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COUNCIL DIRECTIVE 96/48/EC

of 23 July 1996

on the interoperability of the trans-European high-speed rail system

(OJ L 235, 17.9.1996, p. 6)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003	L 284	1	31.10.2003
►**M2**	Directive 2004/50/EC of the European Parliament and of the Council of 29 April 2004	L 220	40	21.6.2004
►**M3**	Commission Directive 2007/32/EC of 1 June 2007	L 141	63	2.6.2007

Corrected by:

►**C1**	Corrigendum, OJ L 262, 16.10.1996, p. 18 (96/48/EC)

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COUNCIL DIRECTIVE 96/48/EC

of 23 July 1996

on the interoperability of the trans-European high-speed rail system

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular the third paragraph of Article 129d thereof,

Having regard to the proposal from the Commission ([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 laid down in Article 189c ([4]),

Whereas 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 establishing an area without internal frontiers, it is advisable, in particular, to improve the interlinking and interoperability of national high-speed train networks, as well as access thereto;

Whereas a high-level working party consisting of representatives of the governments of the Member States, of the European railways and of the European railway industry convened by the Commission in order to meet the request expressed by the Council in its resolution of 4 and 5 December 1989 drew up the master plan for a European high-speed train network;

Whereas in December 1990 the Commission sent to the Council a communication on the high-speed train network, and whereas the Council gave a favourable reception to that communication in its resolution of 17 December 1990 ([5]);

Whereas Article 129c of the Treaty provides that the Community shall implement any measures that may prove necessary to ensure network interoperability, in particular in the field of technical standardization;

Whereas the commercial operation of high-speed trains requires excellent compatibility between the characteristics of the infrastructure and those of the rolling stock; whereas performance levels, safety, quality of service and cost depend upon such compatibility as does, in particular, the interoperability of the European high-speed rail system;

Whereas pursuant to Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways ([6]) railway companies must have increased access to the rail networks of the Member States, which in turn requires infrastructure, equipment and rolling stock interoperability;

Whereas the 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, placing in

([1]) OJ No C 134, 17. 5. 1994, p. 6.
([2]) OJ No C 397, 31. 12. 1994, p. 8.
([3]) OJ No C 210, 14. 8. 1995, p. 38.
([4]) Opinion of the European Parliament of 19 January 1995 (OJ No C 43, 20. 2. 1995, p. 60), Council common position of 8 December 1995 (OJ No 356, 30. 12. 1995, p. 43) and Decision of the European Parliament of 16 April 1996 (OJ No C 141, 13. 5. 1996, p. 48).
([5]) OJ No C 33, 8. 2. 1991, p. 1.
([6]) OJ No L 237, 24. 8. 1991, p. 25.

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service and operation of those railways; whereas, together with the local authorities, they also have responsibilities in respect of rights in land, regional planning and environmental protection; whereas that is also especially pertinent with regard to high-speed train networks;

Whereas Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment ([1]) requires an assessment of the impact on the environment of the construction of lines for long-distance rail traffic;

Whereas national regulations and the railways' internal rules and the technical specifications which the railways apply contain major differences; whereas those national regulations and internal rules incorporate techniques that are specific to the national industries; whereas they prescribe specific dimensions and devices and special characteristics; whereas this situation runs counter to high-speed trains being able to run normally throughout Community territory;

Whereas, 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 contracts; whereas, in order to enhance their competitiveness at world level those industries require an open, competitive European market;

Whereas it is therefore appropriate to define essential requirements for the whole of the Community which will apply to the trans-European high-speed train system;

Whereas, in view of the extent and complexity of the trans-European high-speed rail system, it has proved necessary for practical reasons to break it down into subsystems; whereas for each of those subsystems the essential requirements must be specified, the basic parameters laid down and the technical specifications determined for the whole of the Community, particularly in respect of constituents and interfaces, in order to meet those essential requirements; whereas, however, certain subsystems (environment, users and operation) will be subject to technical specifications for interoperability (TSIs) only in so far as is necessary to ensure interoperability in the fields of infrastructure, energy, control-and-command and signalling and rolling-stock;

