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NOTE

From:	General Secretariat
To:	Delegations
No. Cion prop.:	6013/13 TRANS 39 CODEC 226
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)

In view of the Land Transport Working Party on 23 May 2013, delegations will find attached a revised version of the above-mentioned document.

The changes with respect to 8323/13 and W. doc. 2013/55 have been marked with **bold** and ~~strikethrough~~.

General scrutiny reservation: all delegations.

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)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union , and in particular Articles 91(1), 170 and 171 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

¹ OJ C , , p. .

² OJ C , , p. .

Whereas:

- (1) Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community³ has been substantially amended several times. Since further amendments are to be made, that Directive should be recast in the interests of clarity.
- (2) In order to enable citizens of the Union, economic operators and regional and local authorities to benefit to the full from the advantages deriving from the establishing of an area without internal frontiers, it is appropriate, in particular, to improve the interlinking and interoperability of the national rail networks as well as access thereto, implementing any measures that may prove necessary in the field of technical standardisation.
- (3) The pursuit of interoperability within the Union's rail system should lead to the definition of an optimal level of technical harmonisation and make it possible to facilitate, improve and develop international rail transport services within the Union and with third countries and contribute to the progressive creation of the internal market in equipment and services for the construction, renewal, upgrading and operation of the rail system within the Union.
- (4) The commercial operation of trains throughout the rail network requires in particular excellent compatibility between the characteristics of the infrastructure and those of the vehicles, as well as efficient interconnection of the information and communication systems of the different infrastructure managers and railway undertakings. Performance levels, safety, quality of service and cost depend upon such compatibility and interconnection, as does, in particular, the interoperability of the rail system.
- (5) The railway regulatory framework should set clear responsibilities for ensuring compliance with the safety, health and consumer protection rules applying to the railway networks.

³ OJ L 191, 18.7.2008, p. 1.

- (6) There are major differences between national regulations, internal rules and technical specifications applicable to rail systems, subsystems and components, since they incorporate techniques that are specific to the national industries and prescribe specific dimensions and devices and special characteristics. This situation prevents trains from being able to run without hindrance throughout the Union .
- (7) Over the years, this situation has created very close links between the national railway industries and the national railways, to the detriment of a genuine opening-up of markets allowing new entrants to emerge. In order to enhance their competitiveness at world level, these industries require an open, competitive European market.
- (8) It is therefore appropriate to define essential requirements related to rail interoperability for the whole of the Union which should apply to its rail system.
- (9) The development of technical specifications for interoperability (TSIs) has shown the need to clarify the relationship between the essential requirements and the TSIs on the one hand, and the European standards and other documents of a normative nature on the other. In particular, a clear distinction should be drawn between the standards or parts of standards which should be made mandatory in order to achieve the objectives of this Directive, and the "harmonised standards" that have been developed in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council⁴. Where strictly necessary, the TSIs may make an explicit reference to European standards or specifications, which become mandatory from the moment the TSI is applicable.

⁴ OJ L 316, 14.11.2012, p. 12.

- (10) In order to genuinely increase the competitiveness of the Union railway sector without distorting competition between key actors of the rail system, the TSIs, should be drafted by respecting the principles of openness, consensus and transparency as defined in Annex II to Regulation (EU) No 1025/2012.
- (11) The quality of rail services in the Union depends, *inter alia*, on excellent compatibility between the characteristics of the network in the broadest sense, including the fixed parts of all the subsystems concerned and those of the vehicles including the onboard components of all the subsystems concerned. Performance levels, safety, quality of service and cost depend upon that compatibility.
- (12) 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 and suitability for the use indicated in the TSIs, and have the corresponding certificate.
- (13) When developing new TSIs the aim should always be to ensure compatibility with the existing system. This will help to promote the competitiveness of rail transport and prevent unnecessary additional costs through the requirement of upgrading or renewal of existing subsystems to ensure backward compatibility. In those exceptional cases where it will not be possible to ensure compatibility, TSIs may establish the framework necessary to decide whether the existing subsystem needs a new decision or authorisation for placing in service, and the corresponding deadlines.
- (14) It is necessary for safety reasons to assign an identification code to each vehicle placed in service. The vehicle should then be entered in a national vehicle register. The registers should be open to consultation by all Member States and by certain economic players within the Union. The national vehicle registers should be consistent as regards the data format. They should therefore be covered by common operational and technical specifications.

- (15) If certain technical aspects corresponding to the essential requirements cannot be explicitly covered in a TSI, such aspects which need still to be addressed are identified in an annex to the TSI as open points. For these open points, pending the completion of the TSI, national rules apply.
- (16) The procedure to be followed in the case of essential requirements applicable to a subsystem which have not yet been covered in the corresponding TSI should be specified. In such case, the bodies responsible for the conformity assessment and verification procedures should be the notified bodies referred to in Article 17 of Directive 2008/57/EC .
- (17) Directive 2008/57/EC applies to the entire rail system within the Union and the scope of the TSIs is being extended to cover also the vehicles and networks not included in the trans-European rail system. Therefore, Annex I should be simplified by removing specific references to the trans-European rail system.
- (18) The functional and technical specifications to be met by the subsystems and their interfaces may vary according to the use of subsystems, for example according to the categories of lines and vehicles.
- (19) In order to ensure the progressive implementation of rail interoperability within the whole Union and gradually reduce the diversity of legacy systems, the TSIs should specify the provisions to be applied in the event of renewal or upgrading of existing subsystems and may specify deadlines for achieving the target system.
- (20) In view of the gradual approach to eliminating obstacles to the interoperability of the rail system and of the time consequently required for the adoption of TSIs, steps should be taken to avoid a situation where Member States adopt new national rules or undertake projects that increase the diversity of the present system.

