects to draw from the accident or incident for the improvement of safety.

4. The investigation shall in no case be concerned with apportioning blame or liability.

Article 21

Status of investigation

1. Member States shall define, within the framework of their respective legal system, the legal status of the investigation that is to enable the investigators-in-charge to carry out their task in the most efficient way and within the shortest time.

2. In accordance with their national legislation, Member States shall ensure full cooperation by the authorities responsible for any judicial inquiry, and shall ensure that the investigators are given access as soon as possible to information and evidence relevant for the investigation. In particular, they shall be granted:

- (a) immediate access to the site of the accident or incident as well as to the rolling stock involved, the related infrastructure and traffic control and signalling installations;
- (b) the right to an immediate listing of evidence and controlled removal of wreckage, infrastructure installations or components for examination or analysis purposes;
- (c) unrestricted access to, and use of, the contents of on-board recorders and equipment for the recording of verbal messages and registration of the operation of the signalling and traffic control system;
- (d) access to the results of examination of the bodies of victims;
- (e) access to the results of examinations of the train staff and other railway staff involved in the accident or incident;
- (f) the opportunity to question the railway staff involved in the accident or incident and other witnesses; and
- (g) access to any relevant information or records held by the infrastructure manager, railway undertakings, entities in charge of maintenance and national safety authority concerned.

3. The Agency shall cooperate with the investigating body when the investigation involves vehicles authorised by the Agency or railway undertakings certified by the Agency. It shall as soon as possible submit all requested information or records to the investigating body and provide explanations, where requested.

4. The investigation shall be carried out independently of any judicial inquiry.

*Article 22***Investigating body**

1. Each Member State shall ensure that investigations of the accidents and incidents referred to in Article 20 are conducted by a permanent body, which shall comprise at least one investigator able to perform the function of investigator-in-charge in the event of an accident or incident. That body shall be independent in its organisation, legal structure and decision-making from any infrastructure manager, railway undertaking, charging body, allocation body and conformity assessment body and from any party whose interests could conflict with the tasks entrusted to the investigating body. It shall, furthermore, be functionally independent from the national safety authority, from the Agency and from any regulator of railways.

2. The investigating body shall perform its tasks independently of the other entities referred to in paragraph 1 and shall be able to obtain sufficient resources to do so. Its investigators shall be afforded status giving them the necessary guarantees of independence.

3. Member States shall provide for railway undertakings, infrastructure managers and, where appropriate, the national safety authority to be obliged to immediately notify the accidents and incidents referred to in Article 20 to the investigating body and to provide all available information. Where appropriate, this notification shall be updated as soon as any missing information becomes available.

The investigating body shall decide, without delay and in any event no later than 2 months after receipt of the notification concerning the accident or incident, whether or not to start the investigation.

4. The investigating body may combine its tasks under this Directive with the work of investigating occurrences other than railway accidents and incidents as long as such other investigations do not endanger its independence.

5. If necessary, and provided it does not undermine the independence of the investigating body as provided for in paragraph 1, the investigating body may request the assistance of investigating bodies from other Member States or from the Agency to supply expertise or to carry out technical inspections, analyses or evaluations.

6. Member States may entrust the investigating body with the task of carrying out investigations of railway accidents and incidents other than those referred to in Article 20.

7. The investigating bodies shall conduct an active exchange of views and experience for the purposes of the development of common investigation methods, drawing up common principles for follow up of safety recommendations and adaptation to the development of technical and scientific progress.

Without prejudice to paragraph 1, the Agency shall support the investigating bodies in the performance of this task in accordance with Article 38(2) of Regulation (EU) 2016/796.

The investigating bodies, with the support of the Agency in accordance with Article 38(2) of Regulation (EU) 2016/796, shall establish a programme of peer reviews where all investigating bodies are encouraged to participate so as to monitor their effectiveness and independence. The investigating bodies, with the support of the secretariat referred to in Article 38(2) of Regulation (EU) 2016/796, shall publish:

- (a) the common peer-review programme and the review criteria; and
- (b) an annual report on the programme, highlighting identified strengths and suggestions for improvements.

The peer review reports shall be provided to all investigating bodies and to the Agency. Those reports shall be published on a voluntary basis.

*Article 23***Investigation procedure**

1. An accident or incident referred to in Article 20 shall be investigated by the investigating body of the Member State in which it occurred. If it is not possible to establish in which Member State it occurred or if it occurred on or close to a border installation between two Member States, the relevant investigating bodies shall agree which of them is to carry out the investigation or agree to carry it out in cooperation with each other. The other investigating body shall, in the first case, be allowed to participate in the investigation and fully share its results.

