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(Acts whose publication is obligatory)

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**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the Commission proposal⁽¹⁾,

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

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

Acting in accordance with the procedure referred to in Article 251 of the Treaty⁽⁴⁾,

Whereas:

- (1) 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.
- (2) By signing the Protocol adopted in Kyoto on 12 December 1997 the European Union has undertaken to reduce its 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.

⁽¹⁾ OJ C 89 E, 28.3.2000, p. 1.

⁽²⁾ OJ C 204, 18.7.2000, p. 13.

⁽³⁾ OJ C 317, 6.11.2000, p. 22.

⁽⁴⁾ Opinion of the European Parliament of 17 May 2000 (OJ C 59, 23.2.2001, p. 106), Council Common Position of 10 November 2000 (OJ C 23, 24.1.2001, p. 15) and Decision of the European Parliament of 13 February 2001.

(3) The Council strategy for the integration of the environment and sustainable development into Community transport policy highlights the need to act to reduce the environmental impact of transport.

(4) The commercial operation of trains throughout the trans-European rail network requires in particular excellent compatibility between the characteristics of the infrastructure and those of the rolling stock, as well as efficient interconnection of the information and communication systems of the different infrastructure managers and operators. Performance levels, safety, quality of service and cost depend upon such compatibility and interconnection, as does, in particular, the interoperability of the trans-European conventional rail system.

(5) To achieve these objectives an initial measure was taken by the Council on 23 July 1996 with the adoption of Directive 96/48/EC concerning the interoperability of the trans-European high-speed rail system⁽⁵⁾.

(6) In its White Paper entitled 'A strategy for revitalising the Community's railways' in 1996, the Commission announced a second measure in the conventional rail sector and then ordered a study on the integration of national rail systems, the results of which were published in May 1998 with the recommendation of the adoption of a Directive based on the approach taken in the high-speed sector. This study also recommended that, rather than tackling all the obstacles to interoperability head on, problems should be solved gradually according to an order of priority based on the cost-benefit ratio of each proposed measure. In this study the harmonisation of procedures and rules in use and the interconnection of information and communication systems were shown to be more effective than measures, for example, concerning the infrastructure loading gauge.

⁽⁵⁾ OJ L 235, 17.9.1996, p. 6.

- (7) The Commission communication on 'Integration of conventional rail systems' recommends the adoption of this Directive and justifies the similarities and main differences compared with Directive 96/48/EC. The main differences lie in the adaptation of the geographical scope, in the extension of the technical scope to take account of the results of the above study and in the adoption of a gradual approach to eliminating obstacles to the interoperability of the rail system, which includes establishing an order of priorities and a timetable for drawing it up.
- (8) In view of that gradual approach and of the time consequently required for the adoption of all the technical specifications for interoperability (TSIs), steps should be taken to avoid a situation where Member States adopt new national rules or undertake projects that increase the heterogeneity of the present system.
- (9) The adoption of a gradual approach satisfies the special needs of the objective of interoperability of the conventional rail system, which is characterised by old national infrastructure and stock 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.
- (10) In its Resolution of 10 March 1999 on the rail package the Parliament asked that the progressive opening up of the rail sector go hand-in-hand with the fastest and most effective possible technical harmonisation measures.
- (11) The Council 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 as well as personnel training and qualifications.
- (12) 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.
- (13) 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.
- (14) There are major differences in the national regulations and 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.
- (15) 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.
- (16) It is therefore appropriate to define basic essential requirements for the whole of the Community which will apply to the trans-European conventional rail system.
- (17) In view of the extent and complexity of the trans-European conventional rail system, it has proved necessary, for practical reasons, to break this down into subsystems. 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.
- (18) Implementation of the provisions on the interoperability of the trans-European conventional 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.
- (19) The technical specifications for interoperability 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.
- (20) Each Member State concerned should be allowed not to apply certain technical specifications for interoperability 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.

⁽¹⁾ OJ L 237, 24.8.1991, p. 25.

