Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 17,311, 12 ta' Novembru, 2002
Taqsima B

L.N. 334 of 2002

PRODUCT SAFETY ACT (ACT NO. V OF 2001)

Interoperability of the Trans-European Conventional 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:-

Citation and commencement

1.1. The title of these regulations is the Interoperability of the Trans-European Conventional Rail System Regulations, 2002.

1.2. These regulations shall become operative on the 20th April, 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.

Scope.

2.1. These regulations set out to establish the conditions to be met to achieve interoperability within the Community territory of the trans-European conventional rail system, as described in Annex I of the Directive, which is set out in Schedule I hereto.

2.1.1. These conditions concern the design, construction, putting into service, upgrading, renewal, operation and maintenance of the parts of this system put into service after the date of entry into force of these regulations, as well as the professional qualifications and health and safety conditions of the staff who contribute to its operation.

2.2. The pursuit of this objective must lead to the definition of a minimum level of technical harmonisation and make it possible to;

2.2.1. facilitate, improve and develop international rail transport services within the European Union and with third countries:

2.2.2. contribute to the progressive creation of the internal market in equipment and services for the construction, renewal, upgrading and operation of the trans-European conventional rail system:

2.2.3. contribute to the interoperability of the trans-European conventional rail system.

Definitions.

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

3.1.1. "The Directive" means Council Directive 2001/16/EC[1] of the European Parliament and of the Council of 19th March, 2001 on the interoperability of the trans-European conventional rail system;

3.1.2. "Trans-European conventional rail system" means the structure, as described in Annex I of the Directive, which is set out in Schedule I hereto, composed of lines and fixed installations, of the trans-European transport network, built or upgraded for conventional rail transport and combined rail transport, plus the rolling stock designed to travel on that infrastructure;

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

3.1.4. "Subsystems" means the result of the division of the trans-European conventional rail system, as shown in Annex II of the Directive, which is set out in Schedule II to these regulations. These subsystems, for which essential requirements must be laid down, are structural and functional;

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 conventional rail system depends directly or indirectly. The concept of a "constituent" covers both tangible objects and intangible objects such as software;

[1] OJ No. L 235, 17-09-96, p. 06-24.

3.1.6. "Essential requirements" means all the conditions set out in Annex III of the Directive, which is set out in Schedule III to these regulations, which must be met by the trans-European conventional rail system, the subsystems, and the interoperability constituents including interfaces;

3.1.7. "European specification" means a common technical specification, a European technical approval or a national standard transposing a European standard, as defined in points 8 to 12 of Article 1 of Directive 93/38/EEC[2];

3.1.8. "Technical specifications for interoperability", hereinafter referred to as "TSIs", means the specifications by which each subsystem or part subsystem is covered in order to meet the essential requirements and ensure the interoperability of the trans-European conventional rail system;

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

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. "Basic parameters" means any regulatory, technical or operational condition which is critical to interoperability and requires a decision in accordance with the procedure laid down in Article 21(2) of the Directive before any development of draft TSIs by the joint representative body;

3.1.12. "Specific case" means any part of the trans-European conventional rail system which needs special provisions in the TSIs, either temporary or definitive, because of geographical, topographical or urban environment constraints or those affecting compatibility with the existing system. This may include in particular railway lines and networks isolated from the rest of the Community or Malta, the loading gauge, the track gauge or space between the tracks and rolling stock strictly intended for local, regional or historical use, as well as rolling stock originating from or destined for third countries, as long as this stock does not cross the border between two Member States;

[2] OJ No. L 199, 09-08-93, p. 084-138.
[3] OJ No. L 237, 24-08-91, p. 25-28.

3.1.13. "Upgrading" means any major modification work on a subsystem or part subsystem which requires fresh authorisation for putting into service within the meaning of regulation 12.1 of these regulations;

3.1.14. "Renewal" means any major substitution work on a subsystem or part subsystem which requires fresh authorisation for putting into service within the meaning of regulation 12.1 of these regulations;

3.1.15. "Existing rail system" means the structure composed of lines and fixed installations of the existing rail system plus the rolling stock of all categories and origin travelling on that infrastructure.

3.1.16. In these regulations, unless the context otherwise requires –

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

3.1.16.2. 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.

3.1.17. "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/EC[4] 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/EC[5] of the European Parliament and of the Council;

3.1.18. "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;

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

[4] OJ No. L 204, 21-07-98, p. 37.
[5] OJ No. L 217, 05-08-98, p. 18.

