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and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) (repealed)

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(Railway Safety Directive) (repealed)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 71(1) thereof,

Having regard to the proposal from the Commission⁽¹⁾,

Having regard to the Opinion of the European Economic and Social Committee⁽²⁾,

Having regard to the Opinion of the Committee of the Regions⁽³⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽⁴⁾, in the light of the joint text approved by the Conciliation Committee on 23 March 2004,

Whereas:

- (1) In order to pursue efforts to establish a single market for rail transport services, initiated by Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways⁽⁵⁾, it is necessary to establish a common regulatory framework for railway safety. Member States have until now developed their safety rules and standards mainly on national lines, based on national technical and operational concepts. Simultaneously, differences in principles, approach and culture have made it difficult to break through the technical barriers and establish international transport operations.
- Directive 91/440/EEC, Council Directive 95/18/EC of 19 June 1995 on the licensing of railway undertakings⁽⁶⁾ and 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 and safety certification⁽⁷⁾ provide the first steps towards regulation of the European rail transport market by opening the market for international rail freight services. However, the provisions on safety have proved to be insufficient and differences between safety requirements remain, which

affect the optimum functioning of rail transport in the Community. It is of particular importance to harmonise the content of safety rules, safety certification of railway undertakings, the tasks and roles of the safety authorities and the investigation of accidents.

- (3) Metros, trams and other light rail systems are in many Member States subject to local or regional safety rules and are often supervised by local or regional authorities and not covered by the requirements on Community interoperability or licensing. Trams are furthermore often subject to road safety legislation and could therefore not be fully covered by railway safety rules. For these reasons and in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty, Member States should be allowed to exclude such local rail systems from the scope of this Directive.
- (4) Safety levels in the Community rail system are generally high, in particular compared to road transport. It is important that safety is at the very least maintained during the current restructuring phase, which will separate functions of previously integrated railway companies and move the railway sector further from self-regulation to public regulation. In line with technical and scientific progress, safety should be further improved, when reasonably practicable and taking into account the competitiveness of the rail transport mode.
- (5) All those operating the railway system, infrastructure managers and railway undertakings, should bear the full responsibility for the safety of the system, each for their own part. Whenever it is appropriate, they should cooperate in implementing risk control measures. Member States should make a clear distinction between this immediate responsibility for safety and the safety authorities' task of providing a national regulatory framework and supervising the performance of the operators.
- (6) The responsibility of infrastructure managers and railway undertakings for operating the railway system does not preclude other actors such as manufacturers, maintenance suppliers, wagon keepers, service providers and procurement entities from assuming responsibility for their products or services in accordance with the provisions of Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system⁽⁸⁾ and of Directive 2001/16/EC of the European Parliament and of the Council of 19 March 2001 on the interoperability of the trans-European conventional rail system⁽⁹⁾ or of other relevant Community legislation.
- (7) Requirements on safety of the subsystems of the trans-European rail networks are laid down in Directive 96/48/EC and Directive 2001/16/EC. However, those Directives do not define common requirements at system level and do not deal in detail with the regulation, management and supervision of safety. When minimum safety levels of the subsystems are defined by technical specifications for interoperability (TSIs) it will be increasingly important to establish safety targets at the system level as well.
- (8) Common safety targets (CSTs) and common safety methods (CSMs) should be gradually introduced to ensure that a high level of safety is maintained and, when and where necessary and reasonably practicable, improved. They should provide tools for assessment of the safety level and the performance of the operators at Community level as well as in the Member States.

