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Subject: Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF
THE COUNCIL on the interoperability of the rail system within the European
Union (Recast)
- General Approach

At its meeting on 10 June 2013, the Transport, Telecommunications and Energy Council reached a general approach on the above proposal, as it appears in the Annex. The recitals to the proposal will be examined at a later stage, in light of the agreement on the substantive provisions.

DK and SI still have a parliamentary reservation, and the Commission maintains its general reservation on the proposal. AT, IT and LV submitted a statement on the text, to be inscribed in the Council minutes.

2013/0015 (COD)

Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on the interoperability of the rail system within the European Union
(Recast)

CHAPTER I
GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Directive establishes the conditions to be met to achieve interoperability within the Union's rail system in a manner compatible with the provisions of Directive .../...on railway safety in order to define an optimal level of technical harmonisation, to make it possible to facilitate, improve and develop rail transport services within the Union and with third countries and to contribute to the completion of the Single European Railway Area. 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.
2. This Directive lays down 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.

3. The following systems are excluded from the scope of this Directive:
 - (a) metros,
 - aa) trams and light rail vehicles, and infrastructure that is used exclusively by these vehicles;
 - (b) networks that are functionally separate from the rest of the rail system and intended only for the operation of local, urban or suburban passenger services, as well as undertakings operating solely on these networks.

4. Member States may exclude from the scope of the measures implementing this Directive:
 - (a) privately owned railway infrastructure, used by the owner or an operator for the purpose of its freight activities or the transport of persons for non-commercial purposes, and vehicles exclusively used on such infrastructure;
 - (b) infrastructure and vehicles reserved for a strictly local, historical or touristic use;
 - (c) light rail infrastructure occasionally used by heavy rail vehicles under the operational conditions of the light rail system, where it is necessary for connectivity purposes for those vehicles only; and
 - (d) vehicles primarily used on light rail infrastructure but equipped with some heavy rail components necessary to enable transit on a confined and limited section of heavy rail infrastructure for connectivity purposes only.

Article 2

Definitions

For the purposes of this Directive:

- (1) 'Union rail system' means the elements listed in Annex I;
- (2) 'interoperability' means the ability of a rail system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance;
- (3) 'vehicle' means a railway vehicle suitable for circulation on wheels on railway lines, with or without traction. A vehicle is composed of one or more structural and functional subsystems;
- (4) 'network' means the lines, stations, terminals, and all kinds of fixed equipment needed to ensure safe and continuous operation of the rail system;
- (5) 'subsystems' means the structural or functional parts of the rail system, as set out in Annex II;
- (6) '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, including both tangible objects and intangible objects;
- (6a) 'product' means a product obtained through a manufacturing process, including interoperability constituents and subsystems;

- (7) ‘essential requirements’ means all the conditions set out in Annex III which must be met by the rail system, the subsystems, and the interoperability constituents, including interfaces;
- (8) ‘European specification’ means a specification which falls into one of the following categories:
- a common technical specification, as defined in Annex XXI, paragraph 4 to Directive 2004/17/EC coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors¹;
 - a European technical approval as defined in Annex XXI, paragraph 3 to Directive 2004/17/EC; or
 - a European standard as defined in Article 2(1)(b) of Regulation (EU) No 1025/2012;
- (9) ‘technical specification for interoperability’ (TSI) means a specification adopted in accordance with this Directive by which each subsystem or part of a subsystem is covered in order to meet the essential requirements and ensure the interoperability of the rail system;
- (10) ‘basic parameter’ means any regulatory, technical or operational condition which is critical to interoperability and is specified in the relevant TSIs;
- (11) ‘specific case’ means any part of the 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, in particular railway lines and networks isolated from the rest of the Union, the loading gauge, the track gauge or space between the tracks and vehicles strictly intended for local, regional or historical use, as well as vehicles originating from or destined for third countries;
- (12) ‘upgrading’ means any modification work on a subsystem or part of it which results in a change in the technical file accompanying the 'EC' declaration of verification, if this technical file exists, and which improves the overall performance of the subsystem;

¹ OJ L 134, 30.4.2004.

- (13) ‘renewal’ means any major substitution work on a subsystem or part of it which does not change the overall performance of the subsystem;
- (14) ‘existing rail system’ means the structure composed of lines and fixed installations of the existing rail network as well as the vehicles of all categories and origin travelling on that infrastructure;
- (15) ‘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;
- (16) ‘placing in service’ means all the operations by which a subsystem is put into its operational service;
- (17) ‘contracting entity’ means public or private entity which orders the design and/or construction or the renewal or upgrading of a subsystem;²
- (18) ‘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 43;
- (18a) ‘applicant’ means a natural or legal person requesting an authorisation, and could be a railway undertaking, an infrastructure manager or other persons or legal entities, such as the manufacturer, an owner or a keeper;

² The following text will be added in a recital to interpret the definition of contracting entity: "*A contracting entity could be a railway undertaking, an infrastructure manager, an entity in charge of maintenance, a keeper, or a concession holder responsible for carrying out a project.*"

- (19) ‘project at an advanced stage of development’ means any project whose planning/construction stage has reached a point where a change in the technical specifications may compromise the viability of the project as planned;
- (20) ‘harmonised standard’ means a European standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;
- (21) ‘national safety authority’ means a safety authority as defined in Article 3 of Directive .../... on railway safety ;
- (22) ‘type’ means a vehicle type defining the basic design characteristics of the vehicle as covered by a type or design examination certificate described in the relevant verification module;
- (23) ‘series’ means a number of identical vehicles of a design type;
- (24) ‘entity in charge of maintenance’ means an entity in charge of maintenance as defined in Article 3 of Directive .../.... on railway safety ;
- (25) ‘tram and light rail’ means an urban and/or sub-urban rail transport system with a crashworthiness of CIII (according to EN 15227:2011) and a maximum strength of vehicle of 800 kN (PIII according to EN12663-1:2010). Light rail systems may have their own right-of-way or share it with road traffic and do not exchange vehicles with long-distance passenger or freight traffic;
- (26) ‘national rules’ means all binding rules adopted at Member State level, irrespective of the body issuing them. These rules contain railway safety or technical requirements imposed within that Member State in addition to European rules and are applicable to railway undertakings, infrastructure managers or third parties;

- (27) ‘design operating state’ means the normal operating mode and the foreseeable degraded conditions (including wear) within the range and the conditions of use specified in the technical and maintenance files;
- (28) ‘acceptable means of compliance’ means non-binding opinions issued by the Agency to define ways of establishing compliance with the essential requirements;
- (28a) ‘acceptable national means of compliance’ means non-binding opinions issued by Member States to define ways of establishing compliance with national rules;
- (29) ‘placing on the market’ means the first making available on the Union’s market of an interoperability constituent, subsystem or vehicle ready to function in its design operating state;
- (30) ‘manufacturer’ means any natural or legal person who manufactures a product in the form of interoperability constituents, subsystems or vehicles or has it designed or manufactured, and markets it under his name or trademark;
- (31) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer or a contracting entity to act on his behalf in relation to specified tasks;
- (32) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by a product, subsystem, process or service;
- (33) ‘accreditation’ has the meaning assigned to it by Regulation (EC) No 765/2008;
- (34) ‘national accreditation body’ has the meaning assigned to it by Regulation (EC) No 765/2008;
- (35) ‘conformity assessment’ means the process demonstrating whether specified requirements relating to a product, process, service, subsystem, person or body have been fulfilled;

- (36) ‘conformity assessment body’ means a body that has been notified or designated to be responsible for conformity assessment activities, including calibration, testing, certification and inspection. A conformity assessment body is classified as a ‘notified body’ following notification by a Member State. A conformity assessment body is classified as a designated body following designation by a Member State;
- (37) ‘disabled person and person with reduced mobility’ shall include any person who has a permanent or temporary physical, mental, intellectual or sensory impairment which, in interaction with various barriers, may hinder their full and effective use of transport on an equal basis with other passengers or whose mobility when using transport is reduced due to age;
- (38) ‘infrastructure manager’ means infrastructure manager as defined in Article 3 of Directive 2012/34/EU establishing a single European railway area³;
- (39) ‘railway undertaking’ means railway undertaking as defined in Article 3 of Directive 2012/34/EU establishing a single European railway area, and any other public or private undertaking, the activity of which is to provide transport of goods and/or passengers by rail on the basis that the undertaking must ensure traction; this also includes undertakings which provide traction only;
- (40) ‘Agency’ means the European Railway Agency, as established by Regulation (EU) No .../... [Agency Regulation].

³ OJ L 343 of 14.12.2012, p. 32.

Article 3

Essential requirements

1. The rail system, subsystems and interoperability constituents including interfaces shall meet the relevant essential requirements.
2. The technical specifications referred to in Article 34 of Directive 2004/17/EC which are necessary to complete European specifications or other standards in use within the Union shall not conflict with the essential requirements.

