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## Legislation

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# EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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## I

(Legislative acts)

## REGULATIONS

**REGULATION (EU) 2016/796 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**of 11 May 2016**  
**on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004**  
**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91(1) 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 <sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(3)</sup>,

Whereas:

- (1) The progressive establishment of a single European railway area requires Union action in the field of the rules applicable to railways with regard to technical safety and interoperability aspects, the two being inextricably linked and both requiring a higher level of harmonisation at Union level. Relevant railway legislation has been adopted in the last two decades, in particular three railway packages of which Directive 2004/49/EC of the European Parliament and of the Council <sup>(4)</sup> and Directive 2008/57/EC of the European Parliament and of the Council <sup>(5)</sup> are the most relevant in this regard.
- (2) The simultaneous pursuit of the goals of railway safety and interoperability requires substantial technical work led by a specialised body. That is why it was necessary, as part of the Second Railway Package in 2004, to create within the existing institutional framework, and with respect for the balance of power in the Union, a European agency dealing with railway safety and interoperability.

<sup>(1)</sup> OJ C 327, 12.11.2013, p. 122.

<sup>(2)</sup> OJ C 356, 5.12.2013, p. 92.

<sup>(3)</sup> 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 (OJ C 56, 12.2.2016, p. 1). Position of the European Parliament of 28 April 2016 (not yet published in the Official Journal).

<sup>(4)</sup> Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) (OJ L 164, 30.4.2004, p. 44).

<sup>(5)</sup> 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).

- (3) Regulation (EC) No 881/2004 of the European Parliament and of the Council <sup>(1)</sup> establishes a European railway agency ('the Agency') in order to promote the establishment of a European railway area without borders and to help revitalise the railway sector while reinforcing its essential advantages in terms of safety. The Fourth Railway Package contains important changes designed to improve the functioning of the single European railway area through amendments by way of recast to Directive 2004/49/EC and Directive 2008/57/EC, both of which are directly linked to the tasks of the Agency. Those Directives provide in particular for the performance of tasks relating to the issuing of vehicle authorisations and safety certificates at Union level. It involves a greater role for the Agency. Due to the substantial number of changes that it introduces to the tasks and internal organisation of the Agency, Regulation (EC) No 881/2004 should be repealed and replaced by a new legal act.
- (4) The Agency should contribute to the development of a genuine European railway culture providing an essential tool for dialogue, consultation and the exchange of views between all the actors in the railway sector, having due regard to their respective functions, as well as the technical characteristics of the railway sector. When performing its tasks, and particularly when drafting recommendations and opinions, the Agency should take utmost account of external railway expertise, in particular that of professionals from the railway sector and from the relevant national authorities. The Agency should therefore set up competent and representative working parties and groups composed predominantly of those professionals.
- (5) In order to provide insight into the economic effects on the railway sector and its impact on society, to allow others, in particular the Commission, the Management Board of the Agency ('the Management Board') and the Executive Director of the Agency ('the Executive Director') to make informed decisions, and to manage the work priorities and resource allocation within the Agency more effectively, the Agency should further develop its engagement in impact-assessment activity.
- (6) The Agency should provide independent and objective technical support predominantly to the Commission. Directive (EU) 2016/797 of the European Parliament and of the Council <sup>(2)</sup> provides for the drafting and revision of technical specifications for interoperability ('TSIs'), while Directive (EU) 2016/798 of the European Parliament and of the Council <sup>(3)</sup> provides for the drafting and revision of common safety methods ('CSMs'), common safety targets ('CSTs') and common safety indicators ('CSIs'). The continuity of the work and of the development of TSIs, CSMs, CSTs and CSIs requires a permanent technical framework and a specialised body with a dedicated staff possessing a high level of expertise. To that end, the Agency should be responsible for providing the Commission with recommendations and opinions in relation to the drafting and revision of TSIs, CSMs, CSTs and CSIs. The Agency should also provide an independent technical opinion, upon request from the national safety authorities and regulatory bodies.
- (7) In order to make the issuing of single safety certificates to railway undertakings more efficient and impartial, it is essential that the Agency be assigned a central role. Where the area of operation is limited to one Member State, the railway undertaking concerned should have the possibility of choosing whether to submit its application for a single safety certificate to the Agency or to the national safety authority. Directive (EU) 2016/798 is to provide for this.
- (8) Currently, Directive 2008/57/EC provides, in the case of rail vehicles, for the granting of authorisation for the placing in service of such vehicles in each Member State, except in certain specific cases. The task force on vehicle authorisation set up by the Commission in 2011 discussed several cases where manufacturers and railway undertakings have suffered as a result of the excessive duration and cost of the authorisation process and proposed a number of improvements. As some problems are due to the complexity of the current vehicle authorisation process, it should be simplified and, where possible, unified under a single procedure. Each rail vehicle should only receive one authorisation. Where the area of use is limited to a network or networks within one Member State only, the applicant should have the possibility of choosing whether to submit its application for vehicle authorisation, through the one-stop shop referred to in this Regulation, to the Agency or to the national safety authority. This would bring tangible benefits for the sector by reducing the cost and duration of the procedure, and would diminish the risk of potential discrimination, especially against new companies wishing to enter a railway market. Directive (EU) 2016/797 is to provide for this.

