

L.N. 332 of 2002**PRODUCT SAFETY ACT
(ACT NO. V OF 2001)****Interoperability of the Trans-European High-Speed Rail System
Regulations, 2002**

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister for Economic Services, on the advice of the Malta Standards Authority, has made the following regulations:-

1.1. The title of these regulations is the Interoperability of the Trans-European High-Speed Rail System Regulations, 2002. Citation and commencement.

1.2. These regulations shall become operative on the 1st January, 2003:

Provided that the requirement to provide information to the European Commission referred to in regulation 15.4 of these regulations shall come into force on such date as the Minister responsible for consumer affairs, after consultation with the Malta Standards Authority, may prescribe.

2.1. In accordance with Articles 129b and 129c of the Treaty, Scope. the aim of these regulations is to establish the conditions to be met in order to achieve interoperability within Community territory of the trans-European high-speed rail system as described in Annex I of the Directive, which is set out in Schedule I hereto.

2.1.1. These conditions concern projects for and the construction, upgrading and operation of the infrastructures and rolling stock which will contribute to the functioning of the system to be put into service after the date of entry into force of these regulations.

3.1. For the purposes of these regulations, the following Definitions. definitions shall apply:

3.1.1. “The Directive” means Council Directive 96/48/EC¹ of the European Parliament and of the Council of 21st May, 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels;

3.1.2. “Trans-European high-speed rail system” means the structure described in Annex I of the Directive, which is set out in Schedule I hereto composed of the railway infrastructures comprising lines and fixed installations, of the trans-European transport network, constructed or upgraded to be travelled on at high speeds, and rolling stock designed for travelling on those infrastructures;

3.1.3. “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;

3.1.4. “Subsystems” means that the trans-European high-speed rail system is subdivided, as described in Annex II of the Directive, which is set out in Schedule II hereto into structural or functional subsystems for which essential requirements must be laid down;

3.1.5. “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;

3.1.6. “Essential requirements” means all the conditions set out in Annex III of the Directive, which is set out in Schedule III hereto which must be met by the trans-European high-speed rail system, subsystems and their interoperability constituents;

3.1.7. “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/EEC²;

3.1.8. “Technical specifications for interoperability (hereinafter TSIs)” means the specifications by which each subsystem is covered in order to meet the essential requirements

¹ OJ No. L 235, 17-09-96, p. 06-24.

² OJ No. L 199, 09-08-93, p. 084-138.

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;

3.1.9. "Joint representative body" means the body bringing together representatives of the infrastructure managers, railway companies and industry which is responsible for drawing up TSIs. 'Infrastructure managers' means those referred to in Articles 3 and 7 of Directive 91/440/EEC³;

3.1.10. "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.

3.1.11. Any word or expression used, but not defined, in these regulations which is also used in the Directive has, in these regulations, the meaning it has in the Directive.

3.1.12. In these regulations, unless the context otherwise requires—

3.1.12.1. any reference to a numbered regulation or Schedule is a reference to the regulation or Schedule in these regulations which bears that number, and

3.1.12.2. any reference in a regulation or Schedule to a numbered paragraph is a reference to the paragraph which bears that number in that regulation or Schedule.

3.1.13. "Harmonised Standard" means a technical specification adopted by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), upon a remit from the European Commission in accordance with Directive 98/34/EC⁴ of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations as amended by Directive 98/48/EC⁵ of the European Parliament and of the Council.

3.1.14. "National Standard transposing the Harmonised Standard" means a Standard issued by one of the members of CEN/CENELEC/ETSI which is declared and noted to be identical to the Harmonised Standard originally issued by CEN/CENELEC/ETSI.

³ OJ No. L237, 24-08-91, p.25-28

⁴ OJ No. L204, 21-07-98, p.37

⁵ OJ No. L217, 05-08-98, p.18

3.1.15. "OJ" means the Official Journal of the European Communities;

3.1.16. "Community" means the European Community.