3.1.20. "Community" means the European Community;

3.1.21. "Manufacturer" means the person:

3.1.21.1. 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;

3.1.21.2. 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;

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

3.1.22. "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;

3.1.23. "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;

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

3.1.25. "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:-

3.1.25.1. that it does not satisfy those provisions; and

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

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

3.1.26.1. the manufacturer thereof

3.1.26.2. the manufacturer's authorised representative; or

3.1.26.3. 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 local market;

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

Applicability.

4.1. These regulations apply to the provisions concerning, for each subsystem, the interoperability constituents, the interfaces and procedures as well as the conditions of overall compatibility of the trans-European conventional rail system required to achieve its interoperability.

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

4.2.1. 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.

General requirements.

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

5.2. The further technical specifications referred to in Article 18 (4) of Directive 93/38/EEC which are necessary to complete European specifications or other standards in use within the Community must not conflict with the essential requirements.

Free movement.

6.1. The placing on the market of interoperability constituents for use in the trans-European conventional rail system where they comply with these regulations may not be prohibited, restricted or hindered.

6.1.1. In particular, checks which have already been carried out as part of the procedure of "EC"declaration of conformity or suitability for use, the components of which are set out in Annex IV of the Directive, which is set out in Schedule IV hereto may not be required.

6.2. Without prejudice to the provisions of Article 19 of the Directive and regulation 13.4 of these regulations, the construction, putting into service and operating of structural subsystems constituting the trans-European conventional rail system which meet the essential requirements may not be prohibited, restricted or hindered.

6.2.1. In particular, checks which have already been carried out as part of the procedure leading to the "EC" declaration of verification, the components of which are set out in Annex V of the Directive, which is set out in Schedule V hereto may not be required.

Technical specifications for interoperability.

7.1. Each of the subsystems shall be covered by a TSI. Where necessary, especially for treating categories of lines, hubs or rolling stock separately, or to solve certain interoperability problems as a matter of priority, a subsystem may be covered by several TSIs. In this case the provisions of this Article also apply to the part of the subsystem concerned.

7.2. Subsystems shall comply with the TSIs; this compliance shall be permanently maintained while each subsystem is in use.

7.3. To the extent necessary in order to achieve the objectives referred to in Article 1 of the Directive[6], each TSI shall:

7.3.1. indicate its intended scope (part of network or rolling stock referred to in Annex I of the Directive, which is set out in Schedule I hereto: subsystem or part of subsystem referred to in Annex II of the Directive, which is set out in Schedule II hereto);

7.3.2. lay down essential requirements for each subsystem concerned and its interfaces *vis-à-vis* other subsystems;

7.3.3. establish the functional and technical specifications to be met by the subsystem and its interfaces *vis-à-vis* other subsystems. If need be, these specifications may vary according to the use of the subsystem, for example according to the categories of line, hub and/or rolling stock provided for in Annex I of the Directive, which is set out in Schedule I hereto;

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[6] Regulations 2.1, 2.1.1, 2.2, 2.2.1, 2.2.2 and 2.2.3 of these regulations.

7.3.4. determine the interoperability constituents and interfaces which must be covered by European specifications, including European standards, which are necessary to achieve interoperability within the trans-European conventional rail system;

7.3.5. state, in each case under consideration, the procedures for the assessment of conformity or suitability of use. This includes in particular the modules defined in Decision 93/465/EEC[7] or, where appropriate, the specific procedures, to be used to assess either the conformity or the suitability for use of interoperability constituents and "EC" verification of subsystems;

7.3.6. 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;

7.3.7. 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.

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

7.5. The TSIs shall retain, in an appropriate manner, the compatibility of the existing rail system. With this objective, provision may be made for specific cases for each set of TSIs, with regard to both infrastructure and rolling stock; special attention must be given to the loading gauge, the track gauge or space between the tracks and wagons from or going to third countries. For each specific case, the TSIs stipulate the implementing rules of the elements of the TSIs indicated in regulations 7.3.3 to 7.3.7 of these regulations.

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

The joint representative body.