Whereas the introduction of provisions on the interoperability of the trans-European high-speed rail system must not create unjustified cost-benefit barriers to the preservation of the existing rail network of each Member State, but must endeavour to maintain the objective of the circulation of high-speed trains throughout the Community;

Whereas individual Member States should be allowed not to apply certain technical specifications for interoperability in specific cases, provided that there are procedures to ensure that such possibilities for derogation are justified; whereas Article 129c of the Treaty requires the Community's activities in the area of interoperability to take into account the potential economic viability of projects;

Whereas in order to comply with the appropriate provisions on government procurement procedures in the rail sector and in particular Directive 93/38/EEC ([2]), contracting entities must include technical specifications in the general documents or the contract documents relating to each contract; whereas it is necessary to build up a body of European specifications to serve as references for those technical specifications;

Whereas, within the meaning of Directive 93/38/EEC, a European specification is a common technical specification, a European technical approval or a national standard implementing a European standard;

([1]) OJ No L 175, 5. 7. 1985, p. 40.

([2]) 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 No L 199, 9. 8. 1993, p. 84), as amended by the 1994 Act of Accession.

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whereas harmonized European standards are to be drawn up by a European standardization body such as the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) or the European Telecommunications Standards Institute (ETSI), to the order of the Commission, and their references published in the *Official Journal of the European Communities*;

Whereas it would be in the Community's interests for there to be an international system of standardization capable of generating standards which are actually used by those involved in international trade and which meet the requirements of Community policy; whereas the European standardization bodies must therefore continue their cooperation with the international standardization bodies;

Whereas contracting entities define such further requirements as are necessary to complete European specifications or other standards; whereas those specifications must not prevent the essential requirements that have been harmonized at Community level and which the trans-European high-speed train system must satisfy, from being met;

Whereas the procedures governing the assessment of conformity or of suitability of use of constituents must be based on the use of the modules covered by Decision 93/465/EEC ([1]); whereas, as far as possible and in order to promote the development of the industries concerned, it is appropriate to expand the procedures involving a system of quality assurance; whereas the notion of constituent covers both tangible objects and intangible objects such as software;

Whereas the suitability for use of the most critical constituents as regards safety, availability or system economy should be assessed;

Whereas in their contract documents, contracting entities, lay down, in particular for constituents, by reference to the European specifications, the characteristics which must be met, in contractual terms, by the manufacturers; whereas, this being the case, constituent conformity is mainly linked to their area of use in order to ensure and guarantee the interoperability of the system, and not only to their free movement on the Community market;

Whereas it is therefore not necessary for a manufacturer to affix the CE mark to constituents that are subject to the provisions of this Directive as, on the basis of the assessment of conformity and/or suitability for use conducted in accordance with the procedures provided for that purpose in the Directive, the manufacturer's declaration of conformity is sufficient; whereas that does not affect the obligation on manufacturers to affix the CE mark to certain components in order to certify their compliance with other Community provisions relating to them;

Whereas the subsystems constituting the trans-European high-speed rail system must be subjected to a verification procedure; whereas that verification must enable the authorities responsible for authorizing their placing in service to be assured that at the stages of design, construction and placing in service the result is in line with the regulations and technical operational provisions in force; whereas that must also enable manufacturers to be able to count upon equality of treatment whatever the country; whereas it is therefore necessary to lay down a module defining the principles and conditions applying to EC verification of subsystems;

Whereas the EC verification procedure is based on TSIs; whereas those TSIs are drawn up to the order of the Commission by the joint body representing the infrastructure managers, the railway companies and the industry; whereas the reference to TSIs is required in order to ensure

([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 harmonization directives (OJ No L 220, 30. 8. 1993, p. 23).

