



**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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE
EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and
in particular Articles 71 and 156 thereof,

Having regard to the proposal from the Commission,

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

After consulting the Committee of the Regions,

Acting in accordance with the procedure referred to in Article 251 of
the Treaty ⁽²⁾,

Whereas:

- (1) Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system ⁽³⁾ and 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 ⁽⁴⁾ were substantially amended by Directive 2004/50/EC of the European Parliament and of the Council ⁽⁵⁾. As new amendments are now being introduced, it is appropriate to recast the Directives for the sake of clarity and merge their provisions together into a single instrument with a view to simplification.
- (2) In order to enable citizens of the Union, economic operators and regional and local authorities to benefit to the full from the advantages deriving from the establishing of an area without internal frontiers, it is appropriate, in particular, to improve the interlinking and interoperability of the national rail networks as well as access thereto, implementing any measures that may prove necessary in the field of technical standardisation, as provided for in Article 155 of the Treaty.

⁽¹⁾ OJ C 256, 27.10.2007, p. 39.

⁽²⁾ Position of the European Parliament of 11 December 2007 and Council Decision of 14 May 2008.

⁽³⁾ OJ L 235, 17.9.1996, p. 6. Directive as last amended by Commission Directive 2007/32/EC (OJ L 141, 2.6.2007, p. 63).

⁽⁴⁾ OJ L 110, 20.4.2001, p. 1. Directive as last amended by Directive 2007/32/EC.

⁽⁵⁾ Directive 2004/50/EC of the European Parliament and of the Council of 29 April 2004 amending Council Directive 96/48/EC on the interoperability of the trans-European high-speed rail system and Directive 2001/16/EC of the European Parliament and of the Council on the interoperability of the trans-European conventional rail system (OJ L 164, 30.4.2004, p. 114. Corrected by OJ L 220, 21.6.2004, p. 40).

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- (3) By signing the Protocol adopted in Kyoto on 12 December 1997 the European Union has undertaken to reduce its greenhouse gas emissions. These objectives require an adjustment to the balance between the various modes of transport, and consequently an increase in the competitiveness of rail transport.
- (4) The Community strategy for the integration of environmental and sustainable development concerns into its transport policy highlights the need to act to reduce the environmental impact of transport.
- (5) The commercial operation of trains throughout the rail network requires in particular excellent compatibility between the characteristics of the infrastructure and those of the vehicles, as well as efficient interconnection of the information and communication systems of the different infrastructure managers and railway undertakings. Performance levels, safety, quality of service and cost depend upon such compatibility and interconnection, as does, in particular, the interoperability of the rail system.
- (6) Member States are responsible for ensuring compliance with the safety, health and consumer protection rules applying to the railway networks in general during the design, construction, putting into service and operation of those railways.
- (7) There are major differences between the national regulations and between internal rules and technical specifications which the railways apply, since they incorporate techniques that are specific to the national industries and prescribe specific dimensions and devices and special characteristics. This situation prevents trains from being able to run without hindrance throughout the Community network.
- (8) Over the years, this situation has created very close links between the national railway industries and the national railways, to the detriment of the genuine opening-up of markets. In order to enhance their competitiveness at world level, these industries require an open, competitive European market.
- (9) It is therefore appropriate to define basic essential requirements for the whole of the Community which will apply to its rail system.

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- (10) To achieve these objectives an initial measure was taken by the Council on 23 July 1996 with the adoption of Directive 96/48/EC. The European Parliament and the Council subsequently adopted Directive 2001/16/EC.
- (11) The entry into force of Directives 2001/12/EC of the European Parliament and of the Council of 26 February 2001 amending Council Directive 91/440/EEC on the development of the Community's railways⁽¹⁾, 2001/13/EC of the European Parliament and of the Council of 26 February 2001 amending Council Directive 95/18/EC on the licensing of railway undertakings⁽²⁾ and 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⁽³⁾ has had an impact on the implementation of interoperability. As in the case of other transport modes, the extension of access rights must be accompanied by the requisite harmonisation measures. It is therefore necessary to implement interoperability on the whole network by extending progressively the geographical scope of Directive 2001/16/EC. It is also necessary to extend the legal basis of Directive 2001/16/EC to Article 71 of the Treaty, on which Directive 2001/12/EC is founded.
- (12) The development of technical specifications for interoperability (TSIs) has shown the need to clarify the relationship between the essential requirements and the TSIs on the one hand, and the European standards and other documents of a normative nature on the other. In particular, a clear distinction should be drawn between the standards or parts of standards which must be made mandatory in order to achieve the objectives of this Directive, and the 'harmonised' standards that have been developed in the spirit of the new approach to technical harmonisation and standardisation.
- (13) As a rule, European specifications are developed in the spirit of the new approach to technical harmonisation and standardisation. They enable a presumption to be made of conformity with certain essential requirements of this Directive, particularly in the case of interoperability constituents and interfaces. These European specifications, or the applicable parts thereof, are not mandatory and no explicit reference to these specifications may be made in the TSIs. References to these European specifications are published in the *Official Journal of the European Union*, and Member States publish the references to the national standards transposing the European standards.

⁽¹⁾ OJ L 75, 15.3.2001, p. 1.

⁽²⁾ OJ L 75, 15.3.2001, p. 26.

⁽³⁾ OJ L 75, 15.3.2001, p. 29. Directive as last amended by Directive 2007/58/EC (OJ L 315, 3.12.2007, p. 44).

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- (14) TSIs may in certain cases make an explicit reference to European standards or specifications where this is strictly necessary in order to achieve the objectives of this Directive. Such explicit reference has consequences which must be made clear; in particular, these European standards or specifications become mandatory from the moment the TSI is applicable.
- (15) A TSI sets all the conditions with which an interoperability constituent must conform, and the procedure to be followed in assessing conformity. In addition, it is necessary to specify that every constituent must undergo the procedure for assessing conformity and suitability for the use indicated in the TSIs, and have the corresponding certificate.
- (16) When developing new TSIs the aim should always be to ensure compatibility with the existing authorised system. This will help to promote the competitiveness of rail transport and prevent unnecessary additional costs through the requirement of upgrading or renewal of existing authorised subsystems to ensure backward compatibility. In those exceptional cases where it will not be possible to ensure compatibility, TSIs may establish the framework necessary to decide whether the existing subsystem may need to be re-authorised, and the corresponding deadlines.
- (17) It is necessary for safety reasons to require Member States to assign an identification code to each vehicle placed in service. The vehicle should then be entered in a national vehicle register. The registers must be open to consultation by all Member States and by certain Community economic players. The registers should be consistent as regards the data format. They should therefore be covered by common operational and technical specifications.
- (18) The procedure to be followed in the case of essential requirements applicable to a subsystem which have not yet been covered by detailed specifications in the corresponding TSI should be specified. In such case, the bodies responsible for the conformity assessment and verification procedures should be the notified bodies referred to in Article 20 of Directives 96/48/EC and 2001/16/EC.

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- (19) The distinction between a high-speed rail system and a conventional rail system does not warrant two separate directives. The procedures for developing TSIs are the same for both systems, as are those for the certification of the interoperability constituents and the subsystems. The essential requirements are practically identical, as is the subdivision of the system into subsystems for which technical specifications have to be prepared. Moreover, since trains have to be able to move freely from the high-speed network to the conventional network, the technical specifications for the two systems overlap to a large extent. Work on developing the TSIs has shown that, for certain subsystems, a single TSI can serve both systems. It is therefore appropriate to combine Directives 96/48/EC and 2001/16/EC.
- (20) Directive 2004/50/EC provided for the progressive extension of the scope of Directive 2001/16/EC as new TSIs were adopted or existing ones revised. When this Directive enters into force, its scope will cover conventional and high-speed European networks as defined in Decision No 1692/96/EC of the European Parliament and of the Council of 23 July 1996 on Community guidelines for the development of the trans-European transport network ⁽¹⁾, and the vehicles likely to travel on those networks. The scope will be progressively extended to the whole network and all vehicles, provided that an impact assessment shows the economic benefit of so doing.
- (21) In view of the gradual approach to eliminating obstacles to the interoperability of the rail system and of the time consequently required for the adoption of TSIs, steps should be taken to avoid a situation where Member States adopt new national rules or undertake projects that increase the diversity of the present system.
- (22) The adoption of a gradual approach satisfies the special needs of the objective of the interoperability of the rail system, which is characterised by old national infrastructure and vehicles requiring heavy investment for adaptation or renewal, and particular care should be taken not to penalise rail economically *vis-à-vis* other modes of transport.

⁽¹⁾ OJ L 228, 9.9.1996, p. 1. Decision as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

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- (23) In its Legislative Resolutions of 10 March 1999 on the railway package, the European Parliament asked that the progressive opening up of the rail sector go hand-in-hand with the fastest and most effective technical harmonisation measures possible.
- (24) The Council, at its meeting on 6 October 1999, asked the Commission to propose a strategy on improving the interoperability of rail transport and reducing bottlenecks with a view to eliminating technical, administrative and economic obstacles to the interoperability of networks without delay while guaranteeing a high level of safety and training and qualifications of the staff concerned.
- (25) Pursuant to Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways ⁽¹⁾, railway companies must have increased access to Member States' rail networks, which in turn requires the interoperability of infrastructure, equipment, rolling stock and systems of management and operation, including those staff qualifications and hygiene and safety conditions at work required for the operation and maintenance of the subsystems in question and for the implementation of each TSI. However, it is not the aim of this Directive, directly or indirectly, to harmonise working conditions in the rail sector.
- (26) In view of the extent and complexity of the rail system, it has proved necessary, for practical reasons, to break it down into the following subsystems: infrastructure, control-command and signalling, energy, rolling stock, operation and traffic management, maintenance and telematics applications for passenger and freight services. For each of these subsystems the essential requirements must be specified and the technical specifications determined for the whole of the Community, particularly in respect of constituents and interfaces, in order to meet these essential requirements. The same system is broken down into fixed and mobile elements comprising on the one hand, the network, composed of the lines, stations, terminals, and all kinds of fixed equipment needed to ensure safe and continuous operation of the system and on the other hand, all vehicles travelling on this network. Therefore, for the purposes of this Directive, a vehicle is composed of one subsystem (rolling stock) and where applicable one or more parts of other subsystems (mainly the onboard part of the control-command and signalling subsystem and the onboard part of the energy subsystem).

⁽¹⁾ OJ L 237, 24.8.1991, p. 25. Directive as last amended by Directive 2007/58/EC.

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- (27) Implementation of the provisions on the interoperability of the rail system should not create unjustified barriers in cost-benefit terms to the preservation of the existing rail network of each Member State, but must endeavour to retain the objective of interoperability.
- (28) TSIs also have an impact on the conditions of use of rail transport by users, and it is therefore necessary to consult these users on aspects concerning them.
- (29) Each Member State concerned should be allowed not to apply certain TSIs in special cases, provided that there are procedures to ensure that these derogations are justified. Article 155 of the Treaty requires Community activities in the field of interoperability to take account of the potential economic viability of projects.
- (30) The drawing up of TSIs and their application to the rail system should not impede technological innovation, which should be directed towards improving economic performance.
- (31) Advantage should be taken of the interoperability of the rail system, particularly in the case of freight, to bring about the conditions for greater interoperability between modes of transport.
- (32) To comply with the appropriate provisions on procurement procedures in the rail sector and in particular Directive 2004/17/EC of the European Parliament and of the Council ⁽¹⁾, the contracting entities should include technical specifications in the general documents or in the terms and conditions for each contract. To this end it is necessary to build up a body of European specifications in order to serve as references for these technical specifications.
- (33) An international system of standardisation capable of generating standards which are actually used by those involved in international trade and which meet the requirements of Community policy would be in the Community's interest. The European standardisation bodies must therefore continue their cooperation with the international standardisation bodies.

⁽¹⁾ Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1). Directive as last amended by Commission Regulation (EC) No 213/2008 (OJ L 74, 15.3.2008, p. 1).

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- (34) The contracting entities are to define the further requirements needed to complete European specifications or other standards. These specifications should meet the essential requirements that have been harmonised at Community level and which the rail system must satisfy.
- (35) The procedures governing the assessment of conformity or of suitability of use of constituents should be based on the use of the modules covered by Council Decision 93/465/EEC ⁽¹⁾. As far as possible and in order to promote industrial development, it is appropriate to draw up the procedures involving a system of quality assurance.
- (36) Conformity of constituents is mainly linked to their area of use in order to guarantee the interoperability of the system and not only to their free movement on the Community market. The suitability for use of the most critical constituents as regards safety, availability or system economy should be assessed. It is therefore not necessary for a manufacturer to affix the CE marking to constituents that are subject to the provisions of this Directive. On the basis of the assessment of conformity and/or suitability for use, the manufacturer's declaration of conformity should be sufficient.
- (37) Manufacturers are nonetheless obliged to affix the CE marking to certain components in order to certify their compliance with other Community provisions relating to them.
- (38) When a TSI enters into force, a number of interoperability constituents are already on the market. A transition period should be provided for so that these constituents can be integrated into a subsystem even if they do not strictly conform to that TSI.
- (39) The subsystems constituting the rail system should be subjected to a verification procedure. This verification must enable the authorities responsible for authorising their placing in service to be certain that, at the design, construction and putting into service stages, the result is in line with the regulations and technical and operational provisions in force. It must also enable manufacturers to be able to count upon equality of treatment whatever the country. It is therefore necessary to lay down one or more modules defining the principles and conditions applying to 'EC' verification of subsystems.
- (40) After a subsystem is placed in service, care should be taken to ensure that it is operated and maintained in accordance with the essential requirements relating to it. Under Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways (Railway Safety Directive) ⁽²⁾, responsibility for meeting these requirements lies, for their respective subsystems, with the infrastructure manager or the railway undertaking. Member States can check compliance with these requirements when granting safety certificates and safety approvals pursuant to Articles 10 and 11 of the Railway Safety Directive.

⁽¹⁾ Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives (OJ L 220, 30.8.1993, p. 23).

⁽²⁾ OJ L 164, 30.4.2004, p. 44. Corrected by OJ L 220, 21.6.2004, p. 16.