Investigating bodies from other Member States shall be invited, if appropriate, to participate in an investigation where:

- (a) a railway undertaking established and licensed in one of those Member States is involved in the accident or incident;
or
- (b) a vehicle registered or maintained in one of those Member States is involved in the accident or incident.

Investigating bodies from invited Member States shall be provided with the powers necessary to enable them, when requested, to assist in the collection of evidence for another Member State's investigating body.

Investigating bodies from invited Member States shall be provided with access to the information and evidence necessary to enable them to participate effectively in the investigation with due respect for national laws relating to judicial proceedings.

This paragraph shall not preclude Member States from agreeing that the relevant bodies shall carry out investigations in cooperation with each other in other circumstances.

2. For each accident or incident the body responsible for the investigation shall arrange for the appropriate means, comprising the necessary operational and technical expertise, to carry out the investigation. The expertise may be obtained from inside or outside the body, depending on the character of the accident or incident to be investigated.

3. The investigation shall be carried out with as much openness as possible, so that all parties can be heard and can share the results. The relevant infrastructure manager and railway undertakings, the national safety authority, the Agency, victims and their relatives, owners of damaged property, manufacturers, the emergency services involved and representatives of staff and users shall be given an opportunity to provide relevant technical information in order to improve the quality of the investigation report. The investigating body shall also take account of the reasonable needs of the victims and their relatives and keep them informed of the progress made in the investigation.

4. The investigating body shall conclude its examinations at the accident site in the shortest possible time in order to enable the infrastructure manager to restore the infrastructure and open it to rail transport services as soon as possible.

Article 24

Reports

1. An investigation of an accident or incident referred to in Article 20 shall be the subject of reports in a form appropriate to the type and seriousness of the accident or incident and the relevance of the investigation findings. The reports shall state the objectives of the investigations as referred to in Article 20(1) and shall contain, where appropriate, safety recommendations.

2. The investigating body shall make public the final report in the shortest possible time and normally not later than 12 months after the date of the occurrence. If the final report cannot be made public within 12 months, the investigating body shall release an interim statement at least on each anniversary of the accident, detailing the progress of the investigation and any safety issues raised. The report, including the safety recommendations, shall be communicated to the relevant parties referred to in Article 23(3) and to bodies and parties concerned in other Member States.

Taking into account experience gained by the investigating bodies, the Commission shall establish, by means of implementing acts, the reporting structure to be followed as closely as possible for accident and incident investigation reports. This reporting structure shall include the following elements:

- (a) a description of the occurrence and its background;
- (b) a record of the investigations and inquiries, including on the safety management system, the rules and regulations applied, the functioning of rolling stock and technical installations, the organisation of man power, the documentation on the operating system and previous occurrences of a similar character;

- (c) analysis and conclusions with regard to the causes of the occurrence, including contributory factors, relating to:
- (i) actions taken by persons involved;
 - (ii) the condition of rolling stock or technical installations;
 - (iii) skills of the staff, procedures and maintenance;
 - (iv) the regulatory framework conditions; and
 - (v) the application of the safety management system.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3).

3. By 30 September every year the investigating body shall publish an annual report accounting for the investigations carried out in the preceding year, the safety recommendations that were issued and actions taken in accordance with recommendations issued previously.

Article 25

Information to be sent to the Agency

1. Within 7 days of the decision to open an investigation, the investigating body shall inform the Agency thereof. The information shall indicate the date, time and place of the occurrence, as well as its type and its consequences as regards fatalities, injuries and material damage.
2. The investigating body shall send the Agency a copy of the final report referred to in Article 24(2) and of the annual report referred to in Article 24(3).

Article 26

Safety recommendations

1. A safety recommendation issued by an investigating body shall in no case create a presumption of blame or liability for an accident or incident.
2. Recommendations shall be addressed to the national safety authority and, where needed by reason of the character of the recommendation, to the Agency, to other bodies or authorities in the Member State concerned or to other Member States. Member States, their national safety authorities and the Agency shall, within the limits of their competence, take the necessary measures to ensure that the safety recommendations issued by the investigating bodies are duly taken into consideration, and, where appropriate, acted upon.
3. The Agency, the national safety authority and other authorities or bodies or, where appropriate, other Member States to which recommendations have been addressed, shall report back periodically to the investigating body on measures that are taken or planned as a consequence of a given recommendation.

CHAPTER VI

TRANSITIONAL AND FINAL PROVISIONS

Article 27

Exercise of delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 6(6) and Article 7(6) shall be conferred on the Commission for a period of 5 years from 15 June 2016. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.
3. It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.