CHAPTER II

TECHNICAL SPECIFICATIONS FOR INTEROPERABILITY

Article 4

Content of Technical Specifications for Interoperability

1. Each of the subsystems defined in Annex II shall be covered by one TSI. Where necessary, a subsystem may be covered by several TSIs and one TSI may cover several subsystems.
2. [...]
3. Subsystems shall comply with the TSIs in force at the time of their placing in service, upgrading or renewal, in accordance with this Directive; this compliance shall be permanently maintained while each subsystem is in use.

4. To the extent necessary to achieve the objectives of this Directive as referred in Article 1, each TSI shall:
- (a) indicate its intended scope (part of network or vehicles referred to in Annex I; subsystem or part of subsystem referred to in Annex II);
 - (b) lay down essential requirements for each subsystem concerned and its interfaces in relation to other subsystems;
 - (c) establish the functional and technical specifications to be met by the subsystem and its interfaces in relation to 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 vehicles provided for in Annex I;
 - (d) determine the interoperability constituents and interfaces which must be covered by European specifications, including European standards, which are necessary to achieve interoperability within the 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 2010/713/EU⁴;
 - (f) indicate the strategy for the application of 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. Where coordinated implementation of the TSI is necessary, such as along a corridor or between infrastructure managers and railway undertakings, the strategy may include proposals for staged completion;

⁴ OJ L 319, 4.12.2010, p. 1.

- (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 application of the TSIs;
 - (h) indicate the provisions applicable to the existing subsystems and vehicles, in particular in the event of upgrading and renewal and in such cases, the modification work which requires an application for a new authorisation;
 - (i) indicate the parameters of the vehicles and fixed subsystems to be checked by the railway undertaking and the procedures to be applied to check those parameters after the delivery of the vehicle authorisation for placing on the market and before the first use of the vehicle to ensure the compatibility between vehicles and routes on which they are intended to be operated.
5. 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 adoption of the TSIs and compliance with them shall gradually facilitate the achievement of the interoperability of the rail system.
6. TSIs shall retain, in an appropriate manner, the compatibility of the existing rail system of each Member State. With this objective, provision may be made for specific cases for each TSI, with regard to both network and vehicles, and in particular for; 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 provided for in paragraph 4(c) to (g).
7. 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.

8. TSIs shall not prevent the Member States from deciding on the use of infrastructures for the movement of vehicles not covered by the TSIs.
9. 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 this Directive. In such case, these standards or specifications (or their 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 that are easily accessible and in the public domain.

Article 5

Drafting, adoption and review of TSIs

1. Implementing powers shall be conferred on the Commission in order to issue a mandate to the Agency to draft TSIs and their amendments and to make the relevant recommendations to the Commission, on the basis of a clear justification of the need for a new or amended TSI and its impact on existing rules and technical specifications. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 48(2).

Each draft TSI shall be drawn up in the following stages:

- (a) the Agency shall identify the basic parameters for the TSI as well as the interfaces with the other subsystems and any other specific cases that may be necessary;
- (b) the Agency shall draw up the draft TSI on the basis of these basic parameters. Where appropriate, the Agency shall take account of technical progress, of standardisation work already carried out, of working parties already in place and of acknowledged research work.

2. 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. This assessment shall indicate the likely impact for all the operators and economic actors involved and take due account of the requirements of the Directive .../... on railway safety. The Member States shall participate in this assessment by providing, where appropriate, the requisite data.
3. The Agency, in order to take account of developments in technology or social requirements, shall draft the TSIs and their amendments under the mandate referred to in paragraph 1, in accordance with Articles 4 and 15 of Regulation (EU) No .../... [Agency Regulation] and by respecting the principles of openness, consensus and transparency as defined in Annex II to Regulation (EU) No 1025/2012.
4. The Committee referred to in Article 48 shall be kept regularly informed of the preparatory work on the TSIs. During this work the Commission may formulate any terms of reference or useful recommendations concerning the design of the TSIs and the cost-benefit analysis. In particular, the Commission may 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. This examination may also be carried out at the request of the Committee.
5. Where different subsystems have to be placed in service simultaneously for reasons of technical compatibility, the dates of entry into force of the corresponding TSIs shall be the same.
6. The drafting, adoption and review of the TSIs shall take account of the opinion of users, as regards the characteristics which have a direct impact on the conditions in which they use the subsystems. To that end the Agency shall consult associations and bodies representing users during the drafting and review phases of the TSIs. It shall enclose with the draft TSI a report on the results of this consultation.

7. In accordance with Article 6 of Regulation (EU) No .../... [Agency Regulation], the Agency shall draw up and regularly update the list of users' associations and bodies to be consulted. This list may be re-examined and updated at the request of a Member State or upon the initiative of the Commission.
8. The drafting, adoption and review of the TSIs shall take account of the opinion of the social partners as regards the conditions referred to in Article 4(4)(g). To this end, the Agency shall consult the social partners before submitting to the Commission recommendations on TSIs and their amendments. The social partners shall be consulted in the context of the Sectoral Dialogue Committee set up in accordance with Commission Decision 98/500/EC of 20 May 1998 on the establishment of Sectoral Dialogue Committees promoting the Dialogue between the social partners at European level⁵. The social partners shall issue their opinion within three months.
9. 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.
10. The Commission shall establish, by means of implementing acts, the content of TSIs in accordance with Article 4(4), and their amendments. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).

⁵ OJ L 225, 12.8.1998, p. 27.

Article 6

Deficiencies in TSIs

1. If, after its adoption, it appears that a TSI has a deficiency, that TSI shall be amended in accordance with Article 5(10). If appropriate, the Commission shall apply this procedure without delay. Such deficiencies shall include cases which could result in unsafe operations within a Member State.
2. Pending the review of the TSI, the Commission may request an opinion from the Agency. The Commission shall analyse the Agency opinion and inform the Committee of its conclusions.
3. At the request of the Commission, the Agency opinions referred to in paragraph 2 shall constitute acceptable means of compliance and may therefore be used for the assessment of projects, pending the adoption of a revised TSI.

Article 7

Non-application of the TSIs

1. Member States may allow the applicant not to apply one or more TSIs or parts of them in the following cases:
 - (a) for a proposed new subsystem or part of it, for the renewal or upgrading of an existing subsystem or part of it, or for any element referred to in Article 1(1) at an advanced stage of development or the subject of a contract in the course of performance at the date of application of these TSIs;
 - (b) where, following an accident or a natural disaster, the conditions for the rapid restoration of the network do not economically or technically allow for partial or total application of the relevant TSIs; in this case, the non-application of the TSIs shall be limited to the period before the restoration of the network;

- (c) for any proposed renewal, extension or upgrading of an existing subsystem or part of it, when the application of these TSIs would compromise the economic viability of the project and/or the compatibility of the rail system in that Member State, such as in relation to the loading gauge, track gauge, space between tracks or electrification voltage;
 - (d) 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 Union;
 - (e) for a proposed new subsystem or for the proposed renewal or upgrading of an existing subsystem in the territory of that Member State when its 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 Union.
2. In the case referred to in paragraph 1(a), each Member State shall communicate to the Commission, within one year of entry into force of each TSI, a list of projects that are taking place within its territory and which, in the view of the Member State concerned, are at an advanced stage of development.
- 2a. In the cases referred to in paragraph 1(a) and (b), the Member State shall communicate to the Commission its decision not to apply one or more TSIs or parts of them.
3. In the cases referred to in paragraph 1(c), (d) and (e), the Member State concerned shall submit to the Commission the request for non-application of the TSI or parts of them, accompanied by a file containing the justification for the request, and specifying the alternative provisions that the Member State intends to apply instead of the TSIs. In the case referred to in paragraph 1(e), the Commission shall analyse the request, decide whether or not to accept it on the basis of the completeness and coherence of the information contained in the file. In the cases referred to in paragraph 1(c) and 1(d), the Commission shall adopt its decision by means of an implementing act on the basis of such analysis. The implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).

In the cases referred to in the third subparagraph of Article 20(1e), the applicant shall submit the file to the Agency. The Agency shall consult the relevant safety authorities and give its final opinion to the Commission.

- 3a. The Commission shall by means of an implementing act establish the information to be included in the file referred to in paragraph 3, the required format of the file and the method for its transmission. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 48(3).
4. Pending the decision of the Commission, the Member State may apply the alternative provisions as referred to in paragraph 3 without delay.
5. The Commission shall give its decision within four months of the submission of the request supported by the complete file. In the absence of such a decision, the request shall be deemed to have been accepted.
6. All Member States shall be informed of the results of the analyses and of the outcome of the procedure set out in paragraph 3.

CHAPTER III

INTEROPERABILITY CONSTITUENTS

Article 8

Conditions for the placing on the market of interoperability constituents

1. Member States shall take all necessary steps to ensure that interoperability constituents:
 - (a) are placed on the market only if they enable interoperability to be achieved within the rail system while at the same time meeting the essential requirements;

(b) are used in their area of use as intended and are suitably installed and maintained.