- (21) In order to eliminate the obstacles to interoperability, and as a consequence of extending the scope of the TSIs to the whole Union's rail system, the amount of national rules should progressively be reduced. National rules should be differentiated between rules strictly related to local requirements and rules needed to cover open points in TSIs. The second type of rules should progressively be removed as a result of closure of open points in the TSIs.
- (22) The adoption of a gradual approach satisfies the special needs of the objective of the interoperability of the rail system, which is characterised by old national infrastructure and vehicles requiring heavy investment for adaptation or renewal, and particular care should be taken not to penalise rail economically vis-à-vis other modes of transport.
- (23) In view of the extent and complexity of the rail system, it has proved necessary, for practical reasons, to break it down into the following subsystems: infrastructure, trackside control-command and signalling, on-board control-command and signalling, energy, rolling stock, operation and traffic management, maintenance and telematics applications for passenger and freight services. For each of these subsystems the essential requirements must be specified and the technical specifications determined, particularly in respect of constituents and interfaces, in order to meet these essential requirements. The same system is broken down into fixed and mobile elements comprising, on the one hand, the network, composed of the lines, stations, terminals, and all kinds of fixed equipment needed to ensure safe and continuous operation of the system and, on the other hand, all vehicles travelling on this network. Therefore, for the purposes of this Directive, a vehicle is composed of one subsystem (rolling stock) and where applicable other subsystems (mainly the on-board control-command and signalling subsystem).

- (24) The United Nations Convention on the Rights of Persons with Disabilities to which the Union is a party establishes accessibility as one of its general principles and requires States Parties to take appropriate measures to ensure to persons with disabilities access on an equal basis with others, including by developing, promulgating and monitoring the implementation of minimum standards and guidelines for accessibility. Accessibility is therefore an important requirement for the interoperability of the rail system.
- (25) Implementation of the provisions on the interoperability of the rail system should not create unjustified barriers in cost-benefit terms to the preservation of the existing rail network of each Member State, but should endeavour to retain the objective of interoperability.
- (26) TSIs also have an impact on the conditions of use of rail transport by users, and it is therefore necessary to consult these users on aspects concerning them.
- (27) Each Member State concerned should be allowed not to apply certain TSIs in a limited number of duly substantiated situations. These situations and the procedures to be followed in case of non-application of the TSI should be clearly defined.
- (28) The drawing up of TSIs and their application to the rail system should not impede technological innovation, which should be directed towards improving economic performance.

- (29) To comply with the appropriate provisions on procurement procedures in the rail sector and in particular Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services⁵, the contracting entities should include technical specifications in the general documents or in the terms and conditions for each contract. To this end it is necessary to build up a set of rules in order to serve as references for these technical specifications.
- (30) An international system of standardisation capable of generating standards which are actually used by those involved in international trade and which meet the requirements of the Union policy would be in the Union's interest. The European standardisation organisations should therefore continue their cooperation with the international standardisation bodies.
- (31) The contracting entities are to define the further requirements needed to complete European specifications or other standards. These specifications should meet the essential requirements that have been harmonised at Union level and which the rail system must satisfy.
- (32) The procedures governing the assessment of conformity or of suitability of use of constituents should be based on the use of the modules covered by Commission Decision 2010/713/EU of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council⁶. As far as possible and in order to promote industrial development, it is appropriate to draw up the procedures involving a system of quality assurance.

⁵ Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.4.2004, p. 1). Directive as last amended by Commission Regulation (EC) No 213/2008 (OJ L 74, 15.3.2008, p. 1).

⁶ OJ L 319, 4.12.2010, pp. 1–52 .

- (33) Conformity of constituents is mainly linked to their area of use in order to guarantee the interoperability of the system and not only their free movement on the Union market. The suitability for use of the most critical constituents as regards safety, availability or system economy should be assessed. It is therefore not necessary for a manufacturer to affix the CE marking to constituents that are subject to the provisions of this Directive. On the basis of the assessment of conformity and/or suitability for use, the manufacturer's declaration of conformity should be sufficient.
- (34) Manufacturers are nonetheless obliged to affix the CE marking to certain components in order to certify their compliance with other Union provisions relating to them.
- (35) When a TSI enters into force, a number of interoperability constituents are already on the market. A transitional period should be provided for so that these constituents can be integrated into a subsystem, even if they do not strictly conform to that TSI.
- (36) The subsystems constituting the rail system should be subject to a verification procedure. This verification should enable the entities responsible for their placing in service to be certain that, at the design, construction and putting into service stages, the result is in line with the regulations and technical and operational provisions in force. It should also enable manufacturers to be able to count upon equality of treatment whatever the Member State.
- (37) After a subsystem is placed in service, care should be taken to ensure that it is operated and maintained in accordance with the essential requirements relating to it. Under Directive [...] [Railway Safety Directive]⁷, responsibility for meeting these requirements lies, for their respective subsystems, with the infrastructure manager or the railway undertaking.

⁷ OJ L...