4. The delegation of power referred to in Article 6(6) and Article 7(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in *the Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 6(6) and Article 7(6) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.

Article 28

Committee procedure

1. The Commission shall be assisted by the committee referred to in Article 51 of Directive (EU) 2016/797. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. 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.

Article 29

Report and further Union action

1. The Commission shall submit to the European Parliament and to the Council by 16 June 2021, and every 5 years thereafter, a report on the implementation of this Directive, in particular to monitor the effectiveness of the measures for the issuing of single safety certificates.

The report shall be accompanied where necessary by proposals for further Union action.

2. The Agency shall evaluate the development of a safety culture including occurrence reporting. It shall submit to the Commission, by 16 June 2024, a report containing, where appropriate, improvements to be made to the system. The Commission shall take appropriate measures on the basis of these recommendations and shall propose, if necessary, amendments to this Directive.
3. By 16 December 2017, the Commission shall report to the European Parliament and to the Council on the actions taken with a view to achieving the following objectives:
 - (a) the obligation for manufacturers to mark with an identification code the safety-critical components circulating on the European rail networks, ensuring that the identification code clearly identifies the component, the name of the manufacturer and the significant production data;
 - (b) the full traceability of the safety-critical components, the traceability of their maintenance activities and the identification of their operational life; and
 - (c) the identification of common mandatory principles for the maintenance of those components.

Article 30

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, non-discriminatory and dissuasive. The Member States shall notify those rules to the Commission by the date specified in Article 33(1) and shall notify it without delay of any subsequent amendment affecting them.

*Article 31***Transitional provisions**

1. Annex V to Directive 2004/49/EC shall apply until the date of application of the implementing acts referred to in Article 24(2) of this Directive.
2. Without prejudice to paragraph 3 of this Article, railway undertakings which need to be certified between 15 June 2016 and 16 June 2019, shall be subject to Directive 2004/49/EC. Such safety certificates shall be valid until their date of expiry.
3. At the latest from 16 June 2019 the Agency shall carry out the certification tasks pursuant to Article 10 in respect of areas of operation in the Member States that have not notified the Agency or the Commission in accordance with Article 33(2). By way of derogation from Article 10, national safety authorities of the Member States which have notified the Agency and the Commission pursuant to Article 33(2) may continue to issue certificates in accordance with Directive 2004/49/EC until 16 June 2020.

*Article 32***Recommendations and opinions of the Agency**

The Agency shall provide recommendations and opinions in accordance with Article 13 of Regulation (EU) 2016/796 for the purpose of the application of this Directive. Those recommendations and opinions may be taken into account when the Union adopts legal acts pursuant to this Directive.

*Article 33***Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 2, 3, 4, Articles 8 to 11, Article 12(5), Article 15(3), Articles 16 to 19, Article 21(2), Article 23(3) and (7), Article 24(2), Article 26(3) and Annexes II and III by 16 June 2019. They shall immediately communicate the text of those measures to the Commission.
2. Member States may extend the transposition period referred to in paragraph 1 by 1 year. For that purpose, by 16 December 2018, Member States which do not bring into force the laws, regulations and administrative provisions within the transposition period referred to in paragraph 1 shall notify the Agency and the Commission thereof and present the reasons for such an extension.
3. When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.
4. The obligation to transpose and implement this Directive shall not apply to Cyprus and Malta for as long as no rail system is established within their territories.

However, as soon as a public or private entity submits an official application to build a railway line with a view to its operation by one or more railway undertakings, the Member States concerned shall put in place measures to implement this Directive within 2 years of the receipt of the application.

*Article 34***Repeal**

Directive 2004/49/EC, as amended by the Directives listed in Annex IV, Part A, is repealed with effect from 16 June 2020, without prejudice to the obligations of the Member States concerning the time limits for transposition into national law and application of the Directives set out in Annex IV, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex V.

Article 35

Entry into force

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

Article 36

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 11 May 2016.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
J.A. HENNIS-PLASSCHAERT

ANNEX I

COMMON SAFETY INDICATORS

Common safety indicators (CSIs) shall be reported annually by the national safety authorities.

If new facts or errors are discovered after the submission of the report, the indicators for one particular year shall be amended or corrected by the national safety authority at the first convenient opportunity and at the latest in the next annual report.

Common definitions for the CSIs and methods to calculate the economic impact of accidents are laid down in the Appendix.

1. Indicators relating to accidents**1.1. Total and relative (to train-kilometres) number of serious accidents and a break-down for the following types of accidents:**

- collision of train with rail vehicle,
- collision of train with obstacle within the clearance gauge,
- derailment of train,
- level crossing accident, including accident involving pedestrians at level crossing, and a further break-down for the five types of level crossings defined in point 6.2,
- accident to persons involving rolling stock in motion, with the exception of suicides and attempted suicides,
- fire in rolling stock,
- other.