- (9) Information on safety of the railway system is scarce and not generally publicly available. It is thus necessary to establish common safety indicators (CSIs) in order to assess that the system complies with the CSTs and to facilitate the monitoring of railway safety performance. However, national definitions relating to the CSIs may apply during a transitional period and due account should therefore be taken of the extent of the development of common definitions of the CSIs when the first set of CSTs is drafted.
- (10) National safety rules, which are often based on national technical standards, should gradually be replaced by rules based on common standards, established by TSIs. The introduction of new specific national rules which are not based on such common standards should be kept to a minimum. New national rules should be in line with Community legislation and facilitate migration towards a common approach to railway safety. All interested parties should therefore be consulted before a Member State adopts a national safety rule that requires a higher safety level than the CSTs. In such cases the new draft rule should be subject to examination by the Commission, which should adopt a Decision if it appears that the draft rule is not in conformity with Community legislation or constitutes a means of arbitrary discrimination or a disguised restriction on rail transport operation between Member States.
- (11) The current situation, in which national safety rules continue to play a role, should be regarded as a transitional stage, leading ultimately to a situation in which European rules will apply.
- (12) The development of CSTs, CSMs and CSIs as well as the need to facilitate progress towards a common approach to railway safety requires technical support at Community level. The European Railway Agency established by Regulation (EC) No /of the European Parliament and of the Council OJ L is set up to issue recommendations concerning CSTs, CSMs and CSIs and further harmonisation measures and to monitor the development of railway safety in the Community.
- (13) In carrying out their duties and fulfilling their responsibilities, infrastructure managers and railway undertakings should implement a safety management system, fulfilling Community requirements and containing common elements. Information on safety and the implementation of the safety management system should be submitted to the safety authority in the Member State concerned.
- (14) The safety management system should take into account the fact that Council Directive 89/391/EC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work⁽¹⁰⁾ and its relevant individual directives are fully applicable to the protection of the health and safety of workers engaged in railway transport. The safety management system should also take account of Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail⁽¹¹⁾.
- (15) To ensure a high level of railway safety and equal conditions for all railway undertakings, they should be subject to the same safety requirements. The safety certificate should give evidence that the railway undertaking has established its safety management system and is able to comply with the relevant safety standards

- and rules. For international transport services it should be enough to approve the safety management system in one Member State and give the approval Community validity. Adherence to national rules on the other hand should be subject to additional certification in each Member State. The ultimate aim should be to establish a common safety certificate with Community validity.
- In addition to the safety requirements laid down in the safety certificate, licensed railway undertakings must comply with national requirements, compatible with Community law and applied in a non-discriminatory manner, relating to health, safety and social conditions, including legal provisions relating to driving time, and the rights of workers and consumers as provided for in Articles 6 and 12 of Directive 95/18/EC.
- (17) Every infrastructure manager has a key responsibility for the safe design, maintenance and operation of its rail network. In parallel to safety certification of railway undertakings the infrastructure manager should be subject to safety authorisation by the safety authority concerning its safety management system and other provisions to meet safety requirements.
- (18) Member States should make efforts to assist applicants wishing to enter the market as railway undertakings. In particular they should provide information and act promptly on requests for safety certification. For railway undertakings operating international transport services, it is important for the procedures to be similar in different Member States. Although the safety certificate will contain national parts for the foreseeable future, it should nevertheless be possible to harmonise the common parts of it and facilitate the creation of a common template.
- (19) Certification of train staff and authorisation of placing in service of in-use rolling stock for the different national networks are often insurmountable barriers to new entrants. Member States should ensure that facilities for the training and certification of train staff necessary to meet requirements under national rules are available to railway undertakings applying for a safety certificate. A common procedure should be established for authorisation of placing in service of in-use rolling stock.
- (20) Driving times and rest periods for train drivers and train staff performing safety tasks have an important impact on the safety level of the rail system. These aspects fall under Articles 137 to 139 of the Treaty and are already subject to negotiations between the social partners under the Sectoral Dialogue Committee set up in accordance with Commission Decision 98/500/EC⁽¹²⁾.
- (21) The development of a safe Community railway system requires the establishment of harmonised conditions for delivering the appropriate licences to train drivers and onboard accompanying staff performing safety tasks, for which the Commission has announced its intention to propose further legislation in the near future. As far as other staff charged with safety-critical tasks are concerned, their qualifications are already being specified under Directives 96/48/EC and 2001/16/EC.
- (22) As part of the new common regulatory framework for railway safety, national authorities should be set up in all Member States to regulate and supervise railway safety. To facilitate cooperation between them at Community level, they should be given

the same minimum tasks and responsibilities. The national safety authorities should be granted a high degree of independence. They should carry out their tasks in an open and non-discriminatory way to help to create a single Community rail system and cooperate to coordinate their decision-making criteria, in particular concerning safety certification of railway undertakings operating international transport services.