- (21) The drawing up of TSIs and their application to the conventional rail system should not impede technological innovation, which should be directed towards improving economic performance.
- (22) Advantage should be taken of the interoperability of the conventional rail system, particularly in the case of freight, to bring about the conditions for greater interoperability between modes of transport.
- (23) To comply with the appropriate provisions on procurement procedures in the rail sector and in particular Directive 93/38/EEC⁽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.
- (24) 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.
- (25) 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 trans-European conventional rail system must satisfy.
- (26) 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 Decision 93/465/EEC⁽²⁾. 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.
- (27) 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 now 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.
- (28) That does not affect the obligation on manufacturers to affix the CE marking to certain components in order to certify their compliance with other Community provisions relating to them.
- (29) The subsystems constituting the trans-European conventional rail system should be subjected to a verification procedure. This verification must enable the authorities responsible for authorising their putting into 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 a module defining the principles and conditions applying to 'EC' verification of subsystems.
- (30) 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.
- (31) These TSIs are drawn up to the order of the Commission by the joint body representing the infrastructure managers, the railway companies and the industry. Representatives of non-member countries, in particular those of the applicant countries, may from the outset be authorised to attend meetings of the joint representative body as observers.
- (32) Directive 91/440/EEC requires a separation of activities, in accounting terms, between transport service operation and railway infrastructure management. This being the case, the specialised services provided by railway infrastructure managers designated as notified bodies should be structured in such a way as to meet the criteria which must apply to this type of body. Other specialised bodies may be notified where these meet the same criteria.
- (33) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 99/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽³⁾.

⁽¹⁾ Council Directive 93/38/EEC of 14 June 1993 coordinating the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors (OJ L 199, 9.8.1993, p. 84). Directive as last amended by Directive 98/4/EC (OJ L 101, 1.4.1998, p. 1).

⁽²⁾ 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).

⁽³⁾ OJ L 184, 17.7.1999, p. 23.

(34) Interoperability within the trans-European conventional rail system is Community-wide in scale. No individual Member State is in a position to take the action needed in order to achieve this interoperability. In accordance with the principle of subsidiarity, the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore by reason of the scale or effects of the proposed action be better achieved by the Community,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER ONE

General provisions

Article 1

1. This Directive sets out to establish the conditions to be met to achieve interoperability within the Community territory of the trans-European conventional rail system, as described in Annex I. These conditions concern the design, construction, putting into service, upgrading, renewal, operation and maintenance of the parts of this system put into service after the date of entry into force of this Directive, as well as the professional qualifications and health and safety conditions of the staff who contribute to its operation.

2. The pursuit of this objective must lead to the definition of a minimum 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 trans-European conventional rail system;
- (c) contribute to the interoperability of the trans-European conventional rail system.

Article 2

For the purposes of this Directive:

- (a) 'trans-European conventional rail system' means the structure, as described in Annex I, composed of lines and

fixed installations, of the trans-European transport network, built or upgraded for conventional rail transport and combined rail transport, plus the rolling stock designed to travel on that infrastructure;

- (b) 'interoperability' means the ability of the trans-European conventional rail system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance for these lines. This ability rests on all the regulatory, technical and operational conditions which must be met in order to satisfy the essential requirements;
- (c) 'subsystems' means the result of the division of the trans-European conventional rail system, as shown in Annex II. These subsystems, for which essential requirements must be laid down, are structural and functional;
- (d) '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 trans-European conventional rail system depends directly or indirectly. The concept of a 'constituent' covers both tangible objects and intangible objects such as software;
- (e) 'essential requirements' means all the conditions set out in Annex III which must be met by the trans-European conventional rail system, the subsystems, and the interoperability constituents including interfaces;
- (f) 'European specification' means a common technical specification, a European technical approval or a national standard transposing a European standard, as defined in points 8 to 12 of Article 1 of Directive 93/38/EEC;
- (g) 'technical specifications for interoperability', hereinafter referred to as 'TSIs', means the specifications by which each subsystem or part subsystem is covered in order to meet the essential requirements and ensure the interoperability of the trans-European conventional rail system;
- (h) 'joint representative body' (JRB) means the body bringing together representatives of the infrastructure managers, railway companies and industry which is responsible for drawing up the TSIs. 'Infrastructure managers' means those referred to in Articles 3 and 7 of Directive 91/440/EEC;
- (i) '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;