3.1.17. "Manufacturer" means the person:

3.1.17.1. who is primarily responsible for the design and construction of the subsystem or interoperability constituent so that it complies with the requirements of these regulations;

3.1.17.2. who is responsible for "re-building" or modifying an existing subsystem or interoperability constituent, and who in so doing is creating an "as-new" subsystem or interoperability constituent;

3.1.17.3. who takes responsibility for the appraisal of the design, construction and any necessary modification of used imported subsystem or interoperability constituents;

3.1.18. "Authorised representative" means any person (or organisation) established in the Community or Malta who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations;

3.1.19. "Importer" means any person who places a subsystem or interoperability constituent from a foreign country on to the Community or Maltese market so that he supplies such a subsystem or interoperability constituent on the first occasion that it is supplied in the Community or Malta;

3.1.20. "Person who supplies interoperability constituents" means wholesalers, distributors, retailers etc;

3.1.21. "Supply" includes offering to supply, agreeing to supply, exposing for supply and possessing for supply, and cognate expressions shall be construed accordingly: Provided that "supply" does not include exhibition at trade fairs and exhibitions of interoperability constituents in respect of which the provisions of these regulations are not satisfied if a notice is displayed in relation to the interoperability constituent in question to the effect:-

3.1.21.1. that it does not satisfy those provisions; and

3.1.21.2. that it may not lawfully be supplied until the responsible person has ensured that those provisions are satisfied;

3.1.22. "Responsible person" in relation to subsystems or interoperability constituents means:

3.1.22.1. the manufacturer thereof;

3.1.22.2. the manufacturer's authorised representative;
or

3.1.22.3. where the manufacturer is not established in the Community or Malta and he has not appointed an authorised representative, the person who places the subsystems or interoperability constituents on the Community or Maltese market;

3.1.23. "Placing on the market" means importation, wholesale, retail, sale and distribution free of charge.

4.1. These regulations apply 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. Applicability.

4.2. The provisions of these regulations shall apply without prejudice to other Community provisions.

4.2.1. In the case of interoperability constituents, compliance with the essential requirements of these regulations may require the use of the individual European specifications drawn up for that purpose.

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

5.2. 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.

6.1. The placing on the market of interoperability constituents for use on the trans-European high-speed rail system may not be prohibited, restricted or hindered if they comply with the regulations. Free movement.

6.2. Without prejudice to in regulation 13.4 of these regulations, the placing in service and operation of structural subsystems constituting the trans-European high-speed rail system which satisfy the essential requirements may not be prohibited, restricted or hindered.

Technical specifications for interoperability.

7.1. Each of the subsystems shall be covered by a TSI. In the case of subsystems concerning the environment, operation or users, TSIs will be drawn up only to the extent necessary to ensure interoperability of the trans-European high-speed rail system in the fields of infrastructure, energy, control and command, signalling and rolling stock.

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

7.3. To the extent necessary in order to achieve interoperability of the trans-European high-speed rail system, the TSIs shall:

7.3.1. Specify the essential requirements for the subsystems and their interfaces;

7.3.2. Establish the basic parameters described in Annex II (3) of the Directive, which is set out in Schedule II hereto necessary to meet the essential requirements;

7.3.3. Establish the conditions to be complied with to achieve the specified performances for each of the following categories of line:

- lines specially built for high speed;
- lines specially upgraded for high speed;
- lines specially upgraded for high speed which have special features as a result of topographical, relief or town-planning constraints;

7.3.4. Establish possible implementing provisions in certain specific cases;

7.3.5. Determine the interoperability constituents and interfaces which must be covered by European specifications, including European standards, which are needed in order to achieve interoperability within the trans-European high-speed rail system while meeting the essential requirements;

7.3.6. State, in each case under consideration, which of the modules defined in Decision 93/465/EEC⁶ or, where appropriate,

⁶ OJ No. L220, 30-08-93, p.23-39

which specific procedures are to be used in order to assess either the conformity or the suitability for use of the interoperability constituents, as well as EC verification of the subsystems.

7.4. 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.

7.5. 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.

8.1. Draft TSIs shall be drawn up to the order of the Commission, to be established in accordance with the procedure laid down in Article 21 (2) of the Directive by the joint representative body.

8.1.1. TSIs shall be adopted and reviewed by the same procedure.

8.1.2. They shall be published by the Commission in the Official Journal of the European Communities.

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

8.3. The preparation, adoption and review of TSIs shall take account of the estimated cost of technical solutions by which they may be met, with a view to defining and implementing the most viable solutions. To that end, the joint representative body shall attach to each draft TSI an assessment of the estimated costs and benefits of those technical solutions for all the economic operators and agents concerned.

