III

(Preparatory acts)

COUNCIL

POSITION (EU) No 2/2016 OF THE COUNCIL AT FIRST READING

with a view to the adoption of 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)

Adopted by the Council on 10 December 2015

(2016/C 057/01)

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 Committee ([1]),

Having regard to the opinion of the Committee of the Regions ([2]),

Acting in accordance with the ordinary legislative procedure ([3]),

Whereas:

(1) Directive 2008/57/EC of the European Parliament and of the Council ([4]) 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 competent authorities to benefit to the full from the advantages deriving from the establishment of a single European railway area, it is appropriate, in particular, to improve the interlinkage and interoperability of the national rail networks as well as access to those networks and to implement any measures that may be necessary in the field of technical standardisation as provided for in Article 171 of the Treaty on the Functioning of the European Union (TFEU).

(3) The pursuit of interoperability within the Union 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 Union rail system.

(4) In order to contribute to the completion of the single European railway area, reduce the costs and duration of authorisation procedures and improve railway safety it is appropriate to streamline and harmonise authorisation procedures at Union level.

([1]) OJ C 327, 12.11.2013, p. 122.
([2]) OJ C 356, 5.12.2013, p. 92.
([3]) Position of the European Parliament of 26 February 2014 (not yet published in the Official Journal) and position of the Council at first reading of 10 December 2015.
([4]) 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 Community (OJ L 191, 18.7.2008, p. 1).

(5) Metros, trams and other light rail systems are subject in many Member States to local technical requirements. Such local public transport systems are usually not subject to licensing within the Union. Trams and light rail systems are furthermore often subject to road legislation because of shared infrastructure. For those reasons, such local systems do not need to be interoperable and should therefore be excluded from the scope of this Directive. This does not prevent Member States from applying the provisions of this Directive to local rail systems on a voluntary basis if they deem this appropriate.

(6) A tram-train is a public-transport concept which allows for a combined operation on both light-rail infrastructure and heavy-rail infrastructure. Member States should be permitted to exclude from the scope of the measures implementing this Directive those vehicles primarily used on light-rail infrastructure but equipped with some heavy-rail components necessary to enable transit to be effected on a confined and limited section of heavy-rail infrastructure for connectivity purposes only. When tram-trains use railway infrastructure, compliance with all essential requirements should be ensured, as well as compliance with the expected safety level on the relevant lines. For cross-border cases, competent authorities should cooperate.

(7) 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 Union rail system.

(8) The railway regulatory framework at Union and Member State level should set clear roles and responsibilities for ensuring compliance with the safety, health and consumer protection rules applying to the railway networks. This Directive should not lead to a reduced level of safety or increase costs in the Union rail system. To that end, the European Union Agency for Railways ('the Agency') established by Regulation (EU) …/… of the European Parliament and of the Council ([1]) (*) and the national safety authorities should take full responsibility for the authorisations they issue.

(9) Major differences exist 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 lay down specific dimensions and devices as well as special characteristics. That situation may prevent trains from running without hindrance throughout the Union.

(10) In order to enhance their competitiveness at world level, the Union railway industries require an open and competitive market.

(11) It is therefore appropriate to define essential requirements relating to rail interoperability for the whole of the Union which should apply to its rail system.

(12) The development of technical specifications for interoperability ('TSIs') has shown the need to clarify the relationship between the essential requirements and 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 ([2]). 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.

([1]) Regulation (EU) …/… of the European Parliament and of the Council of … on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (OJ L …).

(*) Regulation in document 2013/0014 (COD) (OJ C 56, 12.2.2016, p. 1).

([2]) 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 Council (OJ L 316, 14.11.2012, p. 12).

(13) In order to genuinely increase the competitiveness of the Union railway sector without distorting competition between key actors of the Union rail system, the TSIs and the recommendations of the Agency related to these TSIs should be drafted by respecting the principles of openness, consensus and transparency as defined in Annex II to Regulation (EU) No 1025/2012.

(14) The quality of rail services in the Union depends, inter alia, on excellent compatibility between the characteristics of the network (in the broadest sense, i.e. the fixed parts of all the subsystems concerned) and those of the vehicles (including the on-board components of all the subsystems concerned). Performance levels, safety, quality of service and cost depend upon that compatibility.

(15) TSIs have a direct or potential impact on the staff involved in the operation and maintenance of subsystems. When preparing TSIs, therefore, the Agency should consult social partners, where appropriate.

(16) A TSI should set out all the conditions with which an interoperability constituent is to 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 should have the corresponding certificate, comprising either the assessment of the conformity of an interoperability constituent, considered in isolation, to the technical specifications to be met, or the assessment of the suitability for use of an interoperability constituent, considered within its railway environment, in relation to the technical specifications.

(17) In the development of new TSIs, the aim should always be to ensure compatibility with the existing subsystems. 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, it should be possible for TSIs to establish the framework necessary to decide whether the existing subsystem needs a new decision or authorisation for placing in service or placing on the market, and the corresponding deadlines.

(18) If certain technical aspects corresponding to the essential requirements cannot be explicitly covered in a TSI, those aspects which still need to be addressed should be identified in an annex to that TSI as open points. For those open points, as well as for specific cases, and with the aim of compliance with the existing systems, national rules that may be adopted in a Member State by any competent national, regional or local authority should apply. To avoid redundant verifications and unnecessary administrative burdens, national rules should be classified to establish the equivalence between national rules of different Member States covering the same topics.

(19) 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 a case, the bodies responsible for the conformity assessment and verification procedures should be the designated bodies referred to in this Directive.

(20) This Directive should apply to the entire Union rail system and the scope of the TSIs should be extended to cover the vehicles and networks not included in the trans-European rail system. Therefore, Annex I to Directive 2008/57/EC should be simplified.

(21) The functional and technical specifications to be met by subsystems and their interfaces may vary according to the use of the subsystems concerned, for example according to the categories of lines and vehicles, in particular for ensuring coherence between high-speed and conventional rail systems.

(22) In order to ensure the progressive implementation of rail interoperability within the whole of the Union and to 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 include proposals for the staged completion of the target system. However, in order to keep the railway sector competitive and to prevent undue costs, the entry into force of new or amended TSIs should not lead to an immediate adaptation of vehicles and infrastructure to the new specifications.

(23) TSIs should indicate when the upgrade and renewal of infrastructure and vehicles requires a new authorisation. In all cases for the upgrade and renewal of infrastructure, the applicant should submit, through the one-stop-shop referred to in Regulation (EU) …/… (*), a file to the national safety authority so that it can decide whether a new authorisation is needed on the basis of the criteria set out in this Directive. In the case of the upgrade and renewal of

(*) Regulation in document 2013/0014 (COD).

vehicles which have an authorisation to place on the market, the applicant should be able to decide whether it needs to seek a new authorisation from the national safety authority or the Agency on the basis of the criteria set out in this Directive.

(24) In view of the gradual approach to eliminating obstacles to the interoperability of the Union 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.

(25) In order to eliminate the obstacles to interoperability, and as a consequence of extending the scope of the TSIs to the whole of the Union rail system, the volume of national rules should progressively be reduced. National rules strictly relating to existing systems should be differentiated from those needed to cover open points in TSIs. Rules of the latter type should be progressively removed as a result of closure of open points in the TSIs.

(26) National rules should be drafted and published in such a way that any potential user of a national network can understand them. Such rules often refer to other documents such as national standards, European standards, international standards or other technical specifications which might be partly or fully protected by intellectual property rights. Therefore, the obligation of publication should not apply to documents referred to directly or indirectly in the national rule.

(27) The adoption of a gradual approach satisfies the objective of interoperability of the Union rail system, which is characterised by old national infrastructure and vehicles requiring heavy investment for adaptation or renewal, and particular care should be taken to maintain the competitiveness of rail vis-à-vis other modes of transport.

(28) In view of the extent and complexity of the Union 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 those subsystems, the essential requirements need to be specified and the technical specifications determined, particularly in respect of constituents and interfaces, in order to meet those essential requirements. The same system is broken down into fixed and mobile elements comprising, on the one hand, the network, which is 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 that 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). Although the system is divided into several elements, the Agency should retain an overview of the system, in order to promote interoperability and safety.

(29) 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 state Parties to take appropriate measures in order to ensure access for persons with disabilities on an equal basis with others, including by developing, promulgating and monitoring the implementation of minimum standards and guidelines for accessibility. Accessibility for persons with disabilities and persons with reduced mobility is therefore an essential requirement for the interoperability of the Union rail system.

(30) No person is to be discriminated against, either directly or indirectly, on the basis of a disability. In order to ensure that all Union citizens can enjoy the benefits resulting from the establishment of single European railway area, Member States should promote a railway system accessible to all.

(31) Implementation of the provisions on the interoperability of the Union rail system should not give rise to unjustified costs nor undermine the preservation of the interoperability of existing rail networks.

(32) TSIs also have an impact on the conditions of use of rail transport by users, and it is therefore necessary to consult those users on aspects concerning them, including organisations of persons with disabilities, where appropriate.

(33) Each Member State concerned should be allowed not to apply certain TSIs in a limited number of duly substantiated situations. Those situations and the procedures to be followed in cases of non-application of a given TSI should be clearly defined.

(34) The drawing-up of TSIs and their application to the Union rail system should not impede technological innovation, which should be directed towards improving economic performance.

(35) In order to comply with the appropriate provisions on procurement procedures in the rail sector and, in particular, those laid down in Directive 2014/25/EU of the European Parliament and of the Council ([1]), contracting entities are to include technical specifications in the general documents or in the terms and conditions for each contract. To that end, it is necessary to draw up a set of rules to serve as references for those technical specifications.

(36) 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 Union policy would be in the Union's interest. The European standardisation organisations should therefore continue their cooperation with international standardisation bodies.

(37) The contracting entity ordering the design, construction, renewal or upgrading of a subsystem 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. Contracting entities should define the requirements needed to complete European specifications or other standards. Those specifications should meet the essential requirements that have been harmonised at Union level and which the Union rail system is to satisfy.

(38) The procedures governing the assessment of conformity or of suitability of use of constituents should be based on the use of the 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 this Directive. 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.

(39) Conformity of constituents is linked mainly to their area of use in order to guarantee the interoperability of the system and not only their free movement in 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 this Directive. On the basis of the assessment of conformity and/or suitability for use, the manufacturer's declaration of conformity should be sufficient.

(40) Manufacturers are nonetheless obliged to affix the 'CE' marking to certain components in order to certify their compliance with other Union law relating to them.

(41) 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 those constituents can be integrated into a subsystem, even if they do not strictly conform to that TSI.

(42) The subsystems constituting the Union rail system should be subject to a verification procedure. That verification should enable the entities responsible for their placing in service or placing on the market to be certain that, at the design, construction and placing into service stages, the result is in line with the regulations and technical and operational provisions in force. It should also result in manufacturers being able to count upon equality of treatment in all Member States.

(43) After a subsystem is placed in service or on the market, care should be taken to ensure that it is operated and maintained in accordance with the essential requirements relating to it. In accordance with Directive (EU) …/… of the European Parliament and of the Council ([2]) (*), responsibility for meeting those requirements lies, for their respective subsystems, with the infrastructure manager, the railway undertaking or the entity in charge of maintenance, each for their own part.

(44) When during operation it appears that a vehicle or a vehicle type does not meet one of the applicable essential requirements, the necessary corrective measures should be taken by the railway undertakings concerned in order to bring the vehicle(s) into conformity. In addition, if that non-conformity leads to a serious safety risk, it should be possible for the national safety authorities responsible for the supervision of the circulation of the vehicle to take the necessary temporary safety measures, including immediately restricting or suspending the relevant operation. If the corrective measures are insufficient and the serious safety risk generated by the non-conformity remains, national safety authorities or the Agency should be allowed to revoke or amend the authorisation. A serious safety risk in this context should be understood as being serious non-compliance with legal obligations or safety requirements that

([1]) Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).
([2]) Directive (EU) …/… of the European Parliament and of the Council of … on railway safety (OJ L …).
(*) Directive in document 2013/0016 (COD) (see page 64 of this Official Journal).

may in itself or in a series of consequential events cause an accident or a serious accident. The process of revocation should be supported by an appropriate exchange of information between the Agency and the national safety authorities, including the use of registers.

(45) The respective roles and responsibilities of all actors involved should be clarified in relation to the procedures for the placing on the market and use of vehicles, and for the placing in service of fixed installations.

(46) The Agency and national safety authorities should cooperate and share competencies as appropriate for the issuing of authorisations with due regard to safety. To that end, cooperation agreements between the Agency and the national safety authorities should be established.