- (j) 'basic parameters' means any regulatory, technical or operational condition which is critical to interoperability and requires a decision in accordance with the procedure laid down in Article 21(2) before any development of draft TSIs by the joint representative body;
- (k) 'specific case' means any part of the trans-European conventional 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 rolling stock strictly intended for local, regional or historical use, as well as rolling stock originating from or destined for third countries, as long as this stock does not cross the border between two Member States;
- (l) 'upgrading' means any major modification work on a subsystem or part subsystem which requires fresh authorisation for putting into service within the meaning of Article 14(1);
- (m) 'renewal' means any major substitution work on a subsystem or part subsystem which requires fresh authorisation for putting into service within the meaning of Article 14(1);
- (n) 'existing rail system' means the structure composed of lines and fixed installations of the existing rail system plus the rolling stock of all categories and origin travelling on that infrastructure.

Article 3

1. This Directive applies to the provisions concerning, for each subsystem, the interoperability constituents, the interfaces and procedures as well as the conditions of overall compatibility of the trans-European conventional 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.

Article 4

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

2. The further technical specifications referred to in Article 18(4) of Directive 93/38/EEC 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 (TSIs)

Article 5

1. Each of the subsystems shall be covered by a TSI. Where necessary, especially for treating categories of lines, hubs or rolling stock separately, or to solve certain interoperability problems as a matter of priority, a subsystem may be covered by several TSIs. In this case the provisions of this Article also apply to the part of the subsystem concerned.
2. Subsystems shall comply with the TSIs; this compliance shall be permanently maintained while each subsystem is in use.
3. To the extent necessary in order to achieve the objectives referred to in Article 1, each TSI shall:
 - (a) indicate its intended scope (part of network or rolling stock 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 rolling stock 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 trans-European conventional rail system;
 - (e) state, in each case under consideration, the procedures for the assessment of conformity or suitability of use. This includes in particular the modules defined in Decision 93/465/EEC or, where appropriate, the specific procedures, to be used to assess either the conformity or the suitability for use of interoperability constituents and 'EC' verification of subsystems;

- (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 trans-European conventional rail system.

5. The 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 set of TSIs, with regard to both infrastructure and rolling stock; special attention must be given to the loading gauge, the track gauge or space between the tracks and wagons from or going to third countries. For each specific case, the TSIs stipulate the implementing rules of the elements of the TSIs indicated in paragraphs 3(c) to (g).

6. The TSIs shall not be an impediment to decisions by the Member States concerning the use of infrastructures for the movement of rolling stock not covered by the TSIs.

Article 6

1. Draft TSIs shall be drawn up by the joint representative body under a mandate from the Commission in accordance with the procedure set out in Article 21(2). TSIs shall be adopted and reviewed by the same procedure. They shall be published by the Commission in the *Official Journal of the European Communities*.

2. The joint representative body shall be designated in accordance with the procedure set out in Article 21(2); it shall comply with the rules laid down in Annex VIII. Where the joint representative body does not comply with these rules or does not have the authority needed to draw up a particular TSI, another authorised body shall be designated by the same procedure. In the latter case, the joint representative body must be associated with the work of the other body.

3. The joint representative body or, where appropriate, the authorised body in question shall be responsible for preparing the review and updating of TSIs and making appropriate recommendations to the Committee referred to in Article 21 in order to take account of developments in technology or social requirements.

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

First of all, the joint representative body shall identify the basic parameters for this 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. A decision shall be taken in accordance with the procedure set out in Article 21(2); if necessary, specific cases shall be cited.

The joint representative body shall then draw up the draft TSI on the basis of these basic parameters. Where appropriate, the joint representative body 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.

5. 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.