- (38) The procedure for placing in service of vehicles and fixed installations should be clarified taking into account the responsibilities of infrastructure managers and railway undertakings.
- (39) In order to facilitate the placing in service of vehicles and reduce administrative burdens, the notion of a vehicle authorisation for placing on the market valid throughout the Union should be introduced as a precondition to enable railway undertakings to place in service a vehicle. In addition, this notion is more in line with Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC⁸.
- (40) To ensure traceability of the vehicles and their history, the references of the vehicle authorisations for placing on the market should be recorded together with the other vehicle data.
- (41) The TSIs should specify the procedures for checking the compatibility between vehicles and network after the delivery of the vehicle authorisation for placing on the market and before the decision to place into service.
- (42) To help railway undertakings decide on the placing into service of a vehicle and to avoid redundant verifications and unnecessary administrative burden, national rules should also be classified to establish the equivalence between national rules of different Member States covering the same topics.
- (43) The notified bodies responsible for examining the procedures for conformity assessment and suitability for the use of constituents, together with the procedure for the assessment of subsystems should, in particular in the absence of any European specification, coordinate their decisions as closely as possible.

⁸ OJ L 218, 13.8.2008, p. 82.

- (44) Transparent accreditation as provided for in Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93⁹, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union the preferred means of demonstrating the technical competence of notified and, *mutatis mutandis*, the bodies designated to check the compliance with national rules. However, national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (45) This Directive should be limited to establishing the interoperability requirements for interoperability constituents and subsystems. In order to facilitate compliance with those requirements it is necessary to provide for presumption of conformity for interoperability constituents and subsystems which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 for the purpose of expressing detailed technical specifications of those requirements.
- (46) The TSIs should be revised at regular intervals. When deficiencies are discovered in the TSIs, the European Union Agency for Railways (hereinafter referred to as the Agency) should be asked to issue an opinion which, under certain conditions, might be published and used by all stakeholders (including industry and notified bodies) as an acceptable means of compliance pending the revision of the TSIs concerned.

⁹ OJ L 218, 13.8.2008, p. 30.

(47) Since the objective of this Directive, namely interoperability within the rail system on a Union-wide scale, cannot be sufficiently achieved by the Member States acting alone, since no individual Member State is in a position to take the action needed in order to achieve such interoperability and can therefore be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(48) In order to amend non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the adaptation to technical progress of Annex II regarding the breakdown of the rail system into subsystems and to the description of these subsystems, the content of the TSIs and the amendments to TSIs, including those amendments needed to remedy TSIs deficiencies. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

(49) In order to address the deficiencies discovered in TSIs, the Commission should adopt delegated acts amending those TSIs under the urgency procedure.

(50) In order to ensure the implementation of Article 6(1) of this Directive concerning the mandate to the Agency to draft TSIs and their amendments and to make the relevant recommendations to the Commission, implementing powers should be conferred on the Commission.

(51) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission relating to: the content of the file which shall accompany the request of non-application of one or more TSIs or parts of them, the details, the format and the transmission modalities of that file; the scope and the content of the EC declaration of conformity and suitability for use of interoperability constituents, its format and the details of the information included in it; the classification of the notified national rules in different groups with the aim of facilitating the compatibility checks between fixed and mobile equipment; 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; 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 the declaration of verification; the common specifications relating to content, data format, functional and technical architecture, operating mode and rules for data input and consultation for the register of infrastructure. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers¹⁰.

(52) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.

¹⁰ OJ L 55, 28.2.2011, p.13.

(53) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

(54) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex IV, part B.

HAVE ADOPTED THIS DIRECTIVE:

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 the safety of the rail system within the Union] 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:¹¹
- (a) metros,
 - aa) trams and light rail ~~systems~~**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 services¹², as well as ~~railway~~ undertakings operating solely on these networks.
4. Member States may exclude from the scope of the measures implementing this Directive:¹³
- (a) privately owned railway infrastructure, **used by the owner or a single operator for the purpose of its freight activities, including the transport of staff** and vehicles exclusively used on such infrastructure ~~where this exists solely for use by the owner for its own freight operations;~~¹⁴
 - (b) infrastructure and vehicles reserved for a strictly local, historical or touristic use.

Article 2

Definitions

For the purposes of this Directive:

- (1) **Union** rail system' means the elements listed in Annex I;¹⁵
- (2) 'interoperability' means the ability of a rail system to allow the safe and uninterrupted

¹¹ DE, CZ, LV, AT, EL, HU, PT propose to exclude narrow gauge railway. See changes in Article 7.

¹² IT and ES propose to delete the word "passenger" and EL to add "regional" in the text.

¹³ AT and LU propose to merge para 3 and 4 and have an overall exclusion from the scope.

¹⁴ DE, CZ, SI, SK propose to delete the reference to freight.

¹⁵ FR, HU and BG do not agree on the deletion of the distinction between conventional and high-speed rail system. To be discussed with Annex I. HU proposes to limit the scope of TSIs to TEN-T networks.

movement of trains which accomplish the required levels of performance ~~for these lines~~;

- (3) ‘vehicle’ means a railway vehicle suitable for circulation on ~~its own~~ 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;**
 - 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 **parameters** of the subsystem;¹⁶
- (13) ‘renewal’ means any **major** substitution work on a subsystem or part of it which does not change the ~~overall~~ performance **parameters** of the subsystem;
- (14) ‘existing rail system’ means the structure composed of lines and fixed installations of the existing rail ~~system~~ **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 ~~or a vehicle~~ 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;¹⁷

¹⁶ AT, FR, PT and UK propose to reinsert "major" in the text.

¹⁷ The following recital will be added in a recital: "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."

