L.N. 229 of 2011

PRODUCT SAFETY ACT
(CAP. 427)

Interoperability of the Rail System Regulations, 2011

IN exercise of the powers conferred by article 38 of the Product Safety Act, the Prime Minister, on the advice of the Malta Standards Authority, has made the following regulations:-

Citation and scope

1. (1) The title of these regulations is the Interoperability of the Rail System Regulations, 2011.

(2) These regulations transpose Directive 2008/57/EC, as amended by Directive 2009/131/EC, and establish the conditions to be met to achieve interoperability within the Community rail system in a manner compatible with the provisions of Directive 2004/49/EC. These conditions concern the design, construction, placing in service, upgrading, renewal, operation and maintenance of the parts of this system as well as the professional qualifications and health and safety conditions of the staff who contribute to its operation and maintenance.

(3) These regulations concern the provisions relating to, for each subsystem, the interoperability constituents, the interfaces and procedures as well as the conditions of overall compatibility of the rail system required to achieve its interoperability.

(4) When a public or private entity submits an official application for the purpose of building a new railway line which is to be operated in Malta in accordance with the applicability of these regulations and which will be regarded as forming part of the Trans-European conventional rail system and, or as part of the Trans-European high-speed rail system but excluding a metro system, a tram system and any other light rail system, Chapters IV, V, VII and VIII of Directive 2008/57/EC shall apply.

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Applicability.

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

(2) The following shall be excluded from the scope of these regulations:

(a) metros, trams and other light rail systems;

(b) networks that are functionally separate from the rest of the railway system and intended only for the operation of local, urban or suburban passenger services, as well as railway undertakings operating solely on these networks;

(c) privately owned railway infrastructure and vehicles exclusively used on such infrastructure that exist solely for use by the owner for its own freight operations;

(d) infrastructure and vehicles reserved for a strictly local, historical or touristic use.

(3) The scope of the TSIs shall be progressively extended in accordance with regulation 7(1) to the whole rail system, including track access to terminals and main port facilities serving or potentially serving more than one user, without prejudice to the derogations to the application of TSIs as listed in regulation 8.

Definitions.

3. For the purposes of these regulations:

"the Act" means the Product Safety Act;

"the Agency" means the European Railway Agency, as established by Regulation (EC) No 881/2004;

"basic parameters" means any regulatory, technical or operational condition which is critical to interoperability and is specified in the relevant TSIs;

"the Community" means the European Community;

"contracting entity" means any entity, whether public

or private, which orders the design or construction or the renewal or upgrading of a subsystem. This entity may be a railway undertaking, an infrastructure manager or a keeper, or the concession holder responsible for carrying out a project;

"entity in charge of maintenance" means an entity in charge of maintenance of a vehicle, and registered as such in the national vehicle register;

"essential requirements" means all the conditions set out in Schedule III to these regulations which must be met by the rail system, the subsystems, and the interoperability constituents, including interfaces;

"European specification" means a common technical specification, a European technical approval or a national standard transposing a European standard, as defined in Annex XXI to Directive 2004/17/EC;

"existing rail system" means the structure composed of lines and fixed installations of the existing rail system plus the vehicles of all categories and origin travelling on that infrastructure;

"harmonised standard" means a standard adopted by the Malta Standards Authority or one of the European Standardisation bodies listed in Schedule I to the Notification Procedure Regulations, 2003, on the basis of a request made by the Commission in accordance with Article 6 of Directive 98/34/EC; L.N. 373 of 2003.

"interoperability" means the ability of a rail system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance for these lines. This ability depends on all the regulatory, technical and operational conditions which must be met in order to satisfy the essential requirements;

"interoperability constituents" means any elementary component, group of components, subassembly or complete assembly of equipment incorporated or intended to be incorporated into a subsystem, upon which the interoperability of the rail system depends directly or indirectly. The concept of a "constituent" covers both tangible objects and intangible objects such as software;

"keeper" means the person or entity that, being the owner of a vehicle or having the right to use it, exploits the vehicle as a means of transport and is registered as such in the national vehicle register referred to in Article 33 of Directive 2008/57/EC;

L.N. 39 of 2008.

