

Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) (repealed)

CHAPTER I

INTRODUCTORY PROVISIONS

Article 1

Purpose

The purpose of this Directive is to ensure the development and improvement of safety on the Community'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;
- (c) developing common safety targets and common safety methods with a view to greater harmonisation of national rules;
- (d) requiring the establishment, in every Member State, of a 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 railway system in the Member States, which may be broken down into subsystems for structural and operational 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 and infrastructure managers.

2 Member States may exclude from the measures they adopt in implementation of this Directive:

- a metros, trams and other light rail systems;
- 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 railway undertakings operating solely on these networks;
- c privately owned railway infrastructure that exists solely for use by the infrastructure owner for its own freight operations^[F1];
- ^[F2]d heritage vehicles that run on national networks provided that they comply with national safety rules and regulations with a view to ensuring safe circulation of such vehicles;

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- e heritage, museum and tourist railways that operate on their own network, including workshops, vehicles and staff.]

Textual Amendments

- F1** Substituted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).
- F2** Inserted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).

Article 3

Definitions

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

- (a) 'railway system' means the totality of the subsystems for structural and operational areas, as defined in Directives 96/48/EC and 2001/16/EC, as well as the management and operation of the system as a whole;
- (b) 'infrastructure manager' means any body or undertaking that is responsible in particular for establishing and maintaining railway infrastructure, or a part thereof, as defined in Article 3 of Directive 91/440/EEC, which may also include the management of infrastructure control and safety systems. The functions of the infrastructure manager on a network or part of a network may be allocated to different bodies or undertakings;
- (c) 'railway undertaking' means railway undertaking as defined in Directive 2001/14/EC, 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; this also includes undertakings which provide traction only;
- (d) 'technical specification for interoperability (TSI)' means the specifications by which each subsystem or part of a subsystem is covered in order to meet the essential requirements and ensure the interoperability of the trans-European high-speed and conventional rail systems as defined in Directive 96/48/EC and Directive 2001/16/EC;
- (e) 'common safety targets (CSTs)' means the safety levels that must at least be reached 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) and by the system as a whole, expressed in risk acceptance criteria;
- (f) 'common safety methods (CSMs)' means the methods to be developed to describe how safety levels and achievement of safety targets and compliance with other safety requirements are assessed;
- (g) 'safety authority' means the national body entrusted with the tasks regarding railway safety in accordance with this Directive or any binational body entrusted by Member States with these tasks in order to ensure a unified safety regime for specialised cross-border infrastructures;

- (h) ‘national safety rules’ means all rules containing railway safety requirements imposed at Member State level and applicable to more than one railway undertaking, irrespective of the body issuing them;
- (i) ‘safety management system’ means the organisation and arrangements 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 similar accident with an obvious impact on railway safety regulation or the management of safety; ‘extensive damage’ 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, associated with the operation of trains and affecting the safety of operation;
- (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) ‘Agency’ means the European Railway Agency, the Community agency for railway safety and interoperability;
- (q) ‘notified bodies’ means the bodies which are responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the EC procedure for verification of the subsystems, as defined in Directives 96/48/EC and 2001/16/EC;
- (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 high-speed or conventional rail system depends directly or indirectly, as defined in Directive 96/48/EC and 2001/16/EC. The concept of a ‘constituent’ covers both tangible objects and intangible objects such as software^[F1];
- (s) ‘^[F2]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 (NVR) provided for in Article 33 of Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (recast)⁽¹⁾, (hereinafter referred to as the ‘Railway Interoperability Directive’);

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- (t) ‘entity in charge of maintenance’ means an entity in charge of maintenance of a vehicle, and registered as such in the NVR;
- (u) ‘vehicle’ means a railway vehicle suitable for circulation on its own wheels on railway lines, with or without traction. A vehicle is composed of one or more structural and functional subsystems or parts of such subsystems.]

Textual Amendments

- F1** Substituted by Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community’s railways (Railway Safety Directive) (Text with EEA relevance).
- F2** Inserted by Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community’s railways (Railway Safety Directive) (Text with EEA relevance).