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- (41) As far as vehicles are concerned, the procedure for placing in service should be clarified taking into account the definition of vehicle which is composed of one or more subsystems. In addition, as Directives 96/48/EC and 2001/16/EC deal with new and upgraded subsystems and Directive 2004/49/EC deals with in-use vehicles, all provisions regarding authorisations for placing in service of vehicles should be integrated in this Directive. Furthermore, with a view to facilitating the placing in service of vehicles and reducing administrative burdens, a procedure for authorisation of vehicle types should be added. In order to facilitate this procedure and help identify vehicle types, a European register of authorised types of vehicles should be set up and maintained by the European Railway Agency (hereinafter referred to as the Agency).
- (42) Experience has shown that the implementation of such a procedure at national level is often complicated and subject to different national requirements that lack transparency, or even duplicate each other. Consequently, this procedure poses a major obstacle to the creation of new railway undertakings, particularly in the freight sector. Steps should therefore be taken to clarify and simplify the procedures for authorising vehicles. Firstly, the general principle that one authorisation is sufficient for the whole Community rail network should be established. Secondly, the procedure for authorising vehicles which are TSI conform should be simpler and quicker than in the case of non-TSI conform. Thirdly, the principle of mutual recognition should be applied as far as possible: when a vehicle has already been placed in service in one Member States, other Member States should not invoke national rules to impose unnecessary requirements and redundant verifications, unless these are strictly necessary for verifying the technical compatibility of the vehicle with the relevant network. To this end national rules should be classified and compared according to a check-list in order to determine to which extent national rules can be declared as equivalent in terms of requirements, performances and safety. Fourthly, the principle of legal certainty as regards the outcome of the procedure should be pursued. To this end, in the absence of a decision of a national safety authority within the prescribed time limits an applicant should be authorised to place in service a vehicle. Such an authorisation would only be possible if the vehicle has already been authorised in another Member State. In addition, it would only be possible for a railway undertaking or an infrastructure manager duly certified in accordance with Directive 2004/49/EC to use such a vehicle under their full responsibility.
- (43) The authorisation procedures for TSI conform and non-TSI conform vehicles are different. There may be cases where the choice of the procedure is not straightforward. Vehicles which come within the scope of TSI conform vehicles should be those vehicles where all the relevant TSIs have entered into force, including at least the TSI on rolling stock. This would mean that a significant part of the essential requirements has been laid down. For example, until such time that the conventional TSI on locomotives has entered into force, locomotives fall within scope of non-TSI conform vehicles, even though they might comply with other relevant TSIs in force at the time of their placing in service.

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- (44) If certain technical aspects corresponding to the essential requirements cannot be explicitly covered in a TSI, they are identified in an annex to the TSI as open points. When a TSI conform vehicle has already been authorised in one Member State, additional authorisations should only consider those open points that relate to technical compatibility between the vehicle and the network.
- (45) The list of parameters to be checked in conjunction with the placing in service of non-TSI conform vehicles is a key element for the achievement of interoperability of railway systems, in particular with regard to existing vehicles. This list takes into account experience across a limited number of networks. Therefore it is necessary that the Agency review the parameters in Annex VII and make the recommendations it considers appropriate to the Commission.
- (46) The 'EC' verification procedure should be based on TSIs. These TSIs are subject to the provisions of Article 18 of Directive 93/38/EEC. The notified bodies responsible for examining the procedures for conformity assessment and suitability for the use of constituents, together with the procedure for the assessment of subsystems must, in particular in the absence of any European specification, coordinate their decisions as closely as possible.
- (47) The notified bodies should be structured in such a way as to meet the criteria which must apply to this type of body in all sectors of the new approach to technical harmonisation and conformity verification, especially criteria relating to independence and competence.
- (48) TSIs will be revised at regular intervals. When errors are discovered, an ad hoc rapid procedure should be set up in such a way that a provisional corrigendum is first agreed in the context of a committee and then published by the Agency. This will allow an earlier use of this corrigendum by all stakeholders, including industry, notified bodies and authorities, pending a formal revision of the TSI by the Commission. In order to avoid confusion with official corrigenda of the Commission, the term technical opinion will be used. This procedure is in line with the mandate adopted by the Commission in Decision of 13 July 2007 concerning a framework mandate to the European Railway Agency for the performance of certain activities under Directives 96/48/EC and 2001/16/EC. However, if the TSI needs to be amended because of an important or critical error, a revision procedure should be applied.
- (49) The definition of the keeper should be as close as possible to the definition used in the 1999 Convention concerning International Carriage by Rail (COTIF). Many entities can be identified as a keeper of a vehicle, such as the owner, a company carrying on a business with a fleet of wagons, a company leasing vehicles to a railway undertaking, a railway undertaking or an infrastructure manager using vehicles for maintaining its infrastructure. These entities have control over the vehicle with a view to its use as a means of transport by the railway undertakings and the infrastructure managers. In order to avoid any doubt, the keeper should be clearly identified in the national vehicle registers.

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- (50) 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 procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾.
- (51) In particular, the Commission should be empowered to adopt and update the TSIs. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (52) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of measures designed to amend non-essential elements of this Directive by supplementing it with TSIs or amendments thereto.
- (53) Since the objective of this Directive, namely interoperability within the rail system in Community-wide scale, cannot be sufficiently achieved by the Member States since no individual Member State is in a position to take the action needed in order to achieve such interoperability and can therefore 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 that objective.
- (54) In accordance with point 34 of the Interinstitutional Agreement on better law-making ⁽²⁾, Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.
- (55) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with the earlier Directives. The obligation to transpose the provisions which are unchanged arises under the earlier Directives.
- (56) Article 14 of Directive 2004/49/EC and Directives 96/48/EC and 2001/16/EC should therefore be repealed,

HAVE ADOPTED THIS DIRECTIVE:

⁽¹⁾ OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

⁽²⁾ OJ C 321, 31.12.2003, p. 1.



CHAPTER I
GENERAL PROVISIONS

Article 1

Purpose and scope

1. This Directive sets out to establish the conditions to be met to achieve interoperability within the Community rail system in a manner compatible with the provisions of Directive 2004/49/EC. These conditions concern the design, construction, placing in service, upgrading, renewal, operation and maintenance of the parts of this system as well as the professional qualifications and health and safety conditions of the staff who contribute to its operation and maintenance.

2. The pursuit of this objective must lead to the definition of an optimal level of technical harmonisation and make it possible to:

- (a) facilitate, improve and develop international rail transport services within the European Union and with third countries;
- (b) contribute to the progressive creation of the internal market in equipment and services for the construction, renewal, upgrading and operation of the rail system within the Community;
- (c) contribute to the interoperability of the rail system within the Community.

3. 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 and vehicles exclusively used on such infrastructure that exist solely for use by the owner for its own freight operations;
- (d) infrastructure and vehicles reserved for a strictly local, historical or touristic use.

4. The scope of the TSIs shall be progressively extended in accordance with Article 8 to the whole rail system, including track access to terminals and main port facilities serving or potentially serving more than one user, without prejudice to the derogations to the application of TSIs as listed in Article 9.

▼B*Article 2***Definitions**

For the purposes of this Directive:

- (a) ‘trans-European rail system’ means the trans-European conventional and high-speed rail systems as set out in Annex I, points 1 and 2, respectively;
- (b) ‘interoperability’ means the ability of a rail system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance for these lines. This ability depends on all the regulatory, technical and operational conditions which must be met in order to satisfy the essential requirements;
- (c) ‘vehicle’ means a railway vehicle that runs 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;
- (d) ‘network’ means the lines, stations, terminals, and all kinds of fixed equipment needed to ensure safe and continuous operation of the rail system;
- (e) ‘subsystems’ means the result of the division of the rail system, as shown in Annex II. These subsystems, for which essential requirements must be laid down, may be structural or functional;
- (f) ‘interoperability constituents’ means any elementary component, group of components, subassembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem, upon which the interoperability of the rail system depends directly or indirectly. The concept of a ‘constituent’ covers both tangible objects and intangible objects such as software;
- (g) ‘essential requirements’ means all the conditions set out in Annex III which must be met by the rail system, the subsystems, and the interoperability constituents, including interfaces;
- (h) ‘European specification’ means a common technical specification, a European technical approval or a national standard transposing a European standard, as defined in Annex XXI to Directive 2004/17/EC;
- (i) ‘technical specification for interoperability’ (TSI) means a specification adopted in accordance with this Directive by which each subsystem or part subsystem is covered in order to meet the essential requirements and ensure the interoperability of the rail system;
- (j) ‘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;

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- (k) 'basic parameters' means any regulatory, technical or operational condition which is critical to interoperability and is specified in the relevant TSIs;
- (l) 'specific case' means any part of the rail system which needs special provisions in the TSIs, either temporary or definitive, because of geographical, topographical or urban environment constraints or those affecting compatibility with the existing system. This may include in particular railway lines and networks isolated from the rest of the Community, the loading gauge, the track gauge or space between the tracks and vehicles strictly intended for local, regional or historical use, as well as vehicles originating from or destined for third countries;
- (m) 'upgrading' means any major modification work on a subsystem or part subsystem which improves the overall performance of the subsystem;
- (n) 'renewal' means any major substitution work on a subsystem or part subsystem which does not change the overall performance of the subsystem;
- (o) 'existing rail system' means the structure composed of lines and fixed installations of the existing rail system plus the vehicles of all categories and origin travelling on that infrastructure;
- (p) 'substitution in the framework of maintenance' means any replacement of components by parts of identical function and performance in the framework of preventive or corrective maintenance;
- (q) 'placing in service' means all the operations by which a subsystem or a vehicle is put into its design operating state;
- (r) 'contracting entity' means any entity, whether public or private, which orders the design and/or construction or the renewal or upgrading of a subsystem. This entity may be a railway undertaking, an infrastructure manager or a keeper, or the concession holder responsible for carrying out a project;
- (s) 'keeper' means the person or entity that, being the owner of a vehicle or having the right to use it, exploits the vehicle as a means of transport and is registered as such in the national vehicle register referred to in Article 33;
- (t) 'project at an advanced stage of development' means any project whose planning/construction stage has reached a point where a change in the technical specifications would be unacceptable to the Member State concerned. Such an impediment may be legal, contractual, economic, financial, social or environmental in nature and must be duly substantiated;

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- (u) ‘harmonised standard’ means any European standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services ⁽¹⁾ in connection with a mandate by the Commission drawn up in accordance with the procedure referred to in Article 6(3) of that Directive, which, by itself or together with other standards, provides a solution as regards compliance with a legal provision;
- (v) ‘national safety authority’ means a safety authority as defined in Article 3(g) of Directive 2004/49/EC;
- (w) ‘type’ means a vehicle type defining the basic design characteristics of the vehicle as covered by a single type-examination certificate described in module B of Decision 93/465/EEC;
- (x) ‘series’ means a number of identical vehicles of a design type;
- (y) ‘Agency’ means the European Railway Agency, as established by Regulation (EC) No 881/2004 of the European Parliament and of the Council of 29 April 2004 establishing a European railway agency (Agency Regulation) ⁽²⁾;
- (z) ‘entity in charge of maintenance’ means an entity in charge of maintenance of a vehicle, and registered as such in the national vehicle register.

*Article 3***Overall compatibility**

1. This Directive concerns the provisions relating to, for each subsystem, the interoperability constituents, the interfaces and procedures as well as the conditions of overall compatibility of the rail system required to achieve its interoperability.

2. The provisions of this Directive shall apply without prejudice to any other relevant Community provisions. However, in the case of interoperability constituents, including interfaces, compliance with the essential requirements of this Directive may require the use of individual European specifications drawn up for that purpose.

⁽¹⁾ OJ L 204, 21.7.1998, p. 37. Directive as last amended by Council Directive 2006/96/EC (OJ L 363, 20.12.2006, p. 81).

⁽²⁾ OJ L 164, 30.4.2004, p. 1. Corrected by OJ L 220, 21.6.2004, p. 3.

▼B*Article 4***Essential requirements**

1. The rail system, subsystems and interoperability constituents including interfaces shall meet the relevant essential requirements.

2. The further technical specifications referred to in Article 34 of Directive 2004/17/EC which are necessary to complete European specifications or other standards in use within the Community must not conflict with the essential requirements.

CHAPTER II

TECHNICAL SPECIFICATIONS FOR INTEROPERABILITY*Article 5***Content of TSIs**

1. Each of the subsystems shall be covered by one TSI. Where necessary, a subsystem may be covered by several TSIs and one TSI may cover several subsystems. The decision to develop or to revise a TSI and the choice of its technical and geographical scope requires a mandate in accordance with Article 6(1).

2. Subsystems shall comply with the TSIs in force at the time of their placing in service, upgrading or renewal, in accordance with this Directive; this compliance shall be permanently maintained while each subsystem is in use.

3. To the extent necessary to achieve the objective referred to in Article 1, each TSI shall:
 - (a) indicate its intended scope (part of network or vehicles referred to in Annex I; subsystem or part of subsystem referred to in Annex II);

 - (b) lay down essential requirements for each subsystem concerned and its interfaces *vis-à-vis* other subsystems;

 - (c) establish the functional and technical specifications to be met by the subsystem and its interfaces *vis-à-vis* other subsystems. If need be, these specifications may vary according to the use of the subsystem, for example according to the categories of line, hub and/or vehicles provided for in Annex I;

 - (d) determine the interoperability constituents and interfaces which must be covered by European specifications, including European standards, which are necessary to achieve interoperability within the rail system;

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- (e) state, in each case under consideration, which procedures are to be used in order to assess the conformity or the suitability for use of the interoperability constituents, on the one hand, or the 'EC' verification of the subsystems, on the other hand. These procedures shall be based on the modules defined in Decision 93/465/EEC;
- (f) indicate the strategy for implementing the TSIs. In particular, it is necessary to specify the stages to be completed in order to make a gradual transition from the existing situation to the final situation in which compliance with the TSIs shall be the norm;
- (g) indicate, for the staff concerned, the professional qualifications and health and safety conditions at work required for the operation and maintenance of the above subsystem, as well as for the implementation of the TSIs.

4. Each TSI shall be drawn up on the basis of an examination of an existing subsystem and indicate a target subsystem that may be obtained gradually within a reasonable time-scale. Accordingly, the gradual adoption of the TSIs and compliance therewith will help gradually to achieve the interoperability of the rail system.