6. The Committee referred to in Article 21 shall be kept regularly informed of the preparatory work on the TSIs. During this work the Committee may formulate any terms of reference or useful recommendations concerning the design of the TSIs and the cost-benefit analysis. In particular, the Committee 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.

7. On the adoption of each TSI, the date of entry into force of that TSI shall be established in accordance with the procedure provided for in Article 21(2). Where different subsystems have to be put into service simultaneously for reasons of technical compatibility, the dates of entry into force of the corresponding TSIs shall be the same.

8. The drafting and review of the TSIs shall take account of the opinions of the users, as regards the characteristics which have a direct impact on the conditions in which they use the subsystems.

To that end the joint representative body or, where appropriate, the authorised body shall consult associations and bodies representing users during the drafting and review phases of the TSIs.

They 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 finalised by the Committee referred to in Article 21 before adopting the mandate of the first TSI and may be re-examined and updated at the request of a Member State or the Commission.

9. The drafting 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 21.

The social partners shall be consulted in the context of the Sectoral Dialogue Committee set up in accordance with Commission Decision 98/500/EC⁽¹⁾.

The social partners shall issue their opinion within three months.

Article 7

A Member State need not apply one or more TSIs, including those relating to rolling stock, in the following cases and circumstances:

- (a) for a proposed new line, for the upgrading of an existing line, or for any element referred to Article 1(1) at an advanced stage of development or the subject of a contract in course of performance when these TSIs are published;
- (b) for any project concerning the renewal or upgrading of an existing line where the loading gauge, track gauge, space between the tracks, or electrification voltage in these TSIs is not compatible with those of the existing line;
- (c) for a proposed new line or for the proposed renewal or upgrading of an existing line in the territory of that Member State when its rail network is separated or isolated by the sea from the rail network of the rest of the Community;
- (d) for any proposed renewal, extension or upgrading of an existing line, when the application of these TSIs would compromise the economic viability of the project and/or the compatibility of the rail system in the Member State;

⁽¹⁾ Commission Decision 98/500/EC of 20 May 1998 on the establishment of Sectoral Dialogue Committees promoting the Dialogue between the social partners at European level (OJ L 255, 12.8.1998, p. 27).

(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 wagons from or going to third countries the track gauge of which is different from that of the main rail network of the Community.

In all cases the Member State concerned shall serve prior notice of its intended derogation to the Commission and shall forward to it a file setting out the TSIs or the parts of TSIs that it does not wish to be applied as well as the corresponding specifications that it does wish to apply. The Committee provided for in Article 21 shall analyse the measures envisaged by the Member State. In cases (b), (d) and (f), the Commission shall take a decision in accordance with the procedure in Article 21(2). Where necessary, a recommendation shall be drawn up concerning the specifications to be applied. Nevertheless, in the case of (b) the Commission's decision shall not cover the loading gauge and the track gauge.

CHAPTER III

Interoperability constituents

Article 8

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 trans-European conventional 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.

Article 9

Member States may not, in their territory and on grounds concerning this Directive, prohibit, restrict or hinder the placing on the market of interoperability constituents for use in the trans-European conventional 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 10

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

2. Compliance of an interoperability constituent with the respective essential requirements and, where appropriate, its suitability for use shall be established in relation to the conditions laid down by the corresponding TSI, including any relevant European specifications that may exist.

3. The references to European specifications shall be published in the *Official Journal of the European Communities* and mentioned in the respective TSI. When the relevant European specifications are published after adoption of the TSI, they shall be taken into account as soon as the TSIs are revised.

4. Member States shall publish the references to national standards transposing European standards.

5. As regards the period prior to the publication of a TSI, in the absence of any European specifications and without prejudice to Article 20(5), Member States shall notify to the other Member States and the Commission a list of the standards and technical specifications in use in order to implement the essential requirements. This notification shall be made not later than 20 March 2002.

6. Where a European specification is not yet available at the time of adoption of a TSI and compliance with this specification is an essential precondition to guarantee interoperability, the TSI may refer to the most advanced version available of the draft European specification that has to be complied with or that incorporates all or part of that draft.