CHAPTER II

DEVELOPMENT AND MANAGEMENT OF SAFETY

Article 4

Development and improvement of railway safety

1 Member States shall ensure that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Community legislation and technical and scientific progress and giving priority to the prevention of serious accidents.

Member States shall ensure that safety rules are laid down, applied and enforced in an open and non-discriminatory manner, fostering the development of a single European rail transport system.

2 Member States shall ensure that measures to develop and improve railway safety take account of the need for a system-based approach.

3 Member States shall ensure that the responsibility for the safe operation of the railway system and the control of risks associated with it is laid upon the infrastructure managers and railway undertakings, obliging them to implement necessary risk control measures, where appropriate in cooperation with each other, to apply national safety rules and standards, and to establish safety management systems in accordance with this Directive.

Without prejudice to civil liability in accordance with the legal requirements of the Member States, 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 third parties.

4 This shall be without prejudice to the responsibility of each manufacturer, maintenance supplier, [F1keeper], service provider and procurement entity to ensure that rolling stock, installations, accessories and equipment and services supplied by them comply with the

requirements and the conditions for use specified, so that they can be safely put into operation by the railway undertaking and/or infrastructure manager.

Textual Amendments

- F1** Substituted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).

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 safety authorities as referred to in Article 18.

The first reference year for the CSIs shall be 2006; they shall be reported on in the annual report the following year.

The CSIs shall be established as set out in Annex I.

[^{F12} Before 30 April 2009 Annex I shall be revised, in particular to incorporate therein the common definitions of the CSIs and the common methods for calculating accident costs. This measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(2a).]

Textual Amendments

- F1** Substituted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).

Article 6

Common safety methods

[^{F11} An initial series of CSMs covering, as a minimum, the methods described in paragraph 3(a) shall be adopted by the Commission before 30 April 2008. They shall be published in the *Official Journal of the European Union*.

A second series of CSMs covering the remaining methods described in paragraph 3 shall be adopted by the Commission before 30 April 2010. They shall be published in the *Official Journal of the European Union*.

These measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(2a).]

2 Draft CSMs and draft revised CSMs shall be drawn up by the Agency under mandates which shall be adopted in accordance with the procedure referred to in Article 27(2).

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The draft CSMs shall be based on an examination of existing methods in the Member States.

3 The CSMs shall describe how the safety level, and the achievement of safety targets and compliance with other safety requirements, are assessed 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 11,

and

[^{F1}c as far as they are not yet covered by TSIs, methods to check that the structural subsystems of the railway system are operated and maintained in accordance with the relevant essential requirements.]

[^{F1}4 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 the obligations on Member States as laid down in Article 4(1). This measure, designed to amend non-essential elements of this Directive, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(2a).]

5 Member States shall make any necessary amendments to their national safety rules in the light of the adoption of CSMs and revisions to them.

Textual Amendments

- F1** Substituted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).

Article 7

Common safety targets

1 The CSTs shall be developed, adopted and revised following the procedures laid down in this Article.

2 Draft CSTs and draft revised CSTs shall be drawn up by the Agency under mandates which shall be adopted in accordance with the procedure referred to in Article 27(2).

3 [^{F1}The first set of draft CSTs shall be based on an examination of existing targets and safety performance in the Member States and shall ensure that the current safety performance of the rail system is not reduced in any Member State. It shall be adopted by the Commission before 30 April 2009 and shall be published in the *Official Journal of the European Union*. This measure, designed to amend non-essential elements of this Directive, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(2a).

The second set of draft CSTs shall be based on the experience gained from the first set of CSTs and their implementation. It shall reflect any priority areas where safety needs to be further improved. It shall be adopted by the Commission before 30 April 2011 and shall be published in the *Official Journal of the European Union*. This measure, designed to amend non-essential elements of this Directive, inter alia, by supplementing

it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(2a).]

4 The CSTs shall define the safety levels that must at least be reached by different parts of the railway system and by the system as a whole in each Member State, expressed in risk acceptance criteria for:

- 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.

[^{F15} The CSTs shall be revised at regular intervals, taking into account the global development of railway safety. This measure, designed to amend non-essential elements of this Directive, inter alia, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(2a).]