5. TSIs shall retain, in an appropriate manner, the compatibility of the existing rail system of each Member State. With this objective, provision may be made for specific cases for each TSI, with regard to both network and vehicles; special attention must be given to the loading gauge, the track gauge or space between the tracks and vehicles originating from or destined for third countries. For each specific case, the TSIs shall stipulate the implementing rules of the elements of the TSIs indicated in paragraph 3(c) to (g).

6. If certain technical aspects corresponding to the essential requirements cannot be explicitly covered in a TSI, they shall be clearly identified in an annex to the TSI as open points. Article 17(3) shall apply to these aspects.

7. TSIs shall not be an impediment to decisions by the Member States concerning the use of infrastructures for the movement of vehicles not covered by the TSIs.

8. TSIs may make an explicit, clearly identified reference to European or international standards or specifications or technical documents published by the Agency where this is strictly necessary in order to achieve the objective of this Directive. In such case, these standards or specifications (or the relevant parts) or technical documents shall be regarded as annexes to the TSI concerned and shall become mandatory from the moment the TSI is applicable. In the absence of such standards or specifications or technical documents and pending their development, reference may be made to other clearly identified normative documents; in such case, this shall concern documents that are easily accessible and in the public domain.

*Article 6***Adoption, review and publication of TSIs**

1. Draft TSIs and subsequent draft amendments to TSIs shall be drafted by the Agency under a mandate from the Commission in accordance with the regulatory procedure referred to in Article 29(3) of this Directive. They shall be drafted in accordance with Articles 3 and 12 of Regulation (EC) No 881/2004 and in cooperation with the working parties mentioned in those Articles.

Measures designed to amend non-essential elements of this Directive by supplementing it with TSIs or amendments thereto shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(4).

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 29(5).

2. The Agency shall be responsible for preparing the review and updating of TSIs and making any recommendations to the Commission in order to take account of developments in technology or social requirements. The Commission shall inform the committee referred to in Article 29 of such recommendations.

3. Each draft TSI shall be drawn up in two stages.

Firstly, the Agency shall identify the basic parameters for the TSI as well as the interfaces with the other subsystems and any other specific cases that may be necessary. The most viable alternative solutions accompanied by technical and economic justification shall be put forward for each of these parameters and interfaces.

Secondly, the Agency shall draw up the draft TSI on the basis of these basic parameters. Where appropriate, the Agency shall take account of technical progress, of standardisation work already carried out, of working parties already in place and of acknowledged research work. An overall assessment of the estimated costs and benefits of the implementation of the TSIs shall be attached to the draft TSI; this assessment shall indicate the likely impact for all the operators and economic agents involved.

4. The drafting, adoption and review of each TSI (including the basic parameters) shall take account of the estimated costs and benefits of all the technical solutions considered, together with the interfaces between them, so as to establish and implement the most viable solutions. The Member States shall participate in this assessment by providing the requisite data.

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5. The committee referred to in Article 29 shall be kept regularly informed of the preparatory work on the TSIs. During this work the Commission may, at the request of the committee, formulate any terms of reference or useful recommendations concerning the design of the TSIs and the cost-benefit analysis. In particular, the Commission may, at the request of a Member State, require that alternative solutions be examined and that the assessment of the cost and benefits of these alternative solutions be set out in the report annexed to the draft TSI.

6. On the adoption of each TSI, the date of entry into force of that TSI shall be established in accordance with the regulatory procedure with scrutiny referred to in Article 29(4). Where different subsystems have to be placed in service simultaneously for reasons of technical compatibility, the dates of entry into force of the corresponding TSIs shall be the same.

7. The drafting, adoption and review of the TSIs shall take account of the opinion of users, as regards the characteristics which have a direct impact on the conditions in which they use the subsystems. To that end the Agency shall consult associations and bodies representing users during the drafting and review phases of the TSIs. It shall enclose with the draft TSI a report on the results of this consultation.

The list of associations and bodies to be consulted shall be drawn up by the Commission, after consulting the committee in accordance with the advisory procedure referred to in Article 29(2), and may be re-examined and updated at the request of a Member State or upon the initiative of the Commission.

8. The drafting, adoption and review of the TSIs shall take account of the opinion of the social partners as regards the conditions referred to in Article 5(3)(g).

To this end, the social partners shall be consulted before the draft TSI is submitted, for adoption or review, to the committee referred to in Article 29.

The social partners shall be consulted in the context of the Sectoral Dialogue Committee set up in accordance with 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⁽¹⁾. The social partners shall issue their opinion within three months.

9. When revision of a TSI leads to a change of requirements, the new TSI version shall ensure compatibility with subsystems placed in service in accordance with former TSI versions.

⁽¹⁾ OJ L 225, 12.8.1998, p. 27. Decision as last amended by Regulation (EC) No 1792/2006 (OJ L 362, 20.12.2006, p. 1).

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In case a new authorisation, renewal or upgrading of these subsystems is needed for duly justified safety or interoperability reasons, corresponding deadlines shall be fixed either in the TSI or, as appropriate, by the Member States.

10. TSIs shall be published by the Commission in the *Official Journal of the European Union*.

*Article 7***Deficiencies in TSIs**

1. If, after its adoption, it appears that a TSI does not fully meet the essential requirements, the committee referred to in Article 29 may be consulted at the request of a Member State or upon the initiative of the Commission.

The Commission may request a technical opinion from the Agency. The Commission, with the involvement of the committee, shall analyse the technical opinion.

2. If the TSI needs to be amended because of a minor error and this does not justify an immediate revision, the Commission may recommend that the technical opinion is used pending the review of the TSI in accordance with Article 6(1). In that case, the Agency shall publish the technical opinion.

3. If the TSI needs to be amended because of an important or critical error, the revision procedure referred to in Article 6(1) shall be applied forthwith.

*Article 8***Extension of the scope of TSIs**

1. The Commission shall adopt, in accordance with the regulatory procedure referred to in Article 29(3), one or more mandates aiming at the development of new TSIs and/or the review of TSIs already adopted with a view to covering lines and vehicles not yet covered.

2. The first such mandate shall indicate a first group of new TSIs and/or amendments to TSIs to be adopted by January 2012, without prejudice to Article 5(5) as regards the possibility of providing for specific cases and without prejudice to Article 9 allowing for derogations in particular circumstances. This first mandate shall be drawn up on the basis of a recommendation from the Agency with a view to determining new TSIs to be developed and/or existing TSIs to be amended in the light of the expected cost-effectiveness of each proposed measure and on the basis of the principle of proportionality of measures to be taken at Community level. To this end, appropriate consideration shall be given to Annex I, point 4 and the necessary balance between, on the one hand, the objectives of uninterrupted movement of trains and of technical harmonisation, and, on the other hand, the trans-European, national, regional or local level of traffic concerned.

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3. Until such time as the extension of the scope of the TSIs to cover the whole of the rail network takes effect:

(a) authorisations for the placing in service

— of vehicles and on-board control-command and signalling subsystems to be used at least partially on the part of the network that does not yet fall within the scope of the TSIs, in respect of that part of the network,

— of infrastructure, energy and trackside control-command and signalling subsystems on the parts of the network that do not yet fall within the scope of the TSIs,

shall be granted in accordance with the national rules referred to in Article 8 of Directive 2004/49/EC, or, where applicable, Article 17(3) of this Directive;

(b) authorisations for the placing in service of vehicles to be used occasionally on the part of the network that does not yet fall within the scope of the TSIs, in respect of that part of the network, shall be granted in accordance with Articles 21 to 27 and the national rules referred to in Article 8 of Directive 2004/49/EC, or, where applicable, Article 17(3) of this Directive.

4. A Member State need not apply the new or revised TSIs adopted in accordance with paragraph 2 in the case of projects at an advanced stage of development or subject to a contract in the course of performance when the relevant group of TSIs is published.

Article 9

Derogations

1. In the absence of relevant specific cases, a Member State need not apply one or more TSIs in accordance with this Article in the following cases:

(a) for a proposed new subsystem, for the renewal or upgrading of an existing subsystem, or for any element referred to in Article 1(1) at an advanced stage of development or the subject of a contract in the course of performance when these TSIs are published;

(b) for any project concerning the renewal or upgrading of an existing subsystem where the loading gauge, track gauge, space between the tracks or electrification voltage in these TSIs is not compatible with those of the existing subsystem;

(c) for a proposed new subsystem or for the proposed renewal or upgrading of an existing subsystem in the territory of that Member State when its rail network is separated or isolated by the sea or separated as a result of special geographical conditions from the rail network of the rest of the Community;

(d) for any proposed renewal, extension or upgrading of an existing subsystem, when the application of these TSIs would compromise the economic viability of the project and/or the compatibility of the rail system in that Member State;

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- (e) where, following an accident or a natural disaster, the conditions for the rapid restoration of the network do not economically or technically allow for partial or total application of the relevant TSIs;
 - (f) for vehicles coming from or going to third countries the track gauge of which is different from that of the main rail network within the Community.
2. In the cases referred to in paragraph 1, the Member State concerned shall communicate to the Commission a file containing the information set out in Annex IX. The Commission shall analyse the measures proposed by the Member State and shall inform the committee referred to in Article 29.
 3. In the case referred to in paragraph 1(a), within one year of entry into force of each TSI each Member State shall communicate to the Commission a list of projects that are taking place within its territory and are at an advanced stage of development.
 4. In the cases referred to in paragraph 1(a), (c) and (e), the Commission shall check that the file is in conformity and shall inform the Member State of the results of its analysis. Where necessary, a recommendation shall be drawn up concerning the specifications to be applied. The Member State may apply the alternative provisions referred to in Annex IX without delay.
 5. In the cases referred to in paragraph 1(b), (d) and (f), the Commission shall decide, in accordance with the regulatory procedure referred to in Article 29(3), whether to accept a request for a derogation. In the case referred to in paragraph 1(b), the Commission's decision shall not cover the loading gauge and the track gauge. The Commission shall give its decision within six months of the submission of the request supported by the complete file. In the absence of such a decision, the request shall be deemed to have been accepted. Pending the Commission's decision, in the case referred to in paragraph 1(f), a Member State may apply the alternative provisions referred to in Annex IX.
 6. All Member States shall be informed of the results of the analyses and of the outcome of the procedure set out in paragraphs 4 and 5.

CHAPTER III

INTEROPERABILITY CONSTITUENTS*Article 10***Placing on the market of interoperability constituents**

1. Member States shall take all necessary steps to ensure that interoperability constituents:
 - (a) are placed on the market only if they enable interoperability to be achieved within the rail system while at the same time meeting the essential requirements;
 - (b) are used in their area of use as intended and are suitably installed and maintained.

These provisions shall not obstruct the placing on the market of these constituents for other applications.

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2. Member States may not, in their territory and on the basis of this Directive, prohibit, restrict or hinder the placing on the market of interoperability constituents for use in the rail system where they comply with this Directive. In particular, they may not require checks which have already been carried out as part of the procedure of 'EC' declaration of conformity or suitability for use, the components of which are set out in Annex IV.

*Article 11***Conformity or suitability for use**

1. Member States shall consider those interoperability constituents which bear the 'EC' declaration of conformity or suitability for use as complying with the essential requirements of this Directive.

2. All interoperability constituents shall be subject to the procedure for assessing conformity and suitability for the use indicated in the relevant TSI and shall be accompanied by the corresponding certificate.

3. Member States shall consider that an interoperability constituent meets the essential requirements if it complies with the conditions laid down by the corresponding TSI or the corresponding European specifications developed to comply with these conditions.

4. Spare parts for subsystems that are already placed in service when the corresponding TSI enters into force may be installed in these subsystems without being subject to the procedure referred to in paragraph 2.

5. TSIs may provide for a period of transition for rail products identified by those TSIs as interoperability constituents which have already been placed on the market when the TSIs enter into force. Such constituents shall satisfy the requirements of Article 10(1).

*Article 12***Non-compliance of European specification with essential requirements**

Where it appears to a Member State or the Commission that European specifications used directly or indirectly to achieve the objectives of this Directive do not meet the essential requirements, the committee referred to in Article 29 shall be informed thereof and the Commission shall adopt the most appropriate measure, being:

(a) partial or total withdrawal of the specifications concerned from the publications containing them, or their amendment, after consultation, where European standards are involved, of the Committee set up under Directive 98/34/EC, or

(b) review of the TSI in accordance with Article 7.

*Article 13***Procedure for ‘EC’ declaration of conformity or suitability for use**

1. In order to establish the ‘EC’ declaration of conformity or suitability for use of an interoperability constituent, the manufacturer or his authorised representative established in the Community shall apply the provisions laid down by the relevant TSIs.
2. Where the corresponding TSI so requires, assessment of the conformity or suitability for use of an interoperability constituent shall be carried out by the notified body with which the manufacturer or his authorised representative established in the Community has lodged the application.
3. Where interoperability constituents are the subject of other Community directives covering other aspects, the ‘EC’ declaration of conformity or suitability for use shall, in such cases, state that the interoperability constituents also meet the requirements of those other directives.
4. Where neither the manufacturer nor his authorised representative established in the Community has met the obligations of paragraphs 1 and 3, those obligations shall be incumbent on any person who places interoperability constituents on the market. The same obligations shall apply to whomsoever assembles interoperability constituents or parts of interoperability constituents having diverse origins or manufactures interoperability constituents for his own use, for the purposes of this Directive.
5. Without prejudice to the provisions of Article 14:
 - (a) in each instance where the Member State finds that the ‘EC’ declaration of conformity has been drawn up improperly, the manufacturer or his authorised representative established in the Community shall be required, if necessary, to restore the interoperability constituent to a state of conformity and to terminate the infringement under the conditions laid down by that Member State;
 - (b) where non-conformity persists, the Member State shall take all appropriate steps to restrict or prohibit the placing on the market of the interoperability constituent in question, or to ensure that it is withdrawn from the market in accordance with the procedures provided for in Article 14.

*Article 14***Non-compliance of interoperability constituents with essential requirements**

1. Where a Member State finds that an interoperability constituent covered by the ‘EC’ declaration of conformity or suitability for use and placed on the market is unlikely, when used as intended, to meet the essential requirements, it shall take all necessary steps to restrict its field of application, prohibit its use or withdraw it from the market. The Member State shall forthwith inform the Commission of the measures taken and give the reasons for its decision, stating in particular whether failure to conform is due to:
 - (a) failure to meet the essential requirements;

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(b) incorrect application of European specifications where application of such specifications is relied upon;

(c) inadequacy of European specifications.