"Market Surveillance Directorate" means the Market Surveillance Directorate of the Malta Standards Authority as described in the Establishment of Directorates of the Malta Standards Authority Order, 2008;

"national safety authority" means a safety authority as defined in Article 3(g) of Directive 2004/49/EC;

"network" means the lines, stations, terminals, and all kinds of fixed equipment needed to ensure safe and continuous operation of the rail system;

L.N. 136 of 2003.

"notified body" means a body designated in accordance with the Method for Designating Conformity Assessment Bodies Regulations, 2003, which is responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the 'EC' procedure for verification of the subsystems;

"placing in service" means all the operations by which a subsystem or a vehicle is put into its design operating state;

"project at an advanced stage of development" means any project whose planning or construction stage has reached a point where a change in the technical specifications would be unacceptable to the Regulatory Affairs Directorate. Such an impediment may be legal, contractual, economic, financial, social or environmental in nature and must be duly substantiated;

"Regulatory Affairs Directorate" means the Regulatory Affairs Directorate of the Malta Standards Authority as described in the Establishment of Directorates of the Malta Standards Authority Order, 2008;

"renewal" means any major substitution work on a subsystem or part subsystem which does not change the overall performance of the subsystem;

"series" means a number of identical vehicles of a design type;

"specific case" means any part of a future planned rail system which needs special provisions in the TSIs, either temporary or definitive, because of geographical, topographical or urban environment constraints or those effecting compatibility with the existing European system, especially taking into consideration the fact that Malta is an archipelago of islands and does not, and will not, have a railway which connects to mainland Europe or to any other third country.

"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;

"subsystems" means the result of the division of the rail system, as shown in Schedule II. These subsystems, for which essential requirements must be laid down, may be structural or functional;

"technical specification for interoperability" (TSI) means a specification adopted in accordance with these regulations by which each subsystem or part subsystem is covered in order to meet the essential requirements and ensure the interoperability of the rail system;

"trans-European rail system" means the trans-European conventional and high-speed rail systems as set out in Schedule I, points 1 and 2, respectively;

"type" means a vehicle type defining the basic design characteristics of the vehicle as covered by a single type examination certificate described in module B of Decision 93/465/EEC;

"upgrading" means any major modification work on a subsystem or part subsystem which improves the overall performance of the subsystem;

"vehicle" means a railway vehicle that runs on its own wheels on railway lines, with or without traction. A vehicle is composed of one or more structural and functional subsystems or parts of such subsystems.

Essential requirements.

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

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

Content of TSIs.

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

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

(3) To the extent necessary to achieve the objective referred to in regulation 1, each TSI shall:

(a) indicate its intended scope (part of network or vehicles referred to in Schedule I; subsystem or part of subsystem referred to in Schedule II);

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

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

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

(e) state, in each case under consideration, which procedures are to be used in order to assess the conformity or the suitability for use of the interoperability constituents, on the one hand, or the 'EC' verification of the subsystems, on the other hand. These procedures shall be based on the modules defined in Decision 93/465/EEC;

(f) indicate the strategy for implementing the TSIs. In particular, it is necessary to specify the stages to be completed in order to make a gradual transition from the existing situation to the final situation in which compliance with the TSIs shall be the norm;

(g) indicate, for the staff concerned, the professional qualifications and health and safety conditions at work required for the operation and maintenance of the above subsystem, as well as for the implementation of the TSIs.

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

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

(6) If certain technical aspects corresponding to the essential requirements cannot be explicitly covered in a TSI, they shall be clearly identified in an annex to the TSI as open points. Article 17(3) of Directive 2008/57/EC shall apply to these aspects.

(7) TSIs shall not be an impediment to decisions by any local Authority concerning the use of infrastructures for the movement of vehicles not covered by the TSIs.

(8) TSIs may make an explicit, clearly identified reference to European or international standards or specifications or

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

Adoption, review and publication of TSIs.

6. (1) Draft TSIs and subsequent draft amendments to TSIs shall be drafted by the Agency under a mandate from the Commission. The Regulatory Affairs Directorate shall participate by providing the requisite data in the assessment during drafting, adoption and review of each TSI (including the basic parameters).

(2) When revision of a TSI leads to a change of requirements, the new TSI version shall ensure compatibility with subsystems placed in service in accordance with former TSI versions. In case a new authorisation, renewal or upgrading of these subsystems is needed for duly justified safety or interoperability reasons, corresponding deadlines shall be fixed either in the TSI or, as appropriate, by the Regulatory Affairs Directorate.