- (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 railway undertaking, an infrastructure manager or other persons or legal entities, such as the manufacturer, an owner or a keeper;**
- (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 the safety of the rail system within the Union] ;
- (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 .../.... [Railway Safety Directive];
- (25) **‘tram and light rail’ means an urban and/or sub-urban rail transport system vehicle with a strength of vehicle structure lower than 1000 kilonewton-kN. Light rail systems may have their own right-of-way or share it with road traffic and usually 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** containing railway safety or technical requirements imposed within a **that** Member State **in addition to European rules** and **are** applicable to railway undertakings, infrastructure managers or third parties, **irrespective of the body issuing them;**
- (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 or subsystems 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 **is responsible for** conformity assessment activities, including calibration, testing, certification and inspection; **–A conformity assessment body becomes a 'notified body' following notification by a Member State. A conformity assessment body becomes a designated body following designation by a Member State¹⁸ ;**
- (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;¹⁹
- (38) ‘infrastructure manager’ means infrastructure manager as defined in Article 3 of Directive **2012/34/EU** [establishing a single European railway area];
- (39) ‘railway undertaking’ means railway undertaking as defined in Article 3 of Directive 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) **~~'freight terminal' means a structure equipped for transshipment between at least two transport modes and for temporary storage of freight, such as ports, inland ports, airports and rail-road terminals;~~**

¹⁸ IT has a reservation on this addition

¹⁹ This definition is based on the UN definition and adapted to the transport sector, in accordance with the latest amendment of Annex III of the essential requirements (Cion decision 2013/09.)

- (41) ‘Agency’ means the European Railway Agency, as established by Regulation (EU) No .../... [Agency Regulation].

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. The Commission shall be empowered to adopt delegated acts in accordance with Article 46 concerning adaptation to technical progress of Annex II regarding the breakdown of the rail system into subsystems and to the description of these subsystems.~~
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/EU²⁰;
- (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. ~~including setting deadlines~~ **Where coordinated implementation of the TSI is necessary, such as along a corridor or between infrastructure managers and railway undertakings, the strategy may include timeframes for staged completion of those stages where necessary;**
- (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;

²⁰ OJ L 319, 4.12.2010, p. 1.

- (h) indicate the provisions applicable to the existing subsystems and types of vehicles, in particular in the event of upgrading and renewal, ~~with and without a new authorisation or decision for placing in service;~~²¹
- (i) indicate the parameters 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 decision **to use the vehicle** ~~for placing in service~~²² 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 ~~gradual~~ adoption of the TSIs and compliance with them shall **gradually** facilitate ~~gradually within that time scale to achieve 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.

²¹ Subject to further changes depending on the outcome of discussions on Chapter V.

²² Subject to further changes depending on the outcome of discussions on Chapter V.

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. The Commission shall issue a mandate to the Agency to draft TSIs and their amendments and to make the relevant recommendations to the Commission.

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. ~~The most viable alternative solutions accompanied by technical and economic justification shall be put forward for each of these parameters and interfaces.~~
- (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. ~~An overall assessment of the estimated costs and benefits of the implementation of the TSIs shall be attached to the draft TSI. This assessment shall indicate the likely impact for all the operators and economic agents involved.~~

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 ~~agents~~ **actors** involved and take due account of the requirements of the Directive .../... on the safety of the rail system within the European Union. 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.**²³ ~~During the preparatory this work on TSIs~~ 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.

²³ Commission has a reservation on information of the Committee.

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 level²⁴. 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 be empowered to adopt delegated acts in accordance with Article 46 concerning the TSIs and their amendments.~~

~~Where, in the case of deficiencies discovered in TSIs in accordance with Article 6, imperative grounds of urgency so require, the procedure provided for in Article 47 shall apply to delegated acts adopted pursuant to this Article.~~

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).²⁵

²⁴ OJ L 225, 12.8.1998, p. 27.

²⁵ Commission reservation on the deletion of delegated acts and also the involvement of the Committee under paragraphs 2 and 4.

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(310). **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 Member States** of its conclusions.
3. At the request of the Commission, the Agency opinions referred to in paragraph 2 shall constitute acceptable means of compliance ~~to meet the essential requirements~~ 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 are allowed 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 in time to the period before the full 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 ~~all~~ **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. 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. The Commission shall** ~~and~~ inform the Member State of ~~this~~ **its** decision.

- 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.**

~~The Commission shall establish, by means of implementing acts, the scope and the content of the EC declaration of conformity and 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).²⁶~~

²⁶ Recital 12 will be adapted to explain the difference between the concept of conformity and suitability for use 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 and 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*

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 ~~and or~~ suitability for the use. ~~Where relevant, it shall be accompanied by the corresponding certificate of the notified body.~~
- ~~2. Member States and the Agency shall consider as being interoperable and meeting the essential requirements, those interoperability constituents which are covered by the 'EC' declaration of conformity or suitability for use.~~
- 2a. **The Commission shall establish, by means of implementing acts, the scope and the content of the EC declaration of conformity ~~and~~ 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).²⁷**
- ~~3. Member States and the Agency shall consider that an interoperability constituent meets the essential requirements if it complies with the conditions laid down by the corresponding TSI or the corresponding European specifications developed to comply with these conditions.~~
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 ~~procedure~~ **requirements** referred to in paragraph ~~2-1~~.
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

use of an interoperability constituent considered within its railway environment in relation to the technical specifications.