<sup>(1)</sup> Regulation (EC) No 881/2004 of the European Parliament and of the Council of 29 April 2004 establishing a European railway agency (Agency Regulation) (OJ L 164, 30.4.2004, p. 1).

<sup>(2)</sup> Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system (see page 44 of this Official Journal).

<sup>(3)</sup> Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (see page 102 of this Official Journal).

- (9) It is essential that Directive (EU) 2016/797 and Directive (EU) 2016/798 should not lead to a reduced level of safety in the Union rail system. In that respect, the Agency should take full responsibility for the vehicle authorisations and single safety certificates it issues, assuming, inter alia, both contractual and non-contractual liability in respect thereof.
- (10) With regard to liability of the staff of the Agency when carrying out the tasks assigned to the Agency, Protocol No 7 on the privileges and immunities of the European Union should apply. The application of that Protocol should not lead to undue delays or the imposition of unjustified restrictions on the conduct of national judicial proceedings. In the event of judicial proceedings involving the staff of the Agency, in which a member of the staff is requested to appear before a national court, the Management Board should decide without undue delay to waive that member of the staff's immunity, provided that such waiver will not compromise the interests of the Union. Such a decision should be duly justified and should be amenable to judicial review before the Court of Justice of the European Union.
- (11) The Agency should cooperate loyally with the national judicial authorities, in particular in cases in which the participation of the Agency is necessary by reason of the Agency having exercised its powers in relation to vehicle authorisations, single safety certificates issued by it and decisions for the approval of European Rail Traffic Management System (ERTMS) trackside equipment projects. Where the Agency or a member of its staff is requested to provide information in the context of relevant national proceedings, the Agency should ensure that such request for information or, if necessary, participation in proceedings, is handled with due diligence and within a reasonable period of time. To that end, the Management Board should adopt appropriate procedures to be used in such cases.
- (12) In order to further pursue the development of the single European railway area, in particular in relation to providing appropriate information to freight customers and passengers, and to avoid fragmented development of telematics applications, it is necessary to give the Agency a strengthened role in the field of such applications. The Agency, as a competent body at Union level, should be given a prominent role so as to ensure consistency in the development and deployment of all telematics applications. To that end, the Agency should be empowered to act as the system authority for telematics applications, and should, in that capacity, maintain, monitor and manage all corresponding subsystems requirements at Union level.
- (13) Given the importance of the ERTMS for the smooth development of the single European railway area and its safety, and in order to avoid fragmented development of the ERTMS, it is necessary to strengthen overall coordination at Union level. Therefore, the Agency, as the Union body with the greatest expertise in the field, should be given a more prominent role in this field so as to ensure consistency in the development of the ERTMS, to contribute to ensuring that ERTMS equipment complies with the specifications in force and to ensure that ERTMS-related European research programmes are coordinated with the development of ERTMS technical specifications. In particular, the Agency should prevent additional national requirements in relation to the ERTMS from jeopardising its interoperability. However, incompatible national requirements should be applied only on a voluntary basis or repealed.
- (14) In order to make the procedures for issuing authorisations for the placing in service of trackside control-command and signalling subsystems more efficient and to harmonise those procedures at Union level, it is essential that, before any call for tenders relating to ERTMS trackside equipment, the Agency check that the technical solutions envisaged are fully compliant with the relevant TSIs and are therefore fully interoperable. Directive (EU) 2016/797 is to provide for this. The Agency should establish a group composed of notified conformity assessment bodies active in the field of the ERTMS. The participation of such bodies in the group should be encouraged as much as possible.
- (15) In order to facilitate cooperation and guarantee a clear distribution of tasks and responsibilities between the Agency and national safety authorities, a communication protocol between them should be developed. In addition, a common information and communication platform with a virtual one-stop-shop functionality should be developed, if appropriate on the basis of the existing applications and registers, by extending their functionality with the aim of keeping the Agency and national safety authorities informed about all applications for authorisations and safety certifications, the stages of these procedures and their outcome. An important objective of this platform is to identify at an early stage the need to coordinate decisions to be taken by national safety authorities and the Agency in the case of different applications requesting similar authorisations and safety certificates. Such cases should be identified in a summarised way by automatic notifications.