8.1. Draft TSIs shall be drawn up by the joint representative body under a mandate from the Commission in accordance with the procedure set out in Article 21(2). TSIs shall be adopted and reviewed by the

[7] OJ No. L 220, 30-08-93, p. 23-39

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

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

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

8.4. Each draft TSI shall be drawn up in two stages:

8.4.1. First of all, the joint representative body shall identify the basic parameters for this TSI as well as the interfaces with the other subsystems and any other specific cases that may be necessary. The most viable alternative solutions accompanied by technical and economic justification shall be put forward for each of these parameters and interfaces. A decision shall be taken in accordance with the procedure set out in Article 21(2) of the Directive; if necessary, specific cases shall be cited.

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

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

8.6. The Committee referred to in Article 21 of the Directive shall be kept regularly informed of the preparatory work on the TSIs. During this work the Committee may formulate any terms of reference or useful recommendations concerning the design of the TSIs and the cost-benefit analysis. In particular, the Committee may, at the request of a Member State, require that alternative solutions be examined and that the assessment of the cost and benefits of these alternative solutions be set out in the report annexed to the draft TSI.

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

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

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

8.8.2. They shall enclose with the draft TSI a report on the results of this consultation;

8.8.3. The list of associations and bodies to be consulted shall be finalised by the Committee referred to in Article 21 of the Directive before adopting the mandate of the first TSI and may be re-examined and updated at the request of a Member State or the Commission.

8.9. The drafting and review of the TSIs shall take account of the opinion of the social partners as regards the conditions referred to in regulation 7.3.7 of these regulations:

8.9.1. To this end, the social partners shall be consulted before the draft TSI is submitted, for adoption or review, to the Committee referred to in Article 21 of the Directive;

8.9.2. The social partners shall be consulted in the context of the Sectoral Dialogue Committee set up in accordance with Commission Decision 98/500/EC[8];

[8] OJ No. L 225, 12-08-98, p. 27-28.

8.9.3. The social partners shall issue their opinion within three months.

9.1. One or more TSIs, including the ones relating to rolling stock, need not be applied in the following cases and circumstances: Provisions relating to TSIs

9.1.1. for a proposed new line, for the upgrading of an existing line, or for any element referred to regulations 2.1 and 2.1.1 of these regulations at an advanced stage of development or the subject of a contract in course of performance when these TSIs are published;

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

9.1.3. for a proposed new line or for the proposed renewal or upgrading of an existing line in the territory concerned when its rail network is separated or isolated by the sea from the rail network of the rest of the Community;

9.1.4. for any proposed renewal, extension or upgrading of an existing line, when the application of these TSIs would compromise the economic viability of the project and/or the compatibility of the rail system in the territory concerned;

9.1.5. 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;

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

9.2. The intended derogation shall be notified to the Commission and a file shall be forwarded to it setting out the TSIs or the parts of TSIs do not apply as well as the corresponding specifications that apply. The Committee provided for in Article 21 shall analyse the measures envisaged.

9.2.1. In regulations 9.1.2, 9.1.4 and 9.1.6 of these regulations, the Commission shall take a decision in accordance with the procedure in Article 21(2) of the Directive. Where necessary, a recommendation shall be drawn up concerning the

specifications to be applied. Nevertheless, in the case of regulation 9.1.2 of these regulations, the Commission's decision shall not cover the loading gauge and the track gauge.

Interoperability constituents.

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

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

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

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

10.2. Those interoperability constituents which bear the 'EC' declaration of conformity or suitability for use shall be considered as complying with the essential requirements of these regulations which apply to them.

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

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

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

EC declaration of conformity.

11.1. In order to establish the "EC" declaration of conformity or suitability for use of an interoperability constituent, the manufacturer or his authorised representative shall apply the provisions laid down by the relevant TSIs.

11.2. Assessment of the conformity or suitability for use of an interoperability constituent shall be carried out by the notified body with which the manufacturer or his authorised representative has lodged the application.

11.3. Where interoperability constituents are the subject of other Community directives covering other aspects, the "EC" declaration of conformity or suitability for use shall, in such instances, state that the interoperability constituents also meet the requirements of those other directives.

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

11.5. Without prejudice to the provisions of Article 12 of the Directive and regulations 15.1 and 15.2 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 restore the interoperability constituent to a state of conformity and to terminate the infringement 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 at issue, or to ensure that it is withdrawn from the market in accordance with the procedures provided for in Article 12 of the Directive and regulations 15.1 and 15.2 of these regulations.

Subsystems.