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

2. Member States may not, in their territory and on the basis of this Directive, prohibit, restrict or hinder the placing on the market of interoperability constituents for use in the rail system where they comply with this Directive. In particular, they may not require checks which have already been carried out as part of the procedure of 'EC' declaration of conformity or suitability for use as set out in Article 10.

Article 9

Conformity or suitability for use

1. Member States and the Agency shall consider that an interoperability constituent meets the essential requirements if it complies with the conditions laid down in the corresponding TSI or the corresponding European specifications developed to comply with these conditions. The 'EC' declaration of conformity or suitability for use shall attest that the interoperability constituents have been subject to the procedures laid down in the corresponding TSI for assessing conformity or suitability for use.
2. [...]

- 2a. The Commission shall establish, by means of implementing acts, the scope and the content of the EC declaration of conformity or suitability for use of interoperability constituents, its format and the details of the information included in it. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).⁶
3. [...]
4. 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 requirements referred to in paragraph 1.
5. 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 Article 8(1).

Article 10

Procedure for 'EC' declaration of conformity or suitability for use

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 Union shall apply the provisions laid down by the relevant TSIs.

⁶ Recital 12 will be adapted as follows, to explain the difference between the concept of conformity and suitability for use and to clarify which alternatives are covered within a single EC declaration: *"A TSI sets all the conditions with which an interoperability constituent should conform, and the procedure to be followed in assessing conformity. In addition, it is necessary to specify that every constituent should undergo the procedure for assessing conformity or suitability for the use indicated in the TSIs, and have the corresponding certificate comprising either the assessment of the intrinsic conformity of an interoperability constituent, considered in isolation, to the technical specifications to be met, or the assessment of the suitability for use of an interoperability constituent considered within its railway environment in relation to the technical specifications."*

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 Union has lodged the application. The notified body shall issue a certificate to accompany the 'EC' declaration of conformity or suitability for use.
3. Where interoperability constituents are the subject of other Union directives 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 has met the obligations laid down in paragraphs 1 and 3, those obligations shall be incumbent on any person who places interoperability constituents on the market. The same obligations shall apply to any person who assembles interoperability constituents or parts of interoperability constituents having diverse origins or manufactures interoperability constituents for his own use, for the purposes of this Directive.
5. If the Member State finds that the EC declaration has been drawn up improperly, it shall ensure that the interoperability constituent is not placed on the market. In such a case, the manufacturer or his authorised representative established in the Union shall be required to restore the interoperability constituent to a state of conformity under the conditions laid down by that Member State.

Non-compliance of interoperability constituents with essential requirements

1. Where a Member State finds that an interoperability constituent covered by the 'EC' declaration of conformity or suitability for use and placed on the market is unlikely, when used as intended, to meet the essential requirements, it shall take all necessary steps to restrict its field of application, prohibit its use, withdraw it from the market or recall it. The Member State shall forthwith inform the Commission, the Agency and the other Member States of the measures taken and give the reasons for its decision, stating in particular whether failure to conform is due to:
 - (a) failure to meet the essential requirements;
 - (b) incorrect application of European specifications where application of such specifications is relied upon;
 - (c) inadequacy of European specifications.
2. The Agency, on a mandate from the Commission shall start the consultation process with the parties concerned without delay. Where, following that consultation, the Agency establishes that the measure is unjustified it shall forthwith inform the Commission, the Member State that has taken the initiative as well as the other Member States, and the manufacturer or his authorised representative established within the Union. Where the Agency establishes that the measure is justified it shall forthwith inform the Member States.
- 2a. Where the decision referred to in paragraph 1 results from a gap in European specifications, Member States, the Commission or the Agency, as appropriate, shall apply one or more of the following measures:

- a) partial or total withdrawal of the specification concerned from the publications containing them;
 - b) if the relevant specification is a harmonised standard, restriction or withdrawal of this standard in accordance with Article 11 of Regulation 1025/2012/EU;
 - c) the review of the TSI in accordance with Article 6.
3. Where an interoperability constituent bearing the 'EC' declaration of conformity fails to comply, the competent Member State shall take appropriate measures against any entity which has drawn up the declaration and shall inform the Commission and the other Member States thereof.
4. [...]

CHAPTER IV SUBSYSTEMS

Article 12

Free movement of subsystems

1. Without prejudice to the provisions of Chapter V, Member States may not, in their territory and on grounds relating to this Directive, prohibit, restrict or hinder the construction, placing in service and operation of structural subsystems constituting the rail system which meet the essential requirements. In particular, they may not require checks which have already been carried out:
 - (a) either as part of the procedure leading to the 'EC' declaration of verification;
 - (b) or in other Member States, before or after the entry into force of this Directive, with a view to verifying compliance with identical requirements under identical operational conditions.

Article 13

Conformity with TSIs and national rules

1. The Agency and the national safety authorities shall consider as meeting the essential requirements, those structural subsystems constituting the rail system which are covered, as appropriate, by the 'EC' declaration of verification established by reference to TSIs, in accordance with Article 15, or the declaration of verification be established by reference to national rules in accordance with Article 15 (6a), or both.
2. [...]
3. National rules for implementing the essential requirements and, where relevant, acceptable national means of compliance, may apply in the following cases only:
 - (a) when the TSIs do not cover, or do not fully cover, certain aspects corresponding to the essential requirements, including open points as referred to in Article 4(7);
 - (b) when a non-application of one or more TSIs or parts of them has been notified under Article 7;
 - (c) when a specific case requires the application of technical rules not included in the relevant TSI;
 - (d) national rules used to specify existing systems, limited to the aim of assessing technical compatibility of the vehicle with the network;

- (e) networks and vehicles not covered by TSIs;
- (f) as an urgent temporary preventive measure, in particular following an accident.

3a. [...]

4. [...]

Article 14

Notification of national rules⁷

1. Member States shall notify to the Commission the national rules in use referred to in Article 13(3) in the following cases:
 - (aa) where the national rule(s) has not yet been notified by the date of entry into force of this Directive;
 - (a) each time the rules are changed;
 - (b) when a new request has been submitted in accordance with Article 7 for non-application of the TSI;
 - (c) where national rules become redundant after publication or revision of the TSI concerned.

⁷ Final agreement on this Article is subject to the discussions on the relevant articles of the Safety Directive.

2. Member States shall notify the full text of existing national rules to the Agency and the Commission through the appropriate IT system in accordance with Article 23 of Regulation (EU) No .../... [Agency Regulation].⁸
3. Member States may lay down new national rules only in the following cases:
 - (a) when a TSI does not fully meet the essential requirements;
 - (b) as an urgent preventive measure, in particular following an accident.
4. If a Member State intends to introduce a new national rule, it shall notify the draft to the Agency and the Commission through the appropriate IT system in accordance with Article 23 of Regulation (EU) No .../... [Agency Regulation]. Member States shall ensure that the draft is sufficiently developed to allow the Agency to carry out its examination under Article 21(2) of Regulation (EU) No .../... [Agency Regulation].
5. When they adopt the national rule, Member States shall notify it to the Agency and the Commission through the appropriate IT system in accordance with Article 23 of Regulation (EU) No .../... [Agency Regulation]. Member States shall also ensure that national rules in force, including those covering the interfaces between vehicles and network, are accessible to all parties concerned and in a terminology that they can understand.
6. Member States may decide not to notify rules and restrictions of a strictly local nature. In such cases, Member States shall mention these rules and restrictions in the infrastructure registers referred to in Article 45.
7. National rules notified under this Article are not subject to the notification procedure set out in Directive 98/34/EC.

⁸ The link between the publication of the rules and copyright rules will be considered in the context of the Agency Regulation.

8. The Commission shall establish, by means of implementing acts, the classification of the notified national rules in different groups with the aim of facilitating the placing on the market of vehicles, including the compatibility between fixed and mobile equipment. Those implementing acts shall build on progress achieved by the Agency in the field of cross acceptance and shall be adopted in accordance with the examination procedure referred to in Article 48(3).

The Agency shall classify in accordance with the implementing acts referred to in the first subparagraph the national rules which are notified in accordance with this Article.

9. Draft national rules and national rules in force shall be examined by the Agency in accordance with the procedures laid down in Articles 21 and 22 of Regulation (EU) No .../... [Agency Regulation]. National rules not notified in accordance with this Article shall not apply for the purposes of this Directive.

Article 15

Procedure for establishing the 'EC' declaration of verification and for establishing the declaration of verification in the case of national rules

1. In order to establish the 'EC' declaration of verification necessary for placing on the market and placing in service referred to in Chapter V, the applicant shall ask the notified body that it has selected for that purpose to apply the 'EC' verification procedure.
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 placed in service. It shall, in accordance with the relevant TSI, also cover verification of the interfaces of the subsystem in question with the system into which it is incorporated.