8.4. The Committee shall be kept regularly informed of the preparatory work on the TSIs by the joint representative body. The Committee may give the joint body any useful recommendation or brief regarding the design of the TSIs, on the basis of the essential requirements or regarding cost assessment.

8.5. When each TSI is adopted, the date of its entry into force shall be laid down in accordance with the procedure referred to in Article 21 (2).

8.6. The joint representative body must work in an open and transparent manner in accordance with general Community standardization procedures.

9.1. Certain TSIs, including those relating to rolling stock, need not be applied in the following cases:

9.1.1. In the case of a project for a new line or upgrading an existing line for high speed which is at an advanced stage of development when the TSIs in question are published.

9.1.1.1. The intended derogation shall be notified to the Commission in advance, and the Commission shall be informed of the stage the project has reached and a file shall be forwarded to it setting out the TSIs or parts thereof which do not apply, the provisions that apply in carrying out the project in order to promote its eventual interoperability, and the technical, administrative or economic reasons which justify the derogation;

9.1.2. In the case of a project for upgrading an existing line for high speed, where the loading gauge, track gauge or space between the tracks of the line are different from those on the majority of the European rail network, and where the line does not form a direct connection with the high-speed network of another Member State which is a part of the trans-European high-speed network.

9.1.2.1. The intended derogation shall be notified to the Commission in advance, and a file shall be forwarded to it setting out the TSIs or parts thereof concerning the physical parameter(s) referred to in regulation 9.1.2 of these regulations which do not apply, the provisions that apply in carrying out the project in order to promote its eventual interoperability, the transitional measures to take to guarantee compatibility of operation, and the technical, administrative or economic reasons which justify the derogation.

9.1.3. In the case of projects for new lines or upgrading existing lines for high speed carried out in the territory concerned where its rail network is not linked to or is isolated by sea from the high-speed rail network of the rest of the Community.

9.1.3.1. The intended derogation shall be notified to the Commission in advance and a file shall be forwarded to it containing the documents specified in regulation 9.1.2.1 of these regulations.

9.1.4. In the case of a project for upgrading an existing line for high speed, where application of these TSIs compromises the economic viability of the project.

9.1.4.1. The intended derogation shall be notified to the Commission in advance and a file shall be forwarded to it setting out the technical specifications or parts of specifications for interoperability which it wishes not to apply.

10.1 All necessary steps shall be taken to ensure that the interoperability constituents: 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.

10.2. Those interoperability constituents which bear the EC declaration of conformity or suitability for use, the components of which are set out in Annex IV of the Directive, which is set out in Schedule IV hereto shall be considered as complying with the essential requirements of these regulations.

10.3. Compliance of an interoperability constituent with the essential requirements applying to it shall be established in relation to any relevant European specifications that may exist.

10.4. The references to European specifications shall be published in the Official Journal of the European Communities.

10.5. In the absence of any European specifications and without prejudice to Article 20 (5) of the Directive, the Commission shall be informed of the standards and technical specifications in use in order to implement the essential requirements.

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

11.2. 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 authorised representative has lodged the application.

11.3. 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.

11.4. Where neither the manufacturer nor his authorised representative has met the obligations of regulations 11.1, 11.2, and 11.3 of these regulations, 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 these regulations.

11.5. Without prejudice to the provisions of Article 12 of the Directive and regulation 15.1 of these regulations:

11.5.1. In each instance where it is found that the EC declaration of conformity has been drawn up improperly, the manufacturer or his authorised representative 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 the Director of Consumer Affairs;

11.5.2. Where non-conformity persists, the Director of Consumer Affairs 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 of the Directive and regulation 15.1 of these regulations.

Subsystems.

12.1. The placing in service of those structural subsystems constituting the trans-European high-speed rail system which are located in the territory concerned or operated by railway undertakings established in the territory concerned shall be authorised.

12.1.1. For this purpose all necessary steps shall be taken to ensure that these subsystems may be placed in service only if they are designed, constructed and installed and/or operated in such a way as not to hinder satisfaction of the essential requirements concerning them when integrated into the trans-European high-speed rail system.

12.2. Those structural subsystems constituting the trans-European high-speed rail system which are covered by the EC declaration of verification shall be considered as being interoperable and meeting the essential requirements concerning them.

12.3. 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.

12.4. In the absence of TSIs, a list of the technical rules in use for implementing the essential requirements shall be sent to the Commission.

13.1. 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.