- (16) Competent national authorities have, thus far, been charging for issuing vehicle authorisations and single safety certificates. With the transfer of competences to the Union, the Agency should be entitled to charge applicants for issuing the certificates and authorisations mentioned in the preceding recitals. It is important to establish certain principles applicable to fees and charges payable to the Agency. The level of those fees and charges should be estimated in such a way as to cover the full cost of the service delivered, including as appropriate the relevant costs resulting from the tasks assigned to the national safety authorities. Those fees and charges should be equal to or lower than the current average for the relevant services and should be set in a transparent, fair and uniform manner in cooperation with Member States. They should not jeopardise the competitiveness of the European railway sector and should be established on a basis which takes due account of the ability of undertakings to pay and should not result in the imposition of an unnecessary financial burden on companies. They should also take into account, as appropriate, the specific needs of small and medium-sized enterprises.
- (17) It is a general objective that the new allocation of functions and tasks between national safety authorities and the Agency should be done efficiently, without diminishing the current high levels of safety. To that end, cooperation agreements, including cost elements, should be concluded between the Agency and the national safety authorities. The Agency should have sufficient resources to enable it to carry out its new tasks, and the timing of the allocation of those resources should be based on clearly defined needs.
- (18) When drafting recommendations, the Agency should take into account the cases of networks which are isolated from the rest of the Union rail system and which require specific expertise for geographical or historical reasons. In addition, where operation is limited to such networks, it should be possible for applicants for single safety certificates and vehicle authorisations to fulfil the necessary formalities locally through the relevant national safety authorities. To that end, and with a view to reducing administrative burdens and costs, it should be possible for cooperation agreements 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 or the single safety certificate.
- (19) Taking into account the knowledge of national authorities, in particular the national safety authorities, the Agency should be allowed to make appropriate use of that expertise when granting the relevant authorisations and single safety certificates. To that end, secondment of national experts to the Agency should be encouraged.
- (20) Directive (EU) 2016/798 and Directive (EU) 2016/797 are to provide for examination of national measures from the point of view of railway safety and interoperability, and compatibility with competition rules. They are also to limit the possibility for Member States to adopt new national rules. The current system in which numerous national rules continue to exist may lead to possible conflicts with Union rules and give rise to insufficient transparency and possible discrimination against operators, including smaller and new ones. In order to migrate towards a system of truly transparent and impartial railway rules at Union level, a gradual reduction of national rules, including operating rules, needs to be reinforced. An opinion based on independent and neutral expertise is essential at Union level. To that end, the role of the Agency needs to be strengthened.
- (21) Performance, organisation and decision-making procedures in the field of railway safety and interoperability vary substantially among the national safety authorities and notified conformity assessment bodies, with a detrimental effect on the smooth operation of the single European railway area. In particular, small and medium-sized enterprises wishing to enter the railway market in another Member State can be negatively affected. Therefore, strengthened coordination with a view to greater harmonisation at Union level is essential. To that end, the Agency should monitor the performance and decision-making of the national safety authorities and the notified conformity assessment bodies through audits and inspections, where appropriate in cooperation with national accreditation bodies.
- (22) In the field of safety, it is important to ensure the greatest possible transparency and an effective flow of information. An analysis of performance, based on CSIs and linking all parties in the sector, is important and should be carried out. As regards statistics, close collaboration with Eurostat is necessary.

- (23) The Agency should be responsible for publishing a report every 2 years in order to monitor progress in achieving railway safety and interoperability. Given its technical expertise and impartiality, the Agency should also assist the Commission in the performance by the latter of its task of monitoring the implementation of Union railway safety and interoperability legislation.
- (24) The interoperability of the trans-European transport network should be enhanced and the new investment projects chosen for support by the Union should be in line with the objective of interoperability set out in Regulation (EU) No 1315/2013 of the European Parliament and of the Council <sup>(1)</sup>. The Agency is the appropriate body to contribute to the attainment of those objectives and should cooperate closely with competent Union bodies in relation to projects concerning the trans-European transport network. With regard to ERTMS deployment and ERTMS projects, the Agency's role should include helping applicants to implement projects which are compliant with the TSI on control-command and signalling.
- (25) The maintenance of rolling stock is an important part of the safety system. There has been no genuine European market for the maintenance of rail equipment owing to the lack of a system for certification of maintenance workshops. This situation has led to increased costs for the sector and results in journeys without loads. Common conditions for the certification of maintenance workshops and of entities in charge of the maintenance of vehicles other than freight wagons should therefore be gradually developed and updated, with the Agency being the most appropriate body to propose adequate solutions to the Commission.
- (26) The vocational qualifications required of train drivers are a major factor in both railway safety and interoperability within the Union. Vocational qualifications are also a precondition for the free movement of workers in the railway sector. This issue should be addressed within the existing framework for social dialogue. The Agency should provide the technical support necessary in order to take account of this aspect at Union level.
- (27) The Agency should facilitate cooperation between the national safety authorities, the national investigating bodies and representative bodies from the railway sector acting at Union level in order to promote good practice, the exchange of relevant information and the collection of railway-related data, and to monitor the overall safety performance of the Union rail system.
- (28) In order to ensure the greatest possible levels of transparency and equal access for all parties to relevant information, the registers, where relevant, and the documents envisaged for the railway safety and interoperability processes should be accessible to the public. The same applies to licences, single safety certificates and other relevant railway documents. The Agency should provide efficient, user-friendly and easily accessible means of exchanging and publishing that information, in particular through appropriate IT solutions, with a view to improving the cost-effectiveness of the railway system and supporting the operational needs of the sector.
- (29) The promotion of innovation and research in the railway field is important and should be encouraged by the Agency. Any financial assistance provided within the framework of the Agency's activities in this respect should not lead to any distortion in the relevant market.
- (30) In order to increase the efficiency of Union financial support, its quality and its compatibility with relevant technical regulations, the Agency should play an active role in the assessment of rail projects.
- (31) Proper and uniform understanding of legislation on railway safety and interoperability, implementation guides and recommendations of the Agency are preconditions for effective implementation of the railway *acquis* and the functioning of the railway market. Therefore, the Agency should actively engage in training and explanatory activities in that regard.
- (32) Taking into account the new functions of the Agency in relation to the issuing of vehicle authorisations and single safety certificates, there will be an important need for training and publication activities in those areas. The national safety authorities should be invited to participate in training activities free of charge, whenever possible, in particular when they have been involved in their preparation.