Article 11

Where it appears to a Member State or the Commission that European specifications do not meet the essential requirements, partial or total withdrawal of these specifications from the publications containing them, or their amendment, may be decided upon in accordance with the procedure laid down in Article 21(2) after consultation, where European standards are involved, of the Committee set up under Directive 98/34/EC⁽¹⁾.

⁽¹⁾ 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 (OJ L 204, 21.7.1998, p. 37). Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

Article 12

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 States 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;
- (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 defined in Article 11 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.

Article 13

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. 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 instances, 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 arising out of paragraphs 1, 2 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 12:

(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 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 at issue, or to ensure that it is withdrawn from the market in accordance with the procedures provided for in Article 12.

CHAPTER IV

Subsystems

Article 14

1. Each Member State shall authorise the putting into service of those structural subsystems constituting the trans-European conventional 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 put into 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 trans-European conventional rail system. In particular, they shall check the compatibility of these subsystems with the system into which they are being integrated.

2. Each Member State shall check when they are put into service and at regular intervals thereafter, that these subsystems are operated and maintained in accordance with the essential requirements concerning them.

3. In the event of renewal or upgrading, the manager of the rail infrastructure or enterprise 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 size of the works means that a new authorisation for putting into service within the meaning of this Directive is needed. This authorisation for putting into service is required each time the safety level may be affected by the works envisaged.

Article 15

Without prejudice to the provisions of Article 19, Member States may not, in their territory and on grounds concerning this Directive, prohibit, restrict or hinder the construction, putting into service and operating of structural subsystems constituting the trans-European conventional rail system which meet the essential requirements. In particular, they may not require checks which have already been carried out as part of the procedure leading to the 'EC' declaration of verification, the components of which are set out in Annex V.

Article 16

1. Member States shall consider as being interoperable and meeting the essential requirements concerning them, those structural subsystems constituting the trans-European conventional 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 trans-European conventional rail system shall be established by reference to TSIs where they exist.

3. As regards the period prior to the publication of TSIs, Member States shall send the other Member States and the Commission, for each subsystem, a list of the technical rules in use for implementing the essential requirements. This shall be notified not later than 20 March 2002.

Article 17

Where it appears that the TSIs do not fully meet the essential requirements the Committee referred to in Article 21 may be consulted at the request of a Member State or on the initiative of the Commission.

Article 18

1. In order to establish the 'EC' declaration of verification, the procurement entity or its official representative shall invite the notified body that it has selected for that purpose to apply the 'EC' verification procedure referred to in Annex VI.
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 put into 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 Article 24.
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.

Article 19

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 substantiating reasons therefor. The Commission shall without delay initiate the procedure provided for in Article 21(2).

CHAPTER V

Notified bodies*Article 20*

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 Communities* the list of bodies, their identification numbers and areas of responsibility, and shall keep the list updated.

2. Member States shall apply the criteria provided for in Annex VII 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 the said criteria.

3. A Member State shall withdraw approval from a body which no longer meets the criteria referred to in Annex VII. 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 relevant criteria, the matter shall be referred to the Committee provided for in Article 21, which shall deliver its opinion within three months. In the light of the opinion of the Committee, the Commission shall inform the Member State in question of any changes that are necessary for the notified body to retain the status conferred upon it.

5. Where appropriate, coordination of the notified bodies shall be implemented in accordance with Articles 21 and 22.

CHAPTER VI

Committee and work programme*Article 21*

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 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.

3. The Committee shall adopt its rules of procedure.

Article 22

Once this Directive enters into force, the Committee may discuss any matter relating to the interoperability of the trans-European conventional rail system, including questions relating to interoperability between the trans-European rail system and the rail system of third countries.

Article 23

1. The order of priority for the adoption of the TSIs shall be as follows, without prejudice to the order of adoption of the mandates provided for in Article 6(1):

- (a) the first group of TSIs will cover control/command and signalling; telematic applications for freight services; traffic operation and management (including staff qualifications for cross-border services respecting the criteria defined in Annexes II and III); freight wagons; noise problems deriving from rolling stock and infrastructure.