2. The Commission shall consult the parties concerned as quickly as possible. Where, following that consultation, the Commission establishes that the measure is justified it shall forthwith inform the Member State that has taken the initiative as well as the other Member States thereof. Where, after that consultation, the Commission establishes that the measure is unjustified it shall forthwith inform the Member State that has taken the initiative and the manufacturer or his authorised representative established within the Community thereof. Where the decision referred to in paragraph 1 is justified by the existence of a gap in European specifications, the procedure set out in Article 12 shall apply.

3. Where an interoperability constituent bearing the ‘EC’ declaration of conformity fails to comply, the competent Member State shall take appropriate measures against whomsoever has drawn up the declaration and shall inform the Commission and the other Member States thereof.

4. The Commission shall ensure that the Member States are kept informed of the course and results of that procedure.

CHAPTER IV

SUBSYSTEMS

Article 15

Procedure for placing in service

1. Without prejudice to Chapter V, each Member State shall authorise the placing in service of those structural subsystems constituting the rail system which are located or operated in its territory.

To this end, Member States shall take all appropriate steps to ensure that these subsystems may be placed in service only if they are designed, constructed and installed in such a way as to meet the essential requirements concerning them when integrated into the rail system. In particular, they shall check:

- the technical compatibility of these subsystems with the system into which they are being integrated,
- the safe integration of these subsystems in accordance with Articles 4(3) and 6(3) of Directive 2004/49/EC.

2. Each Member State shall check, before these subsystems are placed in service, that they comply, where applicable, with the relevant TSI provisions on operation and maintenance.

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3. After these subsystems have been placed in service, the check shall be carried out:

- (a) for infrastructures, in the context of the granting and supervision of safety authorisations under Article 11 of Directive 2004/49/EC;
- (b) for vehicles, in the context of the granting and supervision of safety certificates under Article 10 of Directive 2004/49/EC.

To that end, the assessment and verification procedures laid down in the relevant structural and functional TSIs shall be used.

*Article 16***Free movement of subsystems**

Without prejudice to the provisions of Article 15(1), Member States may not, in their territory and on grounds relating to this Directive, prohibit, restrict or hinder the construction, placing in service and operation of structural subsystems constituting the rail system which meet the essential requirements. In particular, they may not require checks which have already been carried out:

- either as part of the procedure leading to the ‘EC’ declaration of verification, the components of which are set out in Annex V,
- or in other Member States, before or after the entry into force of this Directive, with a view to verifying compliance with identical requirements under identical operational conditions.

*Article 17***Conformity with TSIs and national rules**

1. Member States shall consider as being interoperable and meeting the essential requirements concerning them, those structural subsystems constituting the rail system which are covered by the ‘EC’ declaration of verification.

2. Verification of the interoperability, in accordance with the essential requirements, of a structural subsystem constituting the rail system shall be established by reference to TSIs, where they exist.

3. Member States shall draw up, for each subsystem, a list of the technical rules in use for implementing the essential requirements and notify this list to the Commission when:

- no relevant TSI exists, or
- a derogation has been notified under Article 9, or
- a specific case requires the application of technical rules not included in the relevant TSI.

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This list shall be notified either:

- each time the list of technical rules that, pursuant to Article 16(3) of Directive 96/48/EC and Article 16(3) of Directive 2001/16/EC, was required to be notified by 30 April 2005 is changed, or
- after the derogation has been notified, or
- after publication of the TSI concerned.

On that occasion, Member States shall also designate the bodies responsible for carrying out, in the case of these technical regulations, the verification procedure referred to in Article 18.

The Commission shall communicate this information to the Agency, which shall publish it.

Member States shall make available the full text of the notified rules at the request of the Commission. In order to prevent further barriers from being created, and with a view to taking forward the classification of national rules in accordance with Article 27, the Commission shall monitor the introduction of new rules by the Member States. If the Commission considers that the new rule 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 regulatory procedure referred to in Article 29(3).

Member States may choose not to notify rules and restrictions of a strictly local nature. In such cases, Member States shall mention such rules and restrictions in the infrastructure registers referred to in Article 35.

Member States shall ensure that binding technical rules are published and made available to all infrastructure managers, railway undertakings and applicants for authorisations for placing in service in clear language that can be understood by the parties concerned.

Article 18

Procedure for establishing the ‘EC’ declaration of verification

1. In order to establish the ‘EC’ declaration of verification, the applicant shall invite the notified body that it has selected for that purpose to apply the ‘EC’ verification procedure referred to in Annex VI. The applicant may be the contracting entity or the manufacturer, or their authorised representative within the Community.
2. The task of the notified body responsible for the ‘EC’ verification of a subsystem shall begin at the design stage and cover the entire manufacturing period through to the acceptance stage before the subsystem is placed in service. It shall also cover verification of the interfaces of the subsystem in question with the system into which it is incorporated, based on the information available in the relevant TSI and in the registers provided for in Articles 34 and 35.

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3. The notified body shall be responsible for compiling the technical file that has to accompany the 'EC' declaration of verification. This technical file must contain all the necessary documents relating to the characteristics of the subsystem and, where appropriate, all the documents certifying conformity of the interoperability constituents. It should also contain all the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance.

4. The notified body may issue intermediate statement verifications to cover certain stages of the verification procedure or certain parts of the subsystem. In such a case, the procedure set out in Annex VI shall apply.

5. If the relevant TSIs allow, the notified body may issue certificates of conformity for a series of subsystems or certain parts of those subsystems.

*Article 19***Non-compliance of subsystems with essential requirements**

1. Where a Member State finds that a structural subsystem covered by the 'EC' declaration of verification accompanied by the technical file does not fully comply with this Directive and in particular does not meet the essential requirements, it may request that additional checks be carried out.

2. The Member State making the request shall forthwith inform the Commission of any additional checks requested and set out the reasons therefor. The Commission shall consult the interested parties.

3. The Member State making the request shall state whether the failure to fully comply with this Directive is due to:

- (a) non-compliance with the essential requirements or with a TSI, or incorrect application of a TSI. In that case, the Commission shall forthwith inform the Member State where the person who drew up the 'EC' declaration of verification in error resides and shall request that Member State to take the appropriate measures;
- (b) inadequacy of a TSI. In that case, the procedure for amending the TSI as referred to in Article 7 shall apply.

*Article 20***Placing in service of existing subsystems after renewal or upgrading**

1. In the event of renewal or upgrading, the contracting entity or the manufacturer shall send the Member State concerned a file describing the project. The Member State shall examine this file and, taking account of the implementation strategy indicated in the applicable TSI, shall decide whether the extent of the works means that a new authorisation for placing in service within the meaning of this Directive is needed.

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Such new authorisation for placing in service shall be required whenever the overall safety level of the subsystem concerned may be adversely affected by the works envisaged. If a new authorisation is needed, the Member State shall decide to what extent the TSIs need to be applied to the project.

The Member State shall take its decision not later than four months after submission of the complete file by the applicant.

2. When a new authorisation is required and if the TSI is not fully applied, the Member States shall notify the following information to the Commission:

- the reason why the TSI is not fully applied,
- the technical characteristics applicable in place of the TSI,
- the bodies responsible for applying, in the case of those characteristics, the verification procedure referred to in Article 18.

3. The Commission shall communicate the information referred to in paragraph 2 to the Agency, which shall publish it.

CHAPTER V

VEHICLES

*Article 21***Authorisation for placing in service of vehicles**

1. Before being used on a network, a vehicle shall be authorised to be placed in service by the national safety authority which is competent for this network, unless otherwise provided for in this Chapter.

2. A TSI conform vehicle shall be authorised in accordance with Articles 22 or 23.

3. A non-TSI conform vehicle shall be authorised in accordance with Articles 24 or 25.

4. A vehicle which conforms to an authorised type shall be authorised in accordance with Article 26.

5. An authorisation granted by one Member State shall be valid in all Member States, without prejudice to the provisions of Articles 23 and 25 concerning additional authorisations. Member States shall clarify, by adopting specific national rules or through national provisions implementing this Directive, whether additional authorisations are needed in accordance with the relevant provisions of Article 23 in the case of TSI conform vehicles or Article 25 in the case of non-TSI conform vehicles.

6. All applications for an authorisation to place in service shall be the subject of a decision by the competent national safety authority, pursuant to Articles 22 and 23 or Articles 24 and 25. The authorisation to place in service may stipulate conditions of use and other restrictions.

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7. Any decision by a competent national safety authority refusing the placing in service of a vehicle shall be duly substantiated. The applicant may within a period of one month from receipt of the negative decision request that the competent national safety authority reviewed the decision for duly justified reasons. The national safety authority shall then have two months starting from receipt of the appeal to confirm or reverse its decision. If the negative decision is confirmed, the applicant may request that the appeal body designated by the competent Member State under Article 17(3) of Directive 2004/49/EC review the decision for duly justified reasons. Member States may designate the regulatory body set up in accordance with Article 30 of Directive 2001/14/EC for the purpose of this appeal procedure.

8. In the absence of a decision of the competent national safety authority as referred to in Articles 23(7) and 25(5) within the prescribed time limits, the placing in service of the vehicle in question shall be deemed to have been authorised after a period of three months starting at the end of these time limits. The authorisations granted pursuant to this paragraph are only valid on the network for which the competent national safety authority did not react within the prescribed limits.

9. A national safety authority which intends to revoke an authorisation to place in service granted by itself or an authorisation granted to the applicant pursuant to paragraph 8 shall use the procedure for revision of safety certificates referred to in Article 10(5) of Directive 2004/49/EC or, where applicable, the procedure for revision of safety authorisations referred to in Article 11(2) of that Directive.

10. In the case of an appeal procedure, the competent appeal body referred to in paragraph 7 may request from the Agency an opinion which, in that case, shall be issued within one month of the request being filed and notified to the applicant, to the competent appeal body and to the competent national safety authority which refuses to grant the authorisation.

11. In the case of vehicles running between a Member State and a third country, on a network whose track gauge is different from that of the main rail network within the Community and for which a derogation may be granted in accordance with Article 9(5) or which are subject to specific cases, the national rules referred to in Articles 22 and 24 may include international agreements in so far as they are compatible with Community legislation.

12. Authorisations for placing in service which have been granted before 19 July 2008, including authorisations delivered under international agreements, in particular RIC (Regolamento Internazionale Carrozze) and RIV (Regolamento Internazionale Veicoli), shall remain valid in accordance with the conditions under which the authorisations have been granted. This provision takes precedence over Articles 22 to 25.

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13. Member States may grant authorisations to place in service a series of vehicles. To that end, the national safety authorities shall notify the applicant of the procedure to be followed.

14. Authorisations for placing in service granted in accordance with this Article shall be without prejudice to other conditions imposed on railway undertakings and infrastructure managers for operating such vehicles on the relevant network, pursuant to Articles 9, 10 and 11 of Directive 2004/49/EC.

*Article 22***First authorisation for placing in service of TSI conform vehicles**

1. This Article shall apply to vehicles which are in conformity with all the relevant TSIs which are in force at the moment of placing in service, provided that a significant part of the essential requirements is laid down in these TSIs and that the relevant TSI on rolling stock has entered into force and is applicable.

2. The first authorisation shall be granted by a national safety authority as follows:

- (a) where all the structural subsystems of a vehicle have been authorised in conformity with the provisions of Chapter IV, the authorisation shall be granted without further checks;
- (b) in the case of vehicles bearing all necessary 'EC' declarations of verification as provided for in Article 18, the criteria which a national safety authority may check with a view to granting an authorisation for placing in service may concern only:

— technical compatibility between the vehicle's relevant subsystems and their safe integration in accordance with Article 15(1),

— technical compatibility between the vehicle and the network concerned,

— national rules applicable to the open points,

— national rules applicable to the specific cases duly identified in the relevant TSIs.

*Article 23***Additional authorisations for placing in service of TSI conform vehicles**

1. Vehicles in complete conformity with TSIs covering all aspects of the relevant subsystems without specific cases and without open points strictly related to technical compatibility between vehicle and network, shall not be subject to any additional authorisation for placing in service as long as they run on TSI conform networks in the other Member States or under the conditions specified in the corresponding TSIs.

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2. In the case of vehicles placed in service in accordance with Article 22 but not covered by paragraph 1, Member States shall decide if additional authorisations are necessary on their territory. In this case, paragraphs 3 to 7 shall apply.

3. The applicant shall submit to the national safety authority a file on the vehicle or type of vehicle and the intended use thereof on the network. The file shall contain the following information:

- (a) documentary evidence that the placing in service of the vehicle has been authorised in another Member State in accordance with Article 22;
- (b) a copy of the technical file as referred to in Annex VI. This shall include, in the case of vehicles equipped with data recorders, information on the data collection procedure, permitting read out and evaluation, as long as this information is not harmonised by the corresponding TSI;
- (c) records showing the vehicle's maintenance history and, where applicable, technical modifications undertaken after the authorisation;
- (d) evidence on technical and operational characteristics that shows that the vehicle is compatible with the infrastructures and fixed installations, including climate conditions, energy supply system, control-command and signalling system, track gauge and infrastructure gauges, maximum permitted axle load and other constraints of the network.

4. The criteria checked by a national safety authority may concern only:

- technical compatibility between the vehicle and the network concerned, including the national rules applicable to the open points needed to ensure such compatibility,
- the national rules applicable to the specific cases duly identified in the relevant TSIs.

5. The national safety authority may request additional information to be supplied, risk analyses to be carried out in accordance with Article 6(3)(a) of Directive 2004/49/EC or tests to be conducted on the network in order to verify the criteria referred to in paragraph 4. However, after the adoption of the reference document referred to in Article 27 of this Directive, the national safety authority may only carry out such verification on the basis of the national rules relating to Group B or C featuring in that document.

6. The national safety authority shall define, after consultation with the applicant, the scope and content of the additional information, the risk analyses and the tests requested. The infrastructure manager, in consultation with the applicant, shall make every effort to ensure that any tests take place within three months of the applicant's request. Where appropriate, the national safety authority shall take measures to ensure that the tests take place.