Each significant accident shall be reported under the type of the primary accident, even if the consequences of the secondary accident are more severe (e.g. a derailment followed by a fire).

1.2. Total and relative (to train-kilometres) number of persons seriously injured and killed by type of accident divided into the following categories:

- passenger (also relative to total passenger-kilometres and passenger train-kilometres),
- employee or contractor,
- level crossing user,
- trespasser,
- other person at a platform,
- other person not at a platform.

2. Indicators relating to dangerous goods

Total and relative (to train-kilometres) number of accidents involving the transport of dangerous goods by rail divided into the following categories:

- accident involving at least one railway vehicle transporting dangerous goods, as defined in the Appendix,
- number of such accidents in which dangerous goods are released.

3. Indicators relating to suicides

Total and relative (to train-kilometres) number of suicides and attempted suicides

4. Indicators relating to precursors of accidents

Total and relative (to train-kilometres) number of precursors to accidents and a break down on the following types of precursor:

- broken rail,
- track buckle and other track misalignment,
- wrong-side signalling failure,

- signal passed at danger when passing a danger point,
- signal passed at danger without passing a danger point,
- broken wheel on rolling stock in service,
- broken axle on rolling stock in service.

All precursors are to be reported, both those resulting and those not resulting in accidents. (A precursor resulting in a significant accident shall also be reported under indicators relating to precursors; a precursor not resulting in a significant accident shall only be reported under indicators relating to precursors).

5. Indicators to calculate the economic impact of accidents

Total in euro and relative (to train-kilometres):

- number of deaths and serious injuries multiplied by the Value of Preventing a Casualty (VPC),
- cost of damages to environment,
- cost of material damages to rolling stock or infrastructure,
- cost of delays as a consequence of accidents.

National safety authorities shall report the economic impact of significant accidents.

The VPC is the value society attributes to the prevention of a casualty and as such shall not form a reference for compensation between parties involved in accidents.

6. Indicators relating to technical safety of infrastructure and its implementation

6.1. Percentage of tracks with Train Protection Systems (TPSs) in operation and percentage of train-kilometres using on-board TPSs, where these systems provide:

- warning,
- warning and automatic stop,
- warning and automatic stop and discrete supervision of speed,
- warning and automatic stop and continuous supervision of speed.

6.2. Number of level crossings (total, per line kilometre and track kilometre) by the following five types:

- (a) passive level crossing
- (b) active level crossing:
 - (i) manual,
 - (ii) automatic with user-side warning,
 - (iii) automatic with user-side protection,
 - (iv) rail-side protected.

—

*Appendix***Common definitions for the CSIs and methods of calculating the economic impact of accidents****1. Indicators relating to accidents**

- 1.1. 'significant accident' means any accident involving at least one rail vehicle in motion, resulting in at least one killed or seriously injured person, or in significant damage to stock, track, other installations or environment, or extensive disruptions to traffic, excluding accidents in workshops, warehouses and depots;
- 1.2. 'significant damage to stock, track, other installations or environment' means damage that is equivalent to EUR 150 000 or more;
- 1.3. 'extensive disruptions to traffic' means that train services on a main railway line are suspended for six hours or more;
- 1.4. 'train' means one or more railway vehicles hauled by one or more locomotives or railcars, or one railcar travelling alone, running under a given number or specific designation from an initial fixed point to a terminal fixed point, including a light engine, i.e. a locomotive travelling on its own;
- 1.5. 'collision of train with rail vehicle' means a front to front, front to end or a side collision between a part of a train and a part of another train or rail vehicle, or with shunting rolling stock;
- 1.6. 'collision of train with obstacle within the clearance gauge' means a collision between a part of a train and objects fixed or temporarily present on or near the track (except at level crossings if lost by a crossing vehicle or user), including collision with overhead contact lines;
- 1.7. 'derailment of train' means any case in which at least one wheel of a train leaves the rails;
- 1.8. 'level crossing accident' means any accident at level crossings involving at least one railway vehicle and one or more crossing vehicles, other crossing users such as pedestrians or other objects temporarily present on or near the track if lost by a crossing vehicle or user;
- 1.9. 'accident to persons involving rolling stock in motion' means accidents to one or more persons who are either hit by a railway vehicle or by an object attached to, or that has become detached from, the vehicle, this includes persons who fall from railway vehicles as well as persons who fall or are hit by loose objects when travelling on board vehicles;
- 1.10. 'fire in rolling stock' means a fire or explosion that occurs in a railway vehicle (including its load) when it is running between the departure station and the destination, including when stopped at the departure station, the destination or intermediate stops, as well as during re-marshalling operations;
- 1.11. 'other (accident)' means any accident other than a collision of train with rail vehicle, collision of train with obstacle within the clearance gauge, derailment of train, level crossing accident, an accident to person involving rolling stock in motion or a fire in rolling stock;
- 1.12. 'passenger' means any person, excluding a member of the train crew, who makes a trip by rail, including a passenger trying to embark onto or disembark from a moving train for accident statistics only;
- 1.13. 'employee or contractor' means any person whose employment is in connection with a railway and is at work at the time of the accident, including the staff of contractors, self-employed contractors, the crew of the train and persons handling rolling stock and infrastructure installations;
- 1.14. 'level crossing user' means any person using a level crossing to cross the railway line by any means of transport or by foot;
- 1.15. 'trespasser' means any person present on railway premises where such presence is forbidden, with the exception of a level crossing user;
- 1.16. 'other person at a platform' means any person at a railway platform who is not defined as 'passenger', 'employee or contractor', 'level crossing user', 'other person not at a platform' or 'trespasser';