As regards rolling stock, that intended for international use will be developed first;

- (b) the following aspects shall also be discussed in the light of the resources of the Commission and the joint representative body: telematic applications for passenger services, maintenance, with particular regard to safety, passenger carriages, traction units and locomotives, infrastructure, energy and air pollution.

As regards rolling stock, that intended for international use will be developed first;

- (c) at the request of the Commission, a Member State or the joint representative body, the Committee may decide, according to the procedure laid down in Article 21(2), to draw up a TSI for an additional subject without prejudicing the order of priorities set out above in so far as it concerns a subsystem mentioned in Annex II.

2. The Committee, following the procedure laid down in Article 21(2), shall draw up a work programme observing the order of priority referred to in paragraph 1 and that of the other tasks entrusted to it by this Directive.

The TSIs mentioned in the first work programme referred to in paragraph 1(a) shall be drawn up not later than 20 April 2004.

3. The work programme shall consist of the following stages:

- (a) designation of the joint representative body;
- (b) development on the basis of a draft established by the joint representative body of a representative architecture of the conventional rail system, based on the list of subsystems (Annex II), to guarantee consistency between TSIs. This architecture must include in particular the different constituents of this system and their interfaces and act as a reference framework for defining the areas of use of each TSI;

(c) adoption of a model structure for developing TSIs;

(d) adoption of a method of cost-benefit analysis of the solutions set out in the TSIs;

(e) adoption of the mandates needed to draw up the TSIs;

(f) adoption of the basic parameters for each TSI;

(g) approval of draft standardisation programmes;

(h) management of the transition period between the date of entry into force of this Directive and publication of the TSIs, including the adoption of the reference system mentioned in Article 25.

CHAPTER VII

Registers of infrastructure and rolling stock*Article 24*

1. The Member States shall ensure that registers of infrastructure and of rolling stock are published and updated annually. Those registers 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 by the applicable TSIs. To that end, each TSI shall indicate precisely which information must be included in the registers of infrastructure and of rolling stock.

2. A copy of those registers shall be sent to the Member States concerned and to the joint representative body and shall be made available to the public.

CHAPTER VIII

Transitional provisions*Article 25*

1. The joint representative body shall develop, on the basis of the information notified by the Member States under Articles 10(5) and 16(3), technical documents by the profession and texts of the relevant international agreements, a draft reference system of technical rules ensuring the current degree of interoperability of the trans-European conventional rail system. The Committee shall examine this draft and decide whether it may constitute a reference system pending the adoption of TSIs.

2. Following adoption of the abovementioned reference system, Member States shall inform the Committee 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 IX

Final provisions

Article 26

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 trans-European conventional rail system and any decision taken pursuant to Articles 11, 12, 17 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 laws in force in the Member State concerned and of the time limits allowed for the exercise of such remedies.

Article 27

1. Member States shall bring into force the laws, regulations and administrative provisions needed to comply with this Directive no later than 20 April 2003, with the exception of the provisions specific to each TSI which shall be implemented in accordance with the arrangements specific to each TSI. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

Article 28

Every two years, and for the first time 20 April 2005 the Commission shall report to the European Parliament and the Council on the progress made towards achieving interoperability of the trans-European conventional rail system. That report shall also include an analysis of the cases set out in Article 7.

The joint representative body 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 trans-European conventional rail system. That tool shall use the information available in the registers provided for in Article 24.

Article 29

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

Article 30

This Directive is addressed to the Member States.

Done at Brussels, 19 March 2001.

For the European Parliament

The President

N. FONTAINE

For the Council

The President

A. LINDH

ANNEX I

THE TRANS-EUROPEAN CONVENTIONAL RAIL SYSTEM

1. INFRASTRUCTURE

The infrastructure of the trans-European conventional rail system shall be that on the lines of the trans-European transport network identified 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⁾ or listed in any update to the same Decision as a result of the revision provided for in Article 21 of that Decision.