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<sup>(1)</sup> Regulation (EU) No 1315/2013 of the European Parliament and of the Council of 11 December 2013 on Union guidelines for the development of the trans-European transport network and repealing Decision No 661/2010/EU (OJ L 348, 20.12.2013, p. 1).

- (33) In order to perform its tasks properly, the Agency should have legal personality and an autonomous budget funded mainly through a contribution by the Union and through fees and charges paid by applicants. The Agency's independence and impartiality should not be compromised by any financial contribution that it receives from Member States, third countries or other entities. In order to ensure independence in its daily management and in the opinions, recommendations and decisions which it issues, the Agency's organisation should be transparent and the Executive Director should have full responsibility. The Agency's staff should be independent and should be employed on both short-term and long-term contracts in order to maintain its organisational knowledge and business continuity, while keeping a necessary and ongoing exchange of expertise with the railway sector. The expenditure of the Agency should include staff, administrative, infrastructure and operational expenses, and, inter alia, the amount paid to the national safety authorities for their work in the vehicle authorisation and the single safety certification process, in accordance with the relevant cooperation agreements and with the provisions of the implementing act concerning the determination of fees and charges.
- (34) With regard to the prevention and management of conflicts of interest, it is essential that the Agency act impartially, demonstrate integrity and establish high professional standards. There should never be any legitimate reason to suspect that decisions might be influenced by interests conflicting with the role of the Agency as a body serving the Union as a whole or by private interests or affiliations of any member of the Agency staff, any seconded national expert, or any member of the Management Board or Boards of Appeal which would create, or have the potential to create, a conflict with the proper performance of the official duties of the person concerned. The Management Board should therefore adopt comprehensive rules on conflicts of interests that cover the entire Agency. Those rules should take account of recommendations issued by the Court of Auditors in its Special Report No 15 of 2012.
- (35) In order to streamline the decision-making process in the Agency and to contribute to enhancing efficiency and effectiveness, a two-level governance structure should be introduced. To that end, the Member States and the Commission should be represented on a Management Board vested with the necessary powers, including the power to establish the budget and approve the programming document. The Management Board should give general orientations for the Agency's activities and be more closely involved in the monitoring of the Agency's activities, with a view to reinforcing supervision on administrative and budgetary matters. A smaller Executive Board should be set up with the task of preparing the meetings of the Management Board in an appropriate manner and supporting its decision-making process. The powers of the Executive Board should be defined in a mandate to be adopted by the Management Board and should, where appropriate, include opinions and provisional decisions subject to final endorsement by the Management Board.
- (36) In order to guarantee the transparency of the Management Board's decisions, representatives of the sectors concerned should attend its meetings, but without the right to vote. The representatives of the various stakeholders should be appointed by the Commission on the basis of their representativeness at Union level of railway undertakings, infrastructure managers, the railway industry, trade-union organisations, passengers and freight customers.
- (37) It is necessary to ensure that parties affected by decisions made by the Agency have the right to seek the necessary remedies, which should be granted in an independent and impartial manner. An appropriate appeal mechanism should be set up in order for decisions of the Executive Director to be subject to appeal before a specialised Board of Appeal.
- (38) In cases of disagreement between the Agency and national safety authorities on the issuing of single safety certificates or vehicle authorisations, an arbitration procedure should be established so that decisions are taken in a concerted and cooperative manner.
- (39) A broader strategic perspective in relation to the activities of the Agency would facilitate the planning and management of its resources in a more effective manner and would contribute to a higher quality of its outputs. This is confirmed and reinforced by the Commission Delegated Regulation (EU) No 1271/2013 <sup>(1)</sup>. Therefore, a single programming document containing the annual and multi-annual work programmes should be adopted and updated periodically by the Management Board, following proper consultation of the relevant stakeholders.