3. The notified body shall be responsible for compiling the technical file that has to accompany the 'EC' declaration of verification. This technical file shall 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 shall 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.
4. In the event of renewal or upgrading resulting in an amendment to the technical file and affecting the validity of the verifications already carried out, the applicant shall assess the need for a new 'EC' declaration of verification.
5. The notified body may issue intermediate statement verifications to cover certain stages of the verification procedure or certain parts of the subsystem. In such a case, the verification procedures established in accordance with paragraph 7(a) shall apply.
6. If the relevant TSIs allow, the notified body may issue certificates of conformity for one or more subsystems or certain parts of those subsystems.
- 6a. The procedures for establishing the EC declaration of verification foreseen in this Article shall also apply, where appropriate, for the establishment of declaration(s) of verification in respect of national rules.
- 6b. Member States shall designate the bodies responsible for carrying out the verification procedure in respect of national rules. In this regard, designated bodies shall be responsible for the tasks involved. Without prejudice to Article 27, a Member State may appoint a notified body as a designated body, in which case the entire process may be carried out by a single conformity assessment body.

7. The Commission shall establish, by means of implementing acts:
 - (a) the verification procedures for subsystems, including the general principles, the content, procedure and documents related to the 'EC' verification procedure, and to the verification procedure in the case of national rules;
 - (b) the templates for the 'EC' declaration of verification and for the declaration of verification in the case of national rules and templates for documents of the technical file that has to accompany these declarations.

Those implementing acts shall be adopted in accordance with the examination procedure referred to Article 48(3).

Article 16

Non-compliance of subsystems with essential requirements

1. Where a Member State finds that a structural subsystem covered by the 'EC' declaration of verification accompanied by the technical file does not fully comply with this Directive and in particular does not meet the essential requirements, it may request that additional checks be carried out.
2. The Member State making the request shall forthwith inform the Commission of any additional checks requested and set out the reasons therefor. The Commission shall consult the interested parties.
3. The Member State making the request shall state whether the failure to fully comply with this Directive is due to:

- (a) non-compliance with the essential requirements or with a TSI, or incorrect application of a TSI; in that case, the Commission shall forthwith inform the Member State where the person who drew up the 'EC' declaration of verification in error resides and shall request that Member State to take the appropriate measures;
- (b) inadequacy of a TSI; in that case, the procedure for amending the TSI as referred to in Article 6 shall apply.

Article 17

Presumption of conformity

Interoperability constituents and subsystems which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the Union shall be presumed to be in conformity with the essential requirements set out in Annex III covered by those standards or parts thereof.

CHAPTER V

PLACING ON THE MARKET AND PLACING IN SERVICE

Article 18

Authorisation for the placing in service of fixed installations

1. The trackside control-command and signalling, energy and infrastructure subsystems shall be placed in service only if they are designed, constructed and installed in such a way as to meet the essential requirements as set out in Annex III, and the relevant authorisation is received in accordance with paragraphs 2b and 3.
2. Each national safety authority shall authorise the placing in service of the energy, infrastructure and trackside control-command and signalling subsystems which are located or operated in the territory of its Member State.

- 2a. In the case of trackside control-command and signalling subsystems involving ETCS and/or GSMR equipment, the national safety authority shall consult the Agency within one month of receipt of the complete application in order to ensure a coherent development of ERTMS into the Union. The Agency shall issue an opinion to the relevant national safety authority regarding the technical and operational compatibility of the subsystem with the vehicles intended to operate on that network within two months. The national safety authority shall, to the extent possible, take this opinion into account before issuing the authorisation, and in case of disagreement, shall inform the Agency stating the reasons therefor. This Article is without prejudice to the Agency's obligations as a system authority under Chapter 6 of Regulation (EU) No .../...[Agency Regulation].
- 2b. National safety authorities shall provide detailed guidance on how to obtain the authorisations referred to in this Article. An application guidance document describing and explaining the requirements for those authorisations and listing the required documents shall be made available to applicants free of charge. The Agency and the national safety authorities shall cooperate in disseminating such information.
3. The applicant shall submit a request for the authorisation of the placing in service of fixed installations to the national safety authority. The application shall be accompanied by a file which includes the documentary evidence of:
- (a) the declarations of verification set out in Article 15;
 - (b) the technical compatibility of these subsystems with the system into which they are being integrated, established on the basis of the relevant TSIs, national rules and registers;

(c) the safe integration of these subsystems, established on the basis of the relevant TSIs, national rules, and the common safety methods set out in Article 6 of Directive.../... on railway safety.

3a. Within one month of the receipt of the request of the applicant, the national safety authority shall inform the applicant that the file is complete or ask for relevant complementary information, setting a reasonable deadline.

The national safety authority shall verify the completeness, relevance and consistency of the file and issue the authorisation for placing in service of fixed installations, or inform the applicant of its negative decision, within a pre-determined, reasonable time, and in any case, within four months from receipt of all relevant information.

4. In the event of renewal or upgrading of existing subsystems, the applicant shall send to the national safety authority a file describing the project. Within one month of the receipt of the request of the applicant, the national safety authority shall inform the applicant that the file is complete or ask for relevant complementary information, setting a reasonable deadline. The national safety authority shall examine the file and shall decide, whether a new authorisation for placing in service is needed, on basis of the following criteria:

(a) the overall safety level of the subsystem concerned may be adversely affected by the works envisaged;

(b) it is required by the relevant TSIs;

(c) it is required by the national implementation plans established by the Member States; or

- (d) changes are made to the values of the parameters on the basis of which the authorisation was already granted.

The national safety authority shall take its decision within a pre-determined, reasonable time, and, in any case, within four months from receipt of all relevant information.

5. *[deleted and merged with paragraph 4]*
6. Any decision refusing the request for an authorization for placing in service of fixed installations shall be duly substantiated by the national safety authority. The applicant may, within one month of receipt of the negative decision, submit a request that the national safety authority review its decision. The request shall be accompanied by a justification. The national safety authority shall have two months from the date of receipt of the request for review to confirm or reverse its decision. If the negative decision of a national safety authority is confirmed, the applicant may bring an appeal to the appeal body designated by the relevant Member State under Article 17(3) of Directive .../... on railway safety.

Article 19

Placing on the market of mobile subsystems

1. The rolling stock subsystem and the on-board control-command and signalling subsystem shall be placed on the market by the applicant only if they are designed, constructed and installed in such a way as to meet the essential requirements as set out in Annex III.
2. In particular, the applicant shall ensure that the relevant declaration of verification has been provided.
3. [...]

Article 20

Vehicle authorisation for placing on the market

1. The applicant shall place a vehicle on the market only after having received the vehicle authorisation for placing on the market issued by the Agency in accordance with paragraph 1d. to 1f., or by the national safety authority in accordance with paragraph 1g.
 - 1a. In its application for a vehicle authorisation for placing on the market, the applicant shall specify the intended area of use of the vehicle, i.e. a network or networks within a Member State, or a group of Member States'. The application shall include evidence that the technical compatibility between the vehicle and the network of the area of use has been checked.
 - 1b. The application shall be accompanied by a file concerning the vehicle or type of vehicle and including the documentary evidence of:
 - (a) the placing on the market of the mobile subsystems composing the vehicle according to Article 19;
 - (b) the technical compatibility of the subsystems referred to in point (a) within the vehicle, established on the basis of the relevant TSIs, and where applicable, national rules;
 - (c) the safe integration of the subsystems referred to in point (a) within the vehicle, established on the basis of the relevant TSIs, and where applicable, national rules; and the common safety methods set out in Article 6(3)(e) of Directive .../... on railway safety;

- (d) the technical compatibility of the vehicle with the network in the area of use referred to in paragraph 1a, established on the basis of the relevant TSIs and, where applicable, national rules and the common safety method on risk assessment referred to in Article 6(3)(e) of Directive .../... on railway safety.

Whenever tests are necessary in order to obtain documentary evidence of the technical compatibility referred to in 1b(b) and 1b(d), the national safety authorities involved may, issue temporary authorisations to the applicant to use the vehicle for practical verifications on the network. The infrastructure manager, in consultation with the applicant, shall make every effort to ensure that any tests take place within three months of the receipt of the applicant's request. Where appropriate, the national safety authority shall take measures to ensure that the tests take place.

- 1c. The Agency or in the case of paragraph 1g., the national safety authority shall issue vehicle authorisations for placing on the market within a pre-determined, reasonable time, and, in any case, within four months from receipt of all relevant information. These authorisations shall allow vehicles to be placed on the Union market.⁹
- 1d. The Agency shall issue vehicle authorisations for placing on the market in respect of vehicles having an area of use in one or more Member State(s). In order to issue such authorisations, the Agency shall:

⁹ The following text will be added as a recital to interpret the concept of placing on the market: *"While authorisations for placing on the market allow for commercial transactions of vehicles anywhere on the Union market, the vehicle may only be used within the area of use for which the authorisation is granted. In this context, any extension of the area of use must be subject to an updated authorisation for the vehicle under Article 20(8a)."*

- (a) assess the elements of the file set out in paragraphs 1b(a), 1b(b) and 1b(c) in order to verify the completeness, relevance and consistency of the file in relation to the relevant TSIs; and
- (b) refer the applicant's file to the national safety authorities concerned by the intended area of use for assessment-of the file in order to verify its completeness, relevance and consistency in relation to-paragraphs 1b(d) and to the elements set out in paragraphs 1b(a), 1b(b) and 1b(c) in relation to the relevant national rules.