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interoperability of the trans-European high-speed rail system and whereas those TSIs are subject to the provisions of Article 18 of Directive 93/38/EEC;

Whereas the notified bodies responsible for examining the conformity assessment procedures or that applying to the use of constituents, together with the procedure for the assessment of subsystems must, particularly in the absence of any European specification, coordinate their decisions as closely as possible;

Whereas Council Directive 91/440/EEC requires a separation of activities, in accounting terms, between transport service operation and those concerning railway infrastructure management; whereas, this being the case, the specialized services provided by the 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; whereas other specialized bodies may be notified where these meet the same criteria;

Whereas interoperability within the trans-European high-speed train system is Community wide in scale; whereas the Member States are unable, on an individual basis, to take the action needed in order to achieve that interoperability; whereas it is therefore necessary, pursuant to the principle of subsidiarity, for this action to be taken at Community level,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

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Article 1

1. The aim of this Directive is to establish the conditions to be met to achieve interoperability within Community territory of the trans-European high-speed rail system as described in Annex I.

These conditions concern the design, construction, placing in service, upgrading, renewal, operation and maintenance of the parts of this system placed in service after 30 April 2004, as well as the 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 an optimal level of technical harmonisation and make it possible to:

(a) facilitate, improve and develop international rail transport services within Community territory and with third countries;

(b) contribute to the gradual creation of the internal market in equipment and services for the construction, operation, renewal and upgrading of the trans-European high-speed rail system;

(c) contribute to the interoperability of the trans-European high-speed rail system.

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Article 2

For the purposes of this Directive:

(a) *trans-European high-speed rail system* means the structure described in Annex I, composed of the railway infrastructures comprising lines and fixed installations, of the trans-European

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transport network, constructed or upgraded to be travelled on at high speeds, and rolling stock designed for travelling on those infrastructures;

(b) *interoperability* means the ability of the trans-European high-speed rail system to allow the safe and uninterrupted movement of high-speed trains which accomplish the specified levels of performance. This ability rests on all the regulatory, technical and operational conditions which must be met in order to satisfy essential requirements;

(c) *subsystems* means that the trans-European high-speed rail system is subdivided, as described in Annex II, into structural or functional subsystems for which essential requirements must be laid down;

(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 high-speed rail system depends either directly or indirectly;

(e) *essential requirements* means all the conditions set out in Annex III which must be met by the trans-European high-speed rail system, subsystems and their interoperability constituents;

(f) *European specification* means a common technical specification, a European technical approval or a national standard implementing a European standard, as defined in points 8 to 12 of Article 1 of Directive 93/38/EEC;

(g) *technical specifications for interoperability* (hereinafter *TSIs*) means the specifications by which each subsystem is covered in order to meet the essential requirements by establishing the necessary reciprocal functional relations between the subsystems of the trans-European high-speed rail system and by ensuring the latter's compatibility;

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(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;

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(j) *basic parameter* means any regulatory, technical or operational condition which is critical to interoperability and requires a decision or recommendation in accordance with the procedure laid down in Article 21(2) before any development of complete draft TSIs;

(k) *specific case* means any part of the trans-European high-speed 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 territory, the loading gauge, the track gauge or space between the tracks;

(l) *upgrading* means any major modification work on a subsystem or part subsystem which improves the overall performance of the subsystem;

(m) *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;

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(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 the railway infrastructures, comprising lines and fixed installations of the existing rail system plus the existing rolling stock of all categories and origin travelling on that infrastructure;

(p) *placing in service* means all the operations by which a subsystem is put into its design operating state.

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Article 3

1. This Directive applies to the provisions concerning, for each subsystem, the parameters, interoperability constituents, interfaces and procedures as well as the conditions for the overall compatibility of the trans-European high-speed rail system required to achieve its interoperability.

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

Article 4

1. The trans-European high-speed rail system, subsystems and their interoperability constituents must meet the relevant essential requirements.

2. The further technical specification referred to in Article 18 (4) of Directive 93/38/EEC, which are necessary to supplement 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

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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 and/or to review a TSI and the choice of its technical and geographical scope requires a mandate in accordance with Article 6(1).

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2. The subsystems must conform to the TSIs; this conformity must be permanently maintained while each subsystem is in use.