(47) In order to ensure that European Rail Traffic Management System (ERTMS) equipment complies with the relevant specifications in force and to prevent additional requirements in relation to the ERTMS from undermining its interoperability, the Agency should act as the ERTMS system authority. To that end, the Agency should be in charge of assessing the technical solutions envisaged before any call for tenders relating to ERTMS trackside equipment is launched or published, in order to check whether those technical solutions are compliant with the relevant TSIs and are fully interoperable.

Any overlap between this assessment by the Agency and the tasks of the notified bodies in the verification procedure should be avoided. The applicant should therefore inform the Agency if the verification procedure carried out by the notified body has already started or if any conformity certificate is already available. The applicant should be able to choose to request such an assessment from the Agency either for each individual ERTMS project or for a combination of projects, a line, a group of lines or a network.

(48) The entry into force of this Directive should not delay the deployment of ERTMS projects for which the tendering or contracting process has been completed.

(49) In order to facilitate the placing on the market of vehicles and to reduce administrative burdens, the notion of a vehicle authorisation for placing on the market that is valid throughout the Union should be introduced. While authorisations for placing on the market allow for commercial transactions of vehicles anywhere on the Union market, a vehicle may only be used within the area of use covered by its authorisation. In that context, any extension of the area of use should be subject to an updated authorisation for the vehicle. It is necessary that vehicles already authorised under earlier Directives also receive an authorisation for placing on the market if they are intended to be used on networks not covered by their authorisation.

(50) When the area of use is limited to a network or networks within one Member State, the applicant should be able to choose whether it submits its application for vehicle authorisation, through the one-stop shop referred to in Regulation (EU) …/… (*), to the national safety authority of that Member State or to the Agency. The choice made by the applicant should be binding until the application is completed or terminated.

(51) An appropriate procedure should be available to enable the applicant to appeal against a decision of, or a failure to act by, the Agency or the national safety authorities. In addition, clear procedural and dispute resolution provisions should be established to address situations where the Agency and the national safety authorities disagree on assessments made in relation to the issuing of vehicle authorisations.

(52) Specific measures, including cooperation agreements, should take account of the specific geographical and historical situation of certain Member States, while ensuring the proper functioning of the internal market.

(53) Where operation is limited to networks requiring specific expertise for geographical or historical reasons, and where such networks are isolated from the rest of the Union rail system, it should be possible for the applicant to fulfil the necessary formalities locally by interacting with the relevant national safety authorities. To that end, for the purpose of reducing administrative burdens and costs, it should be possible for the cooperation agreements that are to be concluded between the Agency and the relevant national safety authorities to provide for the appropriate allocation of tasks, without prejudice to the assumption by the Agency of final responsibility for issuing the authorisation.

(*) Regulation in document 2013/0014 (COD).

(54) The railway networks located in the Baltic States (Estonia, Latvia and Lithuania) have 1 520 mm track gauge, which is the same as in neighbouring third countries, but is different from that of the main rail network within the Union. These Baltic networks have inherited common technical and operational requirements, which provide de facto interoperability between them, and, in this respect, the vehicle authorisation issued in one of these Member States might be valid for the rest of these networks. To facilitate the efficient and proportionate allocation of resources for vehicle authorisation for placing on the market or a type authorisation of vehicles, and to reduce the financial and administrative burden for the applicant in such cases, the specific cooperation arrangements between the Agency and relevant national safety authorities should include, where necessary, the possibility of contracting tasks to these national safety authorities.

(55) Member States with an important share of rail traffic with third countries having the same railway gauge which is different from that of the main rail network within the Union should be able to maintain different vehicle authorisation procedures for freight wagons and passenger coaches which are in shared use with those third countries.

(56) For traceability and safety reasons, Member States' competent authorities should assign a European vehicle number to a vehicle when requested to do so by the vehicle's keeper. The vehicle information should then be entered in a vehicle register. The vehicle registers should be open to consultation by all Member States and by certain economic players within the Union. The vehicle registers should be consistent as regards the data format. They should therefore be covered by common operational and technical specifications. In order to reduce administrative burdens and undue costs, the Commission should adopt a specification for a European vehicle register that would incorporate national vehicle registers, with a view to creating a common tool, while, at the same time, allowing for the maintenance of additional functions relevant to Member States' specific needs.

(57) To ensure traceability of vehicles and their history, the references of the vehicle authorisations for placing on the market should be recorded together with other vehicle data.

(58) Procedures should be established for checking the compatibility between vehicles and the routes on which they are to be deployed after delivery of the vehicle authorisation for placing on the market and before the use by a railway undertaking of a vehicle in its area of use as specified in the vehicle authorisation for placing on the market.

(59) The notified bodies responsible for examining the procedures for assessment of conformity and suitability for 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.

(60) Transparent accreditation, as provided for in Regulation (EC) No 765/2008 of the European Parliament and of the Council ([1]), ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union to be the preferred means of demonstrating the technical competence of notified bodies and, *mutatis mutandis*, of the bodies designated to check compliance with national rules. However, national authorities should be able to 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.

(61) 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 a 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 relating to those requirements.

(62) Measures adopted pursuant to this Directive should be complemented by initiatives aimed at providing financial support to innovative and interoperable technologies in the Union rail sector.

([1]) 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 339/93 (OJ L 218, 13.8.2008, p. 30).

(63) In order to supplement non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the specific objectives of each TSI. 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 to the Council.

(64) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission relating to: TSIs and amendments to TSIs, including those amendments needed to remedy deficiencies in TSIs; the template of the 'EC' declaration of conformity or suitability for use of interoperability constituents and the accompanying documents; the information to be included in the file which should accompany the request for non-application of one or more TSIs or parts of them, the format and the transmission methods of that file and, where appropriate, the decision on non-application of TSIs; the classification of the notified national rules in different groups with the aim of facilitating the compatibility checks between fixed and mobile equipment; the details of the 'EC' verification procedure and the verification procedure in the case of national rules and the templates for the 'EC' declaration of verification and the templates for documents of the technical file that should accompany the declaration of verification as well as the templates for certificates of verification; the practical arrangements for the purposes of vehicle authorisation; the model of the declaration of conformity to type and, where appropriate, ad hoc modules for conformity assessment; the national vehicle registers, the European Vehicle register and the register of authorisation to place types on the market; and 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 ([1]).

(65) The TSIs should be revised at regular intervals. When deficiencies are discovered in the TSIs, 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.

(66) Implementing acts establishing new TSIs or amending TSIs should reflect the specific objectives set out by the Commission by way of delegated acts.

(67) Certain organisational steps are necessary in order to prepare the Agency for its enhanced role under this Directive. Accordingly, an appropriate transitional period should be provided for. During that period, the Commission should review the progress made by the Agency in preparing for its enhanced role. Thereafter, the Commission should report periodically on the progress made in implementing this Directive. In particular, the report should evaluate the vehicle authorisation process, the cases where the TSIs are not applied and the use of registers. The Commission should also report on actions taken regarding the identification and traceability of safety-critical components.

(68) It is necessary to allow Member States, national safety authorities and stakeholders sufficient time in which to prepare to implement this Directive.

(69) 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 but can rather, by reason of its scale and effects, 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.

(70) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to Directive 2008/57/EC. The obligation to transpose the provisions which are unchanged arises under Directive 2008/57/EC.

(71) 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 Part B of Annex V,

([1]) 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 powers (OJ L 55, 28.2.2011, p. 13).

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 rail system in a manner compatible with Directive (EU)…/… (*). 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 and the progressive achievement of the internal market. Those conditions concern the design, construction, placing in service, upgrading, renewal, operation and maintenance of the parts of that system as well as the professional qualifications of, and health and safety conditions applying to, 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, and the conditions of overall compatibility of the Union rail system required in order to achieve its interoperability.

3. This Directive shall not apply to:

(a) metros;

(b) trams and light rail vehicles, and infrastructure used exclusively by those vehicles;

(c) networks that are functionally separate from the rest of the Union rail system and intended only for the operation of local, urban or suburban passenger services, as well as undertakings operating solely on those networks.

4. Member States may exclude from the scope of the measures implementing this Directive:

(a) privately owned railway infrastructure, including sidings, used by its owner or by an operator for the purpose of their respective freight activities or for the transport of persons for non-commercial purposes, and vehicles used exclusively on such infrastructure;

(b) infrastructure and vehicles reserved for a strictly local, historical or touristic use;

(c) light rail infrastructure occasionally used by heavy rail vehicles under the operational conditions of the light rail system, where it is necessary for the purposes of connectivity of those vehicles only; and

(d) vehicles primarily used on light rail infrastructure but equipped with some heavy rail components necessary to enable transit to be effected on a confined and limited section of heavy rail infrastructure for connectivity purposes only.

5. In the case of tram-trains operating in the Union rail system, where there are no TSIs that apply to those tram-trains, the following shall apply:

(a) Member States concerned shall ensure that national rules or other relevant accessible measures are adopted in order to ensure that such tram-trains meet the relevant essential requirements;

(b) Member States may adopt national rules in order to specify the authorisation procedure applicable to such tram-trains. The authority issuing the vehicle authorisation shall consult the relevant national safety authority in order to ensure that mixed operation of tram-trains and heavy rail trains meet all essential requirements as well as relevant common safety targets ('CSTs');

(*) Directive in document 2013/0016 (COD).

(c) by way of derogation from Article 21, in the case of cross-border operation, the relevant competent authorities shall cooperate with a view to issuing the vehicle authorisations.

This paragraph does not apply to vehicles excluded from the scope of this Directive in accordance with paragraphs 3 and 4.

Article 2

Definitions

For the purposes of this Directive:

(1) 'Union rail system' means the elements listed in Annex I;

(2) 'interoperability' means the ability of a rail system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance;

(3) 'vehicle' means a railway vehicle suitable for circulation on wheels on railway lines, with or without traction. A vehicle is composed of one or more structural and functional subsystems;

(4) 'network' means the lines, stations, terminals, and all kinds of fixed equipment needed to ensure safe and continuous operation of the Union rail system;

(5) 'subsystems' means the structural or functional parts of the Union rail system, as set out in Annex II;

(6) 'mobile subsystem' means the rolling stock subsystem and the on-board control-command and signalling subsystem;

(7) '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;

(8) 'product' means a product obtained through a manufacturing process, including interoperability constituents and subsystems;

(9) 'essential requirements' means all the conditions set out in Annex III which must be met by the Union rail system, the subsystems, and the interoperability constituents, including interfaces;

(10) 'European specification' means a specification which falls into one of the following categories:

— a common technical specification as defined in Annex VIII of Directive 2014/25/EU,

— a European technical approval as referred to in Article 60 of Directive 2014/25/EU, or

— a European standard as defined in point (b) of Article 2(1) of Regulation (EU) No 1025/2012;

(11) '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 Union rail system;

(12) 'basic parameter' means any regulatory, technical or operational condition which is critical to interoperability and is specified in the relevant TSIs;

(13) 'specific case' means any part of the rail system which needs special provisions in the TSIs, either temporary or permanent, 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;

(14) 'upgrading' means any major 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 that technical file exists, and which improves the overall performance of the subsystem;

(15) 'renewal' means any major substitution work on a subsystem or part of it which does not change the overall performance of the subsystem;

(16) 'existing rail system' means the infrastructure composed of lines and fixed installations of the existing rail network as well as the vehicles of all categories and origins travelling on that infrastructure;

(17) '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;

(18) 'tram-train' means a vehicle designed for combined use on both a light-rail infrastructure and a heavy-rail infrastructure;

(19) 'placing in service' means all the operations by which a subsystem is put into its operational service;

(20) 'contracting entity' means a public or private entity which orders the design and/or construction or the renewal or upgrading of a subsystem;

(21) 'keeper' means the natural or legal person 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 a vehicle register referred to in Article 47;

(22) 'applicant' means a natural or legal person requesting an authorisation, be it a railway undertaking, an infrastructure manager or any other person or legal entity, such as a manufacturer, an owner or a keeper; for the purpose of Article 15, the 'applicant' means a contracting entity or a manufacturer, or its authorised representatives; for the purpose of Article 19, the 'applicant' means a natural or legal person requesting the Agency's decision for the approval of the technical solutions envisaged for the ERTMS trackside equipment projects;

(23) 'project at an advanced stage of development' means any project the planning or construction stage of which has reached a point where a change in the technical specifications may compromise the viability of the project as planned;

(24) 'harmonised standard' means a European standard as defined in point (c) of Article 2(1) of Regulation (EU) No 1025/2012;

(25) 'national safety authority' means a safety authority as defined in point (7) of Article 3 of Directive (EU) …/… (*);

(26) '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;

(27) 'series' means a number of identical vehicles of a design type;

(28) 'entity in charge of maintenance' ('ECM') means an entity in charge of maintenance as defined in point (20) of Article 3 of Directive (EU)…/… (*);

(29) 'light rail' means an urban and/or suburban rail transport system with a crashworthiness of C-III or C-IV (in accordance with EN 15227:2011) and a maximum strength of vehicle of 800 kN (longitudinal compressive force in coupling area); 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;

(30) 'national rules' means all binding rules adopted in a Member State, irrespective of the body issuing them, which contain railway safety or technical requirements, other than those laid down by Union or international rules which are applicable within that Member State to railway undertakings, infrastructure managers or third parties;

(31) '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;

(32) 'area of use of a vehicle' means a network or networks within a Member State or a group of Member States in which a vehicle is intended to be used;

(33) 'acceptable means of compliance' means non-binding opinions issued by the Agency to define ways of establishing compliance with the essential requirements;

(34) 'acceptable national means of compliance' means non-binding opinions issued by Member States to define ways of establishing compliance with national rules;

(35) '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;

(*) Directive in document 2013/0016 (COD).