²⁷ See footnote 26

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.
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 ~~conformity assessment~~ 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 ~~In order to~~ ensure that the interoperability constituents which do not comply with essential requirements are is not placed on the market. In such a case,**

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

~~(b) where non-conformity persists, the Member State shall take all appropriate steps to restrict or prohibit the placing on the market of the interoperability constituent in question, or to ensure that it is withdrawn from the market in accordance with the procedures provided for in Article 11.~~

~~This paragraph is without prejudice to the provisions of Article 11.~~

Article 11

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 Commission~~ **Agency** shall **start the consultation process with** the parties concerned as ~~quickly as possible~~ **without delay**. Where, following that consultation, the ~~Commission~~ **Agency** establishes that the measure is **unjustified** it shall forthwith inform the Member State that has taken the initiative as well as the other Member States, **the manufacturer or his authorised representative established within the Union** thereof. . Where ~~after that consultation, the Commission~~ **Agency** establishes that the measure is ~~unjustified~~ it shall forthwith inform ~~the Agency, the Member States. that has taken the initiative and the manufacturer or his authorised representative established within the Union~~ thereof.
- 2a. **Where the decision referred to in paragraph 1 results from a gap in European specifications, Member States, 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. *deleted*

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.

Conformity with TSIs and national rules²⁸

1. ~~Member States and 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. ~~The EC declaration of verification is 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. *[deleted]*

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 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;²⁹
- (e) networks and vehicles not covered by TSIs;
- (f) **as an urgent temporary preventive measure, in particular following an accident.**

3a. Member States may lay down new national rules only in the case of points (a) and (f).

²⁸ Reservation: FR and ES.

²⁹ IT and NL propose to delete "*limited to the aim of assessing technical compatibility of the vehicle with the network*".

4. ~~In the cases referred to in paragraph 3, Member States and the Agency shall consider as meeting the essential requirements, those structural subsystems constituting the rail system which are covered by the relevant declaration(s) of verification. The declaration of verification is established by reference to national rules, in accordance with the verification procedure referred to in Article 15.~~

~~In addition to the obligation under Article 23, Member States shall designate the bodies responsible for carrying out such verification procedure.~~

Article 14

Notification of national rules³⁰

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) after a new request for non-application of the TSI has been submitted in accordance with Article 7,
 - (c) where national rules become redundant after publication or revision of the TSI concerned.
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].³¹
3. ~~Member States may lay down new national rules only in the following cases:~~

³⁰ BE and PT have a reservation on this article due to its link with the safety directive.

³¹ The link between the publication of the rules and copyright rules will be considered in the context of the ERA Regulation.

(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 ~~shall be~~ 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 Commission shall establish, by means of implementing acts, the classification of the notified national rules in different groups with the aim of facilitating the ~~compatibility checks between fixed and mobile equipment~~ **placing on the market of vehicles**. 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 ~~conformity assessment~~ body that it has selected for that purpose to apply the 'EC' verification procedure. ~~The applicant may be the contracting entity or the manufacturer, or their authorised representative within the Union.~~
2. The task of the notified ~~conformity assessment~~ 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 ~~may~~ **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, ~~based on the information available in the relevant TSI and in the registers provided for in Articles 44 and 45.~~
3. The notified ~~conformity assessment~~ 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. ~~A new 'EC' declaration of verification shall be required i~~In the event of **renewal or upgrading** and in the event of renewal when the applicant so decides on the basis of the risk analysis, **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 ~~conformity assessment~~ 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 ~~conformity assessment~~ 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 ~~of verification~~.

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

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 ~~before issuing the authorisation~~, **within one month of receipt of the application** in order to ~~avoid technical incompatibility with existing TSI-compliant vehicles~~ **ensure a coherent development of ERTMS into the Union. The Agency shall issue an opinion³² to the relevant national safety authority regarding the technical and operational compatibility of that 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 authorisation, and in case of disagreement, shall inform the Agency stating the reasons therefore. 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 ~~the first subparagraph of 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.

³² Opinions as referred to in Article 3 of the ERA regulation which are not binding.

3. ~~In order to authorise the placing in service of the subsystems referred to paragraphs 1,~~ **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:** ~~The national safety authority shall obtain proof of:~~
- (a) ~~the EC~~ 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, ~~registers~~, and the common safety methods set out in Article 6 of Directive.../... [on the safety of the rail system within the Union].
- 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 file and issue the authorisation for placing in service of fixed installations or, inform the applicant of a 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 this file and shall decide, on the basis of the criteria set out in paragraph 5, whether a new authorisation for placing in service is needed,~~ **on the basis of the criteria:** ~~The national safety authority shall take their decision within a pre-determined, reasonable time, and, in any case, within four months from receipt of all relevant~~

5. ~~In the event of renewal or upgrading of existing subsystems, a new 'EC' declaration of verification shall be needed as set out in Article 15(4). In addition, a new authorisation for placing in service shall be required when:~~
- (a) the overall safety level of the subsystem concerned may be adversely affected by the works envisaged; ~~or~~
 - (b) it is required by the relevant TSIs; ~~or~~
 - (c) it is required by the national implementation plans established by the Member States; **or**
 - (d) **changes are made to the values of the TSI parameters on the basis of which the authorisation was already granted.**

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

6. ~~Member States shall inform the Agency of planned or on-going trackside control-command and signalling projects involving ERTMS installations.~~

~~The Agency shall take account of such projects with a view to ensuring the coherent development of the ERTMS in accordance with its obligations under Chapter 6 of Regulation (EU) No .../...[Agency Regulation]. In cases of non-compliance affecting the interoperability of the rail system, the Agency shall inform the Commission who shall take the necessary measures to rectify any such non-compliance.~~

- 7 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, request that the national safety authority review its decision. 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 the safety of the Union rail system].