Extension of the scope of TSIs.

7. (1) Where the Commission adopts one or more mandates aiming at the development of new TSIs or the review of TSIs already adopted with a view to covering lines and vehicles not yet covered, until such time as the extension of the scope of the TSIs to cover the whole of the rail network takes effect:

(a) authorisations for the placing in service

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

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

shall be granted in accordance with the national rules referred to in Article 8 of Directive 2004/49/EC, or, where applicable, Article 17(3) of Directive 2008/57/EC;

(b) authorisations for the placing in service of vehicles to be used occasionally on the part of the network that does not yet fall within the scope of the TSIs, in respect of that part of the network, shall be granted in accordance with Articles 21 to 27 of Directive 2008/57/EC and the national rules referred to in Article 8 of Directive 2004/49/EC, or, where applicable, Article 17(3) of Directive 2008/57/EC.

(2) The adopted new or revised TSIs need not be applied in the case of projects at an advanced stage of development or subject to a contract in the course of performance when the relevant group of TSIs is published.

Derogations for TSIs.

8. (1) In the absence of relevant specific cases, TSIs need not apply in the following cases:

(a) for a proposed new subsystem, for the renewal or upgrading of an existing subsystem, or for any element referred to in regulation 1(2) at an advanced stage of development or the subject of a contract in the course of performance when these TSIs are published;

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

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

(d) for any proposed renewal, extension or upgrading of an existing subsystem, when the application of these TSIs would compromise the economic viability of the project or the compatibility of the local rail;

(e) where, following an accident or a natural disaster, the conditions for the rapid restoration of the network do not economically or technically allow for partial or total application of the relevant TSIs;

(f) for vehicles coming from or going to third countries the track gauge of which is different from that of the main rail network within the Community.

(2) In the cases referred to in sub-regulation (1), the Regulatory Affairs Directorate shall communicate to the Commission a file containing the information set out in Schedule IX.

(3) In the case referred to in sub-regulation (1)(a), within one year of entry into force of each TSI the Regulatory Affairs Directorate shall communicate to the Commission a list of projects that are taking place within its territory and are at an advanced stage of development.

(4) The alternative provisions referred to in Schedule IX may be applied without delay in the cases referred to in sub-regulations 1(a), (c) and (e).

(5) Pending the Commission's decision, in the case referred to in sub-regulation (1)(f), the alternative provisions referred to in Schedule IX may be applied.

Placing on the market of interoperability constituents.

9. (1) Interoperability constituents shall only be placed on the market if they enable interoperability to be achieved within the rail system while at the same time meeting the essential requirements.

(2) Interoperability constituents shall only be used in their area of use as intended and shall be suitably installed and maintained.

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

(4) The placing on the market of interoperability constituents complying with these regulations for use in the rail system shall not, on the basis of these regulations, be prohibited, restricted or hindered. In particular, no checks which have already been carried out as part of the procedure of EC declaration of conformity or suitability for use, the components of which are set out in Schedule IV, shall be required.

(5) Interoperability constituents bearing the 'EC' declaration of conformity or suitability for use shall be considered as complying with the essential requirements of these regulations.

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

(7) An interoperability constituent shall be considered as meeting the essential requirements if it complies with the conditions laid down by the corresponding TSI or the corresponding European specifications developed to comply with these conditions.

(8) Spare parts for subsystems that are already placed in service when the corresponding TSI enters into force may be installed in these subsystems without being subject to the procedure referred to in regulation 9(6).

(9) TSIs may provide for a period of transition for rail products identified by those TSIs as interoperability constituents which have already been placed on the market when the TSIs enter into force. Such constituents shall satisfy the requirements of regulation 9.

Procedure for EC declaration of conformity or suitability for use.

10. (1) In order to establish the 'EC' declaration of conformity or suitability for use of an interoperability constituent, the manufacturer or his authorised representative established in the Community shall apply the provisions laid down by the relevant TSIs.

(2) Where the corresponding TSI so requires, assessment of the conformity or suitability for use of an interoperability constituent shall be carried out by the notified body with which the manufacturer or his authorised representative established in the Community has lodged the application.