<sup>(1)</sup> Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council (OJ L 328, 7.12.2013, p. 42).



- (40) When a new task is assigned to the Agency in relation to the safety and interoperability of the Union rail system after the adoption of the programming document, the Management Board should, if necessary, amend the programming document to include that new task following an analysis of the impact, in human and budgetary terms, on resources.
- (41) The activity of the Agency should be transparent. Effective control by the European Parliament should be ensured and, to that end, the European Parliament should be consulted on the draft multiannual part of the programming document of the Agency and have the possibility of hearing the Executive Director of the Agency and receiving the annual report on the Agency's activities. The Agency should also apply the relevant Union legislation concerning public access to documents.
- (42) Over the past years, as more decentralised agencies have been created, transparency and control over the management of Union funding allocated to them has improved, in particular as regards the budgetisation of fees, financial control, power of discharge, pension scheme contributions and the internal budgetary procedure (code of conduct). Similarly, Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council <sup>(1)</sup> should apply without restriction to the Agency, which should accede to the Inter-institutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-Fraud Office (OLAF) <sup>(2)</sup>.
- (43) The Agency should actively promote the Union approach to railway safety and interoperability in its relations with international organisations and third countries. That should also include, within the limits of the Agency's competence, facilitating reciprocal access for Union railway undertakings to the rail markets of third countries and access for Union rolling stock to the networks of third countries.
- (44) In order to ensure uniform conditions for the implementation of this Regulation with regard to the examination of draft national rules and existing national rules, the monitoring of national safety authorities and notified conformity assessment bodies, the establishment of the rules of procedure of the Boards of Appeal and the determination of fees and charges which the Agency is entitled to levy, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council <sup>(3)</sup>.
- (45) Since the objective of this Regulation, namely to establish a specialised body to formulate common solutions on matters concerning railway safety and interoperability, cannot be sufficiently achieved by the Member States but can rather, by reason of the joint nature of the work to be done, 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 Regulation does not go beyond what is necessary in order to achieve that objective.
- (46) It is necessary for the proper functioning of the Agency to implement certain principles regarding the governance of the Agency in order to comply with the Joint Statement and Common Approach agreed by the Inter-Institutional Working Group on EU decentralised agencies in July 2012, the purpose of which is to streamline the activities of agencies and increase their performance.
- (47) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union,

<sup>(1)</sup> Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

<sup>(2)</sup> OJ L 136, 31.5.1999, p. 15.

<sup>(3)</sup> 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 the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

HAVE ADOPTED THIS REGULATION:

CHAPTER 1

PRINCIPLES

*Article 1*

**Subject-matter and scope**

1. This Regulation establishes a European Union Agency for Railways ('the Agency').
2. This Regulation provides for:
  - (a) the establishment and tasks of the Agency;
  - (b) the tasks of the Member States in the context of this Regulation.
3. This Regulation supports the establishment of the single European railway area, and in particular the objectives relating to:
  - (a) interoperability within the Union rail system provided for in Directive (EU) 2016/797;
  - (b) safety of the Union rail system provided for in Directive (EU) 2016/798;
  - (c) the certification of train drivers provided for in Directive 2007/59/EC of the European Parliament and of the Council <sup>(1)</sup>.

*Article 2*

**Objectives of the Agency**

The objective of the Agency shall be to contribute to the further development and effective functioning of a single European railway area without frontiers, by guaranteeing a high level of railway safety and interoperability, while improving the competitive position of the railway sector. In particular, the Agency shall contribute, on technical matters, to the implementation of Union legislation by developing a common approach to safety on the Union rail system and by enhancing the level of interoperability on the Union rail system.

Further objectives of the Agency shall be to follow the development of national railway rules in order to support the performance of national authorities acting in the fields of railway safety and interoperability and to promote the optimisation of procedures.

Where provided for by Directive (EU) 2016/797 and Directive (EU) 2016/798, the Agency shall perform the role of Union authority responsible for issuing authorisations for the placing on the market of railway vehicles and vehicle types and for issuing single safety certificates for railway undertakings.

In pursuing those objectives, the Agency shall take full account of the process of enlargement of the Union and of the specific constraints relating to rail links with third countries.

*Article 3*

**Legal status**

1. The Agency shall be a body of the Union with legal personality.
2. In each of the Member States, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under their laws. It may, in particular, acquire or dispose of movable and immovable property and may be a party to legal proceedings.
3. The Agency shall be represented by its Executive Director.
4. The Agency shall have sole responsibility for the functions and powers assigned to it.

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<sup>(1)</sup> Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community (OJ L 315, 3.12.2007, p. 51).