- 1.17. 'other person not at a platform' means any person not at a railway platform who is not defined as 'passenger', 'employee or contractor', 'level crossing user', 'other person at a platform' or 'trespasser';
- 1.18. 'death (killed person)' means any person killed immediately or dying within 30 days as a result of an accident, excluding any suicide;
- 1.19. 'serious injury (seriously injured person)' means any person injured who was hospitalised for more than 24 hours as a result of an accident, excluding any attempted suicide.

2. Indicators relating to dangerous goods

- 2.1. 'accident involving the transport of dangerous goods' means any accident or incident that is subject to reporting in accordance with RID ⁽¹⁾/ADR section 1.8.5;
- 2.2. 'dangerous goods' means those substances and articles the carriage of which is prohibited by RID, or authorised only under the conditions prescribed therein.

3. Indicators relating to suicides

- 3.1. 'suicide' means an act to deliberately injure oneself resulting in death, as recorded and classified by the competent national authority;
- 3.2. 'attempted suicide' means an act to deliberately injure oneself resulting in serious injury.

4. Indicators relating to precursors of accidents

- 4.1. 'broken rail' means any rail which is separated in two or more pieces, or any rail from which a piece of metal becomes detached, causing a gap of more than 50 mm in length and more than 10 mm in depth on the running surface;
- 4.2. 'track buckle or other track misalignment' means any fault related to the continuum and the geometry of track, requiring track to be placed out of service or immediate restriction of permitted speed;
- 4.3. 'wrong side signalling failure' means any technical failure of a signalling system (either to infrastructure or to rolling stock), resulting in signalling information less restrictive than that demanded;
- 4.4. 'Signal Passed at Danger when passing a danger point' means any occasion when any part of a train proceeds beyond its authorised movement and travels beyond the danger point;
- 4.5. 'Signal Passed at Danger without passing a danger point' means any occasion when any part of a train proceeds beyond its authorised movement but does not travel beyond the danger point.

Unauthorised movement as referred to in points 4.4 and 4.5 above means to pass:

- a trackside colour light signal or semaphore at danger, or an order to STOP where a Train Protection system (TPS) is not operational,
- the end of a safety related movement authority provided in a TPS,
- a point communicated by verbal or written authorisation laid down in regulations,
- stop boards (buffer stops are not included) or hand signals.

Any case in which a vehicle without any traction unit attached or a train that is unattended runs away past a signal at danger is not included. Any case in which, for any reason, the signal is not turned to danger in time to allow the driver to stop the train before the signal is not included.

National safety authorities may report separately on the four indices of unauthorised movement listed in the indents in this point and shall report at least an aggregate indicator containing data on all four items indices.

- 4.6. 'broken wheel on rolling stock in service' means a break affecting the wheel and creating a risk of accident (derailment or collision);

⁽¹⁾ RID, Regulations concerning the International Carriage of Dangerous Goods by Rail, as adopted under 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).

4.7. 'broken axle on rolling stock in service' means a break affecting the axle and creating a risk of accident (derailment or collision).

5. Common methodologies to calculate the economic impact of accidents

5.1. The Value of Preventing a Casualty (VPC) is composed of:

(1) Value of safety per se: Willingness to Pay (WTP) values based on stated preference studies carried out in the Member State for which they are applied.