(36) 'manufacturer' means any natural or legal person who manufactures a product in the form of interoperability constituents, subsystems or vehicles, or has it designed or manufactured, and markets it under his name or trademark;

(37) '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 behalf of that manufacturer or contracting entity in relation to specified tasks;

(38) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a product, subsystem, process or service;

(39) 'accreditation' means accreditation as defined in point (10) of Article 2 of Regulation (EC) No 765/2008;

(40) 'national accreditation body' means a national accreditation body as defined in point (11) of Article 2 of Regulation (EC) No 765/2008;

(41) 'conformity assessment' means the process demonstrating whether specified requirements relating to a product, process, service, subsystem, person or body have been fulfilled;

(42) 'conformity assessment body' means a body that has been notified or designated to be responsible for conformity assessment activities, including calibration, testing, certification and inspection. A conformity assessment body is classified as a 'notified body' following notification by a Member State. A conformity assessment body is classified as a 'designated body' following designation by a Member State;

(43) person with disabilities 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 the full and effective use by that person of transport on an equal basis with other passengers or whose mobility when using transport is reduced due to age;

(44) 'infrastructure manager' means an infrastructure manager as defined in point (2) of Article 3 of Directive 2012/34/EU of the European Parliament and of the Council ([1]);

(45) 'railway undertaking' means a railway undertaking as defined in point (1) of Article 3 of Directive 2012/34/EU, 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 is to ensure traction; this also includes undertakings which provide traction only.

Article 3

Essential requirements

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

2. The technical specifications referred to in Article 60 of Directive 2014/25/EU, 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 TSIs

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. Fixed subsystems shall comply with the TSIs and national rules in force at the time of the request for authorisation of placing in service in accordance with this Directive and without prejudice to point (f) of paragraph 3.

([1]) Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area (OJ L 343, 14.12.2012, p. 32).

Vehicles shall comply with TSIs and national rules in force at the time of the request for authorisation of placing on the market in accordance with this Directive and without prejudice to point (f) of paragraph 3.

The conformity and compliance of fixed subsystems and vehicles shall be permanently maintained while they are in use.

3. To the extent necessary to achieve the objectives of this Directive referred to 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 necessary, 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 Union 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. Those procedures shall be based on the modules defined in Commission Decision 2010/713/EU ([1]);

(f) indicate the strategy for the application of the TSI. In particular, it is necessary to specify the stages to be completed, taking into account the estimated costs and benefits and the expected repercussions for the stakeholders affected in order to make a gradual transition from the existing situation to the final situation in which compliance with the TSI shall be the norm. Where coordinated implementation of the TSI is necessary, such as along a corridor or between infrastructure managers and railway undertakings, the strategy may include proposals for staged completion;

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

(h) indicate the provisions applicable to the existing subsystems and vehicles, in particular in the event of upgrading and renewal and, in such cases, the modification work which requires an application for a new authorisation;

(i) indicate the parameters of the vehicles and fixed subsystems to be checked by the railway undertaking and the procedures to be applied to check those parameters after the delivery of the vehicle authorisation for placing on the market and before the first use of the vehicle to ensure compatibility between vehicles and the routes on which they are to be operated.

4. Each TSI shall be drawn up on the basis of an examination of an existing subsystem and indicate a target subsystem that may be obtained gradually within a reasonable timescale. Accordingly, the adoption of the TSIs and compliance with them shall gradually facilitate achievement of the interoperability of the Union rail system.

5. TSIs shall retain, in an appropriate manner, the compatibility of the existing rail system of each Member State. For that purpose, specific cases for each TSI may be provided for, 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 points (c) to (g) of paragraph 3.

([1]) 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 Council (OJ L 319, 4.12.2010, p. 1).

6. If certain technical aspects corresponding to the essential requirements cannot be explicitly covered in a TSI, they shall be clearly identified in an annex to the TSI as open points.

7. TSIs shall not prevent the Member States from deciding on the use of infrastructures for the movement of vehicles not covered by the TSIs.

8. TSIs may make an explicit, clearly identified reference to European or international standards or specifications or technical documents published by the Agency where this is strictly necessary in order to achieve the objectives of this Directive. In such a 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. In order to set out the specific objectives of each TSI, the Commission shall be empowered to adopt delegated acts in accordance with Article 50 concerning, in particular and where appropriate:

(a) the geographical and technical scope of the TSIs;

(b) the applicable essential requirements;

(c) the list of regulatory, technical and operational conditions to be harmonised at the level of subsystems and at the level of the interfaces between subsystems and their expected level of harmonisation;

(d) the railway-specific procedures for assessment of conformity and suitability for use of the interoperability constituents;

(e) the railway-specific procedures to assess the 'EC' verification of the subsystems;

(f) the categories of staff involved in the operation and maintenance of the subsystems concerned and the general objectives for setting the minimum requirements for professional qualifications and health and safety conditions for the staff concerned;

(g) any other necessary element to be taken into account to ensure interoperability pursuant to Article 1(1) and (2) within the Union rail system, such as alignment of TSI with European and international standards or specifications.

When adopting those delegated acts, the Commission shall justify the need for a new or substantially amended TSI, including its impact on existing rules and technical specifications.

2. In order to ensure uniform implementation of the delegated acts referred to in paragraph 1, the Commission shall request that the Agency draft TSIs and amendments thereto and 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;

(b) the Agency shall draw up the draft TSI on the basis of the basic parameters referred to in point (a). 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.

3. When drafting or reviewing each TSI, including the basic parameters, the Agency 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. That assessment shall indicate the likely impact on all the operators and economic actors involved and shall take due account of the requirements of Directive (EU)…/… (*). Member States shall participate in this assessment by providing, where appropriate, the requisite data.

4. The Agency shall draft the TSIs and amendments thereto in accordance with Articles 5 and 19 of Regulation (EU) …/… (**) while fulfilling the criteria of openness, consensus and transparency as defined in Annex II to Regulation (EU) No 1025/2012.

5. The committee referred to in Article 51 ('the committee') shall be kept periodically informed of the preparatory work on the TSIs. During that work, to comply with the delegated acts referred to in paragraph 1 of this Article, the Commission may formulate any terms of reference or useful recommendations concerning the design of the TSIs and a cost-benefit analysis. In particular, the Commission may require that alternative solutions be examined and that the assessment of the cost and benefits of those alternative solutions be set out in the report annexed to the draft TSI.

6. Where different subsystems have to be placed in service simultaneously for reasons of technical compatibility, the dates of application of the relevant TSIs shall be the same.

7. When drafting, adopting or reviewing the TSIs, the Agency 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 that consultation.

8. In accordance with Article 7 of Regulation (EU) …/… (**), the Commission, with the assistance of the committee, shall draw up and periodically update the list of passengers' associations and bodies to be consulted. That list may be re-examined and updated at the request of a Member State or upon the initiative of the Commission.

9. When drafting or reviewing the TSIs, the Agency shall take account of the opinion of the social partners as regards the professional qualifications and health and safety conditions at work referred to in point (g) of Article 4(3). To that 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 within the Sectoral Dialogue Committee set up in accordance with Commission Decision 98/500/EC ([1]). The social partners shall issue their opinion within three months of the consultation.

10. When the 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.

11. The Commission shall establish, by means of implementing acts, TSIs to implement the specific objectives set out in the delegated acts referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(3). They shall include all the elements listed in Article 4(3) and meet all the requirements set out in Article 4(4) to 4(6) and (8).

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(11). If appropriate, the Commission shall apply this procedure without delay. Such deficiencies shall include cases which could result in unsafe operations within a Member State.

2. Pending the review of a TSI, the Commission may request an opinion from the Agency. The Commission shall analyse the Agency's opinion and inform the committee of its conclusions.

(*) Directive in document 2013/0016 (COD).
(**) Regulation in document 2013/0014 (COD).
([1]) 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 level (OJ L 225, 12.8.1998, p. 27).

3. At the request of the Commission, the Agency's opinion referred to in paragraph 2 shall constitute acceptable means of compliance and may therefore be used for the assessment of projects, pending the adoption of a revised TSI.

4. Any member of the network of representative bodies referred to in Article 38(4) of Regulation (EU) …/… (*) may make the Commission aware of possible TSI deficiencies.

Article 7

Non-application of TSIs

1. Member States may allow the applicant not to apply one or more TSIs or parts of them in the following cases:

(a) for a proposed new subsystem or part of it, for the renewal or upgrading of an existing subsystem or part of it, or for any element referred to in Article 1(1) which is at an advanced stage of development or which is the subject of a contract in the course of performance on the date of application of the TSI(s) concerned;

(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 which case the non-application of the TSIs shall be limited to the period before the restoration of the network;

(c) for any proposed renewal, extension or upgrading of an existing subsystem or part of it, when the application of the TSI (s) concerned would compromise the economic viability of the project and/or the compatibility of the rail system in the Member State concerned, for example in relation to the loading gauge, track gauge, space between tracks or electrification voltage;

(d) for vehicles arriving 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 the Member State concerned 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 point (a) of paragraph 1, the Member State concerned 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.

3. In the cases referred to in points (a) and (b) of paragraph 1, the Member State concerned shall communicate to the Commission its decision not to apply one or more TSIs or parts of them.

4. In the cases referred to in points (a), (c), (d) and (e) of paragraph 1 of this Article, the Member State concerned shall submit to the Commission the request for non-application of the TSIs or parts of them, accompanied by a file containing the justification for the request, and specifying the alternative provisions that that Member State intends to apply instead of the TSIs. In the case referred to in point (e) of paragraph 1 of this Article, the Commission shall analyse the request and decide whether or not to accept it on the basis of the completeness and coherence of the information contained in the file. In the cases referred to in points (c) and (d) of paragraph 1 of this Article, the Commission shall adopt its decision by means of implementing acts on the basis of such analysis. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(3).

In the cases referred to in the third subparagraph of Article 21(6), the applicant shall submit the file to the Agency. The Agency shall consult the relevant safety authorities and give its final opinion to the Commission.

5. The Commission shall, by means of an implementing act, establish the information to be included in the file referred to in paragraph 4, the required format of that file and the method to be used for its transmission. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 51(3).

6. Pending the decision of the Commission, the Member State may apply the alternative provisions referred to in paragraph 4 without delay.

7. The Commission shall give its decision within four months of 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.

(*) Regulation in document 2013/0014 (COD).

8. Member States shall be informed of the results of the analyses and of the outcome of the procedure set out in paragraph 4.

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 are:

(a) placed on the market only if they enable interoperability to be achieved within the Union rail system while at the same time meeting the essential requirements;

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

This paragraph shall not prevent the placing on the market of those constituents for other applications.

2. Member States shall 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 Union rail system where these constituents comply with this Directive. In particular, they shall not require checks which have already been carried out as part of the procedure for 'EC' declaration of conformity or suitability for use as provided for in Article 10.

Article 9

Conformity or suitability for use

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

2. Where the TSI so requires, the 'EC' declaration shall be accompanied by:

(a) a certificate, issued by a notified body or bodies, of the intrinsic conformity of an interoperability constituent considered in isolation, to the technical specifications to be met;

(b) a certificate, issued by a notified body or bodies, of the suitability for use of an interoperability constituent considered within its railway environment, particularly in the case of functional requirements concerned.