*Article 4***Type of acts of the Agency**

The Agency may:

- (a) address recommendations to the Commission concerning the application of Articles 13, 15, 17, 19, 35, 36 and 37;
- (b) address recommendations to Member States concerning the application of Article 34;
- (c) issue opinions to the Commission pursuant to Article 10(2) and Article 42, and to the authorities concerned in the Member States pursuant to Articles 10, 25 and 26;
- (d) address recommendations to national safety authorities pursuant to Article 33(4);
- (e) issue decisions pursuant to Articles 14, 20, 21 and 22;
- (f) issue opinions constituting acceptable means of compliance pursuant to Article 19;
- (g) issue technical documents pursuant to Article 19;
- (h) issue audit reports pursuant to Articles 33 and 34;
- (i) issue guidelines and other non-binding documents facilitating application of railway safety and interoperability legislation pursuant to Articles 13, 19, 28, 32, 33 and 37.

## CHAPTER 2

## WORKING METHODS

*Article 5***Creation and composition of the working parties and groups**

1. The Agency shall set up a limited number of working parties for the purpose of drawing up recommendations and, where relevant, guidelines, in particular relating to technical specifications for interoperability ('TSIs'), common safety targets ('CSTs'), common safety methods ('CSMs') and the use of common safety indicators ('CSIs').

The Agency may set up working parties in other duly justified cases at the request of the Commission or the Committee referred to in Article 81 ('the committee') or on its own initiative, after consulting the Commission.

The working parties shall be chaired by a representative of the Agency.

2. The working parties shall be composed of:

- representatives nominated by the competent national authorities to participate in the working parties,
- professionals from the railway sector selected by the Agency from the list referred to in paragraph 3. The Agency shall ensure adequate representation of those sectors of the industry and of those users which could be affected by measures the Commission may propose on the basis of the recommendations addressed to it by the Agency. The Agency shall strive, where possible, for a balanced geographical representation.

The Agency may, if necessary, appoint to the working parties independent experts and representatives of international organisations recognised as competent in the field concerned. Members of the staff of the Agency may not be appointed to the working parties, except for the chair of the working parties, who shall be a representative of the Agency.

3. Each representative body referred to in Article 38(4) shall forward to the Agency a list of the most qualified experts mandated to represent it in each working party and shall update that list whenever changes occur.

4. Whenever the work of such working parties has a direct impact on the working conditions, health and safety of workers in the industry, representatives designated by the trade-union organisations acting at European level shall participate in the relevant working parties as full members.
5. Travel and subsistence expenses of the members of the working parties, based on rules and scales adopted by the Management Board, shall be met by the Agency.
6. The Agency shall take due account of the outcome of the work done by the working parties when drawing up the recommendations and guidelines referred to in paragraph 1.
7. The Agency shall set up groups for the purposes of Articles 24, 29 and Article 38(1).
8. The Agency may set up groups in accordance with Article 38(4) and in duly justified cases at the request of the Commission or of the committee, or on its own initiative.
9. The work of the working parties and of the groups shall be transparent. The Management Board shall adopt the rules of procedure of the working parties and of the groups, including transparency rules.

#### *Article 6*

### **Consultation of the social partners**

Whenever the tasks provided for in Articles 13, 15, 19, and 36 have a direct impact on the social environment or working conditions of workers in the industry, the Agency shall consult the social partners within the framework of the sectoral dialogue committee set up pursuant to Commission Decision 98/500/EC <sup>(1)</sup>. In such cases, the social partners may react to those consultations, provided that they do so within 3 months.

Those consultations shall be held before the Agency addresses its recommendations to the Commission. The Agency shall take due account of those consultations, and shall, at all times, be available to expound on its recommendations. The opinions expressed by the sectoral dialogue committee shall be forwarded by the Agency, together with the recommendation by the Agency, to the Commission and by the Commission to the committee.

#### *Article 7*

### **Consultation of rail freight customers and passengers**

Whenever the tasks provided for in Articles 13 and 19 have a direct impact on rail freight customers and passengers, the Agency shall consult the organisations representing them, including representatives of persons with disabilities and persons with reduced mobility. In such cases, those organisations may react to those consultations, provided that they do so within 3 months.

The list of organisations to be consulted shall be drawn up by the Commission with the assistance of the committee.

Those consultations shall be held before the Agency addresses its recommendations to the Commission. The Agency shall take due account of those consultations, and shall, at all times, be available to expound on its recommendations. The opinions expressed by the organisations concerned shall be forwarded by the Agency, together with the recommendation by the Agency, to the Commission and by the Commission to the committee.

#### *Article 8*

### **Impact assessment**

1. The Agency shall conduct an impact assessment of its recommendations and opinions. The Management Board shall adopt an impact-assessment methodology based on the methodology of the Commission. The Agency shall liaise with the Commission to ensure that relevant work at the Commission is duly taken into account. The Agency shall clearly identify the assumptions used as the basis for the impact assessment and the data sources used in the report accompanying each recommendation.

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<sup>(1)</sup> 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).