(2) Direct and indirect economic costs: cost values appraised in the Member State, composed of:

- medical and rehabilitation cost,
- legal court cost, cost for police, private crash investigations, the emergency service and administrative costs of insurance,
- production losses: value to society of goods and services that could have been produced by the person if the accident had not occurred.

When calculating the costs of casualties, fatalities and serious injuries shall be considered separately (different VPC for fatality and serious injury).

5.2. Common principles to appraise the value of safety per se and direct and/or indirect economic costs:

For the value of safety per se, the assessment of whether available estimates are appropriate or not shall be based on the following considerations:

- estimates shall relate to a system for valuation of mortality risk reduction in the transport sector and follow a WTP approach according to stated preference methods,
- the respondent sample used for the values shall be representative of the population concerned. In particular, the sample has to reflect the age/income distribution along with other relevant socioeconomic and/or demographic characteristics of the population,
- method for eliciting WTP values: survey design shall be such that questions are clear/meaningful to respondents.

Direct and indirect economic costs shall be appraised on the basis of the real costs borne by society.

5.3. Definitions

5.3.1. 'Cost of damage to environment' means costs that are to be met by Railway Undertakings and Infrastructure Managers, appraised on the basis of their experience, in order to restore the damaged area to its state before the railway accident.

5.3.2. 'Cost of material damage to rolling stock or infrastructure' means the cost of providing new rolling stock or infrastructure, with the same functionalities and technical parameters as that damaged beyond repair, and the cost of restoring repairable rolling stock or infrastructure to its state before the accident, to be estimated by Railway Undertakings and Infrastructure Managers on the basis of their experience, including also costs related to the leasing of rolling stock, as a consequence of non-availability due to damaged vehicles.

5.3.3. 'Cost of delays as a consequence of accidents' means the monetary value of delays incurred by users of rail transport (passengers and freight customers) as a consequence of accidents, calculated by the following model:

VT = monetary value of travel time savings

Value of time for a passenger of a train (an hour)

$$VT_p = [VT \text{ of work passengers}] * [\text{Average percentage of work passengers per year}] + [VT \text{ of non-work passengers}] * [\text{Average percentage of non-work passengers per year}]$$

VT_p is measured in EUR per passenger per hour

'Work passenger' means a passenger travelling in connection with their professional activities excluding commuting.

Value of time for a freight train (an hour)

$$VT_f = [VT \text{ of freight trains}] * [(Tonne-km)/(Train-km)]$$

VT_f is measured in EUR per freight tonne per hour

Average tonnes of goods transported per train in 1 year = (Tonne-km)/(Train-km)

CM = Cost of 1 minute of delay of a train

Passenger train

$$CM_p = K1 * (VT_p / 60) * [(Passenger-km) / (Train-km)]$$

Average number of passengers per train in 1 year = (Passenger-km)/(Train-km)

Freight train

$$CM_f = K2 * (VT_f / 60)$$

Factors K1 and K2 are between the value of time and the value of delay, as estimated by stated preference studies, to take into account that the time lost as a result of delays is perceived significantly more negatively than normal travel time.

Cost of delays of an accident = CM_p *(Minutes of delay of passenger trains) + CM_f *(Minutes of delay of freight trains)

Scope of the model

Cost of delays is to be calculated for significant accidents, as follows:

- real delays on the railway lines where accidents occurred as measured at terminal station
- real delays or, if not possible, estimated delays on the other affected lines.

6. Indicators relating to technical safety of infrastructure and its implementation

- 6.1. 'Train Protection System (TPS)' means a system that helps to enforce obedience to signals and speed restrictions.
- 6.2. 'On-board systems' mean systems assisting the driver to observe line-side signalling and in cab signalling and thus providing protection of danger points and enforcement of speed limits. On-board TPSs are described as follows:
 - (a) Warning, providing automatic warning to driver.
 - (b) Warning and automatic stop, providing automatic warning to driver and automatic stop when passing a signal at danger.
 - (c) Warning and automatic stop and discrete supervision of speed, providing protection of danger points, where 'discrete supervision of speed' means supervision of speed at certain locations (speed traps) at the approach of a signal.
 - (d) Warning and automatic stop and continuous supervision of speed, providing protection of danger points and continuous supervision of the speed limits of the line, where 'continuous supervision of speed' means continuous indication and enforcement of the maximal allowed target speed on all sections of the line.

Type (d) is regarded as Automatic Train Protection (ATP) system.