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 **EC relevant** declaration of verification has been provided.
3. ~~In the event of renewal or upgrading of existing subsystems, a new 'EC' declaration of verification shall be needed as set out in Article 15(4).~~

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. ~~the~~ **a network or networks within** of a Member State, ~~a corridor~~ or a group of Member States' ~~networks~~. 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 the safety of the rail system within the Union];
 - (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 the safety of the rail system within the Union].

[Paragraph 1b. is moved from paragraph 4.]

Whenever tests are necessary in order to obtain documentary evidence of the technical compatibility referred to 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 ~~and or in the case of paragraph 1g.,~~ the national safety ~~authorities~~**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.**
~~be valid for placing on the market in all Member States~~

[Paragraph 1c. is moved from paragraph 5, first subparagraph]

- 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:
- (a) assess ~~the file in relation to~~ the elements **of the file** set out in paragraphs 1b(a), 1b(b) and 1b(c)³³ **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 each of the relevant national safety authorities for assessment, ~~insofar as they relate to the jurisdiction of each national safety authority,~~ **of the file in order to verify its completeness, relevance and consistency in relation to the elements set out in 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 Agency national safety authority's request.

- 1e. 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.

In the event of non-application of one or more TSIs or parts of them referred to in Article 7,

³³ Commission reservation on exclusion of 1b(d) from this subparagraph

the Agency shall issue the vehicle authorisation only after application of the procedure set out in that Article.³⁴

The Agency shall take full responsibility for the authorisations it issues.³⁵

- 1f. When the Agency disagrees with an **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 national safety authority shall indicate whether it accepts the Agency's opinion. If it does not accept the Agency's opinion,~~ 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** ~~In any event, the Agency shall take its final decision~~ within one month after the **Agency has informed the** national safety authority ~~was informed of the Agency's~~ **its disagreement opinion, the Agency shall take its final decision unless the national safety authority or authorities has referred the matter for arbitration to the Committee established under Article 51 of Regulation (EU) No .../...[Agency Regulation].**³⁶ **This Committee shall decide whether to confirm the Agency's decision within one month of the request of the national safety authority or authorities.**³⁷
- 1g. Where the area of use is limited to **a network or networks within only** 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**

³⁴ Article 7 will be adapted in order to reflect that when a derogation request relates to a vehicle which is intended to be used in more than one Member State, the applicant lodges his request to the Agency which shall consult the relevant Member States and submits the file referred to in Article 7(3) to the Commission.

³⁵ A recital will be drafted to recall and clarify the legal framework governing the responsibility of the Agency and of its staff under Article 66 of the ERA Regulation and other sources of EU law, and to underline the duty of cooperation between the Agency and Member States' judicial or other authorities, in particular in proceedings initiated in order to establish institutional or personal liability.

³⁶ Article 51 of the ERA regulation to be amended to include an arbitration procedure.

³⁷ Commission reservation

under the provisions of 1h. The authorisation shall also be valid for vehicles travelling to the border stations of neighbouring Member States.

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 two years after the entry into force of this Directive**, by means of implementing acts³⁸, 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 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).

[Paragraph 1h. is moved from paragraph 5, second subparagraph.]

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

³⁸ DK, FR suggests to set out these detailed procedures in this Directive. FR believes that this task should be given to railway experts - namely the Agency - , without adding an additional layer of legislation.

area of use~~network;~~

(c) the vehicle's compliance with the relevant TSIs and sets of national rules, related to the parameters referred to under point ~~(a)~~**(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. ~~The Agency and the national safety authorities may issue a vehicle authorisation for placing on the market for a series of vehicles, under the same conditions as set out in paragraphs 1a to 1g.~~ *[see amendments to Article 22(1) and 22(3)]*

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 .../... [establishing a European railway agency]. 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 the safety of the Union rail system].

8. In the event of renewal or upgrading of existing vehicles which already have a vehicle authorisation for placing on the market, ~~a new 'EC' declaration of verification shall be required as set out in Article 15(4). In addition,~~ a new vehicle authorisation for placing on the market shall be required if:

- (a) any changes are made to the values of the ~~parameters included in the vehicle authorisation already granted~~ **referred to in paragraph 2(b)**, or
- (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.

[Points b) and c) are moved from Article 21(3), points a) and b.)]

- 8a. Where the applicant wishes to extend the area of use of a vehicle already authorised, he/she shall complement the file with the relevant documents **referred to in paragraph 1b.**~~(d)~~ concerning the additional area of use ~~and the elements referred to in paragraph 1b(d)~~. 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. ~~In addition to the~~ **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, **and may also include specific cooperation arrangements in the case of networks with a track gauge different from that of the main rail network within the Union.** ~~these agreements shall contain a clause specifying the respective levels of responsibility of the Agency and the national safety authorities in respect of the assessments carried out.~~ These agreements shall be in place before the Agency is entitled to receive applications in accordance with this

Directive, and in any case by **two years following the date of entry into force of this Directive** at the latest.

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

Article 21

Decision to use vehicles

1. **Before a railway undertakings shall takes a decision to use a vehicle only after having checked, on the basis of the infrastructure register, it shall check:**
 - a) **that the vehicle has been authorised for placing on the market in accordance with Article 20;**
 - b) **the technical compatibility between the vehicle and the route on the basis of the infrastructure register or any relevant information where such a register does not exist; and**
 - c) **the safe integration³⁹ 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.../... [Railway Safety Directive] and the TSI on operation and traffic management.**
- 1a. ~~To this end, For the purposes of paragraph 1, the railway undertaking may decide to carry out tests in cooperation with the infrastructure manager in the following cases:~~

~~— where required by its safety management system as set out in Article 9 of Directive.../... [Railway Safety Directive];~~

~~— if the RINF is not available or not complete.~~

~~In these cases the tests shall be carried out in cooperation with the infrastructure manager.~~
The infrastructure manager shall make every effort to ensure that any tests take place within a reasonable time after the railway undertaking's request.