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7. All applications for an authorisation to place in service submitted in accordance with this Article shall be the subject of a decision by the national safety authority, to be taken as soon as possible and not later than:

- (a) two months after submission of the file referred to in paragraph 3;
- (b) where applicable, one month after provision of any additional information requested by the national safety authority;
- (c) where applicable, one month after provision of the results of any tests requested by the national safety authority.

*Article 24***First authorisation for placing in service of non-TSI conform vehicles**

1. This Article shall apply to vehicles which are not in conformity with all the relevant TSIs in force at the moment of placing in service, including vehicles subject to derogations, or where a significant part of the essential requirements is not laid down in one or more TSIs.

2. The first authorisation shall be granted by a national safety authority as follows:

- for the technical aspects covered by a TSI, if any, the ‘EC’ verification procedure shall apply,
- for the other technical aspects, national rules as notified under Article 17(3) of this Directive and under Article 8 of Directive 2004/49/EC shall apply.

This first authorisation shall be valid only on the network of the Member State granting it.

*Article 25***Additional authorisations for placing in service of non-TSI conform vehicles**

1. In the case of vehicles that have been authorised to be placed in service in one Member State in accordance with Article 21(12) or Article 24, other Member States may decide in accordance with this Article whether additional authorisations to place in service are necessary on their territory.

2. The applicant shall submit to the national safety authority a technical file on the vehicle or type of vehicle, together with details of planned use on the network. The file shall contain the following information:

- (a) documentary evidence that the placing in service of the vehicle has been authorised in another Member State together with documentation on the procedure followed in order to show that the vehicle complied with the safety requirements in force, including, where applicable, information on derogations enjoyed or granted in accordance with Article 9;

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- (b) the technical data, the maintenance programme and the operational characteristics. This shall include, in the case of vehicles equipped with data recorders, information on the data collection procedure, permitting read out and evaluation as provided for in Article 20(2)(c) of Directive 2004/49/EC;
- (c) records showing the vehicle's history of operation, maintenance and, where applicable, technical modifications undertaken after the authorisation;
- (d) evidence on technical and operational characteristics that shows that the vehicle is compatible with the infrastructures and fixed installations, including climate conditions, energy supply system, control-command and signalling system, track gauge and infrastructure gauges, maximum permitted axle load and other constraints of the network.

3. The information referred to in paragraph 2(a) and (b) may not be called into question by the national safety authority, save where the latter is able to demonstrate without prejudice to Article 16 the existence of a substantial safety risk. After the adoption of the reference document referred to in Article 27, the national safety authority may not invoke in this regard any Group A rule listed in that document.

4. The national safety authority may request additional information to be supplied, risk analyses to be carried out in accordance with Article 6(3)(a) of Directive 2004/49/EC or tests to be conducted on the network in order to verify that the information referred to in paragraph 2(c) and (d) of this Article complies with the national rules in force as notified to the Commission pursuant to Article 8 of Directive 2004/49/EC or to Article 17 of this Directive. However, after the adoption of the reference document referred to in Article 27 of this Directive, the national safety authority may only carry out such verification on the basis of the national rules relating to Group B or C listed in that document.

The national safety authority shall define, after consultation with the applicant, the scope and content of the additional information, the risk analyses or the tests requested. The infrastructure manager, in consultation with the applicant, shall make every effort to ensure that any tests take place within three months of the applicant's request. Where appropriate, the national safety authority shall take measures to ensure that the tests take place.

5. All applications for an authorisation to place in service submitted in accordance with this Article shall be the subject of a decision by the national safety authority, to be taken as soon as possible and not later than:

- (a) four months after submission of the technical file referred to in paragraph 2;

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- (b) where applicable, two months after provision of the additional information or risk analyses requested by the national safety authority pursuant to paragraph 4;

- (c) where applicable, two months after provision of the results of the tests requested by the national safety authority pursuant to paragraph 4.

*Article 26***Authorisation for types of vehicles**

1. Member States may grant authorisations for types of vehicles.

2. However, if Member States authorise a vehicle, they shall at the same time authorise the type of vehicle.

3. A vehicle which conforms to a type already authorised in a Member State shall be authorised by that Member State on the basis of a declaration of conformity to this type submitted by the applicant without further checks. However, where the relevant provisions in TSIs and national rules on the basis of which a type of vehicle was authorised have changed, Member States shall decide if authorisations of type already granted remain valid or need to be renewed. The criteria which a national safety authority checks in the case of a renewed authorisation of type may only concern the changed rules. The renewal of the type authorisation does not affect authorisations of vehicles already granted on the basis of previously authorised types.

4. The model of declaration of conformity to type shall be adopted by the Commission by 19 July 2009 on the basis of a draft prepared by the Agency and in accordance with the regulatory procedure referred to in Article 29(3).

5. The declaration of conformity to type shall be established in accordance with:
 - (a) for TSI conform vehicles, the verification procedures of the relevant TSIs;

 - (b) for non-TSI conform vehicles, the verification procedures as defined in modules D or E of Decision 93/465/EEC. Where appropriate, the Commission may adopt an ad hoc verification procedure in accordance with the regulatory procedure referred to in Article 29(3).

6. The applicant may request a type authorisation in several Member States at the same time. In this case, national safety authorities shall cooperate with a view to simplifying the procedure and minimising administrative efforts.

7. Type authorisations shall be registered in the European register of authorised types of vehicles referred to in Article 34. This register shall specify the Member State or Member States in which a type of vehicle is authorised.

*Article 27***Classification of national rules**

1. In order to facilitate the procedure for authorising the placing in service of vehicles referred to in Article 25, national rules shall be classified pursuant to Annex VII.
2. Without prejudice to Article 30(3), the Agency shall, by 19 January 2009, review the parameters set out in section 1 of Annex VII and make the recommendations it considers appropriate to the Commission.
3. The Agency shall draw up a recommendation for a reference document cross-referencing all the national rules applied by the Member States for placing vehicles in service. The national safety authorities shall cooperate with the Agency in this task.
4. The Commission shall adopt the reference document, as well as any decision to update it, on the basis of the Agency's recommendation and in accordance with the regulatory procedure referred to in Article 29(3).

CHAPTER VI

NOTIFIED BODIES*Article 28***Notified bodies**

1. Member States shall notify to the Commission and the other Member States the bodies responsible for carrying out the procedure for the assessment of conformity or suitability for use referred to in Article 13 and the verification procedure referred to in Article 18, indicating each body's area of responsibility, and the identification numbers obtained in advance from the Commission. The Commission shall publish in the *Official Journal of the European Union* the list of bodies, their identification numbers and areas of responsibility, and shall keep this list updated.
2. Member States shall apply the criteria provided for in Annex VIII for the assessment of the bodies to be notified. Bodies meeting the assessment criteria provided for in the relevant European standards shall be deemed to meet those criteria.
3. A Member State shall withdraw approval from a body which no longer meets the criteria referred to in Annex VIII. It shall forthwith inform the Commission and the other Member States thereof.
4. Should a Member State or the Commission consider that a body notified by another Member State does not meet the criteria referred to in Annex VIII, the Commission shall consult the parties concerned. The Commission shall inform the latter Member State of any changes that are necessary for the notified body to retain the status conferred upon it.

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5. The Commission shall set up a notified bodies coordination group (hereinafter referred to as the Coordination Group) which shall discuss any matter relating to the application of the procedures for assessing conformity or suitability for the use referred to in Article 13 and the verification procedure referred to in Article 18, or to application of the relevant TSIs. Member States' representatives may take part in the work of the Coordination Group as observers.

The Commission and the observers shall inform the committee referred to in Article 29 of the work carried out in the framework of the Coordination Group. The Commission, when appropriate, will propose the measures needed to remedy the problems. Where necessary, coordination of the notified bodies shall be implemented in accordance with Article 30(4).

6. The first of the reports referred to in Article 39 shall also assess the implementation of the criteria specified in Annex VIII, and, if necessary, propose appropriate measures.

CHAPTER VII

COMMITTEE AND WORK PROGRAMME

*Article 29***Committee procedure**

1. The Commission shall be assisted by the committee established by Article 21 of Directive 96/48/EC (hereinafter referred to as the Committee).

2. Where reference is made to this paragraph, Articles 3 and 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, 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.

4. 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.

5. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

*Article 30***Complementary tasks**

1. The Commission may submit to the Committee any matter relating to the implementation of this Directive. If necessary, the Commission shall adopt an implementing recommendation in accordance with the advisory procedure referred to in Article 29(2).

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2. The Committee may discuss any matter relating to the interoperability of the rail system, including questions relating to interoperability between the rail system within the Community and the rail system of third countries.
3. Measures designed to amend non-essential elements of this Directive and relating to the adaptation of Annexes II to IX shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(4).
4. Should it prove necessary, the Committee may set up working parties to assist it in carrying out its tasks, in particular with a view to coordinating the notified bodies.

*Article 31***Work programme**

1. The Commission shall draw up a work programme taking account of the extension of the scope provided for in Article 8, the amendment of the TSIs provided for in Article 6(1) and the other obligations imposed on it by this Directive. The Commission shall keep the Committee fully informed on and involved in the drawing up and updating of the programme.
2. The work programme shall consist of the following stages:
 - (a) development on the basis of a draft prepared by the Agency of a model of the Community rail system, based on the list of subsystems (Annex II), to guarantee consistency between TSIs; this model must include in particular the various constituents of the system and their interfaces and act as a reference framework for defining the areas of use of each TSI;
 - (b) development of a model structure for developing TSIs;
 - (c) development of a method of cost-benefit analysis of the solutions set out in the TSIs;
 - (d) adoption of the mandates needed to draw up the TSIs;
 - (e) identification of the basic parameters for each TSI;
 - (f) approval of draft standardisation programmes;
 - (g) management of the transition period between the date of entry into force of Directive 2004/50/EC and publication of the TSIs, including the adoption of the reference system referred to in Article 36.



CHAPTER VIII
REGISTERS OF NETWORK AND VEHICLES

Article 32

Vehicle numbering system

1. Any vehicle placed in service in the Community rail system shall carry a European vehicle number (EVN) assigned when the first authorisation for placing in service is granted.
2. The applicant for the first authorisation shall be responsible for marking the vehicle in question with the EVN assigned to it.
3. The EVN shall be specified in the TSI on operation and traffic management.
4. A vehicle shall be assigned an EVN only once, unless otherwise specified in the TSI on operation and traffic management.
5. Notwithstanding paragraph 1, in the case of vehicles operated or intended to be operated from or to third countries the track gauge of which is different from that of the main rail network within the Community, Member States may accept vehicles clearly identified according to a different coding system.

Article 33

National vehicle registers

1. Each Member State shall keep a register of the vehicles authorised in its territory. This register shall meet the following criteria:
 - (a) it shall comply with the common specifications referred to in paragraph 2;
 - (b) it shall be kept updated by a body independent of any railway undertaking;
 - (c) it shall be accessible to the safety authorities and investigating bodies designated in Articles 16 and 21 of Directive 2004/49/EC; it shall also be made accessible, in response to any legitimate request, to the regulatory bodies designated in Article 30 of Directive 2001/14/EC, and to the Agency, the railway undertaking and the infrastructure managers, as well as those persons or organisations registering vehicles or identified in the register.
2. Common specifications for the register shall be adopted in accordance with the regulatory procedure referred to in Article 29(3) and on the basis of draft specifications prepared by the Agency. Those draft specifications shall include content, data format, functional and technical architecture, operating mode, including arrangements for the exchange of data, and rules for data input and consultation. For each vehicle, the register shall contain at least the following information:
 - (a) the EVN;
 - (b) references to the 'EC' declaration of verification and the issuing body;

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- (c) references to the European register of authorised types of vehicles referred to in Article 34;
- (d) identification of the owner of the vehicle and the keeper;
- (e) restrictions on how the vehicle may be used;
- (f) the entity in charge of maintenance.

3. The registration holder shall immediately declare any modification to the data entered in the national vehicle register, the destruction of a vehicle or its decision to no longer register a vehicle, to the authority of any Member State where the vehicle has been authorised.

4. As long as Member States' national vehicle registers are not linked, each Member State shall update its register with the modifications made by another Member State in its own register, as regards the data with which it is concerned.

5. In the case of vehicles placed in service for the first time in a third country and authorised in a Member State for placing in service on its territory, that Member State shall ensure that the data listed in paragraph 2(d) to (f) can be retrieved through the national vehicle register. Data referred to in paragraph 2(f) may be substituted by safety critical data relating to the maintenance schedule.

*Article 34***European register of authorised types of vehicles**

1. The Agency shall set up and keep a register of types of vehicles authorised by the Member States for placing in service on the Community rail network. This register shall meet the following criteria:

- (a) it shall be public and electronically accessible;
- (b) it shall comply with the common specifications referred to in paragraph 4;
- (c) it shall be linked with all national vehicle registers.

2. This register shall include the following details for each type of vehicle:

- (a) the technical characteristics of the type of vehicle, as defined in the relevant TSIs;
- (b) the manufacturer's name;
- (c) the dates, references and Member States granting the successive authorisations for this type of vehicle, including any restrictions or withdrawals.

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3. When an authorisation of type is granted, modified, suspended or withdrawn in a Member State, the national safety authority of this Member State shall inform the Agency, so that the latter may update the register.

4. Common specifications for the register shall be adopted in accordance with the regulatory procedure referred to in Article 29(3) and on the basis of draft specifications prepared by the Agency. Those draft specifications shall include content, data format, functional and technical architecture, operating mode and rules for data input and consultation.

*Article 35***Register of infrastructure**

1. Each Member State shall ensure that a register of infrastructure is published and updated on the basis of the revision cycle referred to in paragraph 2. This register shall indicate the main features of each subsystem or part subsystem involved (e.g. the basic parameters) and their correlation with the features laid down under the applicable TSIs. To that end, each TSI shall indicate precisely what information must be included in the register of infrastructure.

2. The Agency shall prepare draft specifications on this register regarding its presentation and format, its revision cycle and instructions for use, taking into account an appropriate transition period for infrastructures placed in service before the entry into force of this Directive. The Commission shall adopt the specifications in accordance with the regulatory procedure referred to in Article 29(3).