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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;

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(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 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 high speed rail system;

(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 competences and health and safety conditions at work required for the operation and maintenance of the subsystem, as well as for the implementation of the TSIs.

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4. The TSIs shall not be an impediment to decisions by the Member States concerning the use of new or upgraded infrastructures for running other trains.

5. Compliance with all the TSIs shall enable a compatible trans-European high-speed rail system to be set up that will preserve, as appropriate, the compatibility of each Member State's existing rail network.

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6. TSIs may make an explicit, clearly identified reference to European standards or specifications where this is strictly necessary in order to achieve the objectives of this Directive. In such case, these European standards or specifications (or the relevant parts thereof) shall be regarded as annexes to the TSI concerned and shall become mandatory from the moment the TSI is applicable. In the absence of European standards or specifications 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

1. Draft TSIs and subsequent amendments to TSIs shall be drafted under a mandate from the Commission in accordance with the procedure set out in Article 21(2). They shall be drafted under the responsibility of the Agency in accordance with Articles 3 and 12 of Regulation (EC) No 2004/881/EC of the European Parliament and of the Council of 29 April 2004 establishing a European Railway Agency (Agency Regulation) ([1]) and in cooperation with the Working Parties mentioned in those Articles.

TSIs shall be adopted and reviewed in accordance with the procedure set out in Article 21(2). They shall be published by the Commission in the *Official Journal of the European Union.*

2. The Agency shall be responsible for preparing the review and updating of TSIs and making any recommendations to the Committee

([1]) OJ L 164, 30.4.2004, p. 1.

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referred to in Article 21 in order to take account of developments in technology or social requirements.

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

First of all, 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. A decision shall be taken in accordance with the procedure set out in Article 21(2); if necessary, specific cases shall be cited.

The Agency shall then 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.

5. 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.

6. On the adoption of each TSI, the date of entry into force of that TSI shall be established in accordance with the procedure set out in Article 21(2). 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. 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 it adopts the mandate to review the TSIs and may be re-examined and updated at the request of a Member State or 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 21.

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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 renewal or 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 territory;

(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;

(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.

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 Commission shall analyse the measures envisaged by the Member State. In cases (b) and (d), the Commission shall take a decision in accordance with the procedure set out 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 refer to the loading gauge and the track gauge.

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CHAPTER III

Interoperability constituents

Article 8

Member States shall take all necessary steps to ensure that interoperability constituents:

— are placed on the market only if they enable interoperability to be achieved within the trans-European high-speed rail system while at the same time meeting the essential requirements;

— are used in their area of use as intended and are suitably installed and maintained.

These provisions do not exclude the placing on the market of these constituents for other purposes, nor their use for conventional railway lines.

[1] OJ L 225, 12.8.1998, p. 27

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Article 9

Member States may not, in their territory and on grounds of this Directive, prohibit, restrict or hinder the placing on the market of interoperability constituents for use on the trans-European high-speed rail system if they comply with the Directive.

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In particular, they may not require checks which have already been carried out as part of the procedure leading to the EC declaration of conformity or suitability for use.

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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, the components of which are set out in Annex IV.

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2. All interoperability constituents shall be subject to the procedure for assessing conformity and suitability for the use indicated in the respective TSI and 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 European specifications developed to comply with these conditions.

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Article 11

Where it appears to a Member State or the Commission that European specifications used directly or indirectly for the purposes of this Directive do not meet the essential requirements, partial or total withdrawal of the specifications concerned from the publications containing them, or their amendment, may be decided upon in accordance with the procedure set out in Article 21(2) after consultation of the Committee set up under 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]).

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Article 12

1. Where a Member State confirms that an interoperability constituent covered by the EC declaration of conformity or suitability for use, and placed on the market is likely, when used as intended, not to meet the essential requirements, it shall take all necessary steps to restrict its area of application, prohibit its use or withdraw it from the market. That Member State shall forthwith inform the Commission of the measures taken and shall give the reasons for its decision, stating in particular whether the failure to conform is due to:

— failure to meet the essential requirements;

— incorrect application of the European specifications where application of the specifications is invoked;

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

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— inadequacy of the 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 so inform the Member State that has taken the initiative and the other Member States. Where, following that consultation, the Commission establishes that the measure is unjustified, it shall forthwith so inform the Member State that has taken the initiative and the manufacturer or his authorized representative established within the Community. Where the decision referred to in paragraph 1 is justified by the existence of a gap in the 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 the 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 progress and the results of that procedure.