- (23) Serious accidents on the railways are rare. However, they can have disastrous consequences and raise concern among the public about the safety performance of the railway system. All such accidents should, therefore, be investigated from a safety perspective to avoid recurrence and the results of the investigations should be made public. Other accidents and incidents could be significant precursors to serious accidents and should also be subject to safety investigations, when it is necessary.
- A safety investigation should be kept separate from the judicial inquiry into the same incident and be granted access to evidence and witnesses. It should be carried out by a permanent body that is independent of the actors of the rail sector. The body should function in a way which avoids any conflict of interest and any possible involvement in the causes of the occurrences that are investigated; in particular, its functional independence should not be affected if it is closely linked to the national safety authority or regulator of railways for organisational and legal structure purposes. Its investigations should be carried out under as much openness as possible. For each occurrence the investigation body should establish the relevant investigation group with necessary expertise to find the immediate causes and underlying causes.
- (25) The reports on investigations and any findings and recommendations provide crucial information for the further improvement of railway safety and should be made publicly available at Community level. Safety recommendations should be acted upon by the addressees and actions reported back to the investigating body.
- (26) Since the objectives of the proposed action, namely to coordinate activities in the Member States to regulate and supervise safety and to investigate accidents and to establish at Community level common safety targets, common safety methods, common safety indicators and common requirements of safety certificates, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.
- (27) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedure for the exercise of implementing powers conferred on the Commission⁽¹³⁾.
- (28) This Directive aims at reorganising and bringing together the relevant Community legislation on railway safety. Consequently, provisions for safety certification of railway undertakings that were previously set out in Directive 2001/14/EC should, together with all references to safety certification, be repealed. Directive 95/18/EC included requirements on safety qualifications of operational staff and on safety of rolling stock that are covered by the requirements on safety certification of this Directive and

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- should therefore no longer be part of the licensing requirements. A licensed railway undertaking should hold a safety certificate in order to be granted access to the railway infrastructure.
- (29) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive,

HAVE ADOPTED THIS DIRECTIVE:

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:

- harmonising the regulatory structure in the Member States; (a)
- (b) defining responsibilities between the actors;
- (c) developing common safety targets and common safety methods with a view to greater harmonisation of national rules;
- requiring the establishment, in every Member State, of a safety authority and an (d) accident and incident investigating body;
- (e) defining common principles for the management, regulation and supervision of railway safety.

Article 2

Scope

- 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.
- Member States may exclude from the measures they adopt in implementation of this Directive:
 - a metros, trams and other light rail systems;
 - 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;
 - privately owned railway infrastructure that exists solely for use by the infrastructure owner for its own freight operations.

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.

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.

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

This shall be without prejudice to the responsibility of each manufacturer, maintenance supplier, wagon keeper, 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.

Article 5

Common safety indicators

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 -- (14); they shall be reported on in the annual report the following year.

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

Before ...⁽¹⁵⁾ Annex I shall be revised in accordance with the procedure referred to in Article 27(2), in particular to include common definitions of the CSI and common methods to calculate accident costs.

Article 6

Common safety methods

A first set of CSMs, covering at least the methods described in paragraph 3(a), shall be adopted by the Commission, before...⁽¹⁶⁾, in accordance with the procedure referred to in Article 27(2). They shall be published in the Official Journal of the European Union.

A second set of CSMs, covering the remaining part of the methods as described in paragraph 3, shall be adopted by the Commission before...⁽¹⁷⁾, in accordance with the procedure referred 1 in Article 27(2). They shall be published in the Official Journal of the European Union.

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).

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

- as far as they are not yet covered by TSIs, methods to check that the structural subsystems of the trans-European high-speed and conventional rail systems are operated and maintained in accordance with the relevant essential requirements.
- 4 The CSMs shall be revised at regular intervals, in accordance with the procedure referred to in Article 27(2), taking into account the experience gained from their application and the global development of railway safety and the obligations on Member States laid down in Article 4(1).
- 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.

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).
- 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. They shall be adopted by the Commission, before...⁽¹⁸⁾, in accordance with the procedure referred to in Article 27(2), and shall be published in the Official Journal of the European Union.