As part of the above assessments and in case of justified doubts, the Agency or the national safety authorities may request tests to be conducted on the network. In order to facilitate these tests, the national safety authorities involved may issue temporary authorisations to the applicant to use the vehicle for tests on the network. The infrastructure manager shall make every effort to ensure that any such test takes place within three months from the request of the Agency or the national safety authority.

- 1e. Within one month of the receipt of the request of the applicant, the Agency shall inform the applicant that the file is complete or ask for relevant complementary information, setting a reasonable deadline. With regard to the completeness, relevance and consistency of the file, the Agency may also assess the elements set out in paragraph 1b(d).

The Agency shall take full account of the assessments under paragraph 1d. before taking its decision on the issuance of the vehicle authorisation for placing on the market. The Agency shall issue the authorisation for placing on the market, or inform the applicant of its negative decision, within a pre-determined, reasonable time, and in any case, within four months from receipt of all relevant information.

In the event of non-application of one or more TSIs or parts of them referred to in Article 7, the Agency shall issue the vehicle authorisation only after application of the procedure set out in that Article.

The Agency shall take full responsibility for the authorisations it issues.^{10 11}

- 1f. When the Agency disagrees with a negative assessment carried out by one or more national safety authorities pursuant to paragraph 1d(b), it shall inform the said authority or authorities, giving reasons for the disagreement. The Agency and the national safety authority or authorities shall cooperate with a view to reaching a mutually acceptable assessment. Where necessary, as decided by the Agency and the national safety authority or authorities, this process shall also involve the applicant. If no mutually acceptable assessment can be found within one month after the Agency has informed the national safety authority or authorities of its disagreement, the Agency shall take its final decision unless the national safety authority or authorities have referred the matter for arbitration to the Board of Appeal established under Article 51 of Regulation (EU) No .../...[Agency Regulation].¹² The Board of Appeal shall decide whether to confirm the Agency's draft decision within one month of the request of the national safety authority or authorities.

When the Board of Appeal agrees with the Agency, the Agency may take a decision without delay.

¹⁰ On liability, the following recital will be inserted in the text: *"This Directive should not lead to a reduced level of safety in the European Union's railway sector. To this end, the Agency should take full responsibility for the authorisations it issues, in particular contractual and non-contractual liabilities which are regulated by Article 66 of the Regulation (EU) No .../...[Agency Regulation] and which stipulates that the Agency make good any damage caused by its departments or by its staff during the performance of their duties. In the event of a judicial inquiry involving the Agency or its staff, the Agency should cooperate fully with the competent authorities of the Member States concerned"*. In addition, the agreement of the Council to this Article is conditional on the inclusion in the Agency Regulation of a new recital and provisions based on the principles set out in Annex II to this document.

¹¹ Final agreement on Article 20(1(e)) is subject to the discussions on the relevant articles of the Safety Directive.

¹² Article 51 of the Agency Regulation will be amended to include an arbitration procedure and the new role of the Board of Appeals. The process of appeal in the Agency Regulation will be modified and the provisions will reflect the need for appropriate competence, independence and impartiality of the Board in relation to arbitrations.

When the Board of Appeal agrees with the negative assessment of the national safety authority, the Agency shall issue an authorisation with an area of use excluding the parts of the network which received a negative assessment.

When the Agency disagrees with a positive assessment of one or more national safety authorities pursuant to paragraph 1d(b), it shall inform the said authority or authorities, giving reasons for disagreement. The Agency and the national safety authority or authorities shall cooperate with a view to reaching a mutually acceptable assessment. Where necessary, as decided by the Agency and the national safety authority or authorities, this process shall also involve the applicant. If no mutually acceptable assessment can be found within one month after the Agency has informed the national safety authority and authorities of its disagreement, the Agency shall take its final decision.

- 1g. Where the area of use is limited to a network or networks within one member State only, the national safety authority of that Member State may, under its own responsibility and when the applicant so requests, issue the vehicle authorisation for placing on the market. In order to issue such authorisations, the national safety authority shall assess the file in relation to the elements set out in paragraph 1b and according to the procedures to be established in the implementing act under paragraph 1h. The authorisation shall also be valid without extension of the area of use for vehicles travelling to the stations of neighbouring Member States with similar network characteristics, when those stations are close to the border, following consultation of the relevant national safety authorities. This consultation may be on a case-by-case basis or set out in a cross-border agreement between national safety authorities.

If the area of use is limited to the territory of one Member State and in the event of non-application of one or more TSIs or parts of them referred to in Article 7, the national safety authority shall issue the vehicle authorisation only after application of the procedure set out in that Article.

The national safety authority shall take full responsibility for the authorisations it issues.

- 1h. The Commission shall establish, not later than four years after the entry into force of this Directive, by means of implementing acts, detailed rules on the authorisation procedure, including:
 - a) detailed guidance for the applicant describing and explaining the requirements for the vehicle authorisation for placing on the market and listing the required documents;
 - b) procedural arrangements for the authorisation process, such as content and timeframes for each stage of the process;
 - c) criteria for assessment of the applicants' files.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3). They shall take into account the experience gained during the implementation of the cooperation agreements between the Agency and the national safety authorities referred to in paragraph 8b.

2. Vehicle authorisations for placing on the market shall state:
 - (a) the area(s) of use;
 - (b) the values of the parameters set out in the TSIs and, where applicable, in the national rules, as relevant for checking the technical compatibility between the vehicle and the area of use;

- (c) the vehicle's compliance with the relevant TSIs and sets of national rules, related to the parameters referred to under point (b);
- (d) the conditions for the use of the vehicle and other restrictions.

3. *[moved to paragraph 2, point (d)]*

4. *[moved to paragraph 1b.]*

5. *[moved to paragraph 1c. and 1h.]*

6. [...]

7. Any decision refusing the placing on the market of a vehicle shall be duly substantiated. The applicant may, within a period of one month from receipt of the negative decision, request that the Agency or the national safety authority, as appropriate, review the decision. The Agency or the national safety authority shall have two months from the date of receipt of the request for review to confirm or reverse its decision.

If the negative decision of the Agency is confirmed, the applicant may bring an appeal before the Board of Appeal designated under Article 51 of Regulation (EU) No .../... [Agency Regulation]. If the negative decision of a national safety authority is confirmed, the applicant may bring an appeal to the appeal body designated by the competent Member State under Article 17(3) of Directive .../... on railway safety. Member States may designate the regulatory body set out in Article 56 of Directive 2012/34/EU establishing a single European railway area for the purpose of this appeal procedure.

8. In the event of renewal or upgrading of existing vehicles which already have a vehicle authorisation for placing on the market, a new vehicle authorisation for placing on the market shall be required if:
- (a) changes are made to the values of the parameters referred to in paragraph 2(b);
 - (b) the overall safety level of the vehicle concerned may be adversely affected by the works envisaged; or
 - (c) it is required by the relevant TSIs.
- 8a. Where the applicant wishes to extend the area of use of a vehicle already authorised, it shall complement the file with the relevant documents referred to in paragraph 1b concerning the additional area of use. The applicant shall submit the file to the Agency, which shall, after following the procedures in paragraphs 1c. to 1f., issue an updated authorisation covering the extended area of use.

If the applicant received a vehicle authorisation in accordance with paragraph 1g. and wishes to extend the area of use within that Member State, it shall complement the file with the relevant documents referred to in paragraph 1b. concerning the additional area of use. It shall submit the file to the national safety authority which shall, after following the procedures in paragraphs 1g., issue an updated authorisation covering the extended area of use.

8b. For the purposes of paragraphs 1d. and 1e., the Agency shall conclude cooperation agreements with national safety authorities in accordance with Article 69 of Regulation .../... [Agency Regulation]. These agreements could be specific or framework agreements, and involve one or more national safety authorities. These agreements shall contain a specified description of tasks and conditions for deliverables, the time-limits applying to their delivery, the apportioning of the fees paid by the applicant. They may also include specific cooperation arrangements in the case of networks requiring specific expertise due to geographical or historical reasons, with a view to reducing administrative burden and costs to the applicant. These agreements shall be in place before the Agency is entitled to receive applications in accordance with this Directive, and in any case by three years following the date of entry into force of this Directive at the latest.¹³

9. [*moved to paragraph 1a.*]

9a. This Article shall not apply for freight wagons belonging to a pool of freight wagons in a shared use with third countries the track gauge of which is different from that of the main rail network within the Union and authorized according to a different vehicle authorisation procedure. The rules governing the authorisation procedure of such wagons shall be published and notified to the European Commission. The conformity of these wagons with the essential requirements of this Directive shall be ensured by the railway undertaking in the context of their Safety Management System.