3. The 'EC' declaration shall be dated and signed by the manufacturer or its authorised representative.

4. The Commission shall establish, by means of implementing acts, the template of the 'EC' declaration of conformity or suitability for use of interoperability constituents and the list of accompanying documents. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(3).

5. Spare parts for subsystems that are already placed in service when the corresponding TSI enters into force may be installed in those subsystems without being subject to paragraph 1.

6. TSIs may provide for a period of transition for rail products identified by those TSIs as interoperability constituents which have already been placed on the market when the TSIs enter into force. Such constituents shall comply with 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 shall apply the provisions laid down by the relevant TSIs.

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

3. Where interoperability constituents are the subject of other legal acts of the Union covering other matters, the 'EC' declaration of conformity or suitability for use shall state that the interoperability constituents also meet the requirements of those other legal acts.

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. For the purposes of this Directive, 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.

5. If a Member State finds that the 'EC' declaration has been drawn up improperly, it shall ensure that the interoperability constituent is not placed on the market. In such a case, the manufacturer or his authorised representative shall be required to restore the interoperability constituent to a state of conformity under the conditions laid down by that Member State.

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, when used as intended, unlikely to meet the essential requirements, that Member State 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 reasons for its decision, stating in particular whether the failure to conform is due to:

(a) failure to meet the essential requirements;

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

(c) inadequacy of European specifications.

2. The Agency, on a mandate from the Commission, shall start the consultation process with the parties concerned without delay and in any case within 20 days of the date of receipt of that mandate. Where, following that consultation, the Agency establishes that the measure is unjustified, it shall forthwith inform the Commission, the Member State that has taken the initiative as well as other Member States, and the manufacturer or his authorised representative. Where the Agency establishes that the measure is justified, it shall forthwith inform the Member States.

3. Where the decision referred to in paragraph 1 results from an inadequacy of European specifications, the Member States, the Commission or the Agency, as appropriate, shall apply one or more of the following measures:

(a) partial or total withdrawal of the specification concerned from the publications containing them;

(b) if the relevant specification is a harmonised standard, restriction or withdrawal of that standard in accordance with Article 11 of Regulation (EU) No 1025/2012;

(c) review of the TSI in accordance with Article 6.

4. Where an interoperability constituent bearing the 'EC' declaration of conformity fails to comply with the essential requirements, 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.

CHAPTER IV

SUBSYSTEMS

Article 12

Free movement of subsystems

Without prejudice to the provisions of Chapter V, Member States shall 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 shall not require checks which have already been carried out:

(a) as part of the procedure leading to the 'EC' declaration of verification; or

(b) in other Member States, before or after the entry into force of this Directive, with a view to verifying compliance with identical requirements under identical operational conditions.

Article 13

Conformity with TSIs and national rules

1. The Agency and the national safety authorities shall consider as meeting the essential requirements, those structural subsystems constituting the rail system which are covered, as appropriate, by the 'EC' declaration of verification established by reference to TSIs, in accordance with Article 15, or the declaration of verification established by reference to national rules in accordance with Article 15(8), or both.

2. National rules for implementing the essential requirements and, where relevant, acceptable national means of compliance, shall apply in the following cases:

(a) where 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(6);

(b) where non-application of one or more TSIs or parts of them has been notified under Article 7;

(c) where a specific case requires the application of technical rules not included in the relevant TSI;

(d) national rules used to specify existing systems, limited to the aim of assessing technical compatibility of the vehicle with the network;

(e) networks and vehicles not covered by TSIs;

(f) as an urgent temporary preventive measure, in particular following an accident.

Article 14

Notification of national rules

1. Member States shall notify to the Commission and to the Agency the existing national rules referred to in Article 13 (2) in the following cases:

(a) where the national rule(s) has/have not been notified by … (*). In that case, they shall be notified by … (**);

(b) each time the rules are changed;

(c) when a new request has been submitted in accordance with Article 7 for non-application of the TSI;

(d) where national rules become redundant after publication or revision of the TSI concerned.

(*) Date of entry into force of this Directive.
(**) Six months after the entry into force of this Directive.

2. Member States shall notify the full text of national rules referred to in paragraph 1 through the appropriate IT system in accordance with Article 27 of Regulation (EU) …/… (*).

3. Member States shall ensure that national rules referred to in paragraph 1, including those covering the interfaces between vehicles and networks, are easily accessible, in the public domain and formulated in terminology that all interested parties can understand. Member States may be requested to provide additional information on those national rules.

4. Member States may lay down new national rules only in the following cases:

(a) when a TSI does not fully meet the essential requirements;

(b) as an urgent preventive measure, in particular following an accident.

5. Member States shall submit, through the appropriate IT system in accordance with Article 27 of Regulation (EU) …/… (*), the drafts of new national rules to the Agency and the Commission for consideration before the expected introduction of the proposed new rule into the national legal system, in due time and within the deadlines referred to in Article 25(1) of Regulation (EU) …/… (*) and provide justification for the introduction of that new national rule. Member States shall ensure that the draft is sufficiently developed to allow the Agency to carry out its examination in accordance with Article 25(2) of Regulation (EU) …/… (*).

6. When they adopt a new national rule, Member States shall notify it to the Agency and the Commission through the appropriate IT system in accordance with Article 27 of Regulation (EU) …/… (*).

7. In the case of urgent preventive measures, Member States may adopt and apply a new national rule immediately. That rule shall be notified in accordance with Article 27(2) of Regulation (EU)…/… (*) and subject to the assessment of the Agency in accordance with Article 26(1), (2) and (5) of that Regulation.

8. When notifying a national rule referred to in paragraph 1 or a new national rule, Member States shall provide justification of the need for that rule in order to fulfil an essential requirement not already covered by the relevant TSI.

9. Draft national rules and national rules referred to in paragraph 1 shall be examined by the Agency in accordance with the procedures laid down in Articles 25 and 26 of Regulation (EU) …/… (*).

10. The Commission shall establish, by means of implementing acts, the classification of the notified national rules in different groups with the aim of facilitating cross-acceptance in different Member States and the placing on the market of vehicles, including compatibility between fixed and mobile equipment. Those implementing acts shall build on the 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 51(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.

11. Member States may decide not to notify rules and restrictions of a strictly local nature. In such cases, Member States shall mention those rules and restrictions in the registers of infrastructure referred to in Article 49.

12. National rules notified under this Article are not subject to the notification procedure set out in Directive (EU) 2015/1535 of the European Parliament and of the Council ([1]).

13. National rules not notified in accordance with this Article shall not apply for the purposes of this Directive.

(*) Regulation in document 2013/0014 (COD).

([1]) Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

Article 15

Procedure for establishing the 'EC' declaration of verification

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 request the conformity assessment body or bodies that it has selected for that purpose to apply the 'EC' verification procedure set out in Annex IV.

2. The applicant shall establish the 'EC' declaration of verification of a subsystem. The applicant shall declare on his sole responsibility that the subsystem concerned has been subject to the relevant verification procedures and that it satisfies the requirements of relevant Union law and any relevant national rule. The 'EC' declaration of verification and the accompanying documents shall be dated and signed by the applicant.

3. The task of the notified body responsible for the 'EC' verification of a subsystem shall begin at the design stage and cover the entire manufacturing period through to the acceptance stage before the subsystem is placed on the market or in service. It shall, in accordance with the relevant TSI, also cover verification of the interfaces of the subsystem in question with the system into which it is incorporated.

4. The applicant shall be responsible for compiling the technical file that is to accompany the 'EC' declaration of verification. That 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.

5. In the event of the renewal or upgrading of a subsystem resulting in an amendment to the technical file and affecting the validity of the verification procedures already carried out, the applicant shall assess the need for a new 'EC' declaration of verification.

6. The notified body may issue intermediate statement verifications to cover certain stages of the verification procedure or certain parts of the subsystem.

7. If the relevant TSIs allow, the notified body may issue certificates of verification for one or more subsystems or certain parts of those subsystems.

8. Member States shall designate the bodies responsible for carrying out the verification procedure in respect of national rules. In that regard, designated bodies shall be responsible for the tasks involved. Without prejudice to Article 30, 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.

9. The Commission may specify, by means of implementing acts:

(a) the details of the 'EC' verification procedures for subsystems, including the verification procedure in the case of national rules and the documents to be submitted by the applicant for the purposes of that procedure;

(b) the templates for the 'EC' declaration of verification, including in the case of a modification of the subsystem or in the case of additional verifications, the intermediate statement of verification, and templates for documents of the technical file that is to accompany those declarations as well as templates for the certificate of verification.

Those implementing acts shall be adopted in accordance with the examination procedure referred to Article 51(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 which 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 which 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 European Union*, shall be presumed to be in conformity with the essential requirements covered by those standards or parts thereof.

CHAPTER V

PLACING ON THE MARKET AND PLACING IN SERVICE

Article 18

Authorisation for the placing in service of fixed installations

1. The trackside control-command and signalling, energy and infrastructure subsystems shall be placed in service only if they are designed, constructed and installed in such a way as to meet the essential requirements, and the relevant authorisation is received in accordance with paragraphs 3 and 4.

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.

3. National safety authorities shall provide detailed guidance on how to obtain the authorisations referred to in this Article. An application guidance document describing and explaining the requirements for those authorisations and listing the documents required shall be made available to applicants free of charge. The Agency and the national safety authorities shall cooperate in disseminating such information.

4. The applicant shall submit a request for authorisation of the placing in service of fixed installations to the national safety authority. The application shall be accompanied by a file which includes documentary evidence of:

(a) the declarations of verification referred to in Article 15;

(b) the technical compatibility of the 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 the subsystems, established on the basis of the relevant TSIs, national rules, and the common safety methods ('CSMs') set out in Article 6 of Directive (EU) …/… (*);

(d) in the case of trackside control-command and signalling subsystems involving European train control system (ETCS) and/or global system for mobile communications — railway (GSM-R) equipment, the positive decision of the Agency issued in accordance with Article 19 of this Directive; and, in the case of a change to the draft tender specifications or to the description of the envisaged technical solutions that occurred after the positive decision, the compliance with the result of the procedure referred to in Article 30(2) of Regulation (EU)…/… (**).

5. Within one month of receipt of the applicant's request, the national safety authority shall inform the applicant that the file is complete or ask for relevant supplementary information, setting a reasonable deadline for the provision thereof.

(*) Directive in document 2013/0016 (COD).
(**) Regulation in document 2013/0014 (COD).

The national safety authority shall verify the completeness, relevance and consistency of the file, and, in the case of trackside ERTMS equipment, compliance with the positive decision of the Agency issued in accordance with Article 19 of this Directive and, where appropriate, compliance with the result of the procedure referred to in Article 30(2) of Regulation (EU) …/… (*). Following such verification, the national safety authority shall issue the authorisation for placing in service of fixed installations, or inform the applicant of its negative decision, within a predetermined, reasonable time, and, in any case, within four months of receipt of all relevant information.

6. In the event of renewal or upgrading of existing subsystems, the applicant shall send a file describing the project to the national safety authority. Within one month of receipt of the applicant's request, the national safety authority shall inform the applicant that the file is complete or ask for relevant supplementary information, setting a reasonable deadline for the provision thereof. The national safety authority, in close cooperation with the Agency in the case of trackside ERTMS projects, shall examine the file and shall decide whether a new authorisation for placing in service is needed, on the basis of the following criteria:

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

(b) it is required by the relevant TSIs;

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

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

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

7. A decision refusing a request for an authorisation for the placing in service of fixed installations shall be duly substantiated by the national safety authority. The applicant may, within one month of receipt of the negative decision, submit a request that the national safety authority review its decision. The request shall be accompanied by a justification. The national safety authority shall have two months from the date of receipt of the request for review in which to confirm or reverse its decision. If the negative decision of a national safety authority is confirmed, the applicant may bring an appeal before the appeal body designated by the relevant Member State under Article 18(3) of Directive (EU) …/… (**).

Article 19

Harmonised implementation of ERTMS in the Union

1. In the case of trackside control-command and signalling subsystems involving ETCS and/or GSM-R equipment, the Agency shall ensure the harmonised implementation of ERTMS in the Union.

2. In order to ensure the harmonised implementation of ERTMS and interoperability at Union level, before any call for tenders relating to ERTMS trackside equipment, the Agency shall check that the technical solutions envisaged are fully compliant with the relevant TSIs and are therefore fully interoperable.

3. The applicant shall submit a request for the Agency's approval. The application relating to individual ERTMS projects or for a combination of projects, a line, a group of lines or a network, shall be accompanied by a file which includes:

(a) the draft tender specifications or the description of the envisaged technical solutions;

(b) documentary evidence of the conditions necessary for technical and operational compatibility of the subsystem with the vehicles intended to operate on the relevant network;

(c) documentary evidence of the compliance of technical solutions envisaged with the relevant TSIs;

(d) any other relevant documents, such as national safety authority opinions, declarations of verification or conformity certificates.

(*) Regulation in document 2013/0014 (COD).
(**) Directive in document 2013/0016 (COD).

That application and information about all applications, the stages of the relevant procedures and their outcome, and, where applicable, the requests and decisions of the Board of Appeal, shall be submitted through the one-stop shop referred to in Article 12 of Regulation (EU) …/… (*).

The national safety authorities may issue an opinion on the request for approval either to the applicant before the submission of the request or to the Agency after such a submission.

4. Within one month of receipt of the applicant's request, the Agency shall inform the applicant that the file is complete or ask for relevant supplementary information, setting a reasonable deadline for the provision thereof.

The Agency shall issue a positive decision, or inform the applicant of possible deficiencies, within a predetermined, reasonable time period, and in any case, within two months of receipt of all relevant information. The Agency shall base its opinion on the file of the applicant and on possible opinions from the national safety authorities.

If the applicant agrees with the deficiencies identified by the Agency, the applicant shall rectify the project design and introduce a new request for approval to the Agency.

If the applicant does not agree with the deficiencies identified by the Agency, the procedure referred to in paragraph 5 shall apply.

In the case referred to in point (a) of Article 7(1), the applicant shall not request a new assessment.

5. If the decision of the Agency is not positive, it shall be duly substantiated by the Agency. The applicant may, within one month of receipt of such a decision, submit a reasoned request that the Agency review its decision. The Agency shall confirm or reverse its decision within two months of the date of receipt of the request. If the Agency confirms its initial decision, the applicant is entitled to bring an appeal before the Board of Appeal established under Article 55 of Regulation (EU) …/… (*).

6. In the case of a change to the draft tender specifications or to the description of the envisaged technical solutions that occurred after the positive decision, the applicant shall inform, without undue delay, the Agency and the national safety authority through the one-stop shop referred to in Article 12 of Regulation (EU) …/… (*). In that case, point (a) of Article 30(2) of that Regulation shall apply.

Article 20

Placing on the market of mobile subsystems

1. Mobile subsystems 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.

2. In particular, the applicant shall ensure that the relevant declaration of verification has been provided.

Article 21

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 paragraphs 5 to 7 or by the national safety authority in accordance with paragraph 8.

2. In its application for a vehicle authorisation for placing on the market, the applicant shall specify the area of use of the vehicle. The application shall include evidence that the technical compatibility between the vehicle and the network of the area of use has been checked.

(*) Regulation in document 2013/0014 (COD).

3. The application for a vehicle authorisation for placing on the market shall be accompanied by a file concerning the vehicle or vehicle type and including documentary evidence of:

(a) the placing on the market of the mobile subsystems of which the vehicle is composed in accordance with Article 20, on the basis of the 'EC' declaration of verification;

(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 CSM's referred to in Article 6 of Directive (EU) …/… (*);

(d) the technical compatibility of the vehicle with the network in the area of use referred to in paragraph 2, established on the basis of the relevant TSIs and, where applicable, national rules, registers of infrastructure and the CSM on risk assessment referred to in Article 6 of Directive (EU) …/… (*).

That application and information about all applications, the stages of the relevant procedures and their outcome, and, where applicable, the requests and decisions of the Board of Appeal, shall be submitted through the one-stop shop referred to in Article 12 of Regulation (EU) …/… (**).

Whenever tests are necessary in order to obtain documentary evidence of the technical compatibility referred to in points (b) and (d) of the first subparagraph, 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 receipt of the applicant's request. Where appropriate, the national safety authority shall take measures to ensure that the tests take place.

4. The Agency or, in the case of paragraph 8, the national safety authority shall issue vehicle authorisations for placing on the market or inform the applicant of its negative decision within a predetermined, reasonable time, and in any case within four months of receipt of all relevant information from the applicant. The Agency, or, in the cases provided for in paragraph 8, the national safety authority, shall apply the practical arrangements on the authorisation procedure to be established in an implementing act, as referred to in paragraph 9. Those authorisations shall allow vehicles to be placed on the Union market.

5. 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 States. In order to issue such authorisations, the Agency shall:

(a) assess the elements of the file specified in points (b), (c) and (d) of the first subparagraph of paragraph 3 in order to verify the completeness, relevance and consistency of the file in relation to the relevant TSIs; and

(b) refer the applicant's file to the national safety authorities concerned by the intended area of use for assessment of the file in order to verify its completeness, relevance and consistency in relation to point (d) of the first subparagraph of paragraph 3 and to the elements specified in points (a), (b) and (c) of the first subparagraph of paragraph 3 in relation to the relevant national rules.

As part of the assessments pursuant to points (a) and (b) and in the case of justified doubts, the Agency or the national safety authorities may request that tests be conducted on the network. In order to facilitate those 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 of the request of the Agency or the national safety authority.

6. Within one month of receipt of the applicant's request, the Agency shall inform the applicant that the file is complete or ask for relevant supplementary information, setting a reasonable deadline for the provision thereof. With regard to the completeness, relevance and consistency of the file, the Agency may also assess the elements specified in point (d) of paragraph 3.

(*) Directive in document 2013/0016 (COD).
(**) Regulation in document 2013/0014 (COD).

The Agency shall take full account of the assessments under paragraph 5 before taking its decision on the issuance of the vehicle authorisation for placing on the market. The Agency shall issue the authorisation for placing on the market, or inform the applicant of its negative decision, within a predetermined, reasonable time, and in any case within four months of receipt of all relevant information.

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

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

7. When the Agency disagrees with a negative assessment carried out by one or more national safety authorities pursuant to point (b) of paragraph 5, it shall inform the authority or authorities in question, giving reasons for its disagreement. The Agency and the national safety authority or authorities shall cooperate with a view to reaching a mutually acceptable assessment. Where necessary, as decided by the Agency and the national safety authority or authorities, this process shall also involve the applicant. If no mutually acceptable assessment can be agreed on within one month after the Agency has informed the national safety authority or authorities of its disagreement, the Agency shall take its final decision unless the national safety authority or authorities have referred the matter for arbitration to the Board of Appeal established under Article 55 of Regulation (EU) …/… (*). The Board of Appeal shall decide whether to confirm the Agency's draft decision within one month of the request of the national safety authority or authorities.

Where the Board of Appeal agrees with the Agency, the Agency shall take a decision without delay.

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

Where the Agency disagrees with a positive assessment of one or more national safety authorities pursuant to point (b) of paragraph 5, it shall inform the authority or authorities in question, giving reasons for its disagreement. The Agency and the national safety authority or authorities shall cooperate with a view to agreeing on 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 agreed on within one month after the Agency has informed the national safety authority and authorities of its disagreement, the Agency shall take its final decision.

8. Where the area of use is limited to a network or networks within one Member State only, the national safety authority of that Member State may, under its own responsibility and when the applicant so requests, issue the vehicle authorisation for placing on the market. In order to issue such authorisations, the national safety authority shall assess the file in relation to the elements specified in paragraph 3 and in accordance with the procedures to be established in the implementing act adopted pursuant to paragraph 9. Within one month of receipt of the request of the applicant, the national safety authority shall inform the applicant that the file is complete or ask for relevant supplementary information. The authorisation shall also be valid without extension of the area of use for vehicles travelling to stations in neighbouring Member States with similar network characteristics, when those stations are close to the border, following consultation of the competent national safety authorities. This consultation may be carried out on a case-by-case basis or set out in a cross-border agreement between national safety authorities.

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

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

9. By… (**), the Commission shall adopt by means of implementing acts practical arrangements specifying:

(a) how the requirements for the vehicle authorisation for placing on the market and for vehicle type authorisation laid down in this Article shall be fulfilled by the applicant and listing the documents required;

(*) Regulation in document 2013/0014 (COD).
(**) Two years after the entry into force of this Directive.

(b) the details of the authorisation process, such as procedural stages and timeframes for each stage of the process;

(c) how the requirements laid down in this Article shall be complied with by the Agency and the national safety authority through the different stages of the application and authorisation process including in the assessment of applicants' files.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(3). They shall take into account the experience gained during the preparation of the cooperation agreements referred to in paragraph 14 of this Article.

10. 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, for checking the technical compatibility between the vehicle and the area of use;

(c) the vehicle's compliance with the relevant TSIs and sets of national rules, relating to the parameters referred to in point (b);

(d) the conditions for use of the vehicle and other restrictions.

11. Any decision refusing the vehicle authorisation for placing on the market or excluding part of the network in accordance with a negative assessment as referred to in paragraph 7 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 in which 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 55 of Regulation (EU) …/… (*).

If the negative decision of a national safety authority is confirmed, the applicant may bring an appeal before an appeal body in accordance with the national law. Member States may designate the regulatory body referred to in Article 55 of Directive 2012/34/EU for the purpose of this appeal procedure. In that case, Article 18(3) of Directive (EU) …/… (**) shall apply.

12. In the event of renewal or upgrading of existing vehicles which already have a vehicle authorisation for placing on the market, a new vehicle authorisation for placing on the market shall be required if:

(a) changes are made to the values of the parameters referred to in point (b) of paragraph 10 which are outside the range of acceptable parameters as defined in the TSIs;

(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.

13. Where the applicant wishes to extend the area of use of a vehicle which has already been authorised, it shall supplement the file with the relevant documents referred to in paragraph 3 concerning the additional area of use. The applicant shall submit the file to the Agency, which shall, after following the procedures laid down in paragraphs 4 to 7, issue an updated authorisation covering the extended area of use.

If the applicant has received a vehicle authorisation in accordance with paragraph 8 and wishes to extend the area of use within that Member State, it shall supplement the file with the relevant documents referred to in paragraph 3 concerning the additional area of use. It shall submit the file to the national safety authority which shall, after following the procedures laid down in paragraph 8, issue an updated authorisation covering the extended area of use.

(*) Regulation in document 2013/0014 (COD).
(**) Directive in document 2013/0016 (COD).

14. For the purposes of paragraphs 5 and 6 of this Article, the Agency shall conclude cooperation agreements with national safety authorities in accordance with Article 76 of Regulation (EU) …/… (*). Those agreements may be specific or framework agreements, and may involve one or more national safety authorities. They shall contain a detailed description of tasks and conditions for deliverables, the time-limits applying to their delivery, and an apportionment of the fees payable by the applicant. They may also include specific cooperation arrangements in the case of networks requiring specific expertise for geographical or historical reasons, with a view to reducing administrative burdens and costs to the applicant. Where such networks are isolated from the rest of the Union rail system, such specific cooperation arrangements may include the possibility of contracting tasks to the relevant national safety authorities when this is necessary in order to ensure the efficient and proportionate allocation of resources for authorisation. Those agreements shall be in place before the Agency shall undertake the authorisation tasks in accordance with Article 54(4) of this Directive.

15. In the case of those Member States whose rail networks have a track gauge that is different from that of the main rail network within the Union and share identical technical and operational requirements with neighbouring third countries, in addition to the cooperation agreements referred to in paragraph 14, all national safety authorities concerned in those Member States shall conclude with the Agency a multilateral agreement with a view to defining the conditions under which a vehicle authorisation issued in one of those Member States is also valid for the other Member States concerned.

16. This Article shall not apply to freight wagons or passenger coaches which are in shared use with third countries, the track gauge of which is different from that of the main rail network within the Union and authorised in accordance with a different vehicle authorisation procedure. The rules governing the procedure for authorisation of such vehicles shall be published and notified to the Commission. The conformity of those vehicles with the essential requirements of this Directive shall be ensured by the railway undertaking concerned in the context of its safety management system. The Commission, on the basis of the report by the Agency may give an opinion on whether such rules are compliant with the objectives of this Directive. If such rules are not compliant, the Member States concerned and the Commission may cooperate in order to lay down appropriate actions to be taken, involving relevant international bodies, if necessary.

17. A Member State may decide not to apply this Article to locomotives or self-propelling trains arriving from third countries and intended to run until a station that is situated close to the border in its territory and designated for cross-border operations. The conformity of such vehicles with the essential requirements of this Directive shall be ensured by the railway undertaking concerned in the context of its safety management system and, where relevant, in accordance with Article 10(9) of Directive (EU)…/… (**).

Article 22

Registration of vehicles authorised to be placed on the market

1. Before a vehicle is used for the first time, and after the authorisation to be placed on the market in accordance with Article 21 is granted, it shall be registered in a vehicle register as referred to in Article 47 at the request of the keeper.

2. When the area of use of the vehicle is restricted to the territory of one Member State, it shall be registered in that Member State.

3. When the area of use of the vehicle covers the territory of more than one Member State, it shall be registered in one of the Member States concerned.

Article 23

Checks before the use of authorised vehicles

1. Before a railway undertaking uses a vehicle in the area of use specified in its authorisation for placing on the market, it shall check:

(*) Regulation in document 2013/0014 (COD).
(**) Directive in document 2013/0016 (COD).

(a) that the vehicle has been authorised for placing on the market in accordance with Article 21 and is duly registered;

(b) that the vehicle is compatible with the route on the basis of the infrastructure register, the relevant TSIs or any relevant information to be provided by the infrastructure manager free of charge and within a reasonable period of time, where such a register does not exist or is incomplete; and

(c) that the vehicle is properly integrated in the composition of the train where it is intended to operate, taking into account the safety management system set out in Article 9 of Directive (EU) …/… (*) and the TSI on operation and traffic management.

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

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

Article 24

Type authorisation of vehicles

1. The Agency or a national safety authority may, where appropriate, in accordance with the procedure laid down in Article 21, grant vehicle type authorisations. The application for a vehicle type authorisation and information about all applications, the stages of the relevant procedures and their outcome, and, where applicable, the requests and decisions of the Board of Appeal, shall be submitted through the one-stop shop referred to in Article 12 of Regulation (EU) …/… (**).

2. If the Agency or a national safety authority issues a vehicle authorisation for placing on the market, it shall at the same time as the applicant's request issue the vehicle type authorisation, which is related to the same area of use of the vehicle.

3. In the event of changes to any relevant provisions in TSIs or national rules, on the basis of which an authorisation of a vehicle type has been issued, the TSI or national rule shall determine whether the vehicle type authorisation already granted remains valid or needs to be renewed. If that authorisation needs to be renewed, the checks performed by the Agency or by a national safety authority may only concern the changed rules.

4. The Commission shall establish, by means of implementing acts, the model of declaration of conformity to type. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(3).

5. The declaration of conformity to type shall be established in accordance with:

(a) the verification procedures of the relevant TSIs; or

(b) where TSIs do not apply, the conformity assessment procedures as defined in modules B+D, B+F and H1 of Decision 768/2008/EC of the European Parliament and of the Council ([1]).

6. 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 51(3).

7. The authorisation of vehicle types shall be registered in the European register of authorised vehicle types referred to in Article 48.

(*) Directive in document 2013/0016 (COD).
(**) Regulation in document 2013/0014 (COD).
([1]) 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/EEC (OJ L 218, 13.8.2008, p. 82).

Article 25

Conformity of vehicles with an authorised vehicle type

1. A vehicle or a series of vehicles which is in conformity with an authorised vehicle type shall, without further checks, receive a vehicle authorisation in accordance with Article 21 on the basis of a declaration of conformity to that vehicle type submitted by the applicant.

2. The renewal of the authorisation of a vehicle type as referred to in Article 24(3) shall 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.

Article 26

Non-compliance of vehicles or vehicle types with essential requirements

1. When a railway undertaking finds, during operation, that a vehicle it is using does not meet one of the applicable essential requirements, it shall take the necessary corrective measures in order to bring the vehicle into conformity. Furthermore, it may inform the Agency and any national safety authorities concerned of the measures taken. If the railway undertaking has evidence that the non-compliance existed already at the time when the authorisation for placing on the market was issued, it shall inform the Agency and any other national safety authorities concerned.

2. When a national safety authority becomes aware, for instance within the process of supervision provided for in Article 17 of Directive (EU)…/… (*), that a vehicle or a vehicle type to which an authorisation for placing on the market was granted either by the Agency, in accordance with Article 21(5) or Article 24, or by the national safety authority, in accordance with Article 21(8) or Article 24, when used as intended, does not meet one of the applicable essential requirements, it shall inform the railway undertaking using the vehicle or the vehicle type and ask it to take the necessary corrective measures in order to bring the vehicle(s) into conformity. The national safety authority shall inform the Agency and any other national safety authorities concerned, including those in a territory where application for authorisation for placing on the market for a vehicle of the same type is ongoing.

3. When, in the cases set out in paragraphs 1 or 2 of this Article, the corrective measures applied by the railway undertaking do not ensure conformity with the applicable essential requirements and that non-conformity leads to a serious safety risk, the national safety authority concerned may apply temporary safety measures under its supervision tasks, in accordance with Article 17(6) of Directive (EU)…/… (*). Temporary safety measures in the form of a suspension of type authorisation of a vehicle may be applied in parallel by the national safety authority or by the Agency and shall be subject to judicial review and the arbitration procedure laid down in Article 21(7).

4. In the cases referred to in paragraph 3, the Agency or the national safety authority which issued the authorisation, following a review of the effectiveness of any measures taken to address the serious safety risk, may decide to revoke or amend the authorisation when it is proven that an essential requirement was not met at the time of authorisation. To that end, they shall notify their decision to the holder of the authorisation for placing on the market or of the vehicle type authorisation, giving the reasons for their decisions. The holder may, within a period of one month from receipt of the decision of the Agency or the national safety authority, request them to review the decision. In that case, the decision to revoke shall be temporarily suspended. The Agency or the national safety authority shall have one month from the date of receipt of the request for review in which to confirm or reverse their decision.

Where relevant, in the event of disagreement between the Agency and the national safety authority concerning the need to restrict or revoke the authorisation, the arbitration procedure provided for in Article 21(7) shall be followed. If the result of that procedure is that the vehicle authorisation is neither to be restricted nor revoked, the temporary safety measures referred to in paragraph 3 of this Article shall be suspended.

(*) Directive in document 2013/0016 (COD).

5. If the decision of the Agency is confirmed, the holder of the vehicle authorisation may bring an appeal before the Board of Appeal designated under Article 55 of Regulation (EU) …/… (*) within the time-limit referred to in Article 59 of that Regulation. If the decision of a national safety authority is confirmed, the holder of the vehicle authorisation may bring an appeal, within two months of the notification of that decision, under the national judicial review referred to in Article 18 (3) of Directive (EU) …/… (**). Member States may designate the regulatory body set out in Article 56 of Directive 2012/34/EU for the purpose of this appeal procedure.

6. When the Agency decides to revoke or amend an authorisation for placing on the market which it has granted, it shall directly inform all national safety authorities, giving the reasons for its decision.

When a national safety authority decides to revoke an authorisation for placing on the market which it has granted, it shall forthwith inform the Agency thereof and give the reasons for its decision. The Agency shall then inform the other national safety authorities.

7. The decision of the Agency or the national safety authority to revoke the authorisation shall be reflected in the appropriate vehicle register, in accordance with Article 22 or, in the case of an authorisation of a vehicle type, in the European register of authorised vehicle types in accordance with Article 24(7). The Agency and the national safety authorities shall ensure that railway undertakings using vehicles of the same type as the vehicle or type subject to the revocation are properly informed. Such railway undertakings shall first check whether the same problem of non-compliance applies. In that event, the procedure provided for in this Article shall apply.

8. When an authorisation for placing on the market is revoked, the vehicle concerned shall no longer be used and its area of use shall not be extended. When a vehicle type authorisation is revoked, vehicles built on the basis of it shall not be placed on the market or, if they had already been placed on the market, they shall be withdrawn. A new authorisation may be requested on the basis of the procedure provided for in Article 21 in the case of individual vehicles or Article 24 in the case of a vehicle type.

9. When, in the cases provided for in paragraphs 1 or 2, the non-compliance with the essential requirements is limited to part of the area of use of the vehicle concerned and such non-compliance already existed at the time when the authorisation for placing on the market was issued, the latter shall be amended to exclude the parts of the area of use concerned.

CHAPTER VI

CONFORMITY ASSESSMENT BODIES

Article 27

Notifying authorities

1. Member States shall appoint notifying authorities that shall be responsible for setting up and carrying out the necessary procedures for the assessment, notification and monitoring of conformity assessment bodies, including compliance with Article 34.

2. Member States shall ensure that those authorities notify the Commission and other Member States' bodies authorised to carry out third-party conformity assessment tasks as provided for in Articles 10(2) and 15(1). They shall also ensure that they inform the Commission and the other Member States of the designated bodies referred to in Article 15(8).

3. Member States may decide that the assessment and monitoring referred to in paragraph 1 are to be carried out by a national accreditation body within the meaning of, and in accordance with, Regulation (EC) No 765/2008.

4. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body which is not a governmental entity, that body shall be a legal person and shall comply with the requirements laid down in Article 28. It shall put in place arrangements to cover liabilities arising out of its activities.

5. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

(*) Regulation in document 2013/0014 (COD).
(**) Directive in document 2013/0016 (COD).

Article 28

Requirements relating to notifying authorities

A notifying authority shall:

(a) be established in such a way as to avoid any conflict of interest with conformity assessment bodies;

(b) be organised and operated in such a way as to safeguard the objectivity and impartiality of its activities;

(c) 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;

(d) not offer or provide any activities that are performed by conformity assessment bodies or consultancy services on a commercial or competitive basis;

(e) safeguard the confidentiality of the information it obtains;

(f) have at its disposal a sufficient number of competent personnel for the proper performance of its tasks.

Article 29

Obligation of notifying authorities to provide information

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

The Commission shall make that information publicly available.

Article 30

Conformity assessment bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 7 of this Article and in Articles 31 and 32.

2. A conformity assessment body shall be established under national law and shall 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 product 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 to be carried out, ensuring the transparency and the ability to apply those procedures. It shall have in place appropriate policies and procedures that distinguish between the 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 in an appropriate manner the technical and administrative tasks connected with the conformity assessment activities 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 unless 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 law, and shall 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 trackside and/or on-board control-command and signalling subsystems shall participate in, or shall ensure that their assessment personnel are informed of, the activities of the ERTMS group referred to in Article 29 of Regulation (EU) …/… (*). They shall follow the guidelines produced as a result of the work of that group. In the event that they consider it inappropriate or impossible to apply them, the conformity assessment bodies concerned shall submit their observations for discussion to the ERTMS group for the continuous improvement of the guidelines.

Article 31

Impartiality of conformity assessment bodies

1. A conformity assessment body shall be a third-party body independent of the organisation or of 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 to be such a body.

2. The impartiality of the conformity assessment bodies, of 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, or 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, 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 prohibition shall apply, in particular, 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 32

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;

(*) Regulation in document 2013/0014 (COD).

(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 law;

(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 33

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 30 to 32, in so far as the applicable harmonised standards cover those requirements.

Article 34

Subsidiaries of, and subcontracting by, notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Articles 30 to 32 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 35

Accredited in-house bodies

1. Applicants 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 laid down in Annex II to Decision 768/2008/EC and modules CA1 and CA2 laid down in Annex I to Decision 2010/713/EU. That body shall constitute a separate and distinct part of the applicant concerned 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, within the undertaking of which they form a part, be organisationally identifiable and have reporting methods which ensure their impartiality, and shall demonstrate it to the competent 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 judgement or integrity in relation to their assessment activities;

(d) the body shall supply its services exclusively to the undertaking of which it forms a part.

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

Article 36

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 30 to 32.

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 30 to 32.

Article 37

Notification procedure

1. Notifying authorities shall only notify conformity assessment bodies which comply with the requirements laid down in Articles 30 to 32.

2. Notifying authorities shall notify the bodies referred to in paragraph 1 to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the product or products concerned, and the relevant accreditation certificate or other attestation of competence provided for in paragraph 4.

4. Where a notification is not based on an accreditation certificate as referred to in Article 36(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 periodically and will continue to satisfy the requirements laid down in Articles 30 to 32.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 38

Identification numbers and lists of notified bodies

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

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

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 39

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Articles 30 to 32, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 40

Challenges to the competence of notified bodies

1. The Commission shall investigate all cases where it has any doubt, or where a doubt is brought to its attention, regarding the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet, or no longer meets, the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including withdrawal of notification if necessary.

Article 41

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant TSI.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Notified bodies, when performing their activities, shall 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.

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

3. Where a notified body finds that requirements laid down in the relevant TSI or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies with the relevant TSI or corresponding harmonised standards or technical specifications, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

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

Article 42

Obligation of notified bodies to provide information

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.

The competent national safety authorities shall also be informed of any refusal, restriction, suspension or withdrawal of a certificate under point (a).

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 the Agency with 'EC' certificates of verification of subsystems, 'EC' certificates of conformity of interoperability constituents and 'EC' certificates of suitability of use of interoperability constituents.

Article 43

Exchanges of best practice

The Commission shall provide for the organisation of exchanges of best practice between the Member States' national authorities responsible for notification policy.

Article 44

Coordination of notified bodies

The Commission shall ensure appropriate coordination and cooperation between bodies notified under this Directive through the establishment of a sectoral group of notified bodies. The Agency shall support the activities of notified bodies in accordance with Article 24 of Regulation (EU) …/… (*).

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 45

Designated bodies

1. The requirements relating to conformity assessment bodies set out in Articles 30 to 34 shall also apply to bodies designated under Article 15(8), except:

(a) in the case of skills required by its personnel under point (c) of Article 32(1), where the designated body shall have appropriate knowledge and understanding of national law;

(b) in the case of documents to be kept at the disposal of the notifying authority under Article 34(4), where the designated body shall include documents relating to work carried out by subsidiaries or subcontractors under the relevant national rules.

2. The operational obligations laid down in Article 41 shall also apply to bodies designated under Article 15(8), except that those obligations refer to national rules instead of TSIs.

3. The information obligation laid down in Article 42(1) shall also apply to designated bodies, which shall inform Member States accordingly.

CHAPTER VII

REGISTERS

Article 46

Vehicle numbering system

1. Upon registration in accordance with Article 22, each vehicle shall be assigned a European vehicle number (EVN) by the competent authority in the Member State of registration. Each vehicle shall be marked with an assigned EVN.

(*) Regulation in document 2013/0014 (COD).

2. The specifications of the EVN shall be set out in the measures referred to in Article 47(2), in accordance with the relevant TSI.

3. Each vehicle shall be assigned an EVN only once, unless otherwise specified in the measures referred to in Article 47 (2), in accordance with the relevant TSI.

4. Notwithstanding paragraph 1, in the case of vehicles operated or meant 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 in accordance with a different coding system.

Article 47

Vehicle registers

1. Until the European vehicle register referred to in paragraph 5 is operational, each Member State shall keep a national vehicle register. That register shall:

(a) comply with the common specifications referred to in paragraph 2;

(b) be kept updated by a body independent of any railway undertaking;

(c) be accessible to the national safety authorities and investigating bodies designated in Articles 16 and 22 of Directive (EU) …/… (*); it shall also be made accessible, in response to any legitimate request, to the regulatory bodies referred to in Article 55 of Directive 2012/34/EU, and to the Agency, the railway undertakings and the infrastructure managers, as well as those persons or organisations registering vehicles or identified in the register.

2. The Commission shall adopt common specifications for the national vehicle registers as regards their content, data format, functional and technical architecture, operating mode, including arrangements for the exchange of data, and rules for data input and consultation, by means of implementing acts.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(3).

3. The national vehicle register shall contain at least the following elements:

(a) the EVN;

(b) references to the 'EC' declaration of verification and the issuing body;

(c) references to the European register of authorised vehicle types referred to in Article 48;

(d) identification of the owner of the vehicle and the keeper;

(e) restrictions on how the vehicle may be used;

(f) the entity in charge of maintenance.

4. As long as Member States' national vehicle registers are not linked in accordance with the specification referred to in paragraph 2, each Member State shall update its register, as regards the data with which it is concerned, with the modifications made by another Member State in its own register.

5. With a view to reducing administrative burdens and undue costs for Member States and stakeholders, by… (**), the Commission, taking into account the result of a cost-benefit analysis, shall adopt by means of implementing acts the technical and functional specifications for the European Vehicle Register, which would incorporate the national vehicle registers with a view to providing a harmonised interface to all users for the registration of vehicles and data management. Points (b) and (c) of paragraph 1 and paragraph 3 shall apply. Such a specification shall include content, data format, functional and technical architecture, operating mode, including arrangements for the exchange of data, and rules for data input, and consultation, as well as migration steps.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(3) and on the basis of a recommendation of the Agency.

(*) Directive in document 2013/0016 (COD).
(**) Two years after the entry into force of this Directive.

The European Vehicle Register shall be developed taking into consideration the IT applications and registers already set up by the Agency and the Member States, such as the European Centralised Virtual Vehicle Register connected to the national vehicle registers. The European Vehicle Register shall be operational by… (*).

6. The keeper shall immediately declare any modification to the data entered in the vehicle registers, the destruction of a vehicle or its decision to no longer register a vehicle, to the Member State where the vehicle has been registered.

7. In the case of vehicles authorised for the first time in a third country and subsequently used in a Member State, that Member State shall ensure that the vehicle data, including at least data relating to the keeper of the vehicle concerned, the entity in charge of its maintenance and the restrictions on how the vehicle may be used, can be retrieved through a vehicle register or are otherwise made available without delay in an easily readable format and in accordance with the same non-discriminatory principles that apply to similar data from a vehicle register.

Article 48

European register of authorised vehicle types

1. The Agency shall set up and keep a register of authorisations to place vehicle types on the market issued in accordance with Article 24. That register shall:

(a) be public and electronically accessible;

(b) comply with the common specifications referred to in paragraph 2;

(c) be linked with relevant vehicle registers.

2. The Commission shall adopt common specifications for the register of authorised vehicle types relating to content, data format, functional and technical architecture, operating mode and rules for data input and consultation, by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(3).

3. The register shall include at least the following elements for each type of vehicle:

(a) technical characteristics, including those related to accessibility for persons with disabilities and persons with reduced mobility, of the type of vehicle as defined in the relevant TSIs;

(b) the manufacturer's name;

(c) the data of the authorisations related to the area of use for a vehicle type, including any restrictions or withdrawals.

Article 49

Register of infrastructure

1. Each Member State shall ensure that a register of infrastructure, stating the values of the network parameters of each subsystem or part subsystem concerned, as set out in the relevant TSI, 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 ensure that the register of infrastructure is updated in accordance with paragraph 5.

5. The Commission shall adopt common specifications for the register of infrastructure relating to content, data format, functional and technical architecture, operating mode and rules for data input and consultation, by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(3).

(*) Five years after the entry into force of this Directive.

CHAPTER VIII

TRANSITIONAL AND FINAL PROVISIONS

Article 50

Exercise of delegation

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 Article 5(1) shall be conferred on the Commission for a period of five years from … (*). 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.

3. It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.

4. The delegation of power referred to in Article 5(1) 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.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 5(1) 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 51

Committee procedure

1. The Commission shall be assisted by the committee established by Article 21 of Council Directive 96/48/EC ([1]). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

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

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 52

Motivation

Any decision taken pursuant to this Directive concerning the assessment of conformity or suitability for use of interoperability constituents or the checking of subsystems constituting the Union rail system or any decision taken pursuant to Articles 7, 12 and 17 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 53

Reports and information

1. By …, (**) the Commission shall report on the progress made in preparing for the Agency's enhanced role under this Directive. Additionally, every three years and for the first time three years after the end of the transitional period provided for by Article 54, the Commission shall report to the European Parliament and to the Council on the progress made towards achieving interoperability of the Union rail system and the functioning of the Agency in this context. That report shall also include an evaluation of the implementation and use of the registers under Chapter VII and an analysis of the cases set out in Article 7 and of the application of Chapter V, assessing in particular the functioning of the cooperation agreements concluded between the Agency and national safety authorities. For the purposes of the first report, after the end

(*) Date of entry into force of this Directive.

([1]) Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system (OJ L 235, 17.9.1996, p. 6).

(**) Two years after the entry into force of this Directive.

of the transitional period the Commission shall carry out extensive consultations with the relevant stakeholders and shall establish a programme to allow for the assessment of progress. The Commission shall, if appropriate in the light of the above analysis, propose legislative measures including measures for the future role of the Agency in enhancing interoperability.

2. The Agency shall develop and periodically update a tool capable of providing, at the request of a Member State, the European Parliament or of the Commission, an overview of the interoperability level of the Union rail system. That tool shall use the information included in the registers provided for in Chapter VII.

Article 54

Transitional regime for using vehicles

1. Without prejudice to paragraph 4 of this Article, vehicles which need to be authorised between (*) … and… (**) shall be subject to the provisions set out in Chapter V of Directive 2008/57/EC.

2. Authorisations for the placing in service of vehicles which have been granted pursuant to paragraph 1 and all other authorisations granted prior to… (*), 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 shall receive a new vehicle authorisation for placing on the market in order to operate on one or more networks which are not yet covered by their authorisation. The placing on the market on those additional networks shall be subject to Article 21.

4. By … (**) the Agency shall carry out the authorisation tasks pursuant to Articles 21 and 24 and the tasks referred to in Article 19 in respect of areas of use in the Member States that have not notified the Agency and the Commission in accordance with Article 57(2). By way of derogation from Articles 21 and 24, national safety authorities of Member States which have notified the Agency and Commission pursuant to Article 57(2) may continue to issue authorisations in accordance with Directive 2008/57/EC until … (***).

Article 55

Other transitional provisions

1. Annexes IV, V, VII and IX to Directive 2008/57/EC shall apply until the date of application of the corresponding implementing acts referred to in Article 7(5), Article 9(4), Article 14(10) and Article 15(9) of this Directive.

2. Directive 2008/57/EC shall continue to apply in relation to ERTMS trackside projects which are to be placed in service between … (*) and … (**).

3. Projects which have completed the tendering or contracting phase prior to … (**) are not subject to the pre-authorisation by the Agency referred to in Article 19.

4. Until… (****) options included in contracts which were signed before … (*). shall not be subject to the pre-authorisation by the Agency referred to in Article 19, even if they are exercised after … (*).

(*) Date of entry into force of this Directive.
(**) Three years after the entry into force of this Directive.
(***) Four years after the entry into force of this Directive.
(****) 15 years after the entry into force of this Directive.

5. Before authorising the placing in service of any ERTMS trackside equipment which was not subject to the pre-authorisation by the Agency referred to in Article 19, national safety authorities shall cooperate with the Agency in order to ensure that the technical solutions are fully interoperable, in accordance with Articles 30(3) and 31(2) of Regulation (EU) …/… (*).

Article 56

Recommendations and opinions of the Agency

The Agency shall provide recommendations and opinions in accordance with Article 19 of Regulation (EU) …/… (*) for the purpose of application of this Directive. Where relevant, those recommendations and opinions shall be taken into account when implementing acts are being drawn up pursuant to this Directive.

Article 57

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 1 and 2, Article 7(1) to (4) and (6), Article 8, Article 9(1), Article 10(5), Article 11(1), (3) and (4), Articles 12, 13 and 14, Article 15(1) to (8), Article 16, Article 18, Article 19(3), Articles 21 to 39, Article 40(2), Articles 41, 42, 44, 45 and 46, Article 47(1), (3), (4) and (7), Article 49(1) to (4), Article 54 and Annexes I, II, III and IV by… (**). They shall immediately communicate the text of those measures to the Commission.

2. Member States may extend the transposition period referred to in paragraph 1 by one year. For that purpose, by… (***), Member States which do not bring into force the laws, regulations and administrative provisions within the transposition period referred to in paragraph 1 shall notify the Agency and the Commission thereof and present the reasons for such extension.

3. When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion 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.

4. 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.

5. The obligation to transpose and implement Article 13, Article 14(1) to (8), (11) and (12), Article 15(1) to (9), Article 16(1), Articles 19 to 26, Articles 45, 46 and 47, Article 49(1) to (4) and Article 54 of this Directive shall not apply to Cyprus and Malta for as long as no rail system is established within their territories.

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

Article 58

Repeal

Directive 2008/57/EC, as amended by the Directives listed in Annex V, Part A, is repealed with effect from … (****), 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 V, Part B.

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

(*) Regulation in document 2013/0014 (COD).
(**) Three years after the entry into force of this Directive.
(***) 30 months after the date of entry into force of this Directive.
(****) Four years after the entry into force of this Directive.

Article 59

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*.

Article 60

Addressees

This Directive is addressed to the Member States.

Done at …,

For the European Parliament	*For the Council*
The President	*The President*
…	…

ANNEX I

ELEMENTS OF THE UNION RAIL SYSTEM

1. NETWORK

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

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

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

(c) 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,

(d) conventional lines intended for passenger services,

(e) conventional lines intended for mixed traffic (passengers and freight),

(f) conventional lines intended for freight services,

(g) passenger hubs,

(h) freight hubs, including intermodal terminals,

(i) lines connecting the abovementioned elements.

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

2. VEHICLES

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

— locomotives and passenger rolling stock, including thermal or electric traction units, self-propelling thermal or electric passenger trains, and passenger coaches,

— freight wagons, including low-deck vehicles designed for the entire network and vehicles designed to carry lorries,

— special vehicles, such as on-track machines.

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

ANNEX II

SUBSYSTEMS

1. LIST OF SUBSYSTEMS

For the purposes of this Directive, the system constituting the Union 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; or

(b) functional areas:

— operation and traffic management,

— maintenance,

— telematics applications for passenger and freight services.

2. DESCRIPTION OF THE SUBSYSTEMS

For each subsystem or part of a subsystem, the list of constituents and aspects relating to interoperability is proposed by the Agency at the time of drawing up the relevant draft TSI. Without prejudging the choice of aspects and constituents relating to interoperability or the order in which they will be made subject to TSIs, the subsystems include the following:

2.1. **Infrastructure**

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

2.2. **Energy**

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

2.3. **Trackside control-command and signalling**

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

2.4. **On-board control-command and signalling**

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

2.5. **Operation and traffic management**

The procedures and related equipment permitting 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 disabilities and persons with reduced mobility), 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 Union rail system and guarantee the performance required.

ANNEX III

ESSENTIAL REQUIREMENTS

1. GENERAL REQUIREMENTS

1.1. **Safety**

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

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

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

1.1.4. The design of fixed installations and rolling stock and the choice of the materials used must be aimed at limiting 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 designed in such a way 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 Union law.

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. The design and operation of the rail system must not lead to an inadmissible level of noise generated by it:

— in areas close to railway infrastructure, as defined in point (3) of Article 3 of Directive 2012/34/EU, and

— in the driver's cab.

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

1.5. **Technical compatibility**

The technical characteristics of the infrastructure and fixed installations must be compatible with each other and with those of the trains to be used on the rail system. This requirement includes the safe integration of the vehicle's subsystem with the infrastructure.

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

1.6. **Accessibility**

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

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

2. REQUIREMENTS SPECIFIC TO EACH SUBSYSTEM

2.1. **Infrastructure**

2.1.1. *Safety*

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

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

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

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

2.1.2. *Accessibility*

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

2.2. **Energy**

2.2.1. *Safety*

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

2.2.2. *Environmental protection*

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

2.2.3. *Technical compatibility*

The electricity/thermal energy-supply systems used must:

— enable trains to achieve the specified performance levels,

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

2.3. **Control-command and signalling**

2.3.1. *Safety*

The control-command and signalling installations and procedures used must enable trains to travel with a level of safety which corresponds to the objectives set for the network. The control-command and signalling systems must 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 them.

The safety of passengers boarding and alighting from trains must be ensured. 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.

Passengers must be given easily understandable and comprehensive information about rules applicable to them both in railway stations and in trains.

2.4.2. *Reliability and availability*

The design of the vital equipment and the running, traction and braking equipment as well as the control-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 that device and the processing of the information must be harmonised.

2.4.5. *Accessibility*

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

2.5. **Maintenance**

2.5.1. *Health and safety*

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

2.5.2. *Environmental protection*

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

2.5.3. *Technical compatibility*

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

2.6. **Operation and traffic management**

2.6.1. *Safety*

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

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

2.6.2. *Reliability and availability*

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

2.6.3. *Technical compatibility*

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

2.6.4. *Accessibility*

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

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

2.7.1. *Technical compatibility*

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

Steps must be taken to ensure:

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

— easy access to the information for users.

2.7.2. *Reliability and availability*

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

2.7.3. *Health*

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

2.7.4. *Safety*

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

2.7.5. *Accessibility*

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

ANNEX IV

'EC' VERIFICATION PROCEDURE FOR SUBSYSTEMS

1. GENERAL PRINCIPLES

'EC' verification' means a procedure carried out by the applicant within the meaning of Article 15 to demonstrate that the requirements of the relevant Union law and any relevant national rules relating to a subsystem have been fulfilled and the subsystem may be authorised to be placed in service.

2. CERTIFICATE OF VERIFICATION ISSUED BY A NOTIFIED BODY

2.1. **Introduction**

For the purpose of this Directive, the verification by reference to TSIs is the procedure whereby a notified body checks and certifies that the subsystem complies with the relevant technical specifications for interoperability (TSI).

This is without prejudice to the obligations of the applicant to comply with the other applicable legal acts of the Union and any verifications by the assessment bodies required by the other rules.

2.2. **Intermediate statement of verification (ISV)**

2.2.1. *Principles*

At the request of the applicant the verifications may be done for parts of a subsystem or may be limited to certain stages of the verification procedure. In these cases, the results of verification may be documented in an 'intermediate statement of verification' (ISV) issued by the notified body chosen by the applicant. The ISV must provide reference to the TSIs with which the conformity has been assessed.

2.2.2. *Parts of the subsystem*

The applicant may apply for an ISV for any part into which he decides to split the subsystem. Each part shall be checked at each stage as set out in point 2.2.3.

2.2.3. *Stages of the verification procedure*

The subsystem, or certain parts of the subsystem, shall be checked at each of the following stages:

(a) overall design,

(b) production: construction, including, in particular, civil-engineering activities, manufacturing, constituent assembly and overall adjustment,

(c) final testing.

The applicant may apply for an ISV for the design stage (including the type tests) and for the production stage for the whole subsystem or for any part into which the applicant decided to split it (see point 2.2.2).

2.3. **Certificate of verification**

2.3.1. The notified bodies responsible for the verification assess the design, production and final testing of the subsystem and draw up the certificate of verification intended for the applicant who in turn draws up the 'EC' declaration of verification. The certificate of verification must provide reference to the TSIs with which the conformity has been assessed.

Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case), the certificate of verification shall give the precise reference to the TSI(s) or their parts whose conformity has not been examined by the notified body during the verification procedure.

2.3.2. Where ISV have been issued, the notified body responsible for the verification of the subsystem takes these ISV into account, and, before issuing its certificate of verification:

(a) verifies that the ISV cover correctly the relevant requirements of the TSI(s),

(b) checks all aspects that are not covered by the ISV, and

(c) checks the final testing of the subsystem as a whole.

2.3.3. In the case of a modification to a subsystem already covered by a certificate of verification, the notified body shall perform only those examinations and tests that are relevant and necessary, i.e. assessment shall relate only to the parts of the subsystem that are changed and their interfaces to the unchanged parts of the subsystem.

2.3.4. Each notified body involved in the verification of a subsystem shall draw up a file in accordance with Article 15(4) covering the scope of its activities.

2.4. **Technical file accompanying the 'EC' declaration of verification**

The technical file accompanying the 'EC' declaration of verification shall be assembled by the applicant and must contain the following:

(a) technical characteristics linked to the design including general and detailed drawings with respect to execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems to the level of detail sufficient for documenting the verification of conformity carried out, documentation on operation and maintenance, etc., relevant for the subsystem concerned,

(b) a list of interoperability constituents, referred to in point (d) of Article 4(3), incorporated into the subsystem,

(c) the files referred to in Article 15(4), compiled by each of the notified bodies involved in the verification of the subsystem, which shall include:

— copies of the 'EC' declarations of verification and, where applicable, 'EC' declarations of suitability for use established for interoperability constituents referred to in point (d) of Article 4(3) and accompanied, where appropriate, by the corresponding calculation notes and a copy of the records of the tests and examinations carried out by the notified bodies on the basis of the common technical specifications,

— where available, the ISV that accompany the certificate of verification, including the result of verification by the notified body of the ISV validity,

— the certificate of verification, accompanied by corresponding calculation notes and signed by the notified body responsible for the verification, stating that the subsystem complies with the requirements of the relevant TSI(s) and mentioning any reservations recorded during performance of the activities and not withdrawn; the certificate of verification should also be accompanied by the inspection and audit reports drawn up by the same body in connection with its task, as specified in points 2.5.2 and 2.5.3;

(d) certificates of verification issued in accordance with other legal acts of the Union,

(e) when verification of safe integration is required pursuant to in point (c) of Article 18(4) and in point (c) of Article 21(3), the relevant technical file shall include the assessors' report(s) on the CSM's on risk assessment referred to in Article 6(3) of Directive 2004/49/EC.

2.5. **Surveillance by notified bodies.**

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

2.5.2. The notified body responsible for checking implementation must periodically carry out audits in order to confirm compliance with the relevant TSI(s). It must provide those responsible for implementation with an audit report. Its presence may be required at certain stages of the building operations.

2.5.3. In addition, the notified body may pay unexpected visits to the worksite or to the production workshops. At the time of such visits the notified body may conduct complete or partial audits. It must provide those responsible for implementation with an inspection report and, if appropriate, an audit report.

2.5.4. The notified body shall be able to monitor a subsystem on which an interoperability constituent is mounted in order to assess, where required by the corresponding TSI, its suitability for use in its intended railway environment.

2.6. **Submission**

A copy of the technical file accompanying the 'EC' declaration of verification must be kept by the applicant) throughout the service life of the subsystem. It must be sent to any Member State or the Agency, upon request.

The documentation submitted for an application for an authorisation for placing in service shall be submitted to the authority where the authorisation is sought. The national safety authority or the Agency may request that part (s) of the documents submitted together with the authorisation is/are translated into its own language.

2.7. **Publication**

Each notified body must periodically publish relevant information concerning:

(a) requests for verification and ISV received,

(b) request for assessment of conformity and suitability for use of ICs,

(c) ISV issued or refused,

(d) certificates of verification and 'EC' certificates for suitability for use issued or refused,

(e) certificates of verification issued or refused.

2.8. **Language**

The files and correspondence relating to the 'EC' verification procedure must be written in a Union official language of the Member State in which the applicant is established or in a Union official language accepted by the applicant

3. CERTIFICATE OF VERIFICATION ISSUED BY A DESIGNATED BODY

3.1. **Introduction**

In the case where national rules apply, the verification shall include a procedure whereby the body designated pursuant to Article 15(8), (the designated body) checks and certifies that the subsystem complies with the national rules notified in accordance with Article 14 for each Member State in which the subsystem is intended to be authorised to be placed in service.

3.2. **Certificate of verification**

The designated body draws up the certificate of verification intended for the applicant.

The certificate shall contain a precise reference to the national rule(s) whose conformity has been examined by the designated body in the verification process.

In the case of national rules related to the subsystems composing a vehicle, the designated body shall divide the certificate into two parts, one part including the references to those national rules strictly related to the technical compatibility between the vehicle and the network concerned, and the other part for all other national rules.

3.3. **File**

The file compiled by the designated body and accompanying the certificate of verification in the case of national rules must be included in the technical file accompanying the 'EC' declaration of verification referred to in point 2.4 and shall contain the technical data relevant for the assessment of the conformity of the subsystem with those national rules.

3.4. **Language**

The files and correspondence relating to the 'EC' verification procedure must be written in a Union official language of the Member State in which the applicant) is established or in a Union official language accepted by the applicant.

4. VERIFICATION OF PARTS OF SUBSYSTEMS IN ACCORDANCE WITH ARTICLE 15(7)

If a certificate of verification is to be issued for certain parts of a subsystem, provisions for this Annex shall apply *mutatis mutandis* for those parts.

ANNEX V

PART A

Repealed Directives

with list of the successive amendments thereto

(referred to in Article 58)

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 57)

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

ANNEX VI

Correlation table

Directive 2008/57/EC	This Directive
Article 1	Article 1
Article 2(a) to (z)	Article 2(1) to (5), (7) to (17) and (19) to (28)
—	Article 2(6), (18) and (29) to (45)
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(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, 20, 21, 22 and 23
Article 20	—
Article 21	—
Articles 22 to 25	—
Article 26	Article 24
Article 27	Article 14(10)
—	Article 26
Article 28 and Annex VIII	Articles 27 to 44
—	Article 45

Directive 2008/57/EC	This Directive
Article 29	Article 51
Articles 30 and 31	—
Article 32	Article 46
Article 33	Article 47(3), (4), (6) and (7)
—	Article 47(1), (2) and (5)
Article 34	Article 48
Article 35	Article 49
Article 36	—
—	Article 50 —
Article 37	Article 52
Article 38	Article 57
Article 39	Article 53
—	Articles 54 and 55
—	Article 56
Article 40	Article 58
Article 41	Article 59
Article 42	Article 60
Annex I to III	Annex I to III
Annex IV	Article 9(2)
Annex V	Article 15(9)
Annex VI	Annex IV
Annex VII	Article 14(10)
Annex VIII	Articles 30, 31 and 32
Annex IX	Article 7(5)
Annex X	Annex V
Annex XI	Annex VI