12.1. The putting into service of those structural subsystems constituting the trans-European conventional rail system which are located or operated in the territory concerned, shall be authorised.

12.1.1. To this end, all appropriate steps shall be taken to ensure that these subsystems may be put into service only if they are designed, constructed and installed in such a way as to meet the essential requirements concerning them when integrated into

the trans-European conventional rail system. In particular, the compatibility of these subsystems shall be checked with the system into which they are being integrated.

12.2. It shall be checked, that these subsystems when they are put into service and at regular intervals thereafter, are operated and maintained in accordance with the essential requirements concerning them.

12.3. In the event of renewal or upgrading, a file describing the project shall be sent by the manager of the rail infrastructure or enterprise:

12.3.1. This file shall be examined and, taking account of the implementation strategy indicated in the applicable TSI, it shall be decided whether the size of the works means that a new authorisation for putting into service within the meaning of these regulations is needed;

12.3.2. This authorisation for putting into service is required each time the safety level may be affected by the works envisaged.

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

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

EC declaration of verification.

13.1. In order to establish the 'EC' declaration of verification, the procurement entity or its official representative shall invite the notified body that it has selected for that purpose to apply the 'EC' verification procedure referred to in Annex VI of the Directive, which is set out in Schedule VI hereto.

13.2. The task of the notified body responsible for the 'EC' verification of a subsystem shall begin at the design stage and cover the entire manufacturing period through to the acceptance stage before the subsystem is put into service. It shall also cover verification of the interfaces of the subsystem in question with the system into which it is incorporated, based on the information available in the relevant TSI and in the registers provided for in regulation 17 of these regulations.

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

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 request that additional checks be carried out.

13.4.1. The Commission shall be informed of any additional checks requested and the substantiating reasons thereof shall be set out.

Withdrawal of European Specifications.

14.1. Where it appears that European specifications do not meet the essential requirements, partial or total withdrawal of these specifications from the publications containing them, or their amendment, may be decided upon in accordance with the procedure laid down in Article 21(2) of the Directive after consultation, where European standards are involved, 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.

Withdrawal and prohibition from the market.

15.1. Where it is found that an interoperability consitituent 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, the Director of Consumer Affairs shall take all necessary steps to restrict its field 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 Directorate[9] of the Malta Standards Authority and shall 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.

[9] 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.

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.

Adoption of TSIs.

16.1. The order of priority for the adoption of the TSIs shall be as follows, without prejudice to the order of adoption of the mandates provided for in regulation 8.1 of these regulations:

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

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

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

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

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

16.2. The Committee, following the procedure laid down in Article 21(2) of the Directive, shall draw up a work programme observing the order of priority referred to in regulation 16.1 of these regulations and that of the other tasks entrusted to it by this Directive.

16.2.1. The TSIs mentioned in the first work programme referred to in regulation 16.1.1 of these regulations shall be drawn up not later than 20th April 2004.

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

16.3.1. designation of the joint representative body;

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

16.3.3. adoption of a model structure for developing TSIs;

16.3.4. adoption of a method of cost-benefit analysis of the solutions set out in the TSIs;

16.3.5. adoption of the mandates needed to draw up the TSI

16.3.6. adoption of the basic parameters for each TSI;

16.3.7. approval of draft standardisation programmes;

16.3.8. management of the transition period between the date of entry into force of these regulations and publication of the TSIs, including the adoption of the reference system mentioned in Article 25 of the Directive.

Registration of infrastructure and rolling stock.

17.1. It shall be ensured that registers of infrastructure and of rolling stock are published and updated annually. Those registers shall indicate the main features of each subsystem or part subsystem involved (e.g. the basic parameters) and their correlation with the features laid down by the applicable TSIs. To that end, each TSI shall indicate precisely which information must be included in the registers of infrastructure and of rolling stock.

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

SCHEDULE I

Based on Annex I of the Directive

THE TRANS-EUROPEAN CONVENTIONAL RAIL SYSTEM

1. INFRASTRUCTURE

The infrastructure of the trans-European conventional rail system shall be that on the lines of the trans-European transport network identified in Decision No 1692/96/EC of the European Parliament and of the Council of 23 July 1996 on Community guidelines for the development of the trans-European transport network[10] or listed in any update to the same Decision as a result of the revision provided for in Article 21 of that Decision.

For the purposes of 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 components.