EC declaration of
verification

13.2. 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.

13.3. 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.

13.4. Where it is found that a structural subsystem covered by the EC declaration of verification accompanied by the technical file does not fully comply with these regulations and in particular does not meet the essential requirements, it may be requested that additional checks be carried out.

13.4.1. The Commission shall be informed of any additional checks requested and the reasons which justify them shall be set out.

14.1. Where it appears that European specifications do not meet the essential requirements, partial or total withdrawal of the specifications concerned from the publications containing them, or their

Withdrawal of
European
Specifications.

amendments, may be decided upon in accordance with the procedure laid down in Article 21 (2) of the Directive after consultation of the Committee set up under Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 amending Directive 98/34/EC, laying down a procedure for the provision of information in the field of technical standards and regulations where European standards are concerned.

Withdrawal and prohibition from the market.

15.1. Where it is confirmed 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, the Director of Consumer Affairs shall take all necessary steps to restrict its area of application, prohibit its use or withdraw it from the market.

15.2. The Director of Consumer Affairs shall inform the Consumer and Industrial Goods Directorate⁷ of the Malta Standards Authority and shall give the reasons for the decision, stating in particular whether the failure to conform is due to:

- (a) failure to meet the essential requirements;
- (b) incorrect application of the European specifications where application of the specifications is invoked;
- (c) inadequacy of the European specifications.

15.3. Any decision taken pursuant to these regulations, which contains a restriction on the placing on the market of interoperability constituents, shall state the precise grounds on which it is based.

15.3.1. The party concerned shall be notified without delay of the decision and shall be informed at the same time of the possibilities and time limits regarding the legal remedies available to it under the laws in force in Malta and of the time limits to which such remedies are subject.

15.4. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission of any measures taken in pursuance of regulation 15.2 of these regulations.

15.5. All appropriate measures shall be taken to encourage the local authorities responsible for implementing these regulations to cooperate with each other and provide each other with information in order to assist the functioning of these regulations.

⁷ L.N. 213 of 2000 - Malta Standards Authority (Establishment of Directorates) Order, 2000, published in the Government Gazette No. 17,002 of 20th October, 2000.

Schedule I

Based on Annex I of the Directive

THE TRANS-EUROPEAN HIGH-SPEED RAIL SYSTEM

1. Infrastructure

(a) The infrastructure of the trans-European high-speed rail system shall be that on the lines of the trans-European transport network identified in the framework of the guidelines referred to in Article 129c of the Treaty:

- those specially built for high-speed travel,
- those specially upgraded for high-speed travel.

They may include connecting lines, in particular junctions of new lines or lines upgraded for high speed with town centre stations located on them, on which speeds must take account of local conditions.

(b) 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.

2. Rolling stock

The high-speed advanced-technology trains shall be designed in such a way as to guarantee safe, uninterrupted travel:

- at a speed of at least 250 km/h on the lines specially built for high speed, while enabling speeds of over 300 km/h to be reached in appropriate circumstances;
- at a speed of the order of 200 km/h on existing lines which have been or are to be specially upgraded;
- at the highest possible speed on other lines.

3. Compatibility of infrastructure and rolling stock

High-speed train services presuppose excellent compatibility between the characteristics of the infrastructure and those of the rolling stock. Performance levels, safety, quality of service and cost depend upon that compatibility.

Schedule II

Based on Annex II of the Directive

SUBSYSTEMS

1. For the purposes of these regulations, the system constituting the trans-European high-speed rail system may be broken down into subsystems, as follows:

1.1. basically structural areas:

- infrastructures
- energy
- control and command and signalling
- rolling stock;

1.2. basically operational areas:

- maintenance
- environment
- operation
- users.

2. For each subsystem, the list of aspects relating to interoperability is indicated in the order given to the representative joint body for drawing up draft TSIs.

Under the provisions of regulation 8.1 of these regulations, this order shall be established in accordance with the procedure laid down in Article 21 (2) of the Directive.

Where necessary, the list of aspects relating to interoperability indicated in the order is specified by the representative joint body in accordance with the provisions of regulation 7.3.5 of these regulations.