¹³ A new provision will be inserted into the Agency Regulation pursuant to which the administrative board of the Agency is empowered to adopt a framework model for the financial apportioning of the fees paid by the applicant, which will have to be taken into account for the cooperation agreements between the Agency and the national safety authorities to be established under this paragraph.

Article 20a

Registration of vehicles authorised to be placed on the market

1. Before a vehicle is used for the first time, after the authorisation to be placed on the market according to Article 20 is granted, it shall be registered in accordance with Article 43 in a national vehicle register at the request of the keeper.
2. When the area of use of the vehicle is restricted to the territory of one Member State it shall be registered in the national vehicle register of that Member State.
3. When the area of use of the vehicle covers the territory of more than one Member State it shall be registered in the national vehicle register of one of the concerned Member States.

Article 21

Checks before the use of authorised vehicles

1. Before a railway undertaking uses a vehicle in the area of use specified in its authorisation for placing on the market, it shall check:
 - a) that the vehicle has been authorised for placing on the market in accordance with Article 20 and is duly registered;
 - b) the compatibility between the vehicle and the route on the basis of the infrastructure register, the relevant TSIs or any relevant information to be provided by the infrastructure manager free of charge and within a reasonable period of time, where such a register does not exist or is incomplete; and
 - c) the train composition of the vehicle into the train in which it is intended to operate, on the basis of the safety management system as set out in Article 9 of Directive.../... on railway safety and the TSI on operation and traffic management.

- 1a. For the purposes of paragraph 1, the railway undertaking may carry out tests in cooperation with the infrastructure manager.

The infrastructure manager, in consultation with the applicant, shall make every effort to ensure that any tests take place within three months of the receipt of the applicant's request.

2. [...]

- 2a. [...]

3. *[Moved to Article 20(8) points b) and c).]*

Article 22

Type authorisation of vehicles

1. The Agency or a national safety authority, where appropriate, in accordance with the procedure set out in Article 20, may grant vehicle type authorisations.
2. If the Agency or a national safety authority issue a vehicle authorisation for placing on the market, it shall at the same time at the applicant's request issue the vehicle type authorisation, which is related to the same area of use of the vehicle.
- 2a. [...]
3. *[moved to Article 22a]*
4. In the event of changes to any relevant provisions in TSIs or national rules, on the basis of which an authorisation of a vehicle type has been issued, the TSI or national rule shall determine whether the vehicle type authorisation already granted remains valid or needs to be renewed. If that authorisation needs to be renewed, the checks performed by the Agency or a national safety authority may only concern the changed rules.

5. The Commission shall establish, by means of implementing acts, the model of declaration of conformity to type. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).
6. The declaration of conformity to type shall be established in accordance with:
 - (a) the verification procedures of the relevant TSIs; or
 - (b) where TSIs do not apply, the conformity assessment procedures as defined in modules B+D, B+F and H1 of Decision 768/2008/EC. Where appropriate, the Commission may adopt implementing acts establishing ad hoc modules for conformity assessment. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).
7. The authorisation of vehicle types shall be registered in the European register of authorisations of vehicle types referred to in Article 44.

Article 22a

Conformity of vehicles with an authorised vehicle type

1. A vehicle or a series of vehicles which is in conformity with an authorised vehicle type shall, without further checks, receive a vehicle authorisation in accordance with Article 20 on the basis of a declaration of conformity to this type submitted by the applicant.
2. The renewal of the authorisation of a vehicle type as referred to in Article 22(4) does not affect vehicle authorisations for placing on the market already issued on the basis of the previous authorisation to place that vehicle type on the market.

CHAPTER VI
CONFORMITY ASSESSMENT BODIES

Article 23

Notifying authorities

1. Member States shall appoint notifying authorities that shall be responsible for setting up and carrying out the necessary procedures for the assessment, notification and monitoring of conformity assessment bodies, including compliance with Article 31.
2. Member States shall ensure that these authorities notify the Commission and other Member States' bodies authorised to carry out third-party conformity assessment tasks as set out in Articles 10(2) and 15(1). They shall also ensure that they inform the Commission and the other Member States of the designated bodies referred to in Article 15(6b).

Article 24

[merged with Article 23]

1. *[moved to Article 23(1)]*
2. Member States may decide that the assessment and monitoring referred to in Article 23(1) shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in Article 23(1) to a body which is not a governmental entity, that body shall be a legal entity and shall comply with the requirements laid down in Article 25. It shall put in place arrangements to cover liabilities arising out of its activities.
4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 25

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.
3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
4. A notifying authority shall not offer or provide any activities that are performed by conformity assessment bodies or consultancy services on a commercial or competitive basis.
5. A notifying authority shall safeguard the confidentiality of the information it obtains.
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 26

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment, notification and the monitoring of conformity assessment bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 27

Conformity assessment bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 7 and in Articles 28 and 29.
2. A conformity assessment body shall be established under national law and have legal personality.
3. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by the relevant TSI and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a conformity assessment body shall have at its disposal:

- (a) the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) the relevant descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified conformity assessment body and other activities;

- (c) the proper procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

4. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
5. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under the relevant TSI or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.
6. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified conformity assessment bodies coordination group established under the relevant Union's legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

7. Conformity assessment bodies that are notified for control-command and signalling on track and /or on board subsystems shall participate in, or shall ensure that their assessment personnel are informed of, the activities of the ERTMS ad hoc working group set out in Article 25 of Regulation (EU) No .../... [Agency Regulation]. They shall follow the guidelines produced as a result of the work of that group. In case they consider it inappropriate or impossible to apply them, the conformity assessment bodies concerned shall submit their observations for discussion to the ERTMS ad hoc working group for the continuous improvement of the guidelines.

Article 28

Impartiality of conformity assessment bodies

1. A conformity assessment body shall be a third-party body independent from the organisation or from the manufacturer of the product it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

2. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.
3. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.
5. Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.
6. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

Article 29

Personnel of conformity assessment bodies

1. The personnel responsible for carrying out conformity assessment activities shall have the following skills:
 - (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
 - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

- (c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of Union's legislation and of its implementing regulations;
 - (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
2. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

Article 30

Presumption of conformity of a conformity assesment body

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Articles 27 to 29, in so far as the applicable harmonised standards cover those requirements.

Article 31

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Articles 27 to 29 and shall inform the notifying authority accordingly.
2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.
3. Activities of notified bodies may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under the relevant TSI.

Article 32

Accredited in-house bodies

1. The applicant may use an accredited in-house body to carry out conformity assessment activities for the purpose of implementing the procedures set out in modules A1, A2, C1 or C2 defined in Annex II to Decision 768/2008/EC and modules CA1, and CA2 defined in Annex I to Decision 2010/713/EC. That body shall constitute a separate and distinct part of the applicant and shall not participate in the design, production, supply, installation, use or maintenance of the products it assesses.
2. An accredited in-house body shall meet the following requirements:
 - (a) it shall be accredited in accordance with Regulation (EC) No 765/2008;
 - (b) the body and its personnel shall be organisationally identifiable and have reporting methods within the undertaking of which they form a part which ensure their impartiality and demonstrate it to the relevant national accreditation body;
 - (c) neither the body nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the products they assess nor shall they engage in any activity that might conflict with their independence of judgment or integrity in relation to their assessment activities;
 - (d) the body shall supply its services exclusively to the undertaking of which it forms a part.

3. An accredited in-house body shall not be notified to the Member States or the Commission, but information concerning its accreditation shall be given by the undertaking of which it forms a part or by the national accreditation body to the notifying authority at the request of that authority.

Article 33

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.
2. That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Articles 27 to 29.
3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Articles 27 to 29.

Article 34

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which comply with the requirements laid down in Articles 27 to 29.

2. Notifying authorities shall notify the notified bodies to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and product or products concerned and the relevant accreditation certificate or other attestation of competence as set out in paragraph 4.
4. Where a notification is not based on an accreditation certificate as referred to in Article 33(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Articles 27 to 29.
5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.
6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 35

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

A notified body shall be assigned a single identification number even where it is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been allocated to them and the activities for which they have been notified.

The Commission shall ensure that that list is kept up to date.

Article 36

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Articles 27 to 29, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 37

Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention, regarding the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.
2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including withdrawal of notification if necessary.

Article 38

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant TSI.
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Notified bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless operate with the aim of assessing the compliance of the product with the provisions of this Directive.