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 components.

This infrastructure 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.

2. ROLLING STOCK

The rolling stock shall comprise all the stock 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 rolling stock designed to carry lorries.

Each of the above categories must be subdivided into:

- rolling stock for international use;
- rolling stock for national use;

taking due account of the local, regional or long-distance use of the stock.

3. COMPATIBILITY OF THE TRANS-EUROPEAN CONVENTIONAL RAILWAY SYSTEM

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

⁽¹⁾ OJ L 228, 9.9.1996, p. 1.

ANNEX II

SUBSYSTEMS

1. LIST OF SUBSYSTEMS

For the purposes of this Directive, the system constituting the trans-European conventional rail system may be broken down into the following two subsystems, either:

(a) structural areas:

- infrastructure;
- energy;
- control and command and signalling;
- traffic operation and management;
- rolling stock; or

(b) operational areas:

- 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 joint representative body 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, in particular:

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, overhead lines and current collectors.

2.3. Control and command and signalling:

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

2.4. Traffic operation and management:

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

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

2.5. Telematics applications:

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

- (a) applications for passenger services, including systems providing 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 (real-time 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.

2.6. Rolling stock:

Structure, command and control system for all train equipment, traction and energy conversion units, 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.

2.7. Maintenance:

The procedures, associated equipment, logistics centres for maintenance work and reserves allowing 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.
- 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 foreseeably in a manner 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 infrastructure.
- 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 trans-European conventional 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 infrastructure 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.
- 1.4.4. Operation of the trans-European conventional rail system must respect existing regulations on noise pollution.

- 1.4.5. Operation of the trans-European conventional 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 trans-European conventional 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.

2. 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.

2.2. **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 and command and signalling**

2.3.1. Safety

The control and 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 and 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 and command and signalling systems must be tailored to use of those systems.

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

2.4. **Rolling stock**

2.4.1. Safety

The structure of the rolling stock and 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 and command and signalling installations.

The braking techniques and the stresses exerted must be compatible with the design of the track, 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.

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 of sufficient intensity and duration is compulsory 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 and ground control.

2.4.2. Reliability and availability

The design of the vital equipment, of the running, traction and braking equipment and of the control and command system must be such as to enable the train to continue its mission, in a specific degraded situation, 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 and 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 trans-European conventional 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.

2.5. **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 conventional 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.

2.6. **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 trans-European conventional rail system, bearing in mind the different requirements of cross-border and domestic services.

2.7. 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.

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.

ANNEX IV

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 trans-European conventional 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;
- the name and address of the manufacturer or his 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 or constructor);
- 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;
 - 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.
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ANNEX V

DECLARATION OF VERIFICATION OF SUBSYSTEMS

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

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

- the Directive references;
 - name and address of the contracting entity 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 contracting entity);
 - a brief description of the subsystem;
 - name and address of the notified body which conducted the 'EC' verification referred to in Article 18;
 - the references of the documents contained in the technical file;
 - all the relevant temporary or definitive provisions to be complied with by the subsystems and in particular, where appropriate, any operating restrictions or conditions;
 - if temporary: duration of validity of the 'EC' declaration;
 - identity of the signatory.
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ANNEX VI

VERIFICATION PROCEDURE FOR SUBSYSTEMS

1. INTRODUCTION

'EC' verification is the procedure whereby a notified body checks and certifies, at the request of a contracting entity or of its authorised representative established within the Community, that a subsystem:

- complies with the Directive;
- complies with the other regulations deriving from the Treaty, and may be put into operation.

2. STAGES

The subsystem is checked at each of the following stages:

- overall design;
- construction of subsystem, including, in particular, civil-engineering activities, constituent assembly, overall adjustment;
- final testing of the subsystem.

3. CERTIFICATE

The notified body responsible for 'EC' verification draws up the certificate of conformity intended for the contracting entity or its authorised representative established within the Community, which in turn draws up the 'EC' declaration of verification intended for the supervisory authority in the Member State in which the subsystem is located and/or operates.