The second set of draft CSTs shall be based on the experiences gained from the first set of CSTs and their implementation. They shall reflect any priority areas where safety needs to be further improved. They shall be adopted by the Commission, before...⁽¹⁹⁾, in accordance with the procedure referred to in Article 27(2) and shall be published in the Official Journal of the European Union.

All proposals for draft and revised CSTs shall reflect the obligations on Member States laid down in Article 4(1). Such proposals shall be accompanied by an assessment of the estimated costs and benefits, indicating their likely impact for all the operators and economic agents involved and their impact on the societal acceptance of risk. They shall contain a timetable for gradual implementation, where necessary, in particular to take account of the nature and extent of investment required to apply them. They shall analyse the possible impact on TSI for the subsystems and contain, where appropriate, consequential proposals for amendments to the TSI.

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- 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.
- 5 The CSTs shall be revised at regular intervals, in accordance with the procedure referred to in Article 27(2), taking into account the global development of railway safety.
- 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).

Article 8

National safety rules

- 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...⁽²⁰⁾ 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.

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

- 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.
- 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
- 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.
- 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.

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CHAPTER III

SAFETY CERTIFICATION AND AUTHORISATION

Article 10

Safety certificates

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.

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 operate 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
 - b certification confirming acceptance of the provisions adopted by the railway undertaking to meet specific requirements necessary for the safe operation of the relevant network. The requirements may include application of TSIs and national safety rules, acceptance of staff's certificates and authorisation to place in service the rolling stock used by the railway undertaking. 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.

- 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.

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.

- 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...⁽²¹⁾ 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.

Article 11

Safety authorisation of infrastructure managers

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.
- 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.

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Article 12

Application requirements relating to safety certification and safety authorisation

- 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.
- 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.

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.

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.

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.

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- 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.
- 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.

Article 14

Placing in service of in-use rolling stock

- Rolling stock that has been authorised to be placed in service in one Member State in accordance with Article 10(2)(b) and is not fully covered by the relevant TSIs shall be authorised to be placed in service in another or other Member States in accordance with this Article, if an authorisation is required by the latter Member State or States.
- The railway undertaking applying for authorisation to place rolling stock in service in another Member State shall submit a technical file concerning the rolling stock or type of rolling stock to the relevant safety authority, indicating its intended use on the network. The file shall contain the following information:
 - evidence that the rolling stock has been authorised to be placed in service in another Member State and records that show its history of operation, maintenance and, where applicable, technical modifications undertaken after the authorisation;
 - relevant technical data, maintenance programme and operational characteristics requested by the safety authority and needed for its complementary authorisation;
 - evidence on technical and operational characteristics that shows that the rolling stock is in compliance with the energy supply system, the signalling and control command system, the track gauge and infrastructure gauges, the maximum allowed axle load and other constraints of the network:
 - information on exemptions from national safety rules that are needed to grant authorisation and evidence, based on risk assessment, showing that the acceptance of the rolling stock does not introduce undue risks to the network.
- The safety authority may request that test runs on the network be undertaken to verify compliance with the restrictive parameters referred to in paragraph 2(c) and shall in that case prescribe their range and content.
- The safety authority shall adopt its decision on an application in accordance with this Article without delay and not later than four months after the complete technical file, including documentation of the test runs, has been submitted. The certificate of authorisation may contain conditions for use and other restrictions.

Article 15

Harmonisation of safety certificates

Before...(22), 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).

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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.
- The safety authority shall be entrusted with at least the following tasks:
 - a authorising the bringing into service of the structural subsystems constituting the trans-European high-speed rail system in accordance with Article 14 of Directive 96/48/EC and checking that they are operated and maintained in accordance with the relevant essential requirements;
 - 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;
 - 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;
 - g supervising that rolling stock is duly registered and that safety-related information in the national register, established in accordance with Article 14 of Directive 96/48/EC and of Directive 2001/16/EC, 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.

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

- 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.
- The safely 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.

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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;
 - 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.
- The investigation shall be accomplished independently of any judicial inquiry.

Article 21

Investigating body

- 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.
- 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.
- 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.
- 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.

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Article 22

Investigation procedure

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.
- 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

- 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.
- 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

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.
- 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

Article 26

Adaptation of Annexes

The Annexes shall be adapted to technical and scientific progress, in accordance with the procedure referred to in Article 27(2).