2. Before including an activity in the programming document adopted by the Management Board, in accordance with Article 51(1), the Agency shall conduct an early impact assessment in relation to which it shall state:

- (a) the issue to be solved and the possible solutions;
- (b) the extent to which a specific action, including addressing a recommendation or issuing an opinion of the Agency, would be required;
- (c) the expected Agency contribution to the solution of the problem.

Before any activities or projects are included in the programming document, they shall be made subject to an efficiency analysis individually and in conjunction with each other, in order to make best use of the budget and resources of the Agency.

3. The Agency may conduct an *ex post* assessment of the legislation based on its recommendations.

4. Member States shall provide the Agency with the data necessary for an impact assessment, where available.

At the request of the Agency, the representative bodies shall provide the Agency with non-confidential data necessary for the impact assessment.

#### *Article 9*

#### **Studies**

Where required for the implementation of its tasks, the Agency shall order studies, involving, where appropriate, the working parties and groups referred to in Article 5, and shall finance those studies from its budget.

#### *Article 10*

#### **Opinions**

1. The Agency shall issue opinions at the request of one or more national regulatory bodies referred to in Article 55 of Directive 2012/34/EU of the European Parliament and of the Council <sup>(1)</sup>, in particular concerning safety-related and interoperability-related aspects of matters drawn to their attention.

2. The Agency shall issue opinions at the request of the Commission on amendments to any act adopted on the basis of Directive (EU) 2016/797 or Directive (EU) 2016/798, especially where any alleged deficiency is signalled.

3. All opinions of the Agency, and in particular those referred to in paragraph 2, shall be issued by the Agency as soon as possible and at the latest within 2 months of receipt of the request therefor, unless otherwise agreed with the requesting party. Those opinions shall be made public by the Agency within 1 month after they are issued, in a version from which all commercially confidential material has been removed.

#### *Article 11*

#### **Visits to Member States**

1. In order to perform the tasks entrusted to it, in particular those referred to in Articles 14, 20, 21, 25, 26, 31, 32, 33, 34, 35 and 42, and to assist the Commission in fulfilling its duties under the Treaty on the Functioning of European Union (TFEU), including, in particular the assessment of the effective implementation of relevant Union legislation, the Agency may carry out visits to the Member States, in accordance with the policy, working methods and procedures adopted by the Management Board.

<sup>(1)</sup> 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).

2. Following consultation with the Member State concerned, the Agency shall inform the latter in good time of the planned visit, the names of the Agency officials delegated to carry out the visit, the date on which the visit is to start and its expected duration. The Agency officials delegated to carry out such visits shall do so on presentation of a decision in writing by the Executive Director specifying the purpose and the aims of their visit.
3. The national authorities of the Member States concerned shall facilitate the work of the Agency's staff.
4. The Agency shall draw up a report on each visit referred to in paragraph 1 and send it to the Commission and to the Member State concerned.
5. This Article is without prejudice to the inspections referred to in Articles 33(7) and 34(6).
6. Travel, accommodation, subsistence and other expenses incurred by the Agency's staff shall be met by the Agency.

#### Article 12

#### **One-stop shop**

1. The Agency shall establish and manage an information and communications system with at least the following one-stop-shop functions:
  - (a) a single entry point through which the applicant shall submit its application files for type authorisation, vehicle authorisations for placing on the market and single safety certificates. Where the area of use or operation is limited to a network or networks within one Member State only, the single entry point shall be developed so as to ensure that the applicant selects the authority it wishes to process the application for issuing authorisations or single safety certificates for the whole procedure;
  - (b) a common information-exchange platform, providing the Agency and national safety authorities with information about all applications for authorisations and single safety certificates, the stages of these procedures and their outcome, and, where applicable, the requests and decisions of the Board of Appeal;
  - (c) a common information-exchange platform, providing the Agency and national safety authorities with information about requests for approvals by the Agency in accordance with Article 19 of Directive (EU) 2016/797 and applications for authorisations 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 stages of these procedures and their outcome, and, where applicable, the requests and decisions of the Board of Appeal;
  - (d) an early-warning system able to identify at an early stage the needs for coordination between decisions to be taken by national safety authorities and the Agency in the case of different applications requesting similar authorisations or single safety certificates.
2. The technical and functional specifications of the one-stop shop referred to in paragraph 1 shall be developed in cooperation with the network of national safety authorities referred to in Article 38 on the basis of a draft prepared by the Agency taking into account the results of a cost-benefit analysis. On this basis, the Management Board shall adopt the technical and functional specifications and a plan to establish the one-stop shop. The one-stop shop shall be developed without prejudice to the intellectual property rights and the required confidentiality level, and taking into consideration, if appropriate, the IT applications and registers already set up by the Agency, such as those referred to in Article 37.
3. The one-stop shop shall be operational by 16 June 2019.