- 6.3. 'level crossing' means any level intersection between a road or passage and a railway, as recognised by the infrastructure manager and open to public or private users. Passages between platforms within stations are excluded, as well as passages over tracks for the sole use of employees.
- 6.4. 'road' means, for the purpose of railway accident statistics, any public or private road, street or highway, including adjacent footpaths and bicycle lanes.
- 6.5. 'passage' means any route, other than a road, provided for the passage of people, animals, vehicles or machinery.
- 6.6. 'passive level crossing' means a level crossing without any form of warning system or protection activated when it is unsafe for the user to traverse the crossing.
- 6.7. 'active level crossing' means a level crossing where the crossing users are protected from or warned of the approaching train by devices activated when it is unsafe for the user to traverse the crossing.
 - Protection by the use of physical devices includes:
 - half or full barriers,
 - gates.

- Warning by the use of fixed equipment at level crossings:
 - visible devices: lights,
 - audible devices: bells, horns, klaxons, etc.

Active level crossings are classified as:

- (a) Manual: a level crossing where user-side protection or warning is manually activated by a railway employee.
- (b) Automatic with user-side warning: a level crossing where user-side warning is activated by the approaching train.
- (c) Automatic with user-side protection: a level crossing where user-side protection is activated by the approaching train. This shall include a level crossing with both user-side protection and warning.
- (d) Rail-side protected: a level crossing where a signal or other train protection system permits a train to proceed once the level crossing is fully user-side protected and is free from incursion.

7. **Definitions of the scaling bases**

- 7.1. 'train-km' means the unit of measure representing the movement of a train over one kilometre. The distance used is the distance actually run, if available, otherwise the standard network distance between the origin and destination shall be used. Only the distance on the national territory of the reporting country shall be taken into account.
 - 7.2. 'passenger-km' means the unit of measure representing the transport of one passenger by rail over a distance of one kilometre. Only the distance on the national territory of the reporting country shall be taken into account.
 - 7.3. 'line km' means the length measured in kilometres of the railway network in Member States, whose scope is laid down in Article 2. For multiple-track railway lines, only the distance between origin and destination is to be counted.
 - 7.4. 'track km' means the length measured in kilometres of the railway network in Member States, whose scope is laid down in Article 2. Each track of a multiple-track railway line is to be counted.
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ANNEX II

NOTIFICATION OF NATIONAL SAFETY RULES

National safety rules notified in accordance with point (a) of Article 8(1) include:

1. rules concerning existing national safety targets and safety methods;
 2. rules concerning requirements in respect of safety management systems and safety certification of railway undertakings;
 3. common operating rules of the railway network that are not yet covered by TSIs, including rules relating to the signalling and traffic management system;
 4. rules laying down requirements in respect of additional internal operating rules (company rules) that must be established by infrastructure managers and railway undertakings;
 5. rules concerning requirements in respect of staff executing safety-critical tasks, including selection criteria, medical fitness and vocational training and certification, in so far as they are not yet covered by a TSI;
 6. rules concerning the investigation of accidents and incidents.
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ANNEX III

REQUIREMENTS AND ASSESSMENT CRITERIA FOR ORGANISATIONS APPLYING FOR AN ECM CERTIFICATE OR FOR A CERTIFICATE IN RESPECT OF MAINTENANCE FUNCTIONS OUTSOURCED BY AN ENTITY IN CHARGE OF MAINTENANCE

The organisation management must be documented in all relevant parts and shall in particular describe the distribution of responsibilities within the organisation and with subcontractors. It shall show how control by the management on different levels is secured, how staff and their representatives on all levels are involved and how continuous improvement is ensured.

The following basic requirements shall be applied to the four functions of an entity in charge of maintenance (ECM) to be covered by the organisation itself or through contracting arrangements:

1. Leadership — commitment to the development and implementation of the maintenance system of the organisation and to the continuous improvement of its effectiveness;
2. Risk assessment — a structured approach to assess risks associated with the maintenance of vehicles, including those directly arising from operational processes and the activities of other organisations or persons, and to identify the appropriate risk control measures;
3. Monitoring — a structured approach to ensure that risk control measures are in place, working correctly and achieving the organisation's objectives;
4. Continuous improvement — a structured approach to analyse the information gathered through regular monitoring, auditing, or other relevant sources and to use the results to learn and to adopt preventive or corrective measures in order to maintain or improve the level of safety;
5. Structure and responsibility — a structured approach to define the responsibilities of individuals and teams for secure delivery of the organisation's safety objectives;
6. Competence management — a structured approach to ensure that employees have the competences required in order to achieve the organisation's objectives safely, effectively and efficiently in all circumstances;
7. Information — a structured approach to ensure that important information is available to those making judgments and decisions at all levels of the organisation and to ensure the completeness and appropriateness of the information;
8. Documentation — a structured approach to ensure the traceability of all relevant information;
9. Contracting activities — a structured approach to ensure that subcontracted activities are managed appropriately in order for the organisation's objectives to be achieved and all competences and requirements are covered;
10. Maintenance activities — a structured approach to ensure:
 - that all maintenance activities affecting safety and safety-critical components are identified and correctly managed and that all the necessary changes to those maintenance activities affecting safety are identified, properly managed based upon the return of experience and the application of Common Safety Methods for risk assessment in accordance with point (a) of Article 6(1) and properly documented;
 - conformity with the essential requirements for interoperability;
 - the implementation and check of maintenance facilities, equipment and tools specifically developed and required for maintenance delivery;
 - the analysis of the initial documentation related to the vehicle for providing the first maintenance file and to ensure its correct implementation through the development of maintenance orders;
 - that components (including spare parts) and materials are used as specified in the maintenance orders and supplier documentation; they are stored, handled and transported in an appropriate manner as specified in the maintenance orders and supplier documentation and comply with relevant national and international rules as well as with the requirements of relevant maintenance orders;