Article 13

1. In order to draw up the EC declaration of conformity or suitability for use of an interoperability constituent, its manufacturer or his authorized representative established within the Community must apply the provisions laid down in the TSIs referring to it.

2. Where so required by the TSIs, the assessment of conformity or suitability for use of an interoperability constituent shall be appraised by the notified body with which the manufacturer or his authorized representative established within the Community has lodged the application.

3. Where the 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 authorized representative established within the Community has met the obligations of the paragraphs 1, 2 and 3, those obligations shall be incumbent on any person who places that interoperability constituent on the market. The same obligations shall apply to any person who assembles interoperability constituents or parts of interoperability constituents having diverse origins or who manufactures the 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 a Member State finds that the EC declaration of conformity has been drawn up improperly, the manufacturer or his authorized representative established within the Community shall be required to ensure that the conformity of the interoperability constituent is re-established and that the infringement ceases 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 12.

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CHAPTER IV

Subsystems

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Article 14

1. Each Member State shall authorise the placing in service of those structural subsystems constituting the trans-European high-speed rail system which are located or operated in its territory.

To this end, each Member State 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 that they do not compromise compliance with the essential requirements concerning them when integrated into the trans-European high-speed rail system.

In particular, each Member State shall check the compatibility of these subsystems with the system into which they are being integrated.

2. Each Member State shall check, when the subsystems are placed in service and at regular intervals thereafter, that they are operated and maintained in accordance with the essential requirements concerning them. To that end, the assessment and verification procedures laid down in the respective structural and functional TSIs shall be used.

3. In the event of renewal or upgrading, the infrastructure manager or the railway undertaking 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 placing in service within the meaning of this Directive is needed.

Such new authorisation for placing in service shall be required whenever the overall safety level of the subsystem concerned may be affected by the works envisaged.

4. Where Member States authorise the placing in service of rolling stock, they shall be responsible for ensuring that an alphanumeric identification code is assigned to each vehicle. This code must be marked on each vehicle and be entered in a national vehicle register that meets the following criteria:

(a) the register shall comply with the common specifications defined in paragraph 5;

(b) the register shall be kept and updated by a body independent of any railway undertaking;

(c) the register shall be accessible to the safety authorities and the investigating bodies designated in Articles 16 and 21 of 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) ([1]); 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 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 ([2]), to the Agency, to the railway companies and to the infrastructure managers.

In case of rolling stock placed in service for the first time in a third country, Member States may accept vehicles clearly identified according to a different coding system. However, once a Member State has

([1]) OJ L 164, 30.4.2004, p. 44.
([2]) OJ L 75, 15.3.2001, p. 29. Directive as amended by Commission Decision 2002/844/EC (OJ L 289, 26.10.2002, p. 30).

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authorised the placing in service of such vehicles on its territory, it must be possible to retrieve the corresponding data, listed below in paragraph 5(c), (d) and (e), through the register.

5. The common specifications for the register shall be adopted in accordance with the procedure set out in Article 21(2), on the basis of the draft specifications prepared by the Agency. These draft specifications shall include: content, data format, functional and technical architecture, operating mode, and rules for data input and consultation. The register shall contain at least the following information:

(a) references to the EC declaration of verification and the issuing body;

(b) references to the register of rolling stock mentioned in Article 22a;

(c) identification of the owner of the vehicle or the lessee;

(d) any restrictions on how the vehicle may be used;

(e) safety-critical data relating to the maintenance schedule of the vehicle.

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Article 15

Without prejudice to Article 19, Member States may not, in their territory and on grounds of this Directive, prohibit, restrict or hinder the construction, placing in service and operation of structural subsystems constituting the trans-European high-speed rail system which satisfy the essential requirements.