3. Where a notified body finds that requirements laid down in the relevant TSI or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.
4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies with the relevant TSI or corresponding harmonised standards or technical specifications, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 39

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:
 - (a) any refusal, restriction, suspension or withdrawal of a certificate;
 - (b) any circumstances affecting the scope of and conditions for notification;
 - (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
 - (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

In relation to point a) the relevant national safety authorities shall also be informed.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.
3. Notified bodies shall provide to the Agency the EC certificates of verification of subsystems, the EC certificates of conformity of interoperability constituents and the EC certificates of suitability of use of interoperability constituents.

Article 40

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 41

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group of notified bodies. The Agency shall support the activities of notified bodies in accordance with Article 20 of Regulation (EU) No .../... [Agency Regulation].

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

Article 41a

Designated bodies

1. The requirements relating to conformity assessment bodies set out in Article 27 to 31 shall also apply to bodies designated under Article 13(4), except in the following cases:
 - a) skills required of its personnel under Article 29(1) c), where the designated body shall have appropriate knowledge and understanding of national legislation;
 - b) documents to be kept at the disposal of the notifying authority under Article 31(4) shall include those relating to work carried out by subsidiaries or subcontractors under the relevant national rules;
2. The operational obligations set out in Article 38 shall also apply to bodies designated under Article 15(6b), except that those obligations refer to national rules instead of TSIs.

3. The information obligation set out in Article 39(1) shall also apply to designated bodies which shall inform Member States accordingly.

CHAPTER VII

REGISTERS

Article 42

Vehicle numbering system

1. [...]
2. Upon registration, according to Article 20a the vehicle shall be assigned a European vehicle number (EVN) by the competent authority in the Member State of registration. The vehicle shall be marked with an assigned EVN.
3. The specifications of the EVN shall be set out in the measures referred to in Article 43(2).
4. A vehicle shall be assigned an EVN only once, unless otherwise specified in the measures referred to in Article 43(2).
5. Notwithstanding paragraph 2, in the case of vehicles operated or intended to be operated from or to third countries the track gauge of which is different from that of the main rail network within the Union, Member States may accept vehicles clearly identified according to a different coding system.

Article 43

National vehicle registers

1. Each Member State shall keep a national vehicle register. This register shall meet the following criteria:
 - (a) it shall comply with the common specifications referred to in paragraph 2;
 - (b) it shall be kept updated by a body independent of any railway undertaking;
 - (c) it shall be accessible to the national safety authorities and investigating bodies designated in Articles 16 and 21 of Directive .../... on railway safety; it shall also be made accessible, in response to any legitimate request, to the regulatory bodies designated in Articles 55 and 56 of Directive 2012/34/EU establishing a single European railway area, and to the Agency, the railway undertakings and the infrastructure managers, as well as those persons or organisations registering vehicles or identified in the register.
2. The Commission shall adopt common specifications for the national vehicle registers on content, data format, functional and technical architecture, operating mode, including arrangements for the exchange of data, and rules for data input and consultation, by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).
3. The registration holder shall immediately declare any modification to the data entered in the national vehicle register, the destruction of a vehicle or its decision to no longer register a vehicle, to the Member State where the vehicle has been registered.

4. As long as Member States' national vehicle registers are not linked in accordance with the specification referred to in paragraph 2, each Member State shall update its register with the modifications made by another Member State in its own register, as regards the data with which it is concerned. With a view to reducing administrative burden and undue costs for Member States and stakeholders, the Commission may adopt a specification for a European vehicle register that would gradually replace the need for national vehicle registers. Such specification shall include content, data format, functional and technical architecture, operating mode, including arrangements for the exchange of data, and rules for data input and consultation, as well as migration steps, by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).
5. In the case of vehicles authorised for the first time in a third country and subsequently used in a Member State, that Member State shall ensure that the vehicle data, including at least data relating to the vehicle keeper, the entity in charge of maintenance and the restrictions on how the vehicle may be used, can be retrieved through the national vehicle register or through provisions of an international agreement.

Article 44

European register of authorised vehicle types

1. The Agency shall set up and keep a register of authorisations to place vehicle types on the market issued in accordance with Article 22. This register shall meet the following criteria:
 - (a) it shall be public and electronically accessible;
 - (b) it shall comply with the common specifications referred to in paragraph 2;
 - (c) it shall be linked with all national vehicle registers.

2. The Commission shall adopt common specifications for the register of authorised vehicle types relating to content, data format, functional and technical architecture, operating mode and rules for data input and consultation by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).

Article 45

Register of infrastructure

1. Each Member State shall ensure that a register of infrastructure, stating the values of the network parameters of each subsystem or part of subsystem concerned, is published.
2. The values of the parameters recorded in the register of infrastructure shall be used in combination with the values of the parameters recorded in the vehicle authorisation for placing on the market to check the technical compatibility between vehicle and network.
3. The register of infrastructure may stipulate conditions for the use of fixed installations and other restrictions.
4. Each Member State shall update the register of infrastructure in accordance with paragraph 6 of this Article.
5. [...]
6. The Commission shall adopt common specifications for the register of infrastructure relating to content, data format, functional and technical architecture, operating mode and rules for data input and consultation by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).

CHAPTER VIII
TRANSITIONAL AND FINAL PROVISIONS

Article 46

Exercise of delegation

[...]

Article 47

Urgency procedure

[...]

Article 48

Committee procedure

1. The Commission shall be assisted by the committee established by Article 21 of Directive 96/48/EC. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third paragraph of Article 5(4) of Regulation (EU) 182/2011 shall apply.
4. [...]

Article 49

Motivation

Any decision taken pursuant to this Directive concerning the assessment of conformity or suitability for use of interoperability constituents, the checking of subsystems constituting the rail system or any decision taken pursuant to Articles 6, 11 and 16 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 law in force in the Member State concerned and of the time limits allowed for the exercise of such remedies.

Article 50

Reports and information

1. At the latest 3 years following the entry into force of this Directive, the Commission shall report on progress made in preparing for the Agency's enhanced role under this Directive. Additionally, every three years and for the first time three years after the end of the transitional period under Article 51, the Commission shall report to the European Parliament and the Council on the progress made towards achieving interoperability of the rail system and the functioning of the Agency in this context. That report shall also include an evaluation of the implementation and use of the registers under Chapter VII, an analysis of the cases set out in Article 7 and of the application of Chapter V, assessing in particular the functioning of the cooperation agreements concluded between the Agency and national safety authorities. For the purposes of the first report after the end of the transitional period, the Commission shall carry out extensive consultations with the relevant stakeholders and establish a program to allow for the assessment of progress. The Commission shall, if appropriate in the light of the above analysis, propose legislative measures including for the future role of the Agency in enhancing interoperability.

- 1a. At the latest 18 months following the entry into force of this Directive, the Commission shall report to the European Parliament and the Council on the actions taken towards the following objectives:
- obligation of the manufacturers to mark with an identification code the safety critical components circulating on the European rail networks. The identification code shall clearly identify the component, the name of manufacturer and the significant production data;
 - the full traceability of these safety critical components, the traceability of their maintenance activities and the identification of their operational life; and
 - the identification of common mandatory principles for the maintenance of these components.
2. The Agency shall develop and regularly update a tool capable of providing, at the request of a Member State or the Commission, an overview of the interoperability level of the rail system. That tool shall use the information included in the registers provided for in Chapter VII.

Article 51

Transitional regime for using vehicles

1. Member States may continue to apply the provisions set out in Chapter V of Directive 2008/57/EC until five years after the date of entry into force.

2. Authorisations for placing in service of vehicles which have been granted pursuant to paragraph 1 and all other authorisations granted prior to the entry into force of this Directive, including authorisations delivered under international agreements, in particular RIC (Regolamento Internazionale Carrozze) and RIV (Regolamento Internazionale Veicoli), shall remain valid in accordance with the conditions under which the authorisations have been granted.
3. Vehicles authorised for placing in service pursuant to paragraphs 1 and 2, have to receive a vehicle authorisation for placing on the market in order to operate on one or more networks not covered by their authorisation. The placing on the market on these additional networks is subject to the provisions of Article 20.

Article 52

Other transitional provisions

Annexes IV, V, VI, VII and IX to Directive 2008/57/EC shall apply until the date of application of the corresponding implementing acts referred to in Articles 8(2), 14(8), 15(7) and 7(3) of this Directive.

Article 53

Recommendations and opinions and of the Agency

The Agency shall provide recommendations and opinions in accordance with Article 15 of Regulation .../... [Agency Regulation] for the purpose of application of this Directive. Where relevant, these recommendations and opinions shall be taken into account when drawing up implementing acts adopted pursuant this Directive.

Article 54

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 1, Article 2, Article 7(1) to (4), Article 11(1), Article 13, Article 14(1) to (7), Article 15(1) to (6), Articles 17 to 21, Article 22(3) to (7), Articles 23 to 36, Article 37(2), Article 38, Article 39, Articles 41 to 43, Article 45(1) to (5), Article 51, and Annexes I to III by five years after the date of entry into force at the latest. They shall forthwith communicate to the Commission the text of those measures.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference at the time of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directives repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.
3. The obligation to transpose and implement Article 13, Article 14(1) to (7), Article 15(1) to (6), Articles 17 to 21, Article 42, Article 43, Article 45(1) to (5) and Article 51 of this Directive shall not apply to the Republic of Cyprus and the Republic of Malta for as long as no rail system is established within their territory.¹⁴

¹⁴ The references in this paragraph will be adapted in light of the changes agreed on other, potentially relevant articles.