6 Member States shall make any necessary amendments to their national safety rules in order to achieve at least the CSTs, and any revised CSTs, in accordance with the implementation timetables attached to them. They shall notify these rules to the Commission in accordance with Article 8(3).

Textual Amendments

- F1** Substituted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).

Article 8

National safety rules

1 In application of this Directive, Member States shall establish binding national safety rules and shall ensure that they are published and made available to all infrastructure managers, railway undertakings, applicants for a safety certificate and applicants for a safety authorisation in clear language that can be understood by the parties concerned.

2 Before 30 April 2005 Member States shall notify the Commission of all the relevant national safety rules in force, as set out in Annex II, and indicate their area of application.

The notification shall further provide information on the principal content of the rules with references to the legal texts, on the form of legislation and on which body or organisation is responsible for its publication.

3 Not later than four years after the entry into force of this Directive, the Agency shall evaluate the way in which national safety rules are published and made available in accordance with paragraph 1. It shall also make appropriate recommendations to the Commission for the publication of such rules in order to make the relevant information more easily accessible.

4 Member States shall forthwith notify the Commission of any amendment to the notified national safety rules and of any new such rule that might be adopted, unless the rule is wholly relating to the implementation of TSIs.

5 In order to keep the introduction of new specific national rules to a minimum and thus prevent further barriers from being created, and with a view to the gradual harmonisation of

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safety rules, the Commission shall monitor the introduction of new national rules by Member States.

6 If, after the adoption of CSTs, a Member State intends to introduce a new national safety rule which requires a higher safety level than the CSTs, or if a Member State intends to introduce a new national safety rule which may affect operations of railway undertakings from other Member States on the territory of the Member State concerned, the Member State shall consult all interested parties in due time and the procedure in paragraph 7 shall apply.

7 The Member State shall submit the draft safety rule to the Commission for examination, stating the reasons for introducing it.

If the Commission finds that the draft safety rule is incompatible with the CSMs or with achieving at least the CSTs, or that it constitutes a means of arbitrary discrimination or a disguised restriction on rail transport operations between Member States, a Decision, addressed to the Member State concerned, shall be adopted in accordance with the procedure referred to in Article 27(2).

If the Commission has serious doubts as to the compatibility of the draft safety rule with the CSMs or with achieving at least the CSTs, or considers that it constitutes a means of arbitrary discrimination or a disguised restriction on rail transport operations between Member States, the Commission shall immediately inform the Member State concerned, which shall suspend the adoption, entry into force or implementation of the rule until a Decision is adopted, within a period of six months, in accordance with the procedure referred to in Article 27(2).

Article 9

Safety management systems

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

2 The safety management system shall meet the requirements and contain the elements laid down in Annex III, adapted to the character, extent 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 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 parties

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 safety rules and with conditions laid down in their safety certificate. It shall furthermore 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 safety authority before 30 June 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 laid down in Annex I, 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 safety authority.

CHAPTER III

SAFETY CERTIFICATION AND AUTHORISATION

Article 10

Safety certificates

1 In order to be granted access to the railway infrastructure, a railway undertaking must hold a safety certificate as provided for in this Chapter. The safety certificate may cover the whole railway network of a Member State or only a defined part thereof.

[^{F1}The purpose of the safety certificate is to provide evidence that the railway undertaking has established its safety management system and can meet requirements laid down in TSIs and other relevant Community legislation and in national safety rules in order to control risks and provide transport services safely on the network.]

2 The safety certificate shall comprise:

- a certification confirming acceptance of the railway undertaking's safety management system as described in Article 9 and Annex III,

and

- [^{F1}b certification confirming acceptance of the provisions adopted by the railway undertaking to meet specific requirements necessary for the safe supply of its services on the relevant network. These requirements may concern the application of the TSIs and national safety rules, including the network operating rules, acceptance of staff certificates and authorisation to operate vehicles used by railway undertakings. The certification shall be based on documentation submitted by the railway undertaking as described in Annex IV.]

3 The safety authority in the Member State where the railway undertaking first establishes its operation shall grant the certification in accordance with paragraph 2.