³⁹ A recital will be added in the text to clarify the concept of safe integration.

2. The railway undertaking shall communicate all decisions to use a vehicle to the Agency, the infrastructure manager and the national safety authority concerned. These decisions shall be recorded in the national vehicle registers referred to in Article 43. ~~The railway undertaking shall request one of the national authorities concerned to assign a European vehicle number to the vehicle as provided for in Article 42.~~⁴⁰

~~2a. In the context of the supervisory role set out in Article 16 of Directive .../... [Rail Safety Directive], in case of justified doubts, national safety authorities may question the decision taken by the railway undertaking to use the vehicle. The railway undertaking shall provide the national safety authority with any information requested. **This paragraph is without prejudice to the rights and obligations of national safety authorities under Directive .../... [Rail Safety Directive].**~~⁴¹

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

Article 22

Authorisation to place vehicle types on the market

1. The Agency or a national safety authority, **where appropriate, in accordance with the procedure set out in Article 20**, shall grant authorisations to place vehicle types on the market.
2. If the Agency or a national safety authority issue a vehicle authorisation for placing on the market, it shall at the same time issue the authorisation to place the corresponding vehicle type on the market, which is related to the same area of use of the vehicle.
- ~~2a. Where appropriate, the implementing acts to be adopted in accordance with Article 20(1h) shall determine the specific rules in relation to the granting of authorisations to place vehicle types on the market.~~
3. A vehicle **or a series of vehicles** which is in conformity with a vehicle type for which an authorisation to place the corresponding vehicle type on the market has been already issued

⁴⁰ To be discussed in the context of Article 42

⁴¹ FI has a scrutiny on the deletion of this paragraph.

shall, without further checks, receive a vehicle authorisation for placing on the market on the basis of a declaration of conformity to this type submitted by the applicant.

4. In the event of changes to any relevant provisions in TSIs or national rules, on the basis of which an authorisation to place a vehicle type on the market has been issued, the TSI or national rule shall determine whether the authorisation to place that vehicle type on the market 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. The renewal of the authorisation to place a vehicle type on the market 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.
5. *[deleted, redundant with paragraph 6]*
6. The declaration of conformity to type shall be established in accordance with:
 - (a) ~~for TSI conform vehicles~~, the verification procedures of the relevant TSIs; **or**
 - (b) ~~for non-TSI conform vehicles~~, **where TSIs do not apply**, the conformity assessment procedures as defined in modules B+D, ~~and 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 to place vehicle types on the market shall be registered in the European register of authorisations to place a vehicle types on the market referred to in Article 44.

CHAPTER VI
NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 23

Notification Notifying authorities

1. Member States shall ~~designate~~ appoint a notifying authority authorities that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified ~~conformity assessment~~ bodies, including compliance with the provisions of Articles ~~27 to 29~~ 31.
2. ~~Member States~~ These authorities shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks ~~under as set out in Articles 10(2) and 15(1) this Directive.~~ They shall also inform the Commission and the other Member States of the designated bodies referred to in Article 13(4).

Article 24

Notifying authorities

- ~~1. Member States shall designate a notifying authority authorities that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified conformity assessment bodies, including compliance with the provisions of Articles 27 to 29.~~
2. Member States may decide that the assessment and monitoring referred to in paragraph 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 paragraph 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, ~~and notification~~ **and the monitoring** of conformity assessment bodies ~~and the monitoring of notified bodies~~, and of any changes thereto.

The Commission shall make that information publicly available.

Article 27

~~Requirements relating to~~ 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. ~~These requirements are also applicable to bodies designated by Member States pursuant to Article 13(4).~~
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 .../... [establishing a European railway agency]. 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 assessment 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 ~~conformity assessment~~ notified bodies

1. Where a notified ~~conformity assessment~~ 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 undertaking 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 undertaking 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.⁴²

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** ~~They~~ shall notify the **notified bodies to the** Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

⁴² IT, ES and BE request the information on the accredited in house bodies to be made public.

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 ~~conformity assessment~~ 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 ~~conformity assessment~~ bodies

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

A notified ~~conformity assessment~~ 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 ~~conformity assessment~~ 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 ~~conformity assessment~~ 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 ~~conformity assessment~~ 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 ~~conformity assessment~~ body or the continued fulfilment by a notified ~~conformity assessment~~ 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 ~~conformity assessment~~ 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. ~~Conformity assessment~~ **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 ~~conformity assessment~~ 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 ~~conformity assessment~~ 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 ~~conformity assessment~~ 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 .../... [establishing a European railway agency]. 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 13(4), except that those obligations refer to national rules instead of TSIs.

CHAPTER VII REGISTERS⁴³

Article 42

Vehicle numbering system

1. The national safety authority competent for the territory where the any vehicle is first placed in service in the Union's rail system shall ensure that the vehicle shall carry is assigned a European vehicle number (EVN) at the latest by the date of commencement of operations. assigned by the national safety authority competent for the relevant territory before the first placing in service of the vehicle.
2. The railway undertaking registration holder operating a vehicle shall ensure the vehicle is marked with the assigned EVN.
3. The specifications of the EVN is specified shall be set out in Decision 2007/756/EC the measures referred to in Article 43(2).