CHAPTER IX

TRANSITIONAL PROVISIONS*Article 36***Draft reference systems**

1. The Agency shall develop, in accordance with Articles 3 and 12 of Regulation (EC) No 881/2004 and on the basis of the information notified by the Member States under Article 17(3) of this Directive, technical documents from the profession and the texts of the relevant international agreements, a draft reference system of technical rules ensuring the current degree of interoperability of the networks and vehicles that will be brought within the scope of this Directive, as defined in Article 1 of this Directive. If necessary, the Commission shall adopt the reference system in accordance with the regulatory procedure referred to in Article 29(3) of this Directive.

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2. Following adoption of this reference system, Member States shall inform the Commission of their intention to adopt any national provision or of the development of any project in their territory which diverges from the reference system.

CHAPTER X

FINAL PROVISIONS

*Article 37***Motivation**

Any decision taken pursuant to this Directive concerning the assessment of conformity or suitability for use of interoperability constituents, the checking of subsystems constituting the rail system or any decision taken pursuant to Articles 7, 12, 14 and 19 shall set out in detail the reasons on which it is based. It shall be notified as soon as possible to the party concerned, together with an indication of the remedies available under the law in force in the Member State concerned and of the time limits allowed for the exercise of such remedies.

*Article 38***Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 1, Article 2, Article 4(2), Article 5(2), (5), (6) and (8), Article 6(1), (2), (3), (9) and (10), Articles 7, 8, and 9, Article 11(4) and (5), Article 12, Article 13(5), Articles 15, 16 and 17, Article 18(1), (2), (4) and (5), Article 19(3), Articles 20 to 27, Article 28(4) and (6), Articles 32 to 35 and Annexes I to IX not later than 19 July 2010. They shall forthwith communicate to the Commission the text of those measures.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The methods of making such reference shall be laid down by the Member States. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

2. The obligation to transpose and implement Chapters IV, V, VII and VIII of this Directive shall not apply to the Republic of Cyprus and the Republic of Malta for as long as no railway system is established within their territory.

However, as soon as a public or private entity submits an official application to build a railway line in view of its operation by one or more railway undertakings, the Member States concerned shall put in place legislation to implement the Chapters referred to in the first subparagraph within one year from the receipt of the application.



Article 39

Reports and information

1. Every three years and for the first time 19 July 2011, the Commission shall report to the European Parliament and the Council on the progress made towards achieving interoperability of the rail system. That report shall also include an analysis of the cases set out in Article 9.
2. The Commission shall, by 19 July 2013, publish a report including an analysis of the application of Chapter V and of the improvements in the cross-acceptance of vehicles in the Community in terms of length and costs of the procedures for applicants. Where appropriate, the report shall also assess the impact of various options for further simplifying procedures relating to the authorisation of vehicles. In this case, several options concerning cooperation between national safety authorities and the Agency shall be analysed.
3. The Agency shall develop and regularly update a tool capable of providing, at the request of a Member State or the Commission, a chart of the interoperability level of the rail system. That tool shall use the information included in the registers provided for in Articles 33, 34 and 35.

Article 40

Repeal

Directives 96/48/EC and 2001/16/EC shall be repealed with effect from 19 July 2010, without prejudice to the obligations of the Member States concerning the time limits for transposition into national law and application of those Directives.

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

Article 14 of Directive 2004/49/EC shall be repealed with effect from 19 July 2008.

Article 41

Entry into force

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

Article 42

Addressees

This Directive is addressed to the Member States.

*ANNEX I***SCOPE****1. Trans-European conventional rail system****1.1. Network**

The network of the trans-European conventional rail system will be that on the conventional lines of the trans-European transport network identified in Decision No 1692/96/EC.

For the purposes of this Directive, this network may be subdivided into the following categories:

- lines intended for passenger services,
- lines intended for mixed traffic (passengers and freight),
- lines specially designed or upgraded for freight services,
- passenger hubs,
- freight hubs, including intermodal terminals,
- lines connecting the abovementioned elements.

This network includes traffic management, tracking and navigation systems, technical installations for data processing and telecommunications intended for long-distance passenger services and freight services on the network in order to guarantee the safe and harmonious operation of the network and efficient traffic management.

1.2. Vehicles

The trans-European conventional rail system shall comprise all the vehicles likely to travel on all or part of the trans-European conventional rail network, including:

- self-propelling thermal or electric trains,
- thermal or electric traction units,
- passenger carriages,
- freight wagons, including vehicles designed to carry lorries.

Mobile railway infrastructure construction and maintenance equipment may be included.

Each of the above categories may be subdivided into:

- vehicles for international use,
- vehicles for national use.

2. Trans-European high-speed rail system**2.1. Network**

The network of the trans-European high-speed rail system shall be that of the high-speed lines of the trans-European transport network identified in Decision No 1692/96/EC.

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The high-speed lines shall comprise:

- specially built high-speed lines equipped for speeds generally equal to or greater than 250 km/h,
- specially upgraded high-speed lines equipped for speeds of the order of 200 km/h,
- specially upgraded high-speed lines which have special features as a result of topographical, relief or town-planning constraints, on which the speed must be adapted to each case. This category also includes interconnecting lines between the high-speed and conventional networks, lines through stations, accesses to terminals, depots, etc. travelled at conventional speed by 'high-speed' rolling stock.

This network includes traffic management, tracking and navigation systems, technical installations for data processing and telecommunications intended for services on these lines in order to guarantee the safe and harmonious operation of the network and efficient traffic management.

2.2. *Vehicles*

The trans-European high-speed rail system shall comprise vehicles designed to operate:

- either at speeds of at least 250 km/h on lines specially built for high speeds, while enabling operation at speeds exceeding 300 km/h in appropriate circumstances,
- or at speeds of the order of 200 km/h on the lines of section 2.1, where compatible with the performance levels of these lines.

In addition, vehicles designed to operate with a maximum speed lower than 200 km/h which are likely to travel on all or part of the trans-European high-speed network, where compatible with the performance levels of this network, shall fulfil the requirements ensuring safe operation on this network. To this end, the TSIs for conventional vehicles shall also specify requirements for safe operation of conventional vehicles on high-speed networks.

3. **Compatibility of the railway system**

The quality of rail services in Europe depends, *inter alia*, on excellent compatibility between the characteristics of the network (in the broadest sense, i.e. the fixed parts of all the subsystems concerned) and those of the vehicles (including the onboard components of all the subsystems concerned). Performance levels, safety, quality of service and cost depend upon that compatibility.

4. **Extension of the scope**

4.1. *Subcategories of network and vehicles*

The scope of the TSIs shall be progressively extended to the whole rail system as referred to in Article 1(4). In order to deliver interoperability cost-effectively further subcategories of all categories of network and vehicles mentioned in this Annex will, where necessary, be developed. If necessary, the functional and technical specifications mentioned in Article 5(3) may vary according to the subcategory.

▼B4.2. *Cost safeguards*

The cost-benefit analysis of the proposed measures will take into consideration, among others, the following:

- cost of the proposed measure,
- benefits to interoperability of an extension of the scope to particular subcategories of networks and vehicles,
- reduction of capital costs and charges due to economies of scale and better utilisation of vehicles,
- reduction of investment and maintenance/operating costs due to increased competition between manufacturers and maintenance companies,
- environmental benefits, due to technical improvements of the rail system,
- increase of safety in operation.

In addition, this assessment will indicate the likely impact for all the operators and economic agents involved.

▼ M2*ANNEX II***SUBSYSTEMS****1. List of subsystems**

For the purposes of this Directive, the system constituting the rail system may be broken down into the following subsystems, either:

(a) structural areas:

- infrastructure,
- energy,
- trackside control-command and signalling,
- on-board control-command and signalling,
- rolling stock,

(b) functional areas:

- operation and traffic management,
- maintenance,
- telematics applications for passenger and freight services.

2. Description of the subsystems

For each subsystem or part of a subsystem, the list of constituents and aspects relating to interoperability is proposed by the Agency at the time of drawing up the relevant draft TSI. Without prejudging the choice of aspects and constituents relating to interoperability or the order in which they will be made subject to TSIs, the subsystems include the following:

2.1. *Infrastructure*

The track, points, engineering structures (bridges, tunnels, etc.), associated station infrastructure (platforms, zones of access, including the needs of persons with reduced mobility, etc.), safety and protective equipment.

2.2. *Energy*

The electrification system, including overhead lines and the trackside of the electricity consumption measuring system.

2.3. *Trackside control-command and signalling*

All the trackside equipment required to ensure safety and to command and control movements of trains authorised to travel on the network.

2.4. *On-board control-command and signalling*

All the on-board equipment required to ensure safety and to command and control movements of trains authorised to travel on the network.

▼ M22.5. *Operation and traffic management*

The procedures and related equipment enabling coherent operation of the various structural subsystems, during both normal and degraded operation, including in particular train composition and train driving, traffic planning and management.

The professional qualifications which may be required for carrying out cross-border services.

2.6. *Telematics applications*

In accordance with Annex I, this subsystem comprises two elements:

- (a) applications for passenger services, including systems which provide passengers with information before and during the journey, reservation and payment systems, luggage management and management of connections between trains and with other modes of transport;
- (b) applications for freight services, including information systems (realtime monitoring of freight and trains), marshalling and allocation systems, reservation, payment and invoicing systems, management of connections with other modes of transport and production of electronic accompanying documents.

2.7. *Rolling stock*

Structure, command and control system for all train equipment, electric current collection devices, traction and energy conversion units, on-board equipment for electricity consumption measuring, braking, coupling and running gear (bogies, axles, etc.) and suspension, doors, man/machine interfaces (driver, on-board staff and passengers, including the needs of persons with reduced mobility), passive or active safety devices and requisites for the health of passengers and on-board staff.

2.8. *Maintenance*

The procedures, associated equipment, logistics centres for maintenance work and reserves providing the mandatory corrective and preventive maintenance to ensure the interoperability of the rail system and guarantee the performance required.

*ANNEX III***ESSENTIAL REQUIREMENTS****1. General requirements****1.1. *Safety***

- 1.1.1. The design, construction or assembly, maintenance and monitoring of safety-critical components, and more particularly of the components involved in train movements must be such as to guarantee safety at the level corresponding to the aims laid down for the network, including those for specific degraded situations.
- 1.1.2. The parameters involved in the wheel/rail contact must meet the stability requirements needed in order to guarantee safe movement at the maximum authorised speed. The parameters of brake equipment must guarantee that it is possible to stop within a given brake distance at the maximum authorised speed.
- 1.1.3. The components used must withstand any normal or exceptional stresses that have been specified during their period in service. The safety repercussions of any accidental failures must be limited by appropriate means.
- 1.1.4. The design of fixed installations and rolling stock and the choice of the materials used must be aimed at limiting the generation, propagation and effects of fire and smoke in the event of a fire.
- 1.1.5. Any devices intended to be handled by users must be so designed as not to impair the safe operation of the devices or the health and safety of users if used in a foreseeable manner, albeit not in accordance with the posted instructions.

1.2. *Reliability and availability*

The monitoring and maintenance of fixed or movable components that are involved in train movements must be organised, carried out and quantified in such a manner as to maintain their operation under the intended conditions.

1.3. *Health*

- 1.3.1. Materials likely, by virtue of the way they are used, to constitute a health hazard to those having access to them must not be used in trains and railway infrastructures.
- 1.3.2. Those materials must be selected, deployed and used in such a way as to restrict the emission of harmful and dangerous fumes or gases, particularly in the event of fire.

1.4. *Environmental protection*

- 1.4.1. The environmental impact of establishment and operation of the rail system must be assessed and taken into account at the design stage of the system in accordance with the Community provisions in force.
- 1.4.2. The materials used in the trains and infrastructures must prevent the emission of fumes or gases which are harmful and dangerous to the environment, particularly in the event of fire.
- 1.4.3. The rolling stock and energy-supply systems must be designed and manufactured in such a way as to be electromagnetically compatible with the installations, equipment and public or private networks with which they might interfere.

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- 1.4.4. The design and operation of the rail system must not lead to an inadmissible level of noise generated by it:
- in areas close to railway infrastructure, as defined in Article 3 of Directive 2012/34/EU, and
 - in the driver's cab.

▼ B

- 1.4.5. Operation of the rail system must not give rise to an inadmissible level of ground vibrations for the activities and areas close to the infrastructure and in a normal state of maintenance.

1.5. *Technical compatibility*

The technical characteristics of the infrastructure and fixed installations must be compatible with each other and with those of the trains to be used on the rail system.

If compliance with these characteristics proves difficult on certain sections of the network, temporary solutions, which ensure compatibility in the future, may be implemented.

▼ M31.6. *Accessibility*

- 1.6.1. The 'infrastructure' and 'rolling stock' subsystems must be accessible to persons with disabilities and persons with reduced mobility in order to ensure access on an equal basis with others by way of the prevention or removal of barriers, and by way of other appropriate measures. This shall include the design, construction, renewal, upgrade, maintenance and operation of the relevant parts of the subsystems to which the public has access.

- 1.6.2. The 'operations' and 'telematics applications for passengers' subsystems must provide for the necessary functionality required to facilitate access to persons with disabilities and persons with reduced mobility on an equal basis with others by way of the prevention or removal of barriers, and by way of other appropriate measures.

▼ B2. **Requirements specific to each subsystem**2.1. *Infrastructure*

2.1.1. Safety

Appropriate steps must be taken to prevent access to or undesirable intrusions into installations.

Steps must be taken to limit the dangers to which persons are exposed, particularly when trains pass through stations.

Infrastructure to which the public has access must be designed and made in such a way as to limit any human safety hazards (stability, fire, access, evacuation, platforms, etc.).

Appropriate provisions must be laid down to take account of the particular safety conditions in very long tunnels and viaducts.

▼ M3

2.1.2. Accessibility

- 2.1.2.1. Infrastructure subsystems to which the public has access must be accessible to persons with disabilities and persons with reduced mobility in accordance with 1.6.

▼ B2.2. *Energy*

2.2.1. Safety

Operation of the energy-supply systems must not impair the safety either of trains or of persons (users, operating staff, trackside dwellers and third parties).

2.2.2. Environmental protection

The functioning of the electrical or thermal energy-supply systems must not interfere with the environment beyond the specified limits.

2.2.3. Technical compatibility

The electricity/thermal energy supply systems used must:

- enable trains to achieve the specified performance levels,
- in the case of electricity energy supply systems, be compatible with the collection devices fitted to the trains.