- that suitable and adequate facilities, equipment and tools are determined, identified, provided, recorded and kept available to enable to deliver the maintenance services in accordance with maintenance orders and other applicable specifications, ensuring the safe delivery of maintenance, ergonomics and health protection;
- that the organisation have processes to ensure that its measuring equipment, all facilities, equipment and tools are correctly used, calibrated, preserved and maintained in accordance with documented processes;

11. Control activities — a structured approach to ensure:

- that vehicles are removed from operation for scheduled, conditional or corrective maintenance in due time, or whenever defects or other needs have been identified;
 - the necessary quality control measures;
 - that maintenance tasks are performed in accordance with the maintenance orders and to issue the notice to return to operation that includes eventual restrictions of use;
 - that possible instance of non-compliance in the application of the management system that might result in accidents, incidents, near-misses or other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken in compliance with the common safety method for monitoring provided in point (c) of Article 6(1);
 - recurrent internal auditing and monitoring process compliant with the common safety method for monitoring provided in point (c) of Article 6(1).
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ANNEX IV

PART A

Repealed Directive with a list of the successive amendments thereto

(referred to in Article 34)

Directive 2004/49/EC	(OJ L 164, 30.4.2004, p. 44)
Directive 2008/57/EC	(OJ L 191, 18.7.2008, p. 1)
Directive 2008/110/EC	(OJ L 345, 23.12.2008, p. 62)
Commission Directive 2009/149/EC	(OJ L 313, 28.11.2009, p. 65)
Corrigendum, 2004/49/EC	(OJ L 220, 21.6.2004, p. 16)
Commission Directive 2014/88/EU	(OJ L 201, 10.7.2014, p. 9)

PART B

Time limits for transposition into national law

(referred to in Article 34)

Directive	Deadline for transposition
2004/49/EC	30 April 2006
2008/57/EC	19 July 2010
2008/110/EC	24 December 2010
Commission Directive 2009/149/EC	18 June 2010
Commission Directive 2014/88/EU	30 July 2015

ANNEX V

Correlation table

Directive 2004/49/EC	This Directive
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article 5
Article 6	Article 6
Article 7	Article 7
Article 8	Article 8
Article 9	Article 9
Article 10	Article 10
—	Article 11
Article 11	Article 12
Article 12	—
Article 13	Article 13
Article 14a(1) to (7)	Article 14
Article 14a(8)	Article 15
Article 15	—
Article 16	Article 16
—	Article 17
Article 17	Article 18
Article 18	Article 19
Article 19	Article 20
Article 20	Article 21
Article 21	Article 22
Article 22	Article 23
Article 23	Article 24
Article 24	Article 25
Article 25	Article 26
Article 26	—
—	Article 27
Article 27	Article 28
Article 28	—
Article 29	—
Article 30	—
Article 31	Article 29
Article 32	Article 30
—	Article 31
—	Article 32
Article 33	Article 33

Directive 2004/49/EC	This Directive
—	Article 34
Article 34	Article 35
Article 35	Article 36
Annex I	Annex I
Annex II	Annex II
Annex III	—
Annex IV	—
Annex V	—
—	Annex III

Statement by the Commission on explanatory documents

The Commission recalls that the European Parliament, the Council and the Commission acknowledged in their Joint Political Declaration of 27 October 2011 on explanatory documents that the information Member States supply to the Commission as regards the transposition of directives in national law 'must be clear and precise' in order to facilitate the achievement by the Commission of its task overseeing the application of Union law. In the present case, explanatory documents could have been useful to this end. The Commission regrets that the final text does not contain provisions to this effect.