4. The Agency shall monitor the applications submitted through the one-stop shop, in particular by using the early-warning system referred to in point (d) of paragraph 1. If different applications requesting similar authorisations or single safety certificates are detected, the Agency shall ensure appropriate follow-up, such as:

- (a) informing applicant(s) that there is another or similar request for authorisation or certification;
- (b) coordinating with the relevant national safety authority in order to ensure consistency of decisions to be taken by national safety authorities and the Agency. If no mutually acceptable solution can be found within 1 month of the beginning of the coordination process, the matter shall be referred for arbitration to the Board of Appeal referred to in Articles 55, 61 and 62.

### CHAPTER 3

#### TASKS OF THE AGENCY RELATING TO RAILWAY SAFETY

##### *Article 13*

#### **Technical support – recommendations on railway safety**

1. The Agency shall address recommendations to the Commission on the CSIs, CSMs and CSTs provided for in Articles 5, 6 and 7 of Directive (EU) 2016/798. The Agency shall also address recommendations on periodic revision of CSIs, CSMs and CSTs to the Commission.
2. The Agency shall address recommendations to the Commission, at the request of the Commission or on its own initiative, on other measures in the field of safety, taking into account the experience gained.
3. The Agency shall issue guidelines in order to assist national safety authorities with regard to supervision of railway undertakings, infrastructure managers and other actors, in accordance with Article 17 of Directive (EU) 2016/798.
4. The Agency may address recommendations to the Commission on the CSMs covering any elements of the safety management system which need to be harmonised at Union level, in accordance with Article 9(7) of Directive (EU) 2016/798.
5. The Agency may issue guidelines and other non-binding documents to facilitate the implementation of railway safety legislation, including the provision of assistance to Member States in identifying national rules that can be repealed further to the adoption and/or revision of CSMs and guidelines for the adoption of new national rules or the amendment of existing national rules. The Agency may also issue guidelines on railway safety and safety certification, including lists of examples of good practice, in particular for cross-border transport and infrastructure.

##### *Article 14*

#### **Single safety certificates**

The Agency shall issue, renew, suspend and amend single safety certificates and cooperate with national safety authorities in that respect in accordance with Articles 10, 11 and 18 of Directive (EU) 2016/798.

The Agency shall restrict or revoke single safety certificates and cooperate with national safety authorities in that respect in accordance with Article 17 of Directive (EU) 2016/798.

##### *Article 15*

#### **Maintenance of vehicles**

1. The Agency shall assist the Commission with regard to the system of certification of entities in charge of maintenance in accordance with Article 14(7) of Directive (EU) 2016/798.

2. The Agency shall address recommendations to the Commission for the purposes of Article 14(8) of Directive (EU) 2016/798.
3. The Agency shall analyse any alternative measures decided in accordance with Article 15 of Directive (EU) 2016/798 and shall include the outcome of its analysis in the report referred to in Article 35(4) of this Regulation.
4. The Agency shall support and, upon request, coordinate the national safety authorities in the supervision of entities in charge of maintenance as referred to in point (c) of Article 17(1) of Directive (EU) 2016/798.

#### Article 16

##### **Cooperation with national investigating bodies**

The Agency shall cooperate with national investigating bodies in accordance with Article 20(3), Article 22(1), (2), (5) and (7) and Article 26 of Directive (EU) 2016/798.

#### Article 17

##### **Transport of dangerous goods by rail**

The Agency shall follow developments in the legislation dealing with the transport of dangerous goods by rail within the meaning of Directive 2008/68/EC of the European Parliament and of the Council <sup>(1)</sup> and shall, together with the Commission, ensure that such developments are consistent with the legislation dealing with rail safety and interoperability, in particular the essential requirements. To that end, the Agency shall assist the Commission and may issue recommendations at the Commission's request or on its own initiative.

#### Article 18

##### **Exchange of information on safety-related accidents**

The Agency shall encourage the exchange of information on safety-related accidents, incidents and near misses, taking into account the experience of the railway actors referred to in Article 4 of Directive (EU) 2016/798. That exchange of information shall lead to the development of good practices at Member State level.

#### CHAPTER 4

##### TASKS OF THE AGENCY RELATING TO INTEROPERABILITY

#### Article 19

##### **Technical support in the field of railway interoperability**

1. The Agency shall:
  - (a) address recommendations to the Commission on the TSIs and their revision, in accordance with Article 5 of Directive (EU) 2016/797;
  - (b) address recommendations to the Commission on the templates for the 'EC' declaration of verification and for documents of the technical file that has to accompany it for the purposes of Article 15(9) of Directive (EU) 2016/797;
  - (c) address recommendations to the Commission on specifications for registers and their revision for the purposes of Articles 47, 48 and 49 of Directive (EU) 2016/797;
  - (d) issue opinions which constitute acceptable means of compliance concerning deficiencies in TSIs, in accordance with Article 6(4) of Directive (EU) 2016/797, and provide those opinions to the Commