



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 17 October 2013

14813/13

**Interinstitutional File:
2013/0016 (COD)**

**TRANS 527
CODEC 2278**

OUTCOME OF PROCEEDINGS

From: General Secretariat

To: Delegations

No. prev. doc.: 14258/13 TRANS 499 CODEC 2164 + COR 1 + COR 2

No. Cion prop.: 6014/13 TRANS 40 CODEC 227

Subject: Proposal for a Directive of the European Parliament and of the Council on railway safety (Recast)

- *General approach*

At its meeting on 10 October 2013, the Transport, Telecommunications and Energy Council reached a general approach on the above proposal, as it appears in the Annex. The recitals to the proposal will be examined at a later stage, in light of the agreement on the substantive provisions.

2013/0016 (COD)

Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on railway safety
(Recast)
(Text with EEA relevance)

CHAPTER I
GENERAL PROVISIONS

Article 1

Subject matter

This Directive lays down provisions to ensure the development and improvement of safety of the Union's railways 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 of the rail system ;
- (c) developing common safety targets and common safety methods with a view to gradually removing the need for national rules;
- (cc) setting out the principles for issuing, renewing, amending and revoking safety certificates and authorisations;
- (d) requiring the establishment, for each Member State, of a national safety authority and an accident and incident investigating body;

- (e) defining common principles for the management, regulation and supervision of railway safety.

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 on 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 of the rail system .
2. The following systems are excluded from the scope of this Directive:
 - (a) metros;
 - (aa) trams and light rail vehicles, and infrastructure that is used exclusively by these vehicles
 - (b) networks that are functionally separate from the rest of the railway system and intended only for the operation of local, urban or suburban passenger services, as well as undertakings operating solely on these 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 an operator for the purpose of its freight activities or the transport of persons for non-commercial purposes, and vehicles exclusively used 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 connectivity purposes for those vehicles only; and
- (d) vehicles primarily used on light rail infrastructure but equipped with some heavy rail components necessary to enable transit on a confined and limited section of heavy rail infrastructure for connectivity purposes only.

Article 3

Definitions

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

- a) ‘rail system’ means the Union rail system as defined in Article 2 of Directive [xx on interoperability of the rail system];
- (b) ‘infrastructure manager’ means infrastructure manager as defined in Article 3 of Directive 2012/34/EU establishing a single European railway area¹;
- (c) ‘railway undertaking’ means railway undertaking as defined in Article 3 of Directive 2012/34/EU establishing a single European railway area, 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 must ensure traction, including undertakings which provide traction only;
- (d) ‘technical specification for interoperability’ (TSI) means a specification adopted in accordance with this Directive by which each subsystem or part of a subsystem is covered in order to meet the essential requirements and ensure the interoperability of the rail system as defined in Article 2 of Directive xx on interoperability of the rail system;

¹ OJ L 343 of 14.12.2012, p. 32.

- (e) ‘common safety targets (CSTs)’ means the minimum safety levels that must be reached by the system as a whole, and where feasible, by different parts of the rail system (such as the conventional rail system, the high speed rail system, long railway tunnels or lines solely used for freight transport);
- (f) ‘common safety methods (CSMs)’ means the methods describing the assessment of safety levels and achievement of safety targets and compliance with other safety requirements;
- (g) ‘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 these tasks in order to ensure a unified safety regime;
- (h) ‘national rules’ means all binding rules adopted at Member State level, irrespective of the body issuing them. These rules contain railway safety or technical requirements imposed within that Member State in addition to European rules and are applicable to railway undertakings, infrastructure managers or third parties;
- (i) ‘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;
- (j) ‘investigator-in-charge’ means a person responsible for the organisation, conduct and control of an investigation;
- (k) ‘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 caused by rolling stock in motion, fires and others;

- (l) ‘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 with an obvious impact on railway safety regulation or the management of safety; ‘extensive damage’ above means damage that can immediately be assessed by the investigating body to cost at least EUR 2 million in total;
- (m) ‘incident’ means any occurrence, other than accident or serious accident, affecting the safety of railway operations;
- (n) ‘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;
- (o) ‘causes’ means actions, omissions, events or conditions, or a combination thereof, which led to the accident or incident;
- (p) ‘tram and light rail’ means an urban and/or sub-urban rail transport system with a crashworthiness of CIII (according to EN 15227:2011), and a maximum strength of vehicle of 800kN (PIII according to EN12663-1:2010). 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;
- (q) ‘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;

- (r) ‘interoperability constituents’ means any elementary component, group of components, subassembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem upon which the interoperability of the rail system depends directly or indirectly, as defined in Article 2 of Directive xx on interoperability of the rail system;
- (s) ‘keeper’ means the person or entity 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 the national vehicle register referred to in Article 43 of Directive XX on the interoperability of the rail system;
- (t) ‘entity in charge of maintenance’ means an entity in charge of maintenance of a vehicle, and registered as such in the national vehicle register;
- (u) ‘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;
- (v) ‘manufacturer’ means any natural or legal person who manufactures a product or has it designed or manufactured, and markets it under his name or trademark;
- (w) ‘consignor’ means the enterprise which consigns goods either on its own behalf or for a third party;
- (ww) ‘consignee’ means any natural or legal person who receives the goods according to the contract for carriage. If the transport operation takes place without a contract for carriage, any natural or legal person which takes charge of the goods on arrivals shall be deemed to be the consignee;

- (x) ‘loader’ means any enterprise that loads packaged goods², 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;
- (xx) ‘unloader’ means the 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;
- (y) ‘filler’ means any enterprise that loads goods into a tank (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;
- (yy) ‘unfiller’ means any enterprise that removes goods from a tank (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;
- (yyy) ‘carrier’ means the enterprise which carries out the transport operation, with a contract for carriage;

² The following recital could be added: *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, to improve the safety of railway system, and Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods, which mainly regulates the classification of the substance and the specification of their containments, including the safe loading, unloading and use of the containments within the existing railway system. Consequently the safety management system of the railway undertakings and of the infrastructure managers should take due consideration of the potential additional risks generated by carrying dangerous goods containments, however without prejudice to Directive 2008/68/EC which objective is that dangerous goods are transported in safe containments which are interoperable, where appropriate multimodal, and can be transported everywhere under normal operating conditions.*

- (z) ‘Agency’ means the European Railway Agency, as established by Regulation (EU) No .../... [Agency Regulation];
- (za) ‘contracting entity’ means a public or private entity which orders the design and/or construction or the renewal or upgrading of a subsystem.
- (zb) ‘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;
- (zc) ‘extent of operation’ means the extent characterised by volume of passenger/goods and the estimated size of the railway undertaking in terms of employees working in the railway sector (micro, small, medium sized, large enterprise);
- (zd) ‘area of operation’ means a network or networks within one or more Member States where the railway undertaking provides its services;

CHAPTER II

DEVELOPMENT AND MANAGEMENT OF SAFETY

Article 4

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

[Note: Article 4 of the Commission's proposal is replaced by the following text]:

1. With the aim of developing and improving railway safety, Member States shall:
 - (a) ensure that railway safety is generally maintained and, where reasonably practicable, continuously improved taking into consideration the development of Union legislation and 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;
 - (bb) ensure that measures to develop and improve railway safety take account of the need for a system-based approach;
 - (c) ensure that the responsibility for the safe operation of the 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 Article 6(1(a)), where appropriate in cooperation with each other;
 - (ii) apply Union and national rules;
 - (iii) establish safety management systems in accordance with this Directive;

- (d) without prejudice to civil liability in accordance with the legal requirements of the Member States, ensure that each infrastructure manager and railway undertaking shall be made responsible for its part of the system and its safe operation, including supply of material and contracting of services vis-à-vis users, customers, the workers concerned and other actors referred to in paragraph 5 of this Article;
 - (e) develop and publish annual safety plans setting out the measures envisaged to achieve the common safety targets.
 - (f) where appropriate, support the Agency in its work to monitor the development of railway safety at European 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 legislation and 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 as referred to in Article 6(1(a)), where appropriate in cooperation with each other and with other actors;
 - (b) take account of the risks associated with the activities of other actors and third parties in their safety management systems;
 - (ba) where appropriate, contractually oblige the other actors referred to in Article 4(5) having a potential impact on the safe operation of the railway's system to implement risk control measures.

- (c) ensure that its contractors implement risk control measures through the application of the common safety methods for monitoring processes set out in the CSM on monitoring referred to in Article 6(1c) and that this is stipulated in contractual arrangements which shall be disclosed on request of the Agency or the national safety authority.

4. *[This paragraph has been deleted and moved to Article 14(3)].*

5. Without prejudice to the responsibility of railway undertakings and infrastructure managers as referred to in paragraph 3, entities in charge of maintenance as referred to in Article 14 and all other actors having a potential impact on the safe operation of the railway system, including manufacturers, maintenance suppliers, keepers, service providers, contracting authorities, 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 infrastructure manager;

6. Any actor referred to in paragraphs 3 to 5 who identifies or is informed of a safety risk related to defects and construction non-conformities or malfunctions of technical equipment, including those of structural sub-systems, shall, within the limits of its competence:

- (a) take any necessary corrective measure to tackle the safety risk identified;
- (b) report those risks to the relevant parties involved, to enable them to take any necessary further corrective actions to ensure continuous achievement of the safety performance of the rail system.

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

Article 5

Common safety indicators

1. In order to facilitate the assessment of the achievement of the CST and to provide for the monitoring of the general development of railway safety Member States shall collect information on common safety indicators (CSIs) through the annual reports of the national safety authorities as referred to in Article 18.
2. The Commission shall, by means of implementing acts, adopt common safety indicators (CSIs) and shall update them to take into account technical progress and to adapt the common methods for calculating accident costs. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

Article 6

Common safety methods

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) risk evaluation and assessment methods,
 - (b) methods for assessing conformity with requirements in safety certificates and safety authorisations issued in accordance with Articles 10 and 12,

- (c) methods for supervision to be applied by national safety authorities and methods for monitoring to be applied by railway undertakings, infrastructure managers and entities in charge of maintenance;
 - (d) methods for assessing the safety level and the safety performance of railway operators at national and European Union level;
 - (dd) methods for the assessment of the achievement of safety targets at national and European Union level;
 - (e) any other methods covering a process of the safety management system which need to be harmonised at Union level.
2. Implementing powers shall be conferred on the Commission in order to issue a mandate to the Agency to draft CSMs and their amendments 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 railway system safety level. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 27(2).

The drafting, adoption and review of the CSMs shall take account of the opinion of the users, of the national safety authorities and of the stakeholders. The recommendations shall enclose a report on the results of this consultation and a report assessing the impact of the new CSM to be adopted.

The Committee referred to in Article 27 shall be kept regularly informed of the preparatory work on the CSMs.

3. 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 in view of generally maintaining and where reasonably practicable, continuously improving safety.

4. The Commission shall establish, by means of implementing acts, common safety methods. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).
5. Member States shall make any necessary amendments to their national rules in the light of the adoption of CSMs and revisions to them.

Article 7

Common safety targets

1. The CSTs shall define the minimum safety levels that must 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 European Union. The CSTs may be expressed in risk acceptance criteria or target safety levels and shall take into consideration, in particular:
 - (a) individual risks relating to passengers, staff including the staff of contractors, level crossing users and others, and, without prejudice to existing national and international liability rules, individual risks relating to unauthorised persons on railway premises;
 - (b) societal risks.
2. Implementing powers shall be conferred on the Commission in order to issue a mandate to the Agency to draft CSTs and their amendments 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 advisory procedure referred to in Article 27(2).

The Committee referred to in Article 27 shall be kept regularly informed of the preparatory work on the CSTs.

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

4. The Commission shall establish, by means of implementing acts, the CSTs. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).
5. 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. These amendments shall be taken into account in the annual safety plans referred to in Article 4(1)(e). They shall notify these rules to the Commission in accordance with Article 8.

Article 8³

National rules in the field of safety

1. National safety rules notified until the entry into force of this Directive shall apply if they:
 - (a) fall into one of the types identified under Annex IA of this Directive, 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.

³ A new recital will be added in order to clarify the status of national safety and technical rules. The text of this recital will read as follows: "*National rules often include requirements which are partly relevant for interoperability purposes, and partly for safety purposes. Safety being an essential requirement of the railway interoperability Directive, a national rule may be relevant for both directives. The distinction between the terms "national safety rules" and "national technical rules" as defined in Directive 2004/49/EC and 2008/57/EC respectively is therefore removed and replaced by the notion of "national rules" which must be notified either under the interoperability Directive or under the safety Directive or both. National rules must be notified under the interoperability Directive mainly when they relate to the placing on the market of structural subsystems. They must be notified under the safety Directive when they relate to the operation of the railway system, or to the specific subjects of the safety Directive including the role of the actors, safety certification, safety authorisation and accident investigation.*"

2. Member States shall review the national safety rules referred to in paragraph 1 and take the following actions within two years of the entry into force of this Directive:
 - (a) repeal any national rule which was not notified or which does not meet one of the criteria of paragraph 1.
 - (b) repeal any national rule which has been made redundant by Union legislation, including in particular TSIs, CSTs and CSMs.

To this end, Member States may use the Rule Management Tool referred to in Article 23(4) of Regulation (EU) N° .../...[Agency Regulation] and may request the Agency to examine specific rules against the criteria of this paragraph.

3. Member States may lay down new national rules in the field of safety only in the following cases:
 - (a) where rules concerning existing safety methods are not covered by a CSM ;
 - (aa) where operating rules of the railway network are not yet covered by the TSIs;
 - (b) as an urgent preventive measure, in particular following an accident or an incident;
 - (c) where an already notified rule needs to be revised;
 - (d) where rules concerning requirements on 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 of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community⁴.

⁴ OJ L 315, 3.12.2007 p.51-78

4. If a Member State intends to introduce a new national rule, it shall notify the draft of that rule to the Agency and the Commission using the appropriate IT system in accordance with article 23 of Regulation (EU) No .../... [Agency Regulation]. Member States shall ensure that the draft is sufficiently developed to allow the Agency to carry out its examination under Article 21(2) of Regulation (EU) N°.../...[Agency Regulation].
5. If the Agency becomes aware of any national rule notified or not which that has become redundant or is in conflict with the CSMs or any other Union legislation adopted after the application of the national rule the procedure established in article 22 of Regulation (EU) No .../... [Agency Regulation] shall apply⁵.
6. When they adopt a national rule, Member States shall notify it to the Agency and the Commission through the appropriate IT system in accordance with Article 23 of Regulation (EU) N°.../...[Agency Regulation]. Member States shall ensure that national rules in force are accessible to all parties concerned and in a terminology that they can understand.
- 6a. Member States may decide not to notify rules and restrictions of a strictly local nature. In such cases, Member States shall mention these rules and restrictions in the infrastructure registers referred to in Article 45 of Directive [XX] on interoperability of the rail system or indicate in the network statement referred to Article 27 of Directive 2012/34/EU establishing a single European railway area⁶ where these rules and restrictions are published.
7. National rules notified in accordance with this Article are not subject to the notification procedure set out in Directive 98/34/EC.
8. Draft national rules and national rules in force shall be examined by the Agency in accordance with the procedures laid down in Articles 21 and 22 of Regulation (EU) No .../... [Agency Regulation]. Without prejudice to paragraph 6a, national rules not notified in accordance with this Article shall not apply for the purposes of this Directive.

⁵ Final agreement on Article 8(5) is subject to the discussions on the relevant articles of the Agency Regulation text.

⁶ OJ L 343 of 14.12.2012, p. 32.

Article 9

Safety management systems

1. Infrastructure managers and railway undertakings shall establish their respective safety management systems to ensure that the rail system can achieve at least the CSTs, is in conformity with safety requirements laid down in the TSIs, and that the relevant parts of CSMs and rules notified under Article 8 are applied.
2. The safety management system shall meet the requirements of paragraph 2a, 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.
 - 2a. The Commission shall establish and may revise, by means of implementing acts, elements of the safety management system. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).
3. The safety management system of any infrastructure manager shall take into account the effects of operations by different railway undertakings on the network and make provisions to allow all railway undertakings to operate in accordance with TSIs and national rules and with the conditions laid down in their safety certificate. The 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.
4. Each year all infrastructure managers and railway undertakings shall submit to the national safety authority before 31 May 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) the development of national safety indicators, and of the CSIs referred to in Article 5, as 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 according to Article 4(6)(b);
 - (e) report on the application of the relevant common safety methods.
5. On the basis of the information provided by the national safety authorities in Articles 18 and 16a, the Agency may issue a recommendation for a CSM covering elements of the safety management system which needs to be harmonised at Union level, including through harmonised standards, as referred to in Article 6(1)(e). In such case, the procedure set out in Article 6(2) applies.

CHAPTER III
SAFETY CERTIFICATION AND AUTHORISATION
Article 10

Single safety certificate

[Note: Article 10 of the Commission's proposal is replaced by the following text]:

1. 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 paragraph 1d to 1f or by a national safety authority according to paragraph 1g, without prejudice to paragraph 1ga.
The purpose of the single safety certificate is to provide evidence that the railway undertaking has established its safety management system and is able to operate safely in the intended area of operation.
 - 1a. In its application for a single safety certificate, the applicant shall specify the type and extent of the railway operations covered and the intended area of operation.
 - 1b. The application shall be accompanied by a file including the documentary evidence:
 - (a) that the railway undertaking has established its safety management system in accordance with Article 9 and meets the requirements laid down in TSIs, CSM and CST and in other relevant legislation in order to control risks and provide transport services safely on the network;
 - (b) that the railway undertaking, where applicable, meets the requirements laid down in the relevant national rules notified under Article 8.

- 1c. The Agency or in the case of paragraph 1g., the national safety authority shall issue the safety certificate, or inform the applicant of its negative decision, within a pre-determined, reasonable time, and, in any case, within four months from receipt of all relevant information. The Agency or in the case of paragraph 1g., the national safety authority shall apply the detailed rules on the certification procedure to be established in an implementing act, as referred to in paragraph 1h.
- 1d. The Agency shall issue a single safety certificate to railway undertakings having an area of operation in one or more Member State(s). In order to issue such certification, the Agency shall:
- (a) assess the elements set out in paragraphs 1b(a) and
 - (b) refer immediately the entire applicant's file to the national safety authorities concerned by the intended area of operation for assessing the elements set out in paragraphs 1b(b).

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

- 1e. Within one month of the receipt of the request of the applicant, the Agency shall inform the applicant that the file is complete or ask for relevant complementary information, setting a reasonable deadline. With regard to the completeness, relevance and consistency of the file, the Agency may also assess the elements set out in paragraph 1b(b).

The Agency shall take full account of the assessments under paragraph 1d before taking its decision on the issuing of the single safety certificate.

The Agency shall take full responsibility for the certifications it issues.⁷

- 1f. When the Agency disagrees with a negative assessment carried out by one or more national safety authorities pursuant to paragraph 1d(b), it shall inform the said authority or authorities, giving reasons for the disagreement. The Agency and the national safety authority or authorities shall cooperate with a view to reaching a mutually acceptable assessment. Where necessary, as decided by the Agency and the national safety authority or authorities, this process shall also involve the applicant. If no mutually acceptable assessment can be found within one 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 51 of Regulation (EU) No .../...[Agency Regulation].⁸ The Board of Appeal shall decide whether to confirm the Agency's draft decision within one month of the request of the national safety authority or authorities.

When the Board of Appeal agrees with the Agency, the Agency may take a decision without delay.

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

⁷ On liability, in addition to a new recital and provisions to be included in the Agency Regulation on liability aspects, the following recital will be inserted in the text of the safety Directive: *"This Directive should not lead to a reduced level of safety in the European Union's railway sector. To this end, the Agency should take full responsibility for the certificates it issues, in particular contractual and non-contractual liabilities which are regulated by Article 66 of the Regulation (EU) No .../...[Agency Regulation] and which stipulates that the Agency make good any damage caused by its departments or by its staff during the performance of their duties. 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 States concerned"*.

⁸ Article 51 of the Agency Regulation will be amended to include an arbitration procedure and the new role of the Board of Appeals. The process of appeal in the Agency Regulation will be modified and the provisions will reflect the need for appropriate competence, independence and impartiality of the Board in relation to arbitrations.

When the Agency disagrees with a positive assessment of one or more national safety authorities pursuant to paragraph 1d(b), it shall inform the said authority or authorities, giving reasons for disagreement. The Agency and the national safety authority or authorities shall cooperate with a view to reaching a mutually acceptable assessment. Where necessary, as decided by the Agency and the national safety authority or authorities, this process shall also involve the applicant. If no mutually acceptable assessment can be found within one month after the Agency has informed the national safety authority and authorities of its disagreement, the Agency shall take its final decision.

- 1g. 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 certifications, the national safety authority shall assess the file in relation to all the elements set out in paragraph 1b and according to the procedures to be established in the implementing act under paragraph 1h. As part of the above assessments, the national safety authority is authorised to undertake visits and inspections on the sites of the railway undertaking and audits. Within one month of the receipt of the request of the applicant, the national safety authority shall inform the applicant that the file is complete or ask for relevant complementary information. The safety certificate shall also be valid without extension of the area of operations for railway undertakings travelling to the stations of neighbouring Member States with similar network characteristics and similar operating rules, when those stations are close to the border, following consultation of the relevant national safety authorities. This consultation may be 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 the safety certificates it issues.

1ga. A Member State may allow third country operators to reach a station in its territory designated for the 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:

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

1h.⁹ The Commission shall establish, not later than two years after the entry into force of this Directive, by means of implementing acts, detailed rules on the certification procedure, including:

- a) detailed guidance for the applicant describing and explaining the requirements for the single safety certificate and listing the required documents;
- b) procedural arrangements for the certification process, such as content and timeframes for each stage of the process;
- c) criteria for assessment of the applicants' files.
- d) the validity period of safety certificates issued by the Agency or the national safety authorities, in particular in the case of updates of the safety certificate resulting from changes to type, extent and area of operation.

⁹ The question related to the establishment of fees and charges to be levied on the issuing and renewals of safety certificates will be addressed in the context of the Agency Regulation, including, inter alia, the following principle: *"fees and charges should be set in a transparent, fair and uniform manner in cooperation with Member States and should not jeopardize the competitiveness of the European industries concerned. They should be established on a basis which takes due account of the ability of undertakings to pay and should not lead to unnecessary financial burden on companies"*.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3). They shall take into account the experience gained during the implementation of Regulation (EC) 653/2007 on the use of a common European format for safety certificates and application documents¹⁰ and of Regulation (EU) 1158/2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates¹¹. They shall also take into account the experience gained during the implementation of the Cooperation Agreements between the Agency and the national safety authorities referred to in Article 11(1).

2. Safety certificates shall specify the type and extent of the railway operations covered and the area of operation. The safety certificate may also cover sidings owned by the railway undertaking if they are included in its safety management system.
3. Any decision refusing the issuing of a safety certificate or excluding part of the network in accordance with the negative assessment as referred to in paragraph 1f shall be duly substantiated. The applicant may, within a period of one month from receipt of the decision, request that the Agency or the national safety authority, as appropriate, review its decision. The Agency or the national safety authority shall have two months from the date of receipt of the request for review to confirm or reverse its decision.

If the decision of the Agency is confirmed, the applicant may bring an appeal before the Board of Appeal designated under Article 51 of Regulation (EU) No .../... [Agency Regulation]. If the decision of a national safety authority is confirmed, the applicant may bring an appeal to the appeal body designated by the competent Member State under Article 17(3). Member States may designate the regulatory body set out in Article 56 of Directive 2012/34/EU establishing a single European railway area for the purpose of this appeal procedure.

4. *[Deleted and shifted to new Article 16a]*

¹⁰ OJ L 153, 14.6.2007, p. 9.

¹¹ OJ L 326, 10.12.2010, p. 11.

5. The 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 five years. It shall be fully or partly updated whenever the type or extent of the operation is substantially altered.

[Deleted and shifted to new Article 16a]

- 5a. Where the applicant already has a safety certificate issued in accordance with paragraph 1d to 1f and wishes to extend its area of operations or where he already has a safety certificate issued in accordance with paragraph 1g and wishes to extend its area of operations to another Member State, it shall complement the file with the relevant documents referred to in paragraph 1b concerning the additional area of operation. The applicant shall submit the file to the Agency, which shall, after following the procedures in paragraphs 1c. to 1f., issue an updated certificate covering the extended area of operation. In this case, only the national safety authority concerned by the extension of operation will be consulted for assessing the file set out in paragraph 1b(b).

If the applicant received a safety certificate in accordance with paragraph 1g and wishes to extend the area of operation within that Member State, it shall complement the file with the relevant documents referred to in paragraph 1(b) concerning the additional area of operation. It shall submit the file to the national safety authority which shall, after following the procedures in paragraphs 1g., issue an updated authorisation covering the extended area of operation.

- 5b. 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.

6. *[Deleted and shifted to new Article 16a]*

7. The Agency shall inform the relevant national safety authorities without delay and in any case within two weeks of the issue of a single safety certificate. The Agency shall inform the relevant 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 certificate and, in the case of revocation, the reasons for its decision. In the case of certificates issued by the national safety authorities, the same information shall be provided by the competent national safety authorities to the Agency within the same timeframe.

8. [*Shifted to article 11(1)*]

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

[Note: Article 11 of the Commission's proposal is replaced by the following text]:

1. For the purposes of Article 10(1d) and (1e), the Agency and the national safety authorities shall conclude cooperation agreements in accordance with Article 69 of Regulation .../... [Agency Regulation]. These agreements could be specific or framework agreements, and involve one or more national safety authorities. These agreements shall contain a specified description of tasks and conditions for deliverables, the time-limits applying to their delivery, the apportioning of the fees paid by the applicant. They may also include specific cooperation arrangements in the case of networks requiring specific expertise due to geographical or historical reasons, with a view to reducing administrative burden and costs to the applicant, Where such networks are isolated from the rest of the Union's rail system, such specific cooperation arrangements may include the possibility for contracting tasks to the relevant national safety authorities when it is necessary in order to ensure efficient and proportionate allocation of resources for certification. These agreements shall be in place before the Agency is entitled to receive applications in accordance with this Directive, and in any case by three years following the date of entry into force of this Directive at the latest.¹³

¹² The following recital will be included: *"Where operation is limited to networks requiring specific expertise due to geographical or historical reasons, and that such networks are isolated from the rest of the Union's rail system, it should be possible for the applicant to perform the necessary formalities locally through interacting with the relevant national safety authorities. To this end, for the purposes of reducing administrative burden and costs, the cooperation agreements to be concluded between the Agency and the relevant national safety authorities may provide the appropriate allocation of tasks, without prejudice to the final responsibility of the Agency in issuing the single safety certificate"*.

¹³ A new provision will be inserted into the Agency Regulation pursuant to which the administrative board of the Agency is empowered to adopt a framework model for the financial apportioning of the fees paid by the applicant, which will have to be taken into account for the cooperation agreements between the Agency and the national safety authorities to be established under this paragraph.

2. *[deleted and partly shifted to Article 28]*

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 it is established.

The safety authorisation shall comprise authorisation confirming acceptance of the infrastructure manager's safety management system laid down in Article 9, which 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.

2. The safety authorisation is valid for five years and can be renewed upon application by the infrastructure manager. It shall be wholly or partly updated whenever substantial changes are made to the infrastructure, signalling or energy subsystem or to the principles of its operation and maintenance. The holder of the safety authorisation shall without delay inform the national safety authority of all such changes.

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 four months after all the information required and any supplementary information requested has been submitted.
4. The national safety authority shall inform the Agency without delay and in any event within two 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, the scope and validity of the safety authorisation and, in case 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 deliver the safety authorisations.

Article 13

Access to training facilities

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

The services offered 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 certification.

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

2. If the training facilities are available only through the services of one 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 may include a profit margin.

3. When recruiting new train drivers, staff on board trains and staff performing vital safety tasks, railway undertakings shall be able to take into account any training, qualifications and experience acquired previously from other railway undertakings. For this purpose, such members of staff shall be entitled to have access to, obtain copies 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-related work.

Article 14

Maintenance of vehicles

1. Each vehicle, before it is used on the network, shall have an entity in charge of maintenance assigned to it and this entity shall be registered in the national vehicle register in accordance with Article 43 of Directive XX on interoperability of the rail system.
2. [Deleted]
3. 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 which it is in charge of maintenance are in a safe state of running by means of a system of maintenance which also provides for the traceability of maintenance activities. To this end, the entity in charge of maintenance shall ensure:
 - (a) that vehicles are maintained in accordance with the maintenance file of each vehicle and the requirements in force including maintenance rules and TSI provisions.
 - (b) implement the necessary risk control measures as referred to in Article 6(1a), where appropriate in cooperation with other actors;

- (c) ensure that its contractors implement risk control measures through the application of the common safety methods for monitoring processes set out in the CSM on monitoring referred to in Article 6(1c) and that this is stipulated in contractual arrangements which shall be disclosed on request of the Agency or the national safety authority.