3. Within the meaning of regulation 7.3.2 of these regulations, the following are regarded as basic parameters for achieving interoperability:

BASIC PARAMETERS

- Minimum infrastructure gauges
 - Minimum radius of curvature
 - Track gauge
 - Maximum track stressing
 - Minimum platform length
 - Platform height
 - Power-supply voltage
 - Catenary geometry
 - ERTMS characteristics (1*)
 - Axle loading
 - Maximum train length
 - Gauge of rolling stock
 - Minimum braking characteristics
 - Boundary electrical characteristics of rolling stock
 - Boundary mechanical characteristics of rolling stock
 - Operating characteristics linked to train safety
 - Boundary characteristics linked to outside noise
 - Boundary characteristics linked to outside vibrations
 - Boundary characteristics linked to outside electromagnetic interference
 - Boundary characteristics linked to inside noise
 - Boundary characteristics linked to air conditioning
 - Characteristics linked to the carriage of disabled persons.
- (1*) European Rail Traffic Management System.

Schedule III

Based on Annex III of the Directive

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 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.

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

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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.

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.

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 infrastructure 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.

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.

Schedule IV

Based on Annex IV of the Directive

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 regulation 4 of these regulations.

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, 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 regulations references;
- the name and address of the manufacturer or his authorised representative (give trade name and full address and 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, suitability for use (regulation 11 of these regulations);
- 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 authorised representative.

Schedule V

Based on Annex V of the Directive

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 regulations references;
- name and address of the contracting entity or its authorised representative.
(Give trade name and full address, and 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 has conducted the EC inspection referred
to in regulation 13 of these regulations;
- 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.

Schedule VI

Based on Annex VI of the Directive

SUBSYSTEM

EC VERIFICATION

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

- complies with the regulations;

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

2. The subsystem is checked at each of the following stages:

- overall design;

- structure of subsystem, including, in particular, civil-engineering activities, constituent assembly, overall adjustment;

- final testing of the subsystem.

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

4. The technical record accompanying the verification statement must be made up as follows:

- for infrastructures: 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 regulation 4 of these regulations, incorporated into the subsystem;

- copies of the EC declarations of conformity or suitability for use with which said constituents must be provided in accordance with regulation 11 of these regulations, 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 these regulations and mentioning, where appropriate, reservations recorded during performance of the activities and not withdrawn; the certificate should also be accompanied by the inspection and audit reports drawn up in connection with the verification, as specified in points 5.3 and 5.4 of this Schedule.

5. Monitoring

5.1. The aim of EC monitoring is to ensure that the obligations deriving from the technical record 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 must send it or have sent to it all the documents needed for that purpose and in particular the implementation plans and technical records concerning the subsystem.

5.3. The body notified responsible for checking implementation must periodically carry out audits in order to confirm compliance with the regulations. 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. The complete record referred to in paragraph 4 of this Schedule must be lodged with the contracting entity or its authorised agent in support of the certificate of conformity issued by the notified body responsible for checking the subsystem in working order. The record 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 record must be kept by the contracting entity throughout the service life of the subsystem. It must be sent to any other Member States who so request.

7. Each body must periodically pass on relevant information concerning the following:

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

8. The records and correspondence relating to the EC verification procedures must be written in Maltese or in any other language of the Community acceptable to the Maltese authorities.

Schedule VII

Based on Annex VII of the Directive

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

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

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.

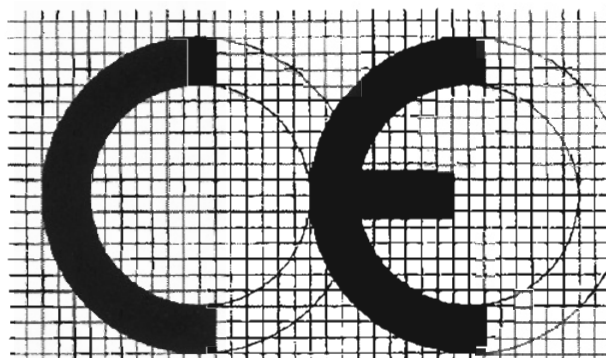
5. The independence of the staff responsible for inspections must be guaranteed. No official must be remunerated either on the basis of the number of inspections performed or of the results of those inspections.

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 these regulations or any provision of national law implementing the regulations.

Schedule VIII**CE CONFORMITY MARKING**

The CE conformity marking shall consist of the initials “CE” taking the following form:



For the avoidance of doubt, it is hereby declared that the grid providing the background in the above graduated drawing is not part of the CE marking.

- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5mm.

This minimum dimension may be waived for small-scale devices.