(3) Where interoperability constituents are the subject of other regulations or Community legislation covering other aspects, the 'EC' declaration of conformity or suitability for use shall, in such cases, state that the interoperability constituents also meet the requirements of those other directives.

(4) Where neither the manufacturer nor his authorised representative established in the Community has met the obligations of regulations 10(1) and 10(3), those obligations shall be incumbent on any person who places interoperability constituents on the market. The same obligations shall apply to

whomsoever assembles interoperability constituents or parts of interoperability constituents having diverse origins or manufactures interoperability constituents for his own use, for the purposes of these regulations.

(5) Without prejudice to the provisions of regulation 11:

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(a) in each instance where the Market Surveillance Directorate finds that the 'EC' declaration of conformity has been drawn up improperly, the manufacturer or his authorised representative established in the Community shall be required, if necessary, to restore the interoperability constituent to a state of conformity and to terminate the infringement under the conditions laid down by the Act;

(b) where non-conformity persists, the Market Surveillance Directorate 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 regulation 11.

Non-compliance of interoperability constituents.

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

(a) failure to meet the essential requirements;

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

(c) inadequacy of European specifications.

(2) Where an interoperability constituent bearing the 'EC' declaration of conformity fails to comply, the Market Surveillance Directorate shall take appropriate measures against whomsoever has drawn up the declaration and shall inform the Commission and the other Member States thereof.

(3) Any decision taken pursuant to these regulations concerning the assessment of conformity or suitability for use of interoperability constituents, the checking of subsystems constituting the rail system or any decision taken pursuant to regulation 11 or 12 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 Act and of the time limits allowed for the exercise of such remedies.

Non-compliance of European specifications.

12. (1) Where it appears to the Regulatory Affairs Directorate that European specifications used directly or indirectly to achieve the objectives of these regulations do not meet the essential requirements, it shall inform the Committee referred to in Article 29 of Directive 2008/57/EC.

Notified bodies.

13. (1) For the purposes of notification under these regulations, a notified body shall meet the requirements laid down hereunder and, in addition, the criteria provided for in Schedule VIII and the Method for Designating Conformity Assessment Bodies Regulations, 2003.

(2) The Regulatory Affairs Directorate shall notify to the Commission and the other Member States the bodies responsible for carrying out the procedure for the assessment of conformity or suitability for use referred to in regulation 10 and the verification procedure referred to in Article 18 of Directive 2008/57/EC, indicating each body's area of responsibility, and the identification numbers obtained in advance from the Commission.

(3) The Regulatory Affairs Directorate shall withdraw approval from a body which no longer meets the criteria referred to in Schedule VIII. It shall forthwith inform the Commission and the other Member States thereof.

Draft reference systems.

14. (1) Following the adoption of any draft reference system of technical rules developed by the Agency to ensure the current degree of interoperability of the networks and vehicles that will be brought within the scope of these regulations, the Regulatory Affairs Directorate shall inform the Commission of any intention to adopt any national provision or of the development of any project which diverges from the reference system.

Penalties.

15. The penalties applicable for the infringement of any of the provisions above shall be those provided for in Part IV of the Act.

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Revokes L.N. 332 of 2002 and L.N. 334 of 2002.

16. The Interoperability of the Trans-European High-Speed Rail System Regulations, 2002, and the Interoperability of the Trans-European Conventional Rail System Regulations, 2002, are being revoked.

Saving.

17. References to the revoked regulations shall be construed as references to these regulations.

Schedule I
SCOPE

1. **Trans-European conventional rail system**

1.1 *Network*

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

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

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

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

1.2 *Vehicles*

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

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

Mobile railway infrastructure construction and maintenance equipment may be included.

Each of the above categories may be subdivided into:

- vehicles for international use,

- vehicles for national use.

2. Trans-European high-speed rail system

2.1 *Network*

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

The high-speed lines shall comprise:

- specially built high-speed lines equipped for speeds generally equal to or greater than 250 km/h,

- specially upgraded high-speed lines equipped for speeds of the order of 200 km/h,

- specially upgraded high-speed lines which have special features as a result of topographical, relief or town planning constraints, on which the speed must be adapted to each case. This category also includes interconnecting lines between the high-speed and conventional networks, lines through stations, accesses to terminals, depots, etc. travelled at conventional speed by 'high-speed' rolling stock.