However, as soon as a public or private entity submits an official application to build a railway line in view of its operation by one or more railway undertakings, the Member States concerned shall put in place legislation to implement the Articles referred to in the first subparagraph within two years from the receipt of the application.

Article 55

Repeal

Directive 2008/57/EC, as amended by the Directives listed in Annex IV, Part A, is repealed with effect from five years after the date of entry into force, without prejudice to the obligations of the Member States relating to the time limits for the transposition into national law of the Directives set out in Annex IV, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex V.

Article 56

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Articles 3 to 10, Article 11(2), (3) and (4), Article 12, Article 16, shall apply from five years after the date of entry into force.

Article 57
Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

Elements of Union rail system

1. Network

For the purposes of this Directive, the Union's network shall include:

- specially built high-speed lines equipped for speeds generally equal 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, to which the speed must be adapted in each case. This category includes interconnecting lines between high-speed and conventional networks, lines through stations, accesses to terminals, depots, etc. travelled at conventional speed by 'high-speed' rolling stock,
- conventional lines intended for passenger services,
- conventional lines intended for mixed traffic (passengers and freight),
- conventional lines intended 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.

2. Vehicles

For the purposes of this Directive, Union vehicles shall comprise all vehicles likely to travel on all or part of the Union's network:

- locomotives and passenger rolling stock, including thermal or electric traction units, self-propelling thermal or electric passenger trains, passenger coaches;
- freight wagons, including vehicles designed to carry lorries;
- special vehicles, such as on-track machines.

These vehicles shall include those which are specially designed to operate on the different types of high-speed lines as described in point 1.

SUBSYSTEMS

1. List of subsystems

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

(a) structural areas:

- infrastructure,
- energy,
- trackside control-command and signalling,
- on-board control-command and signalling,
- rolling stock.

(b) functional areas:

- operation and traffic 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 the following:

2.1. Infrastructure

The track, points, level crossings, engineering structures (bridges, tunnels, etc.), rail-related elements of stations (including entrances, platforms, zones of access, service venues, toilets and information systems, as well as their accessibility features for persons with reduced mobility and persons with disabilities), safety and protective equipment.

2.2. Energy

The electrification system, including overhead lines, the trackside electricity consumption measuring and charging system.

2.3. Trackside control-command and signalling

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

2.4. On-board control-command and signalling

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

2.5. Operation and traffic management

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

The professional qualifications which may be required for carrying out any type of railway service.

2.6. Telematics applications

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

- (a) applications for passenger services, including systems which provide 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.

2.7. Rolling stock

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

2.8. Maintenance

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

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 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 in a foreseeable manner, albeit 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 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 Union 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. This requirement includes the safe integration of the vehicle's subsystem with the infrastructure.

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

1.6. Accessibility

1.6.1. The “infrastructure” and “rolling stock” subsystems must be accessible to persons with disabilities and persons with reduced mobility in order to ensure access on an equal basis with others by way of the prevention or removal of barriers, and by way of other appropriate measures. This shall include the design, construction, renewal, upgrade, maintenance and operation of the relevant parts of the subsystems to which the public has access.

1.6.2. The “operations” and “telematics applications for passengers” subsystems must provide for the necessary functionality required to facilitate access to persons with disabilities and persons with reduced mobility on an equal basis with others by way of the prevention or removal of barriers, and by way of other appropriate measures.

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.

2.1.2. Accessibility

2.1.2.1. Infrastructure subsystems to which the public has access must be accessible to persons with disabilities and persons with reduced mobility in accordance with 1.6.

2.2. Energy

2.2.1. Safety

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

2.2.2. Environmental protection

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

2.2.3. Technical compatibility

The electricity/thermal energy supply systems used must:

- enable trains to achieve the specified performance levels,
- in the case of electricity energy supply systems, be compatible with the collection devices fitted to the trains.

2.3. Control-command and signalling

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 control-command 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 signalling installations.

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

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

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

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

Emergency exits must be provided and indicated.

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

An emergency lighting system having a sufficient intensity and duration is an absolute requirement on board trains.

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

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 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 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.

2.4.5. Accessibility

2.4.5.1. Rolling stock subsystems to which the public has access must be accessible to persons with disabilities and persons with reduced mobility in accordance with 1.6.

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 cross-border and domestic services.

2.6.4. Accessibility

2.6.4.1. Appropriate steps must be taken to ensure that operating rules provide for the necessary functionality required to ensure accessibility for persons with disabilities and persons with reduced mobility.

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.

2.7.5. Accessibility

2.7.5.1. Appropriate steps must be taken to ensure that telematics applications for passengers subsystems provide for the necessary functionality required to ensure accessibility for persons with disabilities and persons with reduced mobility.

PART A

Repealed Directives

with list of the successive amendments thereto

(referred to in Article 55)

Directive 2008/57/EC	(OJ L 191, 18.7.2008, p.1.)
Directive 2009/131/EC	(OJ L 273, 17.10.2009, p.12.)
Directive 2011/18/EU	(OJ L 57, 2.3.2011, p.21.)

PART B

Time limits for transposition into national law

(referred to in Article 55)

Directive	Deadline for transposition
2008/57/EC	19 July 2010
2009/131/EC	19 July 2010
2011/18/EU	31 December 2011

CORRELATION TABLE

Directive 2008/57/EC	This Directive
Article 1	Article 1
Article 2(a) to (z)	Article 2(1) to (24)
-----	Article 2(25) to (41)
Article 3	-----
Article 4	Article 3
Article 5(1) to (3)(g)	Article 4(1) to (3)(g)
-----	Article 4(3)(h) and (i)
Article 5(4) to (8)	Article 4(4) to (8)
Article 6	Article 5
Article 7	Article 6
Article 8	-----
Article 9	Article 7
Article 10	Article 8
Article 11	Article 9
Article 12	-----
Article 13	Article 10
Article 14	Article 11
Article 15(1)	Articles 18(3) and 19(2)
Article 15(2) and (3)	-----
Article 16	Article 12
Article 17	Articles 13 and 14
Article 18	Article 15
Article 19	Article 16
-----	Article 17
-----	Article 18 (except 18(3))
-----	Articles 19 and 20

Article 20	-----
Article 21	Article 21
Articles 22 to 25	-----
Article 26	Article 22
Article 27	Article 14(8)
Article 28 and Annex VIII	Articles 23 to 41
Article 29	Article 48
Articles 30 and 31	-----
Article 32	Article 42
Article 33	Article 43
Article 34	Article 44
Article 35	Article 45
Article 36	-----
-----	Article 46 and 47
Article 37	Article 49
Article 38	Article 54
Article 39	Article 50
-----	Articles 51 and 52
-----	Article 53
Article 40	Article 55
Article 41	Article 56
Article 42	Article 57
Annex I to III	Annex I to III
Annex IV	Article 8(2)
Annexes V and VI	Article 15(7)
Annex VII	Article 14(8)
Annex VIII	Articles 27, 28 and 29
Annex IX	Article 7(3)
Annex X	Annex IV
Annex XI	Annex V

The agreement of the Council to Article 20 is conditional on the inclusion in the Agency Regulation of new a recital and provisions based on the following principles (as referred to in footnote 10):

"The recast of the interoperability Directive should not lead to a reduced level of safety in the European Union's railway sector. In this respect, the Agency should take full responsibility for the authorisations it issues, including contractual and non-contractual liabilities. Concerning the non-contractual liability, the Regulation stipulates that the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its departments or by its staff during the performance of their duties.

With regard to liability of both of the Agency and of its staff, the application of the Protocol on the Privileges and Immunities of the European Union, which is also applicable to the staff of the Agency, should not lead to undue delays or unfounded restrictions to the conduct of national inquiries. In the event of a judicial inquiry involving the Agency or its staff, in which the Agency or any member or members of its staff are requested to appear in a national court of law, the Agency should cooperate fully with the responsible authorities of the Member States concerned. In the event that the Agency is asked for information or a member of its staff is requested to appear in proceedings before a national court, the Agency should respond to such a request within a reasonable time period. The Board of the Agency should ensure that such request for information or participation in proceedings is treated with due diligence. In the event that the Board is requested to waive the immunity granted to the Agency or the Agency's staff, it should take its decision within a reasonable time period. A negative decision should be duly justified and demonstrate that the granting of the request would compromise the interests of the Union. Such a negative decision may be referred to the European Court of Justice for judicial review. The Agency Regulation-should establish the rules of procedure for cooperation of the Agency and its staff in judicial proceedings."