Article 27

Committee procedure

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

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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.

- 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.
- 4 The Committee shall adopt its Rules of Procedure.

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).
- 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.

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⁽²³⁾ as amended by Directive 2004/xx/EC of the European Parliament and of the Council of... amending Council Directive 91/440/EEC on the development of the Community's railways⁽²⁴⁾.
- 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...⁽²⁵⁾ 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 ... (26) at the latest. They shall forthwith inform the Commission thereof.

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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.

Done at Strasbourg, 29 April 2004.

For the European Parliament

The President

P. COX

For the Council

The President

M. MCDOWELL

ANNEX I

Common Safety Indicators

Common Safety Indicators to be reported by the safety authorities:

Indicators relating to activities referred to in Article 2(2), (a) and (b), should be accounted for separately, if they are submitted.

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

For indicators relating to accidents under heading 1 below, Regulation (EC) No 91/2003 of the European Parliament and of the Council of 16 December 2002 on rail transport statistics⁽²⁷⁾ shall be applied as far as the information is available.

- (1) Indicators relating to accidents
 - 1. Total and relative (to train kilometres) number of accidents and a break-down on the following types of accidents:
 - collisions of trains, including collisions with obstacles within the clearance gauge,
 - derailments of trains.
 - level-crossing accidents, including accidents involving pedestrians at level-crossings,
 - accidents to persons caused by rolling stock in motion, with the exception of suicides,
 - suicides,
 - fires in rolling stock,
 - others.

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

- 2. Total and relative (to train kilometres) number of persons seriously injured and killed by type of accident divided into the following categories:
 - passengers (also in relation to total number of passenger-kilometres),
 - employees including the staff of contractors,
 - level-crossing users,
 - unauthorised persons on railway premises,
 - others.
- (2) Indicators relating to incidents and near-misses
 - 1. Total and relative (to train kilometres) number of broken rails, track buckles and wrong-side signalling failures.
 - 2. Total and relative (to train kilometres) number of signals passed at danger.
 - 3. Total and relative (to train kilometres) number of broken wheels and axles on rolling stock in service.

- (3) Indicators relating to consequences of accidents
 - 1. Total and relative (to train kilometres) costs in euro of all accidents where, if possible, the following costs should be calculated and included:
 - deaths and injuries,
 - compensation for loss of or damage to property of passengers, staff
 or third parties including damage caused to the environment,
 - replacement or repair of damaged rolling stock and railway installations,
 - delays, disturbances and re-routing of traffic, including extra costs for staff and loss of future revenue.

From the above costs shall be deducted indemnity or compensation recovered or estimated to be recovered from third parties such as motor vehicle owners involved in level crossing accidents. Compensation recovered by insurance policies held by railway undertakings or infrastructure managers shall not be deducted.

- 2. Total and relative (to number of hours worked) number of working hours of staff and contractors lost as a consequence of accidents.
- (4) Indicators relating to technical safety of infrastructure and its implementation
 - 1. Percentage of tracks with Automatic Train Protection (ATP) in operation, percentage of train kilometres using operational ATP systems.
 - 2. Number of level crossings (total and per line kilometre). Percentage of level crossings with automatic or manual protection.
- (5) Indicators relating to the management of safety

Internal audits accomplished by infrastructure managers and railway undertakings as set out in the documentation of the safety management system. Total number of accomplished audits and the number as a percentage of audits required (and/or planned).

(6) Definitions

The reporting authorities may use nationally applied definitions of the indicators and methods for calculation of costs when data according to this Annex are submitted. All definitions and calculation methods in use shall be explained in an Annex to the annual report described in Article 18.

ANNEX II

Notification of national safety rules

National safety rules that are to be notified to the Commission according to the procedure described in Article 8 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. rules concerning requirements for the authorisation of placing in service and maintenance of new and substantially altered rolling stock that is not yet covered by a TSI. The notification shall include rules for exchange of rolling stock between railway undertakings, registration systems and requirements on testing procedures;
- 4. common operating rules of the railway network that are not yet covered by TSIs, including rules relating to the signalling and traffic management system;
- 5. rules laying down requirements on additional internal operating rules (company rules) that must be established by infrastructure managers and railway undertakings;
- 6. 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;
- 7. rules concerning the investigation of accidents and incidents.

ANNEX III

Safety Management Systems

1. Requirements on the safety management system

The safety management system must be documented in ail relevant parts and shall in particular describe the distribution of responsibilities within the organisation of the infrastructure manager or the railway undertaking. It shall show how control by the management on different levels is secured, how staff and their representatives on all levels are involved and how continuous improvement of the safety management system is ensured.

2. Basic elements of the safety management system

The basic elements of the safety management system are:

- (a) a safety policy approved by the organisation's chief executive and communicated to all staff;
- (b) qualitative and quantitative targets of the organisation for the maintenance and enhancement of safety, and plans and procedures for reaching these targets;
- (c) procedures to meet existing, new and altered technical and operational standards or other prescriptive conditions as laid down
 - in TSIs, or
 - in national safety rules referred to in Article 8 and Annex II, or
 - in other relevant rules, or
 - in authority decisions,

and procedures to assure compliance with the standards and other prescriptive conditions throughout the life-cycle of equipment and operations;

- (d) procedures and methods for carrying out risk evaluation and implementing risk control measures whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operations;
- (e) provision of programmes for training of staff and systems to ensure that the staffs competence is maintained and tasks carried out accordingly;

- (f) arrangements for the provision of sufficient information within the organisation and, where appropriate, between organisations operating on the same infrastructure;
- (g) procedures and formats for how safety information is to be documented and designation of procedure for configuration control of vital safety information;
- (h) procedures to ensure that accidents, incidents, near misses and other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken;
- (i) provision of plans for action and alerts and information in case of emergency, agreed upon with the appropriate public authorities;
- (j) provisions for recurrent internal auditing of the safety management system.

ANNEX IV

Declarations for network specific part of safety certificate

The following documents must be submitted to enable the safety authority to deliver the network-specific part of the safety certificate:

- documentation from the railway undertaking on the TSIs or parts of TSIs and, where relevant, national safety rules and other rules applicable to its operations, its staff and its rolling stock and how compliance is ensured by the safety management system,
- documentation from the railway undertaking on the different categories of staff employed or contracted for the operation, including evidence that they meet requirements of TSIs or national rules and have been duly certified,
- documentation from the railway undertaking on the different types of rolling stock used for the operation, including evidence that they meet requirements of TSIs or national rules and have been duly certified.

To avoid duplication of work and to reduce the amount of information only summary documentation should be submitted concerning elements that comply with TSIs and other requirements of Directives 96/48/EC and 2001/16/EC.

ANNEX V

Principal content of accident and incident investigation report

(1) Summary

The summary shall contain a short description of the occurrence, when and where it took place and its consequences. It shall state the direct causes as well as contributing factors and underlying causes established by the investigation. The main recommendations shall be quoted and information shall be given on the addressees.

- (2) Immediate facts of the occurrence
 - 1. The occurrence:
 - date, exact time and location of the occurrence,

5.

Documentation on the operating system:

(3)

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	_	description of the events and the accident site including the efforts of the rescue and emergency services, the decision to establish an investigation, the composition of the team of investigators and the conduct of the investigation.	
2	The he		
2.	i ne ba	ckground to the occurrence: staff and contractors involved and other parties and witnesses,	
	—	the trains and their composition including the registration numbers of the items of rolling stock involved,	
	_	the description of the infrastructure and signalling system - track types, switches, interlocking, signals, train protection,	
		means of communication,	
	_	works carried out at or in the vicinity of the site,	
	_	trigger of the railway emergency plan and its chain of events, trigger of the emergency plan of the public rescue services, the police and the medical services and its chain of events.	
3.	Fatalit	ies, injuries and material damage:	
	_	passengers and third parties, staff, including contractors,	
	_	cargo, luggage and other property,	
	_	rolling stock, infrastructure and the environment.	
4.	Extern	al circumstances:	
		weather conditions and geographical references.	
Record	of invest	tigations and inquiries	
1.	Summ	ary of testimonies (subject to the protection of identity of the persons):	
	_	railway staff, including contractors,	
		other witnesses.	
2.	The safety management system:		
		the framework organisation and how orders are given and carried out,	
	_	requirements on staff and how they are enforced,	
	_	routines for internal checks and audits and their results,	
		interface between different actors involved with the infrastructure.	
3.	Rules and regulations:		
		relevant Community and national rules and regulations,	
		other rules such as operating rules, local instructions, staff requirements, maintenance prescriptions and applicable standards.	
4.	Functioning of rolling stock and technical installations:		
	_	signalling and control command system, including registration	
		from automatic data recorders, infrastructure,	
		communications equipment,	
	_	rolling stock, including registration from automatic data recorders.	

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- measures taken by staff for traffic control and signalling,
- exchange of verbal messages in connection with the occurrence, including documentation from recordings,
- measures taken to protect and safeguard the site of the occurrence.
- 6. Man-machine-organisation interface:
 - working time applied to the staff involved,
 - medical and personal circumstances with influence on the occurrence, including existence of physical or psychological stress,
 - design of equipment with impact on man-machine interface.
- 7. Previous occurrences of a similar character.

(4) Analysis and conclusions

- 1. Final account of the event chain:
 - establishing the conclusions on the occurrence, based on the facts established in heading (3).

2. Discussion:

— analysis of the facts established in heading (3) with the aim of drawing conclusions as to the causes of the occurrence and the performance of the rescue services.

3. Conclusions:

- direct and immediate causes of the occurrence including contributory factors relating to actions taken by persons involved or the condition of rolling stock or technical installations,
- underlying causes relating to skills, procedures and maintenance,
- root causes relating to the regulatory framework conditions and application of the safety management system.

4. Additional observations:

 deficiencies and shortcomings established during the investigation, but without relevance to the conclusions on causes.

(5) Measures that have been taken

Record of measures already taken or adopted as a consequence of the occurrence.

(6) Recommendations

- (1) OJ C 126 E, 28.5.2002, p. 332.
- (2) OJ C 61, 14.3.2003, p. 131.
- (**3**) OJ C 66, 19.3.2003, p. 5.
- (4) Opinion of the European Parliament of 14 January 2003 (OJ C 38 E, 12.2.2004, p. 92), Council Common Position of 26 June 2003OJ C 270 E, 11.11.2003, p. 25) and Position of the European Parliament of 23 October 2003 (not yet published in the Official Journal). Legislative Resolution of the European Parliament of 22 April 2004 and Council Decision of 26 April 2004.
- (5) OJ L 237, 24.8.1991, p. 25. Directive as amended by Directive 2001/12/EC of the European Parliament and of the Council (OJ L 75, 15.3.2001, p. 1).
- (6) OJ L 143, 27.6.1995, p. 70. Directive as amended by Directive 2001/13/EC of the European Parliament and of the Council (OJ L 75, 15.3.2001, p. 26).
- (7) OJ L 75, 15.3.2001, p. 29. Directive as amended by Commission Decision 2002/844/EC (OJ L 289, 26.10.2002, p. 30).
- (8) OJ L 235, 17.9.1996, p. 6.
- (9) OJ L 110, 20.4.2001, p. 1.
- (10) OJ L 183, 29.6.1989, p. 1.
- (11) OJ L 235, 17.9.1996, p. 25. Directive as last amended by Commission Directive 2003/29/EC (OJ L 90, 8.4.2003, p. 47).
- (12) Commission Decision 98/500/EC of 20 May 1998 on the establishment of Sectoral Dialogue Committees promoting the Dialogue between the social partners at European level (OJ L 225, 12.8.1998, p. 27).
- (13) OJ L 184, 17.7.1999, p. 23.
- (14) Two years after the year of entry into force of this Directive.
- (15) Five years after the entry into force of this Directive.
- (16) Four years after the entry into force of this Directive.
- (17) Six years after the entry into force of this Directive.
- (18) Five years after entry into force of this Directive.
- (19) Seven years after entry into force of this Directive.
- (20) Twelve months after the entry into force of this Directive.
- (21) Five years after the entry into force of this Directive.
- (22) Five years after entry into force of this Directive.
- (23) OJ L 237, 24.8.1991, p. 25.
- (24) OJ L "
- (25) Three years after the entry into force of this Directive.
- (26) Two years after the entry into force of this Directive.
- (27) OJ L 14, 21.1.2003, p. 1.