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

2. ROLLING STOCK

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

- self-propelling thermal or electric trains;

- thermal or electric traction units;

- passenger carriages;

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[10] OJ No L 228, 09-09-96, p. 01.

- freight wagons, including rolling stock designed to carry lorries.

Each of the above categories must be subdivided into:

- rolling stock for international use;

- rolling stock for national use;

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

3. COMPATIBILITY OF THE TRANS-EUROPEAN CONVENTIONAL RAILWAY SYSTEM

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

SCHEDULE II

Based on Annex II of the Directive

SUBSYSTEMS

1. LIST OF SUBSYSTEMS

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

(a) structural areas:

- infrastructure;

- energy;

- control and command and signalling;

- traffic operation and management;

- rolling stock; or

(b) operational areas:

- maintenance;

- telematics applications for passenger and freight services.

2. DESCRIPTION OF THE SUBSYSTEMS

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

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

2.1. **Infrastructure:**

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

2.2. **Energy:**

The electrification system, overhead lines and current collectors.

2.3. Control and command and signalling:

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

2.4. Traffic operation and management:

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

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

2.5. Telematics applications:

In accordance with Annex I of the Directive, which is set out in Schedule I hereto, this subsystem comprises two elements:

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

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

2.6. Rolling stock:

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

2.7. Maintenance:

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

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 the safe operation of the devices or the health and safety of users if used foreseeably in a manner not in accordance with the posted instructions.

1.2. **Reliability and availability**

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

1.3. **Health**

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

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

1.4. **Environmental protection**

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

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

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

1.4.4. Operation of the trans-European conventional rail system must respect existing regulations on noise pollution.

1.4.5. Operation of the trans-European conventional rail system must not give rise to an

inadmissible level of ground vibrations for the activities and areas close to the infrastructure and in a normal state of maintenance.

1.5. **Technical compatibility**

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

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

2. REQUIREMENTS SPECIFIC TO EACH SUBSYSTEM

2.1. **Infrastructure**

2.1.1. Safety

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

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

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

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

2.2. **Energy**

2.2.1. Safety

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

2.2.2. Environmental protection

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

2.2.3. Technical compatibility

The electricityćthermal energy supply systems used must:

- enable trains to achieve the specified performance levels;

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

2.3. **Control and command and signalling**

2.3.1. Safety

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

2.3.2. Technical compatibility

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

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

2.4. **Rolling stock**

2.4.1. Safety

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

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

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

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

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

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

Emergency exits must be provided and indicated.

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

An emergency lighting system of sufficient intensity and duration is compulsory on board trains.

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

2.4.2. Reliability and availability

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

2.4.3. Technical compatibility

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

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

The characteristics of the rolling stock must be such as to allow it to travel on any line on which it is expected to operate.

2.5. **Maintenance**

2.5.1. Health and safety

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

2.5.2. Environmental protection

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

2.5.3. Technical compatibility

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

2.6. **Operation and traffic management**

2.6.1. Safety

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

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

2.6.2. Reliability and availability

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

2.6.3. Technical compatibility

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

2.7. **Telematics applications for freight and passengers**

2.7.1. Technical compatibility

The essential requirements for telematics applications guarantee a minimum quality of

service for passengers and carriers of goods, particularly in terms of technical compatibility.

Steps must be taken to ensure:

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

- easy access to the information for users.

2.7.2. Reliability and availability

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

2.7.3. Health

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

2.7.4. Safety

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

SCHEDULE IV

Based on Annex IV of the Directive

CONFORMITY AND SUITABILITY FOR USE OF INTEROPERABILITY CONSTITUENTS

1. INTEROPERABILITY CONSTITUENTS

The "EC" declaration applies to the interoperability constituents involved in the interoperability of the trans-European conventional rail system, as referred to in regulations 4.1, 4.2 and 4.2.1 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 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 assessmentcjudgement by a notified body or bodies of the suitability for use of an interoperability constituent, considered within its railway environment and, in particular in cases where the interfaces are involved, in relation to the technical specifications, particularly those of a functional nature, which are to be checked.

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

3. CONTENTS OF THE "EC" DECLARATION

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

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

- the Directive references;

- the name and address of the manufacturer or his authorised representative (give trade name and full address, in the case of the authorised representative, also give the trade name of the manufacturer or constructor);

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

- description of the procedure followed in order to declare conformity or suitability for use (Article 13 of the Directive[1]);

- 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.