4. TECHNICAL FILE

The technical file accompanying the declaration of verification must be made up as follows:

- for infrastructure: engineering-structure plans, approval records for excavations and reinforcement, testing and inspection reports on concrete;
- for the other subsystems: general and detailed drawings in line with execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems, operating and maintenance manuals, etc.;
- list of interoperability constituents, as referred to in Article 3, incorporated into the subsystem;
- copies of the 'EC' declarations of conformity or suitability for use with which the abovementioned constituents must be provided in accordance with Article 13 of the Directive 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;
- certificate from the notified body responsible for 'EC' verification, accompanied by corresponding calculation notes and countersigned by itself, stating that the project complies with this Directive and mentioning any reservations recorded during performance of the activities and not withdrawn; the certificate should also be accompanied by the inspection and audit reports drawn up by the same body in connection with its task, as specified in sections 5.3 and 5.4.

5. MONITORING

- 5.1. The aim of 'EC' monitoring is to ensure that the obligations deriving from the technical file have been met during production of the subsystem.

- 5.2. 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 contracting entity or its authorised representative within the Community must send it or have sent to it all the documents needed for that purpose and, in particular, the implementation plans and technical documentation concerning the subsystem.
- 5.3. The notified body responsible for checking implementation must periodically carry out audits in order to confirm compliance with the Directive. It must provide those responsible for implementation with an audit report. It may require to be present at certain stages of the building operations.
- 5.4. 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.

6. SUBMISSION

The complete file referred to in paragraph 4 must be lodged with the contracting entity or its authorised agent established within the Community in support of the certificate of conformity issued by the notified body responsible for verification of the subsystem in working order. The file must be attached to the 'EC' declaration of verification which the contracting entity sends to the supervisory authority in the Member State concerned.

A copy of the file must be kept by the contracting entity throughout the service life of the subsystem. It must be sent to any other Member States which so request.

7. PUBLICATION

Each notified body must periodically publish relevant information concerning:

- requests for 'EC' verification received;
- certificates of conformity issued;
- certificates of conformity refused.

8. LANGUAGE

The files and correspondence relating to the 'EC' verification procedures must be written in an official language of the Member State in which the contracting entity or its authorised representative within the Community is established or in a language accepted by the entity.

ANNEX VII

**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 checks 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 or constructor 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.
 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 the checks must be guaranteed. No official must be remunerated either on the basis of the number of checks performed or of the results of those checks.
 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 in the State where they perform those activities) in pursuance of this Directive or any provision of national law implementing the Directive.
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ANNEX VIII

GENERAL RULES TO BE OBSERVED BY THE JOINT REPRESENTATIVE BODY (JRB)

1. In line with the general Community standardisation procedures, the JRB must work openly and transparently, based on consensus and independent of any particular interests. To this end, all members of the three categories represented on the JRB — infrastructure managers, railway companies and industry — must have the opportunity to express their opinion during the process of drafting TSIs, in accordance with the JRB's rules of procedure and before finalisation of the draft TSIs by the JRB.
 2. If the JRB lacks the expertise required in order to draft a particular TSI, it must inform the Commission immediately.
 3. The JRB must set up the working parties necessary for the purposes of drafting TSIs; these working parties must have a flexible, efficient structure. To this end, the number of experts must be limited. Balanced representation must be ensured between infrastructure managers and railway companies on the one hand and industry on the other; an appropriate balance must be struck between different nationalities. Experts from non-Community countries may sit in on working parties as observers.
 4. Any difficulties which emerge in relation with this Directive and which cannot be resolved by the JRB's working parties must be reported to the Commission without delay.
 5. All the working papers necessary in order to monitor the JRB's work must be placed at the disposal of the Commission and the Committee referred to in Article 21.
 6. The JRB must take all measures necessary to safeguard the confidentiality of any critical information which comes to its knowledge in the course of its activities.
 7. The JRB must take all measures necessary to inform all its members and all experts participating in the working parties of the results of the work of the Committee referred to in Article 21 and of the recommendations made by the Committee and by the Commission.
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