The entity in charge of maintenance shall carry out the maintenance itself or make use of contracted maintenance workshops.

4. In the case of freight wagons, each entity in charge of maintenance shall be certified in accordance with the implementing measures referred to in point (a) of paragraph 7 by a body accredited or recognised or by a national safety authority. The accreditation and recognition processes shall also be based on criteria of independence, competence and impartiality.

Where the entity in charge of maintenance is an infrastructure manager or a railway undertaking, compliance with the implementing measures referred to in paragraph 7 may be checked by the relevant national safety authority pursuant to the procedures referred to in Articles 10 or 12 and may be confirmed on the certificates specified in those procedures.

5. The certificates granted in accordance with paragraph 4 shall be valid throughout the Union .
6. The Agency shall evaluate the system of certification of the entity in charge of maintenance for freight wagons and shall consider the opportunity for an extension of that system to all vehicles and the mandatory certification of the maintenance workshops and shall submit a report to the Commission.
7. On the basis of the evaluation carried out by the Agency pursuant to paragraph 6, the Commission shall, by means of implementing acts, adopt, if appropriate, by 24 December 2016:
 - (a) common conditions for certification of the entity in charge of maintenance for freight wagons;

- (b) common conditions for the certification of maintenance workshops;
- (c) common conditions for certification of the entity in charge of maintenance for vehicles other than freight wagons.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27 (3).

The certification system applicable to freight wagons adopted by Regulation (EU) No 445/2011 shall continue to apply until the implementing acts referred to in point (a) is adopted.

Article 15

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

1. Member States may fulfil the obligations 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 according to the law of that country;
 - (b) vehicles which are used on networks or lines the track gauge of which is different from that of the main rail network within the Union and for which fulfilment of the requirements referred to in Article 14(3) is ensured by international agreements with third countries;
 - (bb) freight wagons belonging to a pool of freight wagons in shared use with third countries the track gauge of which is different from that of the main rail network within the Union.

- (c) vehicles covered by Article 2, and military equipment and special transport requiring an ad hoc national safety authority permit to be delivered prior to the service. In this case derogations shall be granted for periods not longer than five years.
- 2. Alternative measures referred to in paragraph 1 shall be implemented through derogations to be granted by the relevant national safety authority or the Agency:
 - (a) when registering vehicles pursuant to Article 43 of Directive xx on interoperability of the rail system, as far as the identification of the entity in charge of maintenance is concerned;
 - (b) when delivering safety certificates and 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. Such derogations shall be identified and justified in the annual safety report referred to in Article 18. 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 involved and, where appropriate, request the Member State to withdraw its derogation decision.

CHAPTER IV

NATIONAL SAFETY AUTHORITIES

Article 16

Tasks

1. Each Member State shall establish a safety authority. This authority shall be independent in its organisation, legal structure and decision making from any railway undertaking, infrastructure manager, applicant, contracting entity and any entity awarding public service contracts. Provided that this independence is guaranteed, this authority may be a department within the 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 rail system in accordance with Article 18(2) of Directive [XX] on interoperability of the rail system;

 - (aa) issuing, renewing, amending and revoking vehicle authorisations for placing on the market according to Article 20(1g) of Directive [XX] on interoperability of the rail system;

 - (aaa) supporting the Agency in the issue, renewal, amendment and revocation of vehicle authorisations for placing on the market according to Article 20 (1d) and type authorisation of vehicle according to Article 22 of Directive [XX] on the interoperability of the rail system;

 - (b) supervising in its territory that the interoperability constituents are in compliance with the essential requirements as required by Article 8 of Directive [XX] on interoperability of the rail system;

- (c) ensuring that a European vehicle numbering has been assigned in accordance with Article 42 of Directive [XX] on interoperability of the rail system and without prejudice to Article 43(4) of that Directive.
- (d) supporting the Agency in the issue, renewal, amendment and revocation of single safety certificates granted in accordance with Article 10(1d);
- (dd) issuing, renewing, amending and revoking national safety certificates granted in accordance with Article 10 (1g);
- (e) issuing, renewing, amending and revoking safety authorisations granted in accordance with Article 12;
- (f) monitoring, promoting, and, where appropriate, enforcing and updating the safety regulatory framework including the system of national rules;
- (g) supervising the railway undertakings and the infrastructure managers according to Article 16a;
- (h) *[deleted]*
- (ha) where relevant, and in accordance with national law, issuing, renewing, amending and revoking train driving licences in accordance with 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 Community¹⁴.
- (hb) where relevant, and in accordance with national law, issuing, renewing, amending and revoking ECM certificates in accordance with Article 14.

3. *[Deleted and shifted to new Article 16a]*

¹⁴ OJ L 315, 3.12.2007, p.51-78

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

Article 16a

Supervision

[new Article]

1. Each national safety authority in the territory of the Member State where it is established shall oversee continued compliance with the legal obligation on a railway undertaking or infrastructure manager to use a safety management system as referred to in Article 9.

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

- (a) the safety management system to control 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 control their effectiveness;
 - (c) the relevant common safety methods set out in Article 6. The supervision activities related to this point shall also apply to entities in charge of maintenance.
2. The railway undertaking shall inform the relevant national safety authorities at least two months before starting operation of a new service to allow them to plan the supervision activities. The railway undertaking shall also provide a breakdown of the categories of staff and the types of vehicles.
3. The holder of the single safety certificate shall inform without delay the competent national safety authorities of any major changes to the information referred to in paragraph 2

4. 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 it. The Agency shall immediately inform all the national safety authorities concerned by the area of operation of the railway undertaking. The Agency may revoke or restrict the single safety certificate, giving reasons for its decision.

In case of disagreement between the Agency and the national safety authority, the appeal procedure indicated in article 10(1f) shall be followed. If the result of such appeal procedure is that the single safety certificate shall neither be restricted nor revoked, the temporary safety measures referred to in paragraph 4a shall be suspended.

Where the national safety authority has itself issued the single safety certificate according to article 10(1g), it may restrict or revoke the single safety 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, has the right to appeal according to Article 10(3).

- 4a. ¹⁵If, during supervision, a national safety authority identifies a serious safety risk, it may at any time apply temporary safety measures, including restricting or suspending immediately the relevant operations. If the safety certificate of the railway undertaking concerned 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 the safety certificate no longer satisfies the conditions for certification, it shall immediately restrict or revoke the safety certificate

¹⁵ The following recital will be included: *"If a national safety authority identifies a serious safety risk during supervision, it should be allowed to apply temporary safety measures, including restricting or suspending immediately the relevant operations. A serious safety risk in this context should be understood as being an intentional or negligent 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."*

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 to adapt such 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 remains in force.

The decision of the national safety authority related to temporary safety measures is subject to judicial review in accordance with Article 17(3). In such a case, the temporary safety measures may apply until the end of the judicial review, without prejudice to paragraph 4.

If the duration of the temporary measure is longer than three months the national safety authority shall ask the Agency to restrict or revoke the certificate and the procedure of paragraph 4 shall apply.

4aa. The national safety authority shall supervise that the trackside, control-command and signalling, energy and infrastructure subsystems are in compliance with the essential requirements. If the national safety authority finds that an authorised infrastructure manager no longer satisfies the conditions for a safety authorisation it shall restrict or revoke the authorisation, giving reasons for its decisions. *[moved from Article 12(2) subpara 3]*

4aaa. When supervising the effectiveness of the safety management systems of infrastructure managers and railway undertakings, the national safety authorities may supervise the safety performance of actors as referred to in Article 4(5), and, where appropriate, of the training centers referred to in 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 Community¹⁶ as long as their activities have an impact on railway safety. This provision applies without prejudice to the responsibility of the railway undertakings and infrastructure managers referred to in Article 4(3).

¹⁶ OJ L 315, 3.12.2007 p.51-78

5. The national safety authorities of Member States where the railway undertaking operates shall cooperate in coordinating their supervision activities concerning the 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.

The 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 regularly, 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.

6. Each national safety authority may address notices to warn infrastructure managers and railway undertakings in case of non-compliance with their obligations referred to in paragraph 1.
7. The national safety authority shall use information gathered by the Agency during the assessment of the file set out in Article 10 (1d(a)) for the purposes of supervision of the railway undertaking after issuing the safety certificate. The national safety authority shall use information gathered during the process of safety authorisation according to Article 12 for the purposes of supervision of the infrastructure manager .
8. For the purpose of renewing safety certificates, the Agency or the competent national safety authorities in the case of a safety certificate granted according to Article 10 (1g), 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.

9. 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 6, 7 and 8.

Article 17

Decision-making principles

1. The Agency in its role of certification and the national safety authorities shall carry out their tasks in an open, non-discriminatory and transparent way. In particular they shall allow all 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 four months after all relevant information has been provided. 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 authority shall consult all actors and interested parties involved, 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 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 according to Article 10(1d).
3. Member States shall take the measures necessary to ensure that decisions taken by the national safety authority 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.
5. *[Deleted]*

Article 18

Annual report

Each year the national safety authority shall publish an annual report concerning its activities in the preceding year and send it to the Agency by 30 September at the latest. The report shall contain information on:

- (a) the development of railway safety, including an aggregation at Member State level of the CSIs and in accordance with Article 5(2);
- (b) important changes in legislation and regulation concerning railway safety;
- (c) the development of safety certification and safety authorisation
- (d) results of and experience relating to the supervision of infrastructure managers and railway undertakings, including the outcome of inspections and audits;
- (e) the derogations decided in accordance with Article 15;
- (f) *[deleted]*
- (g) the experience of the railway undertakings and infrastructure managers on the application of the relevant CSMs.

CHAPTER V

ACCIDENT AND INCIDENT INVESTIGATION

Article 19

Obligation to investigate

1. Member States shall ensure that an investigation is carried out by the investigating body referred to in Article 21 after serious accidents on the rail system, the objective of which is possible improvement of railway safety and the prevention of accidents.

2. In addition to serious accidents, the investigating body referred to in Article 21 may 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 European rail system.

The investigating body shall, at its discretion, decide whether or not an investigation of such an accident or incident shall be undertaken. In 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;

 - (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 such investigations shall be determined by the investigating body, taking into account Articles 20 and 22 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 20

Status of investigation

1. Member States shall define, in the framework of their respective legal system, the legal status of the investigation that shall 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, as soon as possible, given access 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 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 and other witnesses;

- (g) access to any relevant information or records held by the infrastructure manager, the railway undertakings involved, entities in charge of maintenance, and the national safety authority.
- 2a. The Agency shall cooperate with the investigation body when the investigation involves vehicles authorised by the Agency or railway undertakings certified by the Agency. It shall submit as soon as possible all requested information or records to the investigation body and provide explanation, where requested.
- 3. The investigation shall be accomplished independently of any judicial inquiry.

Article 21

Investigating body

- 1. Each Member State shall ensure that investigations of accidents and incidents referred to in Article 19 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. This 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 organisations 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 make provision that railway undertakings, infrastructure managers and, where appropriate, the national safety authority, are obliged immediately to notify accidents and incidents referred to in Article 19 to the investigating body. The investigating body shall decide without delay and in any event no later than two 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 investigations do not endanger its independence.
5. If necessary, and provided it does not undermine the independence of investigating body as set out 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 19.
7. The investigating bodies shall conduct an active exchange of views and experience for the purpose of developing 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 this task.

Article 22

Investigation procedure

1. An accident or incident referred to in Article 19 shall be investigated by the investigation 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 bodies shall agree which one of them shall carry out the investigation or shall agree to carry it out in cooperation. The other body shall in the first case be allowed to participate in the investigation and fully share its results.

Investigation bodies from another Member State or from other Member States shall be invited, if appropriate, and participate in an investigation:

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

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

National investigation 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 of national laws related to judicial proceedings.

This paragraph shall not preclude Member States from agreeing that the relevant bodies shall carry out investigations in cooperation 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 technical relevant 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 regarding the progress.¹⁷
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 23

Reports

1. An investigation of an accident or incident referred to in Article 19 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 19(1) and contain, where appropriate, safety recommendations.

¹⁷ A new recital will be added to clarify that the objective of the consultation is to receive relevant information in order to ensure that the investigation is exhaustive. The following recital shall be included: "*The investigation carried out after a serious accident should be carried out with as much openness as possible, so that all parties can be heard and can share the results. In particular, during the investigation, the investigating body should update the parties, who it judges as having related safety responsibility, on the progress of the investigation and take account of their views and opinions. This will allow the investigation body to receive any additional relevant information and to be aware of different opinions on its work so that it can complete at best its investigation. The purpose of this consultation should in no case lead to apportioning blame or liability but rather to collect factual evidences and taking lessons for future improvement of safety. The investigating body should however be free of choosing the information it will share with such parties in order to avoid any undue pressure, except when this is requested by the judicial procedure. In addition, the investigating body should also take account of the reasonable information needs of the victims and their relatives.*"

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 at 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 22(3) and to bodies and parties concerned in other Member States.

The Commission shall take into account experience gained by the investigating bodies and shall establish, by means of implementing acts, the principal content of accident and incident investigation reports. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).

3. Each year the investigating body shall publish by 30 September at the latest 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 24

Information to be sent to the Agency

1. Within one week after 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 23(2) and of the annual report referred to in Article 23(3).

Article 25

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 other bodies or authorities in the Member State or to other Member States. Member States, their national safety authorities and the Agency within the limits of their competence shall 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 , when appropriate, other Member States to which recommendations have been addressed, shall report back at least regularly to the investigating body on measures that are taken or planned as a consequence of the recommendation.

CHAPTER VI

FINAL PROVISIONS

Article 26

Exercise of delegation

[Deleted]

Article 27

Committee procedure

1. The Commission shall be assisted by the committee established by Article 48 of Directive Directive [XX] on interoperability of the rail system. 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 paragraph of Article 5(4) of Regulation (EU) 182/2011 shall apply.

Article 28

Report and further Union action

The Commission shall submit to the European Parliament and to the Council before [specific date to be inserted by OPOCE - *five years after the date of entry into force*] and every five 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.

Article 29

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 32(1) and shall notify it without delay of any subsequent amendment affecting them.

Article 30

Transitional provisions

Annexes I, III and V to Directive 2004/49/EC shall apply until the date of application of the implementing acts referred to in Articles 5(2), 6(2) and (3), 9(2), 14(7) and 23(2) of this Directive. Until [specific date to be inserted by OPOCE - *five years after the date of entry into force*], the national safety authorities shall continue to grant safety certificates in accordance with the provisions of Directive 2004/49/EC. Such safety certificates shall be valid until their date of expiry.

Article 31

Recommendations and opinions of the Agency

The Agency shall provide recommendations and opinions in accordance with Article 15 of Regulation .../... [Agency Regulation] for the purpose of application of this Directive. These recommendations and opinions may be taken into account when the Union adopts measures pursuant this Directive.

Article 32

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 2, 3, 4, 8, 10, 16, 18 and 20 by [specific date to be inserted by OPOCE - *five years after the date of entry into force*] at the latest. They shall forthwith communicate to the Commission the text of those provisions.
2. 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 directives 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.
3. The obligation to transpose and implement this Directive shall not apply to the Republic of Cyprus and the Republic of Malta for as long as no rail system is established within their territory.

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 legislation to implement this Directive within two years from receipt of the application.

Article 33

Repeal

Directive 2004/49/EC, as amended by the Directives listed in Annex II, Part A, is repealed with effect from [specific date to be inserted by OPOCE five years after the *[date of entry into force]*], 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 II, 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 III.

Article 34

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*.

Articles 10 and 11 shall apply from [specific date to be inserted by OPOCE - five years after *the date of entry into force*].

Article 35

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament

The President

For the Council

The President

ANNEX I on COMMON SAFETY INDICATORS

[Deleted]

NOTIFICATION OF NATIONAL SAFETY RULES

[new Annex to be seen in conjunction with Article 8]

National safety rules notified under Article 8.1(a) include:

1. rules concerning existing national safety targets and safety methods;
2. rules concerning requirements on 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 on additional internal operating rules (company rules) that must be established by infrastructure managers and railway undertakings;
5. rules concerning requirements on staff executing safety critical tasks, including selection criteria, medical fitness and vocational training and certification as far as they are not yet covered by a TSI;
6. rules concerning the investigation of accidents and incidents.

PART A

Repealed Directive with list of the successive amendments thereto
(referred to in Article 32)

| | |
|-------------------------------------|-------------------------------|
| 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) |

PART B**(1) Time limits for transposition into national law**

(referred to in Article 32)

| Directive | Deadline for transposition |
|-------------|----------------------------|
| 2004/49/EC | 30 April 2006 |
| 2008/57/EC | 19 July 2010 |
| 2008/110/EC | 24 December 2010 |
| 2009/149/EC | 18 June 2010 |

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 |
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| Article 14a (1) to (7) | Article 14 |
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| Article 15 | -- |
| Article 16 | Article 16 |
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| Article 21 | Article 21 |
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| Article 35 | Article 35 |
| Annex I | Annex I |
| Annex II | -- |
| Annex III | -- |
| Annex IV | -- |
| Annex V | -- |
| -- | Annex II |