Schedule V

Based on Annex V of the Directive

DECLARATION OF VERIFICATION OF SUBSYSTEMS

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

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

- the Directive references;

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

- a brief description of the subsystem;

- name and address of the notified body which conducted the "EC" verification referred to in regulations 13.1, 13.2 and 13.3 of these regulations;

- 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

Based on Annex VI of the Directive

VERIFICATION PROCEDURE FOR SUBSYSTEMS

1. INTRODUCTION

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

- complies with the 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;

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

- final testing of the subsystem.

3. CERTIFICATE

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

4. TECHNICAL FILE

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

- for infrastructure: engineering-structure plans, approval records for excavations and reinforcement, testing and inspection reports on concrete;

- for the other subsystems: general and detailed drawings in line with execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems, operating and maintenance manuals, etc.;

- list of interoperability constituents, as referred to in regulations 4.1, 4.2 and 4.2.1 of these regulations, 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 of the Directive[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;

- certificate from the notified body responsible for "EC" verification, accompanied by corresponding calculation notes and countersigned by itself, stating that the project complies with this Directive and mentioning any reservations recorded during performance of the activities and not withdrawn; the certificate should also be accompanied by the inspection and audit reports drawn up by the same body in connection with its task, as specified in sections 5.3 and 5.4 of this Schedule.

5. MONITORING

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

5.2. The notified body responsible for checking production must have permanent access to building sites, production workshops, storage areas and, where appropriate, prefabrication or testing facilities and, more generally, to all premises which it considers necessary for its task. The contracting entity or its authorised representative must send it or have sent to it all the documents needed for that purpose and, in particular, the implementation plans and technical documentation concerning the subsystem.

5.3. The notified body responsible for checking implementation must periodically carry out audits in order to confirm compliance with the 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.

[11] Regulations 11.1, 11.2, 11.3, 11.4, 11.5, 11.5.1 and 11.5.2 of these regulations.

6. SUBMISSION

The complete file 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 verification of the subsystem in working order. The file must be attached to the "EC" declaration of verification which the contracting entity sends to the supervisory authority in the Member State concerned.

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

7. PUBLICATION

Each notified body must periodically publish relevant information concerning:

- requests for "EC" verification received;

- certificates of conformity issued;

- certificates of conformity refused.

8. LANGUAGE

The files and correspondence relating to the "EC" verification procedures must be written in the 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 checks may not become involved, either directly or as authorised representatives, in the design, manufacture, construction, marketing or maintenance of the interoperability constituents or subsystems or in their use. This does not exclude the possibility of an exchange of technical information between the manufacturer or constructor and that body.

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

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

4. The staff responsible for the checks must possess:

- proper technical and vocational training;

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

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

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

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

7. The staff of the body are bound by professional secrecy with regard to everything they learn in the performance of their duties (with the exception of the competent administrative authorities in the State where they perform those activities) in pursuance of these regulations or any provision of national law implementing the regulations.

Schedule VIII

Based on Annex VIII of the Directive

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

1. In line with the general Community standardisation procedures, the JRB must work openly and transparently, based on consensus and independent of any particular interests. To this end, all members of the three categories represented on the JRB - infrastructure managers, railway companies and industry - must have the opportunity to express their opinion during the process of drafting TSIs, in accordance with the JRB's rules of procedure and before finalisation of the draft TSIs by the JRB.

2. If the JRB lacks the expertise required in order to draft a particular TSI, it must inform the Commission immediately.

3. The JRB must set up the working parties necessary for the purposes of drafting TSIs; these working parties must have a flexible, efficient structure. To this end, the number of experts must be limited. Balanced representation must be ensured between infrastructure managers and railway companies on the one hand and industry on the other; an appropriate balance must be struck between different nationalities. Experts from non-Community countries may sit in on working parties as observers.

4. Any difficulties which emerge in relation with these regulations and which cannot be resolved by the JRB's working parties must be reported to the Commission without delay.

5. All the working papers necessary in order to monitor the JRB's work must be placed at the disposal of the Commission and the Committee referred to in Article 21 of the Directive.

6. The JRB must take all measures necessary to safeguard the confidentiality of any
critical information which comes to its knowledge in the course of its activities.

7. The JRB must take all measures necessary to inform all its members and all experts participating in the working parties of the results of the work of the Committee referred to in Article 21 of the Directive and of the recommendations made by the Committee and by the Commission.