▼M2

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.

▼B

Article 16

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

▼M2

3. In the absence of TSIs, and including cases when a derogation has been notified under Article 7, 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 by 30 April 2005 and thereafter each time the list of technical rules is changed. 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.

▼B

Article 17

If it emerges 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.

▼M2

In such a case, the TSIs shall be reviewed in accordance with Article 6 (2). 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. Article 16(3) shall apply to these aspects.

▼B

Article 18

1. In order to draw up the EC declaration of verification, the awarding authority or its official representative shall cause the EC checking procedure to be appraised by the notified body chosen by it for that purpose.

2. The activities of the notified body responsible for the EC verification of a subsystem shall begin at the design stage and shall cover all of the manufacturing period up to the type-approval stage before a subsystem is placed in service.

▼M2

They shall also cover verification of the interfaces of the subsystem in question in relation to the system in which it is integrated, on the basis of the information available in the respective TSI and the registers defined in Article 22a.

▼B

3. The notified body shall be responsible for compiling the technical file that has to accompany the EC declaration of verification. The 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 constituents of interoperability. It must also contain all of 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 reasons which justify them. 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 the Commission and the other Member States of the bodies responsible for carrying out the procedure for the assessment of conformity or suitability for use referred to in Article 13 and the checking procedure referred to in Article 18, indicating each body's area of responsibility.

The Commission shall assign identification numbers to them. It shall publish in the *Official Journal of the European Communities* the list of bodies, their identification numbers and the tasks entrusted to them, and shall ensure that the list is kept updated.

▼B

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 no longer meets 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 Committee's opinion, the Commission shall inform the Member State concerned of all the changes needed if the notified body is to maintain the status awarded to it.

▼M2

5. The Commission shall set up a notified bodies coordination group (hereinafter 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 the 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 21 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 21.

▼B

CHAPTER VI

Committee

▼M2

Article 21

1. The Commission shall be assisted by a committee.

2. Where reference is made to this paragraph, Articles 5 and 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([1]) 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.

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 21a

1. The Committee may discuss any matter relating to the interoperability of the trans-European high-speed rail system, including questions relating to interoperability between this system and the rail system of third countries.

([1]) OJ L 184, 17.7.1999, p. 23

▼M2

2. The Committee may discuss any matter relating to the implementation of this Directive. If necessary, the Commission shall adopt an implementing recommendation in accordance with the procedure set out in Article 21(2).

Article 21b

1. The Commission may decide, on its own initiative or at the request of a Member State, in accordance with the procedure set out in Article 21(2), to mandate the drafting of a TSI for an additional subject, insofar as it concerns a subsystem mentioned in Annex II.

2. In accordance with the procedure set out in Article 21(2), the Committee shall, on the basis of a proposal by the Commission, adopt a work programme conforming to the objectives of this Directive 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 [1].

Article 21c

Annexes II to VI may be amended in accordance with the procedure set out in Article 21(2).

▼B

CHAPTER VII

Final provisions

Article 22

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 high-speed 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 States concerned and of the time limits allowed for the exercise of such remedies.

▼M2

Article 22a

1. Member States shall ensure that a register of infrastructure and a register of rolling stock are published and updated annually. These 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 Agency and shall be made available for consultation by interested parties, including at least the professional actors from the sector.

[1] OJ L 110, 20.4.2001, p. 1.

▼B

Article 23

1. Member States shall amend and adopt their laws, regulations and administrative provisions so as to authorize the use of interoperability constituents and the putting into service and operation of subsystems which comply with this Directive no later than 30 months after entry into force of this Directive. They shall forthwith inform the Commission thereof.

2. When Member States adopt the provisions referred to in paragraph 1, 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 Member States.

Article 24

Every two years the Commission shall report to the European Parliament and the Council on the progress made towards achieving interoperability of the trans-European high-speed rail system.

Article 25

This Directive shall enter into force on the 21st day following that of its publication in the *Official Journal of the European Communities*

▼C1

Article 26

This Directive is addressed to the Member States.