2.3. *Control-command and signalling*

2.3.1. Safety

The control-command and signalling installations and procedures used must enable trains to travel with a level of safety which corresponds to the objectives set for the network. The control-command and signalling systems should continue to provide for safe passage of trains permitted to run under degraded conditions.

2.3.2. Technical compatibility

All new infrastructure and all new rolling stock manufactured or developed after adoption of compatible control-command and signalling systems must be tailored to the use of those systems.

The control-command and signalling equipment installed in the train drivers' cabs must permit normal operation, under the specified conditions, throughout the rail system.

2.4. *Rolling stock*

2.4.1. Safety

The rolling-stock structures and those of the links between vehicles must be designed in such a way as to protect the passenger and driving compartments in the event of collision or derailment.

The electrical equipment must not impair the safety and functioning of the control-command and signalling installations.

The braking techniques and the stresses exerted must be compatible with the design of the tracks, engineering structures and signalling systems.

Steps must be taken to prevent access to electrically-live constituents in order not to endanger the safety of persons.

▼ B

In the event of danger devices must enable passengers to inform the driver and accompanying staff to contact him.

The access doors must incorporate an opening and closing system which guarantees passenger safety.

Emergency exits must be provided and indicated.

Appropriate provisions must be laid down to take account of the particular safety conditions in very long tunnels.

An emergency lighting system having a sufficient intensity and duration is an absolute requirement on board trains.

Trains must be equipped with a public address system which provides a means of communication to the public from on-board staff.

2.4.2. Reliability and availability

The design of the vital equipment and the running, traction and braking equipment and also the control and command system must, in a specific degraded situation, be such as to enable the train to continue without adverse consequences for the equipment remaining in service.

2.4.3. Technical compatibility

The electrical equipment must be compatible with the operation of the control-command and signalling installations.

In the case of electric traction, the characteristics of the current-collection devices must be such as to enable trains to travel under the energy-supply systems for the rail system.

The characteristics of the rolling stock must be such as to allow it to travel on any line on which it is expected to operate, taking account of relevant climatic conditions.

2.4.4. Controls

Trains must be equipped with a recording device. The data collected by this device and the processing of the information must be harmonised.

▼ M3

2.4.5. Accessibility

- 2.4.5.1. Rolling stock subsystems to which the public has access must be accessible to persons with disabilities and persons with reduced mobility in accordance with 1.6.

▼ B2.5. *Maintenance*

2.5.1. Health and safety

The technical installations and the procedures used in the centres must ensure the safe operation of the subsystem and not constitute a danger to health and safety.

2.5.2. Environmental protection

The technical installations and the procedures used in the maintenance centres must not exceed the permissible levels of nuisance with regard to the surrounding environment.

2.5.3. Technical compatibility

The maintenance installations for rolling stock must be such as to enable safety, health and comfort operations to be carried out on all stock for which they have been designed.

▼ B2.6. *Operation and traffic management*

2.6.1. Safety

Alignment of the network operating rules and the qualifications of drivers and on-board staff and of the staff in the control centres must be such as to ensure safe operation, bearing in mind the different requirements of cross-border and domestic services.

The maintenance operations and intervals, the training and qualifications of the maintenance and control centre staff and the quality assurance system set up by the operators concerned in the control and maintenance centres must be such as to ensure a high level of safety.

2.6.2. Reliability and availability

The maintenance operations and periods, the training and qualifications of the maintenance and control centre staff and the quality assurance system set up by the operators concerned in the control and maintenance centres must be such as to ensure a high level of system reliability and availability.

2.6.3. Technical compatibility

Alignment of the network operating rules and the qualifications of drivers, on-board staff and traffic managers must be such as to ensure operating efficiency on the rail system, bearing in mind the different requirements of cross-border and domestic services.

▼ M3

2.6.4. Accessibility

2.6.4.1. Appropriate steps must be taken to ensure that operating rules provide for the necessary functionality required to ensure accessibility for persons with disabilities and persons with reduced mobility.

▼ B2.7. *Telematics applications for freight and passengers*

2.7.1. Technical compatibility

The essential requirements for telematics applications guarantee a minimum quality of service for passengers and carriers of goods, particularly in terms of technical compatibility.

Steps must be taken to ensure:

— that the databases, software and data communication protocols are developed in a manner allowing maximum data interchange between different applications and operators, excluding confidential commercial data,

— easy access to the information for users.

2.7.2. Reliability and availability

The methods of use, management, updating and maintenance of these databases, software and data communication protocols must guarantee the efficiency of these systems and the quality of the service.

▼ B

2.7.3. Health

The interfaces between these systems and users must comply with the minimum rules on ergonomics and health protection.

2.7.4. Safety

Suitable levels of integrity and dependability must be provided for the storage or transmission of safety-related information.

▼ M3

2.7.5. Accessibility

- 2.7.5.1. Appropriate steps must be taken to ensure that telematics applications for passengers subsystems provide for the necessary functionality required to ensure accessibility for persons with disabilities and persons with reduced mobility.

*ANNEX IV***‘EC’ DECLARATION OF CONFORMITY AND SUITABILITY FOR USE OF INTEROPERABILITY CONSTITUENTS****1. Interoperability constituents**

The ‘EC’ declaration applies to the interoperability constituents involved in the interoperability of the rail system, as referred to in Article 3. These interoperability constituents may be:

1.1. *Multiple-use constituents*

These are constituents that are not specific to the railway system and which may be used as such in other areas.

1.2. *Multiple-use constituents having specific characteristics*

These are constituents which are not, as such, specific to the railway system, but which must display specific performance levels when used for railway purposes.

1.3. *Specific constituents*

These are constituents that are specific to railway applications.

2. Scope

The ‘EC’ declaration covers:

- either the assessment by a notified body or bodies of the intrinsic conformity of an interoperability constituent, considered in isolation, to the technical specifications to be met,
- or the assessment/judgement by a notified body or bodies of the suitability for use of an interoperability constituent, considered within its railway environment and, in particular in cases where the interfaces are involved, in relation to the technical specifications, particularly those of a functional nature, which are to be checked.

The assessment procedures implemented by the notified bodies at the design and production stages will draw upon the modules defined in Decision 93/465/EEC, in accordance with the conditions referred to in the TSIs.

3. Contents of the ‘EC’ declaration

The ‘EC’ declaration of conformity or of suitability for use and the accompanying documents must be dated and signed.

That declaration must be written in the same language as the instructions and must contain the following:

- the Directive references,
- name and address of the manufacturer or its authorised representative established within the Community (give trade name and full address; in the case of the authorised representative, also give the trade name of the manufacturer),
- description of interoperability constituent (make, type, etc.),
- description of the procedure followed in order to declare conformity or suitability for use (Article 13),
- all the relevant descriptions met by the interoperability constituent and, in particular, its conditions of use,

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- name and address of the notified body or bodies involved in the procedure followed in respect of conformity or suitability for use and date of examination certificate together with, where appropriate, the duration and conditions of validity of the certificate,
- where appropriate, reference to the European specifications,
- identification of the signatory empowered to enter into commitments on behalf of the manufacturer or of the manufacturer's authorised representative established within the Community.

▼ **M5***ANNEX V***‘EC’ DECLARATION OF VERIFICATION OF SUBSYSTEMS**

1. ‘EC’ DECLARATION OF VERIFICATION OF SUBSYSTEMS

The ‘EC’ declaration of verification of a subsystem is a declaration established by the ‘applicant’ within the meaning of Article 18 in which he declares on his sole responsibility that the subsystem concerned, which has been subject to the relevant verifications procedures, satisfies the requirements of the relevant Union legislation, including any relevant national rules.

The ‘EC’ declaration of verification and the accompanying documents must be dated and signed.

The ‘EC’ declaration of verification must be based on the information resulting from the ‘EC’ verification procedure for subsystems set out in Annex VI. It must be written in the same language as the technical file accompanying the ‘EC’ declaration of verification and must contain at least the following:

- (a) the reference to this Directive, TSIs and applicable national rules,
- (b) the reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure and to the national rules which have been applied in case of a derogation, partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case,
- (c) name and address of the ‘applicant’ within the meaning of Article 18 (specifying the trade name and full address; in the case of the authorised representative, specifying also the trade name of the contracting entity or the manufacturer),
- (d) a brief description of the subsystem,
- (e) name(s) and address(es) and the identification number(s) of the notified body(ies) which conducted the ‘EC’ verification(s) referred to in Article 18,
- (f) name(s) and address(es) and the identification number(s) of the notified body(ies) which conducted the assessment of conformity with other regulations deriving from the Treaty,
- (g) name(s) and address(es) of the designated body(ies) which conducted the verification(s) of conformity with national rules referred to in Article 17(3),
- (h) name and address of the assessment body(ies) which established the safety assessment reports related to the use of the CSM on risk assessment where required by this Directive,
- (i) the references of the documents contained in the technical file accompanying the ‘EC’ declaration of verification,
- (j) all the relevant temporary or final provisions to be complied with by the subsystems and in particular, where appropriate, any operating restrictions or conditions,

▼M5

- (k) the identity of the signatory (i.e. the physical person or persons authorised to sign the declaration)

Where reference is made in Annex VI to the 'intermediate statement of verification' (ISV), the provisions of this Section shall apply to that declaration.

2. 'EC' DECLARATION OF VERIFICATION OF SUBSYSTEMS IN THE CASE OF MODIFICATIONS

In a case of a modification, which is not a substitution in the framework of maintenance, of a subsystem covered by an 'EC' declaration of verification, without prejudice to Article 20, the following provisions apply.

- 2.1. If the entity introducing the modification demonstrates that the modification does not affect the basic design characteristics of the subsystem which are relevant for the compliance with the requirements concerning the basic parameters:
 - (a) the entity introducing the modification shall update the references of the documents contained in the technical file accompanying the 'EC' declaration of verification;
 - (b) no new 'EC' declaration of verification needs to be established.
- 2.2. If the entity introducing the modification demonstrates that the modification affects the basic design characteristics of the subsystem which are relevant for the compliance with the requirements concerning some basic parameters:
 - (a) the entity introducing the modification shall establish a complementary 'EC' declaration of verification with reference to the basic parameters concerned;
 - (b) the complementary 'EC' declaration of verification shall be accompanied by a list of documents of the original technical file accompanying the original 'EC' declaration of verification that are no more valid;
 - (c) the technical file accompanying the 'EC' declaration of verification shall include a demonstration that the impact of modifications is limited to the basic parameters referred to in point (a);
 - (d) provisions of Section 1 of this Annex shall apply *mutatis mutandis* to this complementary 'EC' declaration of verification;
 - (e) the original 'EC' declaration of verification shall be considered valid for the basic parameters not concerned by the modification.

3. 'EC' DECLARATION OF VERIFICATION OF SUBSYSTEMS IN THE CASE OF ADDITIONAL VERIFICATIONS

An 'EC' declaration of verification of a subsystem may be complemented in the case of additional verifications carried out, in particular when such additional verifications are necessary for an additional authorisation for placing in service. In this case the scope of the complementary declaration shall be limited to the scope of the additional verifications.

▼ **M5***ANNEX VI***‘EC’ VERIFICATION PROCEDURE FOR SUBSYSTEMS**

1. GENERAL PRINCIPLES

“EC” verification’ means a procedure carried out by the applicant within the meaning of Article 18 to demonstrate that the requirements of the relevant Union legislation including any relevant national rules relating to a subsystem have been fulfilled and the subsystem may be authorised to be placed in service.

2. CERTIFICATE OF VERIFICATION ISSUED BY A NOTIFIED BODY

2.1. **Introduction**

For the purpose of this Directive, the verification by reference to TSIs is the procedure whereby a notified body checks and certifies that the subsystem complies with the relevant technical specifications for interoperability (TSI).

This is without prejudice of the obligations of the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18) to comply with the other applicable legislation deriving from the Treaty, including any verifications by the assessment bodies required by the other legislation.

2.2. **Intermediate statement of verification (ISV)**2.2.1. *Principles*

At the request of the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18), the verifications may be done for parts of a subsystem or may be limited to certain stages of the verification procedure. In these cases, the results of verification may be documented in an ‘intermediate statement of verification’ (ISV) issued by the notified body chosen by the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18).

The ISV must provide reference to the TSIs with which the conformity has been assessed.

2.2.2. *Parts of the subsystem*

The applicant within the meaning of Article 18 may apply for an ISV for any part into which he decides to split the subsystem. Each part shall be checked at each stage as set out in point 2.2.3.

2.2.3. *Stages of the verification procedure*

The subsystem, or certain parts of the subsystem, shall be checked at each of the following stages:

- (a) overall design,
- (b) production: construction, including, in particular, civil-engineering activities, manufacturing, constituent assembly and overall adjustment,
- (c) final testing.

The applicant (within the meaning of Article 18) may apply for an ISV for the design stage (including the type tests) and for the production stage for the whole subsystem or for any part into which the applicant decided to split it (see paragraph 2.2.2).

▼ M5**2.3. Certificate of verification**

- 2.3.1. The notified bodies responsible for the verification assesses the design, production and final testing of the subsystem and draw up the certificate of verification intended for the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18), who in turn draws up the 'EC' declaration of verification. The certificate of verification must provide reference to the TSIs with which the conformity has been assessed.

Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case), the certificate of verification shall give the precise reference to the TSI(s) or their parts whose conformity has not been examined by the notified body during the verification procedure.

- 2.3.2. Where ISV have been issued, the notified body responsible for the verification of the subsystem takes these ISV into account, and, before issuing its certificate of verification:

- (a) verifies that the ISV cover correctly the relevant requirements of the TSI(s),
- (b) checks all aspects that are not covered by the ISV, and
- (c) checks the final testing of the subsystem as a whole.

- 2.3.3. In the case of a modification to a subsystem already covered by a certificate of verification, the notified body shall perform only those examinations and tests that are relevant and necessary, i.e. assessment shall relate only to the parts of the subsystem that are changed and their interfaces to the unchanged parts of the subsystem.

- 2.3.4. Each notified body involved in the verification of a subsystem shall draw up a technical file in accordance with Article 18(3) covering the scope of its activities.