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

2.2. *Vehicles*

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

- either at speeds of at least 250 km/h on lines specially built for high speeds, while enabling operation at speeds exceeding 300 km/h in appropriate circumstances,

- or at speeds of the order of 200 km/h on the lines of section 2.1, where compatible with the performance levels of these lines.

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

4. Extension of the scope

4.1. *Subcategories of network and vehicles*

The scope of the TSIs shall be progressively extended to the whole rail system as referred to in regulation 2(3). In order to deliver interoperability cost-effectively further subcategories of all categories of network and vehicles mentioned in this Schedule will, where necessary, be developed. If necessary, the functional and technical specifications mentioned in regulation 5(3) may vary according to the subcategory.

4.2. *Cost safeguards*

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

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

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

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Schedule II
SUBSYSTEMS

1. **List of subsystems**

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

(a) structural areas:

- infrastructure,
- energy,
- control-command and signalling,
- rolling stock;

(b) functional areas:

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

2. **Description of the subsystems**

For each subsystem or part of a subsystem, the list of constituents and aspects relating to interoperability is proposed by the Agency at the time of drawing up the relevant draft TSI.

Without prejudging the choice of aspects and constituents relating to interoperability or the order in which they will be made subject to TSIs, the subsystems include, in particular:

2.1 *Infrastructure*

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

2.2 *Energy*

The electrification system, including overhead lines and on-board parts of the

electric consumptions measuring equipment.

2.3 *Control-command and signalling*

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

2.4 *Operation and traffic management*

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

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

2.5 *Telematics applications*

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

(a) applications for passenger services, including systems providing passengers with information before and during the journey, reservation and payment systems, luggage management and management of connections between trains and with other modes of transport;

(b) (b) applications for freight services, including information systems (real-time monitoring of freight and trains), marshalling and allocation systems, reservation, payment and invoicing systems, management of connections with other modes of transport and production of electronic accompanying documents.

2.6 *Rolling stock*

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

2.7 *Maintenance*

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

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Schedule III
ESSENTIAL REQUIREMENTS

1. General requirements

1.1 *Safety*

1.1.1 The design, construction or assembly, maintenance and monitoring of safety-critical components, and more particularly of the components involved in train movements must be such as to guarantee safety at the level corresponding to the aims laid down for the network, including those for specific degraded situations.

1.1.2 The parameters involved in the wheel/rail contact must meet the stability requirements needed in order to guarantee safe movement at the maximum authorised speed. The parameters of brake equipment must guarantee that it is possible to stop within a given brake distance at the maximum authorised speed.

1.1.3 The components used must withstand any normal or exceptional stresses that have been specified during their period in service. The safety repercussions of any accidental failures must be limited by appropriate means.

1.1.4 The design of fixed installations and rolling stock and the choice of the materials used must be aimed at limiting thegeneration, propagation and effects of fire and smoke in the event of a fire.

1.1.5 Any devices intended to be handled by users must be so designed as not to impair the safe operation of the devices or the health.

1.2 *Reliability and availability*

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

1.3 *Health*

1.3.1 Materials likely, by virtue of the way they are used, to constitute a health hazard to those having access to them must not be used in trains and railway infrastructures.

1.3.2 Those materials must be selected, deployed and used in such a way as to restrict the emission of harmful and dangerous fumes or gases, particularly in the event of fire.

1.4 *Environmental protection*

1.4.1 The environmental impact of establishment and operation of the rail system must be assessed and taken into account at the design stage of the system in accordance with the Community provisions in force.

1.4.2 The materials used in the trains and infrastructures must prevent the emission of fumes or gases which are harmful and dangerous to the environment, particularly in the event of fire.

1.4.3 The rolling stock and energy-supply systems must be designed and manufactured in such a way as to be electromagnetically compatible with the installations, equipment and public or private networks with which they might interfere.

1.4.4 Operation of the rail system must respect existing regulations on noise pollution.

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

1.5 *Technical compatibility*

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

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

2. Requirements specific to each subsystem

2.1 *Infrastructure*

2.1.1 Safety

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

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

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

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

2.2 *Energy*

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2.2.1 Safety

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

2.2.2 Environmental protection

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

2.2.3 Technical compatibility

The electricity/thermal energy supply systems used must:

- enable trains to achieve the specified performance levels,

- in the case of electricity energy supply systems, be compatible with the collection devices fitted to the trains.

2.3 *Control-command and signaling*

2.3.1 Safety

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

2.3.2 Technical compatibility

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

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

2.4 *Rolling stock*

2.4.1 Safety

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

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

2.4.2 Reliability and availability

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

2.4.3 Technical compatibility

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

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

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

2.4.4 Controls

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

2.5 *Maintenance*

2.5.1 Health and safety

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

2.5.2 Environmental protection.

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

2.5.3 Technical compatibility

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

2.6 *Operation and traffic management*

2.6.1 Safety

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

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

2.6.2 Reliability and availability

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

2.6.3 Technical compatibility

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

2.7 *Telematics applications for freight and passengers*

2.7.1 Technical compatibility

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

Steps must be taken to ensure:

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

- easy access to the information for users.

2.7.2 Reliability and availability

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

2.7.3 Health

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

2.7.4 Safety

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

Schedule IV
'EC' DECLARATION OF CONFORMITY AND SUITABILITY FOR USE OF INTEROPERABILITY CONSTITUENTS

1. **Interoperability constituents**

The 'EC' declaration applies to the interoperability constituents involved in the interoperability of the rail system, as referred to in regulations 1(3) and 2(1). These interoperability constituents may be:

1.1 *Multiple-use constituents*

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

1.2 *Multiple-use constituents having specific characteristics*

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

1.3 *Specific constituents*

These are constituents that are specific to railway applications.

2. **Scope**

The 'EC' declaration covers:

- either the assessment by a notified body or bodies of the intrinsic conformity of an interoperability constituent, considered in isolation, to the technical specifications to be met,

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

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

3. **Contents of the 'EC' declaration**

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

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

- the reference to applicable regulations,

- name and address of the manufacturer or its authorised representative established within the Community (give trade name and full address; in the case of the authorised representative, also give the trade name of the manufacturer),

- description of interoperability constituent (make, type, etc.),

- description of the procedure followed in order to declare conformity or suitability for use (regulation 10),

- all the relevant descriptions met by the interoperability constituent and, in particular, its conditions of use,

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

- where appropriate, reference to the European specifications,

- identification of the signatory empowered to enter into commitments on behalf of the manufacturer or of the manufacturer's authorised representative established within the Community.

Schedule V
‘EC’ DECLARATION OF VERIFICATION OF SUBSYSTEMS

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

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

- the references to applicable regulations,

- name and address of the contracting entity or the manufacturer, or its authorised representative established within the Community (give trade name and full address; in the case of the authorised representative, also give the trade name of the contracting entity or the manufacturer),

- a brief description of the subsystem,

- name and address of the notified body which conducted the ‘EC’ verification referred to in Article 18 of Directive 2008/57/EC,

- the references of the documents contained in the technical file,

- all the relevant temporary or definitive provisions to be complied with by the subsystems and in particular, where appropriate, any operating restrictions or conditions,

- if temporary: duration of validity of the ‘EC’ declaration,

- identity of the signatory.

Schedule VI
'EC' VERIFICATION PROCEDURE FOR SUBSYSTEMS

1. **Introduction**

'EC' verification is the procedure whereby a notified body checks and certifies that the subsystem:

- complies with these Regulations,

- 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, in particular, civil-engineering activities, manufacturing, constituent assembly, overall adjustment,

- final testing of the subsystem.

For the design stage (including the type tests) and for the production stage the applicant may apply for an assessment as a first step.

In this case, this assessment or assessments lead to one or more intermediate statement verifications (ISV) issued by the notified body chosen by the applicant. The notified body in turn draws up an 'EC' declaration of intermediate subsystem conformity for the relevant stages.

3. **Certificate**

The notified body responsible for 'EC' verification assesses the design and production of the subsystem and draws up the certificate of verification intended for the applicant, which in turn draws up the 'EC' declaration of verification intended for the Regulatory Affairs Directorate.

If available, the notified body takes into account the ISVs, and, in order to issue the 'EC' certificate of verification, it:

- checks that the subsystem:

- is covered by relevant design and production ISVs, if the applicant has asked

the notified body for these two phases, or

- corresponds as produced to all aspects covered by the design ISV delivered to the applicant, 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).

4. **Technical file**

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

- for infrastructure: engineering-structure plans, approval records for excavations and reinforcement, testing and inspection reports on concrete, 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 regulations 1(3) and 2(1), incorporated into the subsystem,

- copies of the 'EC' declarations of conformity or suitability for use with which the abovementioned constituents must be provided in accordance with regulation 10 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 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 these Regulations 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 applicant 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 these regulations. It must provide those responsible for implementation with an audit report. It may need 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.

5.5 With a view to deliver the 'EC' declaration of suitability for use referred to in section 2 of Schedule IV, the notified body shall be able to monitor a subsystem on which an interoperability constituent is mounted in order to assess, where the corresponding TSI so requires, its suitability for use in its intended railway environment.

6. **Submission**

The complete file referred to in paragraph 4 must be lodged with the applicant in support of the ISV, if available, issued by the notified body responsible for this or in support of the certificate of conformity issued by the notified body responsible for verification of the subsystem in working order. The file must be attached to the ISV or to the 'EC' declaration of verification which the applicant sends to the Regulatory Affairs Directorate.

A copy of the file must be kept by the applicant 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,
- ISVs issued or refused,
- certificates of verification issued or refused,
- certificates of conformity refused.

8. **Language**

The files and correspondence relating to the ‘EC’ verification procedures must be written in at least the English or Maltese language.

Schedule VII
PARAMETERS TO BE CHECKED IN CONJUNCTION WITH THE PLACING IN SERVICE OF NON-TSI CONFORMING VEHICLES AND THE CLASSIFICATION OF THE NATIONAL RULES

1. **List of parameters**

1.1 *General documentation*

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

1.2 *Structure and mechanical parts*

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

1.3 *Track interaction and gauging*

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

1.4 *Braking equipment*

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

1.5 *Passenger-related items*

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

1.6 *Environmental conditions and aerodynamic effects*

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

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

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

1.8 *Onboard power supply and control systems*

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

1.9 *Staff facilities, interfaces and environment*

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

1.10 *Fire safety and evacuation*

1.11 *Servicing*

Onboard facilities and interfaces for servicing.

1.12 *Onboard control, command and signalling*

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

1.13 *Specific operational requirements*

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

1.14 *Freight related items*

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

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

2. **Classification of the rules**

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

Group A

Group A covers:

- international standards,

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

Group B

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

Group C

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

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Schedule VIII
MINIMUM CRITERIA FOR NOTIFICATION OF NOTIFIED BODIES

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

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

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

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

4. The staff responsible for the checks must possess:

   - proper technical and vocational training,

   - a satisfactory knowledge of the requirements relating to the checks that they carry out and sufficient practice in those checks,

   - the ability to draw up the certificates, records and reports which constitute the formal record of the inspections conducted.

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

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

7. The staff of the body are bound by professional secrecy with regard to everything

they learn in the performance of their duties (with the exception of the competent administrative authorities and accident investigation bodies in the State where they perform those activities as well as accident investigation bodies responsible for the investigation of accidents caused by the failure of the interoperability constituents or subsystems checked) in pursuance of this these regulations or any provision of national law implementing these regulations.

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Schedule IX
FILE FOR SUBMITTING A DEROGATION

When submitting a request for a derogation, the Regulatory Affairs Directorate must supply the following documents:

(a) A formal letter communicating the proposed derogation to the Commission.

(b) A file, annexed to the letter, comprising at least:

- a description of the work, goods and services subject to the derogation, specifying the key dates, the geographical location and the operational and technical area,

- a precise reference to the TSIs (or their parts) for which a derogation is requested,

- a precise reference to and details of the alternative provisions which will be applied,

- for requests made under Article 7(1)(a) of Directive 2008/57/EC, justification of the advanced stage of development of the project,

- justification of the derogation, including the main reasons of a technical, economic, commercial, operational and/or administrative nature,

- any other information justifying the request for a derogation,

- a description of the measures that the Regulatory Affairs Directorate proposes to take in order to promote the final interoperability of the project. In the case of a minor derogation, this description is not required.

Documentation must be supplied in paper form and as electronic files.

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