⁴³ This Chapter is subject to further modifications, depending on the outcome of discussions on Chapter V. Alternative wordings proposed by ES, PL, IT are to be considered in this context. DK in general questions the need of having several registers, taking into account the costs and administrative burden involved.

4. A vehicle shall be assigned an EVN only once, unless otherwise specified in **the measures referred to in Article 43(2) Decision 2007/756/EC**.
5. Notwithstanding paragraph 1, 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 register of the vehicles **placed in service** in its territory. 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 the safety of the rail system within the Union] ; 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 of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area⁴⁴ , 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.

⁴⁴ OJ L 343 of 14.12.2012, p. 32.

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, ~~for the national vehicle registers~~ 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 ~~national safety authority of any~~ Member State where the vehicle has been ~~placed in service~~ **registered**.
4. As long as Member States' national vehicle registers are not linked, 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.
5. In the case of vehicles placed in service for the first time in a third country and ~~subsequently placed in service~~ 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 authorisation to place vehicle types on the market

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 3;
 - (c) it shall be linked with all national vehicle registers.

2. The Commission shall adopt common specifications relating to content, data format, functional and technical architecture, operating mode and rules for data input and consultation for the register of authorisations to place vehicle types on the market 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 ~~publish~~ **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 Commission Decision 2011/633/EU.
5. ~~Other registers, such as a register on accessibility, may also be associated to the register of infrastructure.~~
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 ~~for the register of infrastructure~~ by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).⁴⁵

⁴⁵ IT suggests the inclusion of a new Article 45a to set up a new register of safety critical components.

CHAPTER VIII
TRANSITIONAL AND FINAL PROVISIONS

Article 46

Exercise of delegation⁴⁶

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Articles 4(2) and 5(3) shall be conferred on the Commission for ~~an indeterminate~~ **a period of 5 years** ~~of time~~ from the date of entry into force of this Directive. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**⁴⁷
3. The delegation of power referred to in Articles 4(2) and 5(3) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

⁴⁶ Reservation on delegated acts: all delegations, except HU, PL, RO, SK.

⁴⁷ Commission reservation on the restriction of the delegation.

5. A delegated act adopted pursuant to Articles 4(2) and 5(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 47

Urgency procedure⁴⁸

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 46(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or the Council.

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.

⁴⁸ Reservation on this article: all delegations, except ES which proposes deletion.

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.**⁴⁹
4. ~~Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011 shall apply.~~

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. Every three years and for the first time three years after the publication of this Directive, the Commission shall report to the European Parliament and the Council on the progress made towards achieving interoperability of the rail system. That report shall also include 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. The Commission shall, if appropriate in the light of the above analysis, propose legislative measures to enhance the role of the Agency towards becoming a European authority responsible for issuing all vehicle authorisations.**

⁴⁹ Commission reservation on the opinion clause.

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 placing in service of vehicles

1. Member States may continue to apply the provisions set out in Chapter V of Directive 2008/57/EC until [two⁵⁰ years after the date of entry into force].
2. Authorisations for placing in service of vehicles which have been granted pursuant to paragraph 1, 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 in service on these additional networks is subject to the provisions of Article 21.

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.

⁵⁰ PL suggests to increase the transitional period to 5 years. FR: reservation subject to the outcome of discussions on Chapter V.

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 will serve shall be taken into account as basis for any Union measure when drawing up delegated or implementing acts adopted pursuant this Directive.**⁵¹

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 [two years⁵² after the date of entry into force] at the latest. They shall forthwith communicate to the Commission the text of those measures ~~and a correlation table between those measures and this Directive. The correlation tables are needed to enable all actors concerned to clearly identify the relevant provisions applicable at national level for the implementation of this Directive.~~⁵³

⁵¹ Commission reservation due to the link of this Article to Article 31 of the Safety proposal.

⁵² To be adapted on basis of Article 51.

⁵³ Commission reservation on deletion. A standard recital on explanatory documents appears in recital 52.

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.⁵⁴

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 one year 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 [two years⁵⁵ 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.

⁵⁴ CY: scrutiny reservation.

⁵⁵ To be adapted on basis of Article 51.

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 [two years⁵⁶ 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

⁵⁶ To be adapted on basis of Article 51.

Elements of Union rail system⁵⁷**1. Network**

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

- specially built high-speed lines equipped for speeds generally ~~equal to or~~ greater than 250 km/h,
- specially upgraded high-speed lines equipped for speeds of the order of 200 km/h,
- specially upgraded high-speed lines which have special features as a result of topographical, relief or town-planning constraints, 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,⁵⁸
- lines connecting the abovementioned elements.

⁵⁷ DE, FR, IT, HU oppose the deletion of the distinction between high-speed and conventional lines.

⁵⁸ IT proposes to delete the reference to intermodal terminals.

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, including:

- 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.⁵⁹

~~Each of the above categories may be subdivided into:~~

~~— vehicles for international use,~~

~~— vehicles for national use.~~

~~The TSIs shall specify the requirements to ensure the safe operation of these vehicles on different categories of line.~~

⁵⁹ ES proposes the deletion of special vehicles.

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 components** (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, ~~and the trackside of the~~ 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

To be checked with 2013/9 and 2010/57

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.

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

2. Requirements specific to each subsystem

2.1. Infrastructure

2.1.1. Safety

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

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

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

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

2.2. Energy

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.

2.5. 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.

2.7. 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.

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