The certification granted in accordance with paragraph 2 must specify the type and extent of the railway operations covered. The certification granted in accordance with paragraph 2(a) shall be valid throughout the Community for equivalent rail transport operations.

4 The safety authority in the Member State in which the railway undertaking is planning to operate additional rail transport services shall grant the additional national certification necessary in accordance with paragraph 2(b).

5 The safety certificate shall be renewed upon application by the railway undertaking at intervals not exceeding five years. It shall be wholly or partly updated whenever the type or extent of the operation is substantially altered.

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The holder of the safety certificate shall without delay inform the competent safety authority of all major changes in the conditions of the relevant part of the safety certificate. It shall furthermore notify the competent safety authority whenever new categories of staff or new types of rolling stock are introduced.

The safety authority may require that the relevant part of the safety certificate be revised following substantial changes in the safety regulatory framework.

If the safety authority finds that the holder of the safety certificate no longer satisfies the conditions for a certification which it has issued, it shall revoke part (a) and/or (b) of the certificate, giving reasons for its decision. The safety authority that has revoked an additional national certification granted in accordance with paragraph 4 shall promptly inform the safety authority that granted the certification under paragraph 2(a) of its decision.

Similarly, a safety authority must revoke a safety certificate if it is apparent that the holder of the safety certificate has not used it as intended in the year following its issue.

6 The safety authority shall inform the Agency within one month of the safety certificates referred to in paragraph 2(a) that have been issued, renewed, amended or revoked. It shall state the name and address of the railway undertaking, the issue date, scope and validity of the safety certificate and, in case of revocation, the reasons for its decision.

7 Before 30 April 2009 the Agency shall evaluate the development of safety certification and submit a report to the Commission with recommendations on a strategy for migration towards a single Community safety certificate. The Commission shall take appropriate action following the recommendation.

Textual Amendments

- F1** Substituted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).

Article 11

Safety authorisation of infrastructure managers

1 In order to be allowed to manage and operate a rail infrastructure the infrastructure manager must obtain a safety authorisation from the safety authority in the Member State where he is established.

The safety authorisation shall comprise:

- a authorisation confirming acceptance of the infrastructure manager's safety management system as described in Article 9 and Annex III,
- and
- b authorisation confirming acceptance of the provisions of the infrastructure manager to meet specific 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 shall be renewed upon application by the infrastructure manager at intervals not exceeding five years. It shall be wholly or partly updated whenever

substantial changes are made to the infrastructure, signalling or energy supply or to the principles of its operation and maintenance. The holder of the safety authorisation shall without delay inform the safety authority of all such changes.

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

If the safety authority finds that an authorised infrastructure manager no longer satisfies the conditions for a safety authorisation it shall revoke the authorisation, giving reasons for its decisions.

3 The safety authority shall inform the Agency within one month 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.

Article 12

Application requirements relating to safety certification and safety authorisation

1 The safety authority shall take a decision on an application for safety certification or safety authorisation without delay and in any event not more than four months after all information required and any supplementary information requested by the safety authority has been submitted. If the applicant is requested to submit supplementary information, such information shall be submitted promptly.

2 In order to facilitate the establishment of new railway undertakings and the submission of applications from railway undertakings from other Member States, the safety authority shall give detailed guidance on how to obtain the safety certificate. It shall list all requirements that have been laid down for the purpose of Article 10(2) and make all relevant documents available to the applicant.

Special guidance shall be given to railway undertakings that apply for a safety certificate concerning services on a defined limited part of an infrastructure, specifically identifying the rules that are valid for the part in question.

3 An application guidance document describing and explaining the requirements for the safety certificates and listing the documents that must be submitted shall be made available to the applicants free of charge. All applications for safety certificates shall be submitted in the language required by the safety authority.

Article 13

Access to training facilities

1 Member States shall ensure that railway undertakings applying for a safety certificate have fair and non-discriminatory access to training facilities for train drivers and staff accompanying the trains, whenever such training is necessary for the fulfilment of requirements to obtain the safety certificate.

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

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Member States shall also ensure that infrastructure managers and their staff performing vital safety tasks have fair and non-discriminatory access to training facilities.

If the training services do not include examinations and granting of certificates, Member States shall ensure that railway undertakings have access to such certification if it is a requirement of the safety certificate.

The safety authority shall ensure that the provision of training services or, where appropriate, the granting of certificates meets the safety requirements laid down in TSIs or national safety rules described in Article 8 and Annex II.

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 must 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 In every case each railway undertaking and each infrastructure manager shall be responsible for the level of training and qualifications of its staff carrying out safety-related work as set out in Article 9 and Annex III.

^{F3}Article 14

[^{F3}Placing in service of in-use rolling stock]

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Textual Amendments

F3 Deleted by [Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community \(Recast\) \(Text with EEA relevance\)](#).

[^{F2}Article 14a

Maintenance of vehicles

1 Each vehicle, before it is placed in service or used on the network, shall have an entity in charge of maintenance assigned to it and this entity shall be registered in the NVR in accordance with Article 33 of the Railway Interoperability Directive.

2 A railway undertaking, an infrastructure manager or a keeper may be an entity in charge of maintenance.

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 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. To this end, the entity in charge of maintenance shall ensure that vehicles are maintained in accordance with:

- a the maintenance file of each vehicle;
- b the requirements in force including maintenance rules and TSI provisions.

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 by a body accredited or recognised in accordance with paragraph 5, or by a national safety authority. The accreditation process shall be based on criteria of independence, competence and impartiality, such as the relevant EN 45 000 series European standards. The recognition process shall also be based on criteria of independence, competence and impartiality.

Where the entity in charge of maintenance is a railway undertaking or an infrastructure manager, compliance with the requirements to be adopted under paragraph 5 shall be checked by the relevant national safety authority pursuant to the procedures referred to in Articles 10 or 11 and shall be confirmed on the certificates specified in those procedures.

5 Based on a recommendation by the Agency, the Commission shall, by 24 December 2010, adopt a measure establishing a system of certification of the entity in charge of maintenance for freight wagons. Certificates granted in accordance with this system shall confirm compliance with the requirements referred to in paragraph 3.

The measure shall include the requirements concerning:

- a the maintenance system established by the entity;
- b the format and validity of the certificate granted to the entity;
- c the criteria for accreditation or recognition of body or bodies responsible for issuing certificates and ensuring controls necessary for the functioning of the certification system;
- d the date of application of the certification system, including a transition period of one year for existing entities in charge of maintenance.

This measure, designed to amend non-essential elements of this Directive, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(2a).

Based on a recommendation by the Agency, the Commission shall, by 24 December 2018 review this measure in order to include all vehicles and to update, if necessary, the certification system applicable to freight wagons.

6 The certificates granted in accordance with paragraph 5 shall be valid throughout the Community.

7 The Agency shall evaluate the certification process implemented in accordance with paragraph 5 by submitting a report to the Commission, no later than three years after the entry into force of the relevant measure.

8 Member States may decide to fulfil the obligations to identify the entity in charge of maintenance and to certify it through alternative measures, 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 Community and for which fulfilment of the requirements referred to in paragraph 3 are ensured by international agreements with third countries;

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- c vehicles identified in Article 2(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.

Such alternative measures shall be implemented through derogations to be granted by the relevant national safety authority:

- a when registering vehicles pursuant to Article 33 of the Railway Interoperability Directive, 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 11 of this Directive, as far as the identification or certification of the entity in charge of maintenance is concerned.

Such derogations shall be identified and justified in the annual safety report referred to in Article 18 of this Directive. Where it appears that undue safety risks are being taken on the Community 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.]

Textual Amendments

- F2** Inserted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).

Article 15

Harmonisation of safety certificates

- 1 Before 30 April 2009 decisions on common harmonised requirements in accordance with Article 10(2)(b) and Annex IV and a common format for application guidance documents shall be adopted in accordance with the procedure referred to in Article 27(2).
- 2 The Agency shall recommend common harmonised requirements and a common format for application guidance documents under a mandate which shall be adopted in accordance with the procedure referred to in Article 27(2).

CHAPTER IV

SAFETY AUTHORITY

Article 16

Tasks

- 1 Each Member State shall establish a safety authority. This authority may be the Ministry responsible for transport matters and shall be independent in its organisation, legal structure and decision making from any railway undertaking, infrastructure manager, applicant and procurement entity.
- 2 The safety authority shall be entrusted with at least the following tasks:

- [^{F1}a authorising the placing in service of the structural subsystems constituting the rail system in accordance with Article 15 of the Railway Interoperability Directive and checking that they are operated and maintained in accordance with the relevant essential requirements;]
 - [^{F4}b authorising the bringing into service of the structural subsystems constituting the trans-European conventional rail system, in accordance with Article 14 of Directive 2001/16/EC and checking that they are operated and maintained in accordance with the relevant essential requirements;]
 - c supervising that the interoperability constituents are in compliance with the essential requirements as required by Article 12 of Directives 96/48/EC and 2001/16/EC;
 - d authorising the placing in service of new and substantially altered rolling stock that is not yet covered by a TSI;
 - e the issue, renewal, amendments and revocation of relevant parts of safety certificates and of safety authorisations granted in accordance with Articles 10 and 11 and checking that conditions and requirements laid down in them are met and that infrastructure managers and railway undertakings are operating under the requirements of Community or national law;
 - f monitoring, promoting, and, where appropriate, enforcing and developing the safety regulatory framework including the system of national safety rules;
 - [^{F1}g supervising that vehicles are duly registered in the NVR and that safety related information contained therein, is accurate and kept up to date;]
- 3 The tasks referred to in paragraph 2 may not be transferred or subcontracted to any infrastructure manager, railway undertaking or procurement entity.

Textual Amendments

- F1** Substituted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).
- F4** Deleted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).

Article 17

Decision-making principles

1 The safety authority shall carry out its tasks in an open, non-discriminatory and transparent way. In particular it shall allow all parties to be heard and give reasons for its decisions.

It shall promptly respond to requests and applications and communicate its requests for information without delay and adopt all its decisions within four months after all requested information has been provided. It may at any time request the technical assistance of infrastructure managers and railway undertakings or other qualified bodies when it is carrying out the tasks referred to in Article 16.

In the process of developing the national regulatory framework, the safety authority shall consult all persons involved and interested parties, including infrastructure

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managers, railway undertakings, manufacturers and maintenance providers, users and staff representatives.

2 The safety authority shall be free to carry out all inspections and investigations that are needed for accomplishment of its tasks and it shall be granted access to all relevant documents and to premises, installations and equipment of infrastructure managers and railway undertakings.

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

4 The safety authorities shall conduct an active exchange of views and experience for the purpose of harmonising their decision-making criteria across the Community. Their cooperation shall in particular aim at facilitating and coordinating the safety certification of railway undertakings which have been granted international train paths in accordance with the procedure laid down in Article 15 of Directive 2001/14/EC.

The Agency shall support the safety authorities in these tasks.

Article 18

Annual report

Each year the 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 laid down in Annex I;
- (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^{[F1];}
- (e) ^[F2]the derogations that have been decided in accordance with Article 14a(8).]

Textual Amendments

F1 Substituted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).

F2 Inserted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).

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 railway 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 trans-European high-speed or conventional rail systems.

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 on a Community level,
- and
- d requests from infrastructure managers, railway undertakings, the 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 the principles and the objectives of 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 will enable the investigators-in-charge to carry out their task in the most efficient way and within the shortest time.

2 In accordance with the legislation in force in the Member States and, where appropriate, in cooperation with the authorities responsible for the judicial inquiry, the investigators shall, as soon as possible, be given:

- a 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 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;

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- 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 and the safety authority.
- 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 notified 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 safety authority 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 safety authority, are obliged immediately to report accidents and incidents referred to in Article 19 to the investigating body. The investigating body shall be able to respond to such reports and make the necessary arrangements to start the investigation no later than one week after receipt of the report concerning the accident or incident.

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 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.

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 will 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 shall be invited to participate in an investigation whenever a railway undertaking established and licensed in that Member State is involved in the accident or incident.

This paragraph shall not preclude Member States from agreeing that the relevant bodies should 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 safety authority, victims and their relatives, owners of damaged property, manufacturers, the emergency services involved and representatives of staff and users shall be regularly informed of the investigation and its progress and, as far as practicable, shall be given an opportunity to submit their opinions and views to the investigation and be allowed to comment on the information in draft reports.

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.

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. The report shall, as close as possible, follow the reporting structure laid down in Annex V. 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.

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

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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 safety authority and, where needed by reason of the character of the recommendation, to other bodies or authorities in the Member State or to other Member States. Member States and their safety authorities 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 safety authority and other authorities or bodies or, when appropriate, other Member States to which recommendations have been addressed, shall report back at least annually to the investigating body on measures that are taken or planned as a consequence of the recommendation.

CHAPTER VI

IMPLEMENTING POWERS

[^{F1}Article 26

Adaptation of the Annexes

The Annexes shall be adapted to scientific and technical progress. This measure, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 27(2a).]

Textual Amendments

- F1** Substituted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).

Article 27

Committee procedure

1 The Commission shall be assisted by the Committee set up by Article 21 of Directive 96/48/EC.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

[^{F2a} Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.]

3 Where reference is made to this paragraph, Article 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

^{F4}

Textual Amendments

- F2** Inserted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).
- F4** Deleted by [Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways \(Railway Safety Directive\)](#) (Text with EEA relevance).

Article 28

Implementing measures

1 Member States may bring any measures concerning the implementation of this Directive to the attention of the Commission. Appropriate decisions shall be adopted in accordance with the procedure referred to in Article 27(2).

2 At the request of a Member State or on its own initiative the Commission shall, in a specific case, examine the application and enforcement of provisions concerning safety certification and safety authorisation, and within two months of receipt of such a request decide in accordance with the procedure referred to in Article 27(2) whether the related measure may continue to be applied. The Commission shall communicate its decision to the European Parliament, the Council and the Member States.

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CHAPTER VII

GENERAL AND FINAL PROVISIONS

Article 29

Amendments to Directive 95/18/EC

Directive 95/18/EC is hereby amended as follows:

1. Article 8 shall be replaced by the following:
Article 8

The requirements relating to professional competence shall be met when an applicant railway undertaking has or will have a management organisation which possesses the knowledge and/or experience necessary to exercise safe and reliable operational control and supervision of the type of operations specified in the licence.

2. in the Annex, Section II shall be deleted.

Article 30

Amendments to Directive 2001/14/EC

Directive 2001/14/EC is hereby amended as follows:

1. the title shall be replaced by the following:

Directive 2001/14/EC of the European Parliament and of the Council of 26 February 2001 on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure

2. in Article 30(2), point (f) shall be replaced by the following:

(f) arrangements for access in accordance with Article 10 of Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways⁽²⁾ as amended by Directive 2004/51/EC of the European Parliament and of the Council of 30 April 2004 amending Council Directive 91/440/EEC on the development of the Community's railways⁽³⁾.

3. Article 32 shall be deleted,

4. in Article 34, paragraph 2 shall be replaced by the following:

2. At the request of a Member State or on its own initiative the Commission shall, in a specific case, examine the application and enforcement of provisions concerning charging, capacity allocation, and within two months of receipt of such a request decide in accordance with the procedure referred to in Article 35(2) whether the related measure may continue to be applied. The Commission shall communicate its decision to the European Parliament, the Council and to the Member States.

Article 31

Report and further Community action

The Commission shall submit to the European Parliament and to the Council before 30 April 2007 and every five years thereafter a report on the implementation of this Directive.

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

Article 32

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, non-discriminatory and dissuasive.

The Member States shall notify those rules to the Commission by the date specified in Article 33 and shall notify it without delay of any subsequent amendment affecting them.

Article 33

Implementation

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 April 2006 at the latest. They shall forthwith inform the Commission thereof.

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. The methods of making such reference shall be laid down by Member States.

Article 34

Entry into force

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

Article 35

Addressees

This Directive is addressed to the Member States.

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- (1) [^{F2}OJ L 191, 18.7.2008, p. 1.]
- (2) OJ L 237, 24.8.1991, p. 25.
- (3) OJ L 164, 30.4.2004, p. 164.?

Textual Amendments

- F2** Inserted by Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways (Railway Safety Directive) (Text with EEA relevance).