2.4. Technical file accompanying the EC declaration of verification

The technical file accompanying the EC declaration of verification shall be assembled by the applicant (in the meaning of Article 18) and must contain the following:

- (a) technical characteristics linked to the design including general and detailed drawings with respect to execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems to the level of detail sufficient for documenting the verification of conformity carried out, documentation on operation and maintenance, etc., relevant for the subsystem concerned;
- (b) a list of interoperability constituents, referred to in Article 5(3)(d), incorporated into the subsystem;
- (c) the technical files referred to in Article 18(3), compiled by each of the notified bodies involved in the verification of the sub-system, which shall include:
 - copies of the 'EC' declarations of conformity and, where applicable, 'EC' declarations of suitability for use established for interoperability constituents referred to in Article 5(3)(d) and accompanied, where appropriate, by the corresponding calculation notes and a copy of the records of the tests and examinations carried out by the notified bodies on the basis of the common technical specifications,

▼ M5

- where available, the ISV that accompany the certificate of verification, including the result of verification by the notified body of the ISV validity,
 - the certificate of verification, accompanied by corresponding calculation notes and signed by the notified body responsible for the verification, stating that the subsystem complies with the requirements of the relevant TSI(s) and mentioning any reservations recorded during performance of the activities and not withdrawn; the certificate of verification should also be accompanied by the inspection and audit reports drawn up by the same body in connection with its task, as specified in points 2.5.2 and 2.5.3;
- (d) certificates of verification issued in accordance with other legislation deriving from the Treaty;
- (e) when verification of safe integration is required pursuant to Article 15, the relevant technical file shall include the assessors' report(s) on the common safety methods (CSM) on risk assessment referred to in Article 6(3) of Directive 2004/49/EC.

2.5. Surveillance by notified bodies

- 2.5.1. The notified body responsible for checking production must have permanent access to building sites, production workshops, storage areas and, where appropriate, prefabrication or testing facilities and, more generally, to all premises which it considers necessary for its task. The notified body must receive from the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18) all the documents needed for that purpose and, in particular, the implementation plans and technical documentation concerning the subsystem.
- 2.5.2. The notified body responsible for checking implementation must periodically carry out audits in order to confirm compliance with the relevant TSI(s). It must provide those responsible for implementation with an audit report. Its presence may be required at certain stages of the building operations.
- 2.5.3. In addition, the notified body may pay unexpected visits to the worksite or to the production workshops. At the time of such visits the notified body may conduct complete or partial audits. It must provide those responsible for implementation with an inspection report and, if appropriate, an audit report.
- 2.5.4. The notified body shall be able to monitor a subsystem on which an interoperability constituent is mounted in order to assess, where required by the corresponding TSI, its suitability for use in its intended railway environment.

2.6. Submission

A copy of the technical file accompanying the EC declaration of verification must be kept by the manufacturer or contracting entity (i.e. by the applicant in the meaning of Article 18) throughout the service life of the subsystem. It must be sent to any Member State which so requests.

▼ M5

The documentation submitted for an application for an authorisation for placing in service shall be submitted to the national safety authority of the Member State where the authorisation is sought. The national safety authority may request that part(s) of the documents submitted together with the authorisation is/are translated into its own language.

2.7. Publication

Each notified body must periodically publish relevant information concerning:

- (a) requests for verification and ISV received,
- (b) request for assessment of conformity and suitability for use of ICs,
- (c) ISV issued or refused,
- (d) certificates of conformity and 'EC' certificates for suitability for use issued or refused,
- (e) certificates of verification issued or refused.

2.8. Language

The files and correspondence relating to the 'EC' verification procedure must be written in a Union official language of the Member State in which the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18) is established or in a Union official language accepted by the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18).

3. CERTIFICATE OF VERIFICATION ISSUED BY A DESIGNATED BODY**3.1. Introduction**

In the case where national rules apply, the verification shall include a procedure whereby the body designated pursuant to Article 17(3), third subparagraph, (the designated body) checks and certifies that the subsystem complies with the national rules notified in accordance with Article 17(3) for each Member State in which the subsystem is intended to be authorised to be placed in service.

3.2. Certificate of verification

The designated body draws up the certificate of verification intended for the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18).

The certificate shall contain a precise reference to the national rule(s) whose conformity has been examined by the designated body in the verification process.

In the case of national rules related to the subsystems composing a vehicle, the designated body shall divide the certificate into two parts, one part including the references to those national rules strictly related to the technical compatibility between the vehicle and the network concerned, and the other part for all other national rules.

▼ M5**3.3. Technical file**

The technical file compiled by the designated body and accompanying the certificate of verification in the case of national rules must be included in the technical file accompanying the 'EC' declaration of verification referred to in point 2.4 and shall contain the technical data relevant for the assessment of the conformity of the subsystem with those national rules.

3.4. Language

The files and correspondence relating to the 'EC' verification procedure must be written in a Union official language of the Member State in which the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18) is established or in a Union official language accepted by the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18).

4. VERIFICATION OF PARTS OF SUBSYSTEMS IN ACCORDANCE WITH ARTICLE 18(5)

If a certificate of verification is to be issued for certain parts of a subsystem, provisions for this Annex shall apply *mutatis mutandis* for those parts.

▼ B

ANNEX VII

PARAMETERS TO BE CHECKED IN CONJUNCTION WITH THE
PLACING IN SERVICE OF NON-TSI CONFORM VEHICLES AND THE
CLASSIFICATION OF THE NATIONAL RULES**▼ M1**1. **List of parameters**

1.1. General documentation

General documentation (including description of new, renewed or upgraded vehicle and its intended use, design, repair, operation and maintenance information, technical file, etc.)

1.2. Structure and mechanical parts

Mechanical integrity and interface between vehicles (including draw and buffer gear, gangways), strength of vehicle structure and fittings (e.g. seats), loading capability, passive safety (including interior and exterior crashworthiness)

1.3. Track interaction and gauging

Mechanical interfaces to the infrastructure (including static and dynamic behaviour, clearances and fits, gauge, running gear, etc.)

1.4. Braking equipment

Braking-related items (including wheel-slide protection, braking control, and braking performance in service, emergency and parking modes)

1.5. Passenger-related items

Passenger facilities and passenger environment (including passenger windows and doors, requirements for persons with reduced mobility, etc.)

1.6. Environmental conditions and aerodynamic effects

Impact of the environment on the vehicle and impact of the vehicle on the environment (including aerodynamic conditions and both the interface between the vehicle and the trackside part of the railway system and the interface with the external environment)

1.7. External warning, marking, functions and software integrity requirements

External warnings, markings, functions and integrity of software, e.g. safety-related functions with an impact on train behaviour including train bus

1.8. Onboard power supply and control systems

Onboard propulsion, power and control systems, plus the interface of the vehicle with the power supply infrastructure and all aspects of electromagnetic compatibility

1.9. Staff facilities, interfaces and environment

Onboard facilities, interfaces, working conditions and environment for staff (including drivers cabs, driver machine interface)

▼ M1

1.10. Fire safety and evacuation

1.11. Servicing

Onboard facilities and interfaces for servicing

1.12. Onboard control, command and signalling

All the onboard equipment necessary to ensure safety and to command and control movements of trains authorised to travel on the network and its effects on the trackside part of the railway system

1.13. Specific operational requirements

Specific operational requirements for vehicles (including degraded mode, vehicle recovery etc.)

1.14. Freight related items

Freight-specific requirements and environment (including facilities specifically required for dangerous goods)

Explanations and examples *in italics* above are for information only and are not definitions of the parameters.

▼ B

2. Classification of the rules

The national rules relating to the parameters identified in section 1 shall be attributed to one of the following three groups. Rules and restrictions of a strictly local nature are not involved; their verification involves checks to be put in place by mutual agreement between the railway undertakings and the infrastructure managers.

Group A

Group A covers:

- international standards,
- national rules deemed to be equivalent, in railway safety terms, to national rules of other Member States.

Group B

Group B covers all rules that do not fall within the scope of Group A or Group C, or that it has not yet been possible to classify in one of these groups.

Group C

Group C covers rules that are strictly necessary and are associated with technical infrastructure characteristics, in order to ensure safe and interoperable use in the network concerned (e.g. the loading gauge).

*ANNEX VIII*MINIMUM CRITERIA WHICH MUST BE TAKEN INTO ACCOUNT BY
THE MEMBER STATES WHEN NOTIFYING BODIES

1. The body, its Director and the staff responsible for carrying out the checking operations may not become involved either directly or as authorised representatives in the design, manufacture, construction, marketing or maintenance of the interoperability constituents or subsystems or in their use. This does not exclude the possibility of an exchange of technical information between the manufacturer and that body.

2. The body and the staff responsible for the checks must carry out the checks with the greatest possible professional integrity and the greatest possible technical competence and must be free of any pressure and incentive, in particular of a financial type, which could affect their judgement or the results of their inspection, in particular from persons or groups of persons affected by the results of the checks.

In particular, the body and the staff responsible for the checks must be functionally independent of the authorities designated to issue authorisations for placing in service in the framework of this Directive, licences in the framework of Directive 95/18/EC and safety certificates in the framework of Directive 2004/49/EC, and of the bodies in charge of investigations in the event of accidents.

3. The body must employ staff and possess the means required to perform adequately the technical and administrative tasks linked with the checks; it should also have access to the equipment needed for exceptional checks.

4. The staff responsible for the checks must possess:

- proper technical and vocational training,
- a satisfactory knowledge of the requirements relating to the checks that they carry out and sufficient practice in those checks,
- the ability to draw up the certificates, records and reports which constitute the formal record of the inspections conducted.

5. The independence of the staff responsible for inspections must be guaranteed. No official must be remunerated either on the basis of the number of inspections performed or of the results of those inspections.

6. The body must take out civil liability insurance unless that liability is covered by the State under national law or unless the checks are carried out directly by that Member State.

7. The staff of the body are bound by professional secrecy with regard to everything they learn in the performance of their duties (with the exception of the competent administrative authorities and accident investigation bodies in the State where they perform those activities as well as accident investigation bodies responsible for the investigation of accidents caused by the failure of the interoperability constituents or subsystems checked) in pursuance of this Directive or any provision of national law implementing the Directive.

*ANNEX IX***FILE FOR SUBMITTING A DEROGATION**

When submitting a request for a derogation, Member States must supply the following documents:

- (a) A formal letter communicating the proposed derogation to the Commission.
- (b) A file, annexed to the letter, comprising at least:
 - a description of the work, goods and services subject to the derogation, specifying the key dates, the geographical location and the operational and technical area,
 - a precise reference to the TSIs (or their parts) for which a derogation is requested,
 - a precise reference to and details of the alternative provisions which will be applied,
 - for requests made under Article 7(1)(a), justification of the advanced stage of development of the project,
 - justification of the derogation, including the main reasons of a technical, economic, commercial, operational and/or administrative nature,
 - any other information justifying the request for a derogation,
 - a description of the measures that the Member State proposes to take in order to promote the final interoperability of the project. In the case of a minor derogation, this description is not required.

Documentation must be supplied in paper form and as electronic files, so that it can be distributed among the members of the Committee.

▼B*ANNEX X***PART A****Directives repealed**

(referred to in Article 40)

Directive 96/48/EC		
Directive 2001/16/EC		
Directive 2004/49/EC		Only Article 14

PART B**Time limits for transposition into national law**

(referred to in Article 40)

Directive	Deadline for transposition
96/48/EC	9 April 1999
2001/16/EC	20 April 2003
2004/49/EC	30 April 2006



ANNEX XI

CORRELATION TABLE

Directive 96/48/EC	Directive 2001/16/EC	This Directive
Article 1(1)	Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2)	Article 1(2)
—	—	Article 1(3)
—	Article 1(3)	Article 1(4)
Article 2, introductory wording	Article 2, introductory wording	Article 2, introductory wording
Article 2(a) to (l)	Article 2(a) to (l)	Article 2(a) to (b) and (e) to (m)
—	—	Article 2(c) and (d)
Article 2(n)	Article 2(m)	Article 2(n)
Article 2(o)	Article 2(n)	Article 2(o)
Article 2(m)	Article 2(o)	Article 2(p)
Article 2(p)	Article 2(p)	Article 2(q)
—	—	Article 2(r) to (z)
Articles 3, 4 and 5	Articles 3, 4 and 5	Articles 3, 4 and 5(1) to (5)
Article 5(6)	Article 5(7)	Article 5(7)
—	—	Article 5(6)
—	—	Article 5(8)
Article 6(1) to (8)	Article 6(1) to (8)	Article 6(1) to (8)
—	—	Article 6(9) to (10)
—	—	Articles 7 and 8
Article 7	Article 7	Article 9
Article 8	Article 8	Article 10(1)
Article 9	Article 9	Article 10(2)
Article 10(1) to (3)	Article 10(1) to (3)	Article 11(1) to (3)
—	Article 10(6)	Article 11(4)
—	—	Article 11(5)
Articles 11 to 13	Articles 11 to 13	Articles 12 to 14
Article 14(1) and (2)	Article 14(1) and (2)	Article 15(1) and (2)
Article 14(3)	Article 14(3)	Article 20
Article 14(4) and (5)	Article 14(4) and (5)	Article 33
—	—	Article 15(2) and (3)

▼B

Directive 96/48/EC	Directive 2001/16/EC	This Directive
Articles 15 and 16	Articles 15 and 16	Articles 16 and 17
Article 16(3)	Article 16(3)	Article 17(3)
—	—	—
Article 18(1) to (3)	Article 18(1) to (3)	Article 18(1) to (3)
—	—	Article 18(4) and (5)
Article 19	Article 19	Article 19
Article 20	Article 20	Article 28
—	—	Articles 21 to 27
Article 21(1) to (3)	Article 21(1) to (3)	Article 29(1) to (3)
—	—	Article 29(4) and (5)
—	—	—
Article 21a(1)	Article 22	Article 30(2)
Article 21(4)	21(4)	Article 30(4)
Article 21a(2)	Article 21a	Article 30(1)
Article 21b	—	—
Article 21c	Article 21b	Article 30(3)
Article 22	Article 26	Article 37
Article 22a	Article 24	Articles 34 and 35
—	—	Article 32
—	Article 23	Article 31
—	Article 25	Article 36
Article 23	Article 27	Article 38
Article 24	Article 28	Article 39
—	—	Article 40
Article 25	Article 29	Article 41
Article 26	Article 30	Article 42
Annexes I to VI	Annexes I to VI	Annexes I to VI
—	—	Annex VII
Annex VII	Annex VII	Annex VIII
—	—	Annexes IX to XI