▼M2

ANNEX I

THE TRANS-EUROPEAN HIGH-SPEED RAIL SYSTEM

1. **THE INFRASTRUCTURE**

The infrastructure of the trans-European high-speed rail system shall be that of 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 of that Decision as a result of the revision provided for in Article 21 of that Decision.

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

2. **THE ROLLING STOCK**

The rolling stock referred to in this Directive shall comprise trains 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 1, where compatible with the performance levels of these lines.

3. **COMPATIBILITY OF THE TRANS-EUROPEAN HIGH-SPEED RAIL 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).

([1]) OJ L 228, 9.9.1996, p. 1. Decision amended by Decision 1346/2001/EC (OJ L 185, 6.7.2001, p. 1).

▼M2

ANNEX II

SUBSYSTEMS

1. **LIST OF SUBSYSTEMS**

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

(a) either structural areas:

— infrastructure,

— energy,

— control and command and signalling,

— traffic operation and management,

— rolling stock,

(b) or operational areas:

— maintenance,

— telematics applications for passenger and freight services.

2. **AREAS TO BE COVERED**

For each subsystem, the list of aspects relating to interoperability is indicated in the mandates for drawing up TSIs given to the Agency.

Under Article 6(1), these mandates shall be established in accordance with the procedure set out in Article 21(2).

Where necessary, the list of aspects relating to interoperability indicated in the mandates is specified by the Agency in accordance with Article 5(3)(c).

▼B

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 authorized 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 their safety 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 organized, 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 repercussions on the environment of the establishment and operation of the trans-European high-speed 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.

1.5. *Technical compatibility*

The technical characteristics of the infrastructures and fixed installations must be compatible with each other and with those of the trains to be used on the trans-European high-speed rail system.

If adherence to 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. *Infrastructures*

2.1.1. Safety

Appropriate steps must be taken to prevent access to or undesirable intrusions into installations on lines travelled at high speed.

▼B

Steps must be taken to limit the dangers to which persons are exposed, particularly in stations through which trains pass at high speed.

Infrastructures to which the public has access must be designed and made in such a way as to limit any human health 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 high-speed trains or of persons (users, operating staff, trackside dwellers and third parties).

2.2.2. Environmental protection

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

2.2.3. Technical compatibility

The electricity supply systems used throughout the trans-European high-speed rail system must:

— enable trains to achieve the specified performance levels;

— 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 installation and procedures used on the trans-European high-speed rail system must enable trains to travel with a level of safety which corresponds to the objectives set for the network.

2.3.2. Technical compatibility

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

The control and command and signalling equipment installed within the train drivers' cabs must permit normal operation, under the specified conditions, throughout the trans-European high-speed 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 and 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.

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.

▼B

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 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 and command and signalling installations.

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 high-speed 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.

▼M2

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.

▼B

2.5. *Maintenance*

2.5.1. Health

The technical installations and the procedures used in the maintenance centres must not constitute a danger to human health.

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 on high-speed trains must be such as to enable safety, health and comfort operations to be carried out on all trains for which they have been designed.

2.6. *Environment*

2.6.1. Health

Operation of the trans-European high-speed rail system must remain within the statutory noise-nuisance limits.

2.6.2. Environmental protection

Operation of the trans-European high-speed rail system must not cause a level of ground vibrations which is unacceptable for activities and the immediate environment in the vicinity of the infrastucture and in a normal state of maintenance.

2.7. *Operation*

2.7.1. Safety

Alignment of the network operating rules and the qualifications of drivers and on-board staff must be such as to ensure safe international operation.

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

2.7.2. Reliability and availability

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

▼B

2.7.3. Technical compatibility

The alignment of the operating rules of the networks and the qualifications of drivers, on-board staff and managers in charge of traffic must be such as to ensure operating efficiency on the trans-European high-speed rail system.

▼B

ANNEX IV

INTEROPERABILITY CONSTITUENTS

EC declaration

— **of conformity**

— **of suitability for use**

1. *Interoperability constituents*

The EC declaration applies to the interoperability constituents involved in the interoperability of the trans-European high-speed rail systems, 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 multiple-use constituents which are not, as such, specific to a 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/judgment 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, particulary 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 authorized representative established within the Community (give trade name and full address and in the case of the authorized 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, suitability for use (Article 13);

— all of the relevant descriptions met by the interoperability constituent and in particular its conditions of use;

— name and address of notified body (bodies) involved in the procedure followed in respect of conformity or suitability for use and date of examination certificate together, where appropriate, with the duration and conditions of validity of the certificate;

— where appropriate, reference to the European specification;

— identification of signatory having received powers to engage the manufacturer or his authorized representative established within the Community.

▼B

ANNEX V

SUBSYSTEMS

EC DECLARATION OF VERIFICATION

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 authorized representative established within the Community. (Give trade name and full address, and in the case of the authorized representative also give the trade name of the contracting entity);

— a brief description of the subsytem;

— name and address of the notified body which has conducted the EC inspection referred to in Article 18;

— the references of the documents contained in the technical file;

— all of the relevant temporary or final 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 signatory.

▼M3

ANNEX VI

VERIFICATION PROCEDURE FOR SUBSYSTEMS

1. INTRODUCTION

"EC" verification is the procedure whereby a notified body checks and certifies 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,

— production: construction of subsystem, including, for example civil-engineering activities, manufacturing, constituent assembly, overall adjustment,

— final testing of the subsystem.

For the design phase (including the type tests) and for the production phase the main contractor (or the manufacturer) or its authorised representative established within the Community may apply for an assessment as a first step.

In this case, this (these) assessment(s) lead to intermediate statement verification(s) (ISV) issued by the Notified Body chosen by the main contractor (or the manufacturer). This one in turn draws up an "EC declaration of intermediate subsystem conformity" for the relevant phase(s).

3. CERTIFICATE

The Notified Body responsible for the "EC" verification draws up the certificate of verification 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.

The Notified Body responsible for "EC" verification assesses the design and production of the subsystem.

If available, the Notified Body takes into account the "Intermediate Statements of Verification" (ISV(s)), and, in order to issue the "EC" certificate of verification, it:

— Checks that the subsystem:

  — is covered by relevant design and production ISVs delivered to the main contractor (or the manufacturer) if it has asked the Notified Body for these two phases,

  — or corresponds as produced to all aspects covered by the design ISV delivered to the main contractor (or the manufacturer) if it has asked the Notified Body only for the design phase,

— Verifies that they cover correctly the requirement of the TSI and assesses the design and production elements that are not covered by the design and/or production ISV(s) delivered to the main contractor (or the manufacturer).

4. TECHNICAL FILE

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

— for the infrastructure: engineering-structure plans, approval records for excavations and reinforcement, testing and inspection reports on concrete, etc.,

— 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,

▼M3

— copies of the "EC" declarations of conformity or suitability for use with which the above mentioned 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,

— if available, the intermediate statement(s) of verification (ISV) and, in such a case, the "EC" declaration(s) of intermediate subsystem conformity, that accompany the "EC" certificate of verification, including the result of verification by the Notified Body of their validity,

— 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 verification 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;

— intermediate statements of verification (ISVs) issued or refused;

— certificates of verification issued or 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.

▼B

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 checking operations may not become involved either directly or as authorized 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 inspection must carry out the checking operations 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 may affect their judgment or the results of their inspection, and in particular those generated by persons or groups of persons affected by the results of the checks.

▼M2

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 Council Directive 95/18/EC of 19 June 1995 on the licensing of railway undertakings [1] and safety certificates in the framework of Directive 200./49/EC, and of the bodies in charge of investigations in the event of accidents.

▼B

3. That body must employ staff and possess the means required to perform adequately the technical and administrative tasks linked with the conducting of 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 inspections are carried out directly by that Member State.

7. The staff of that 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.

[1] OJ L 143, 27.6.1995, p. 70. Directive as amended by Directive 2001/13/EC of the European Parliament and of the Council (OJ L 75, 15.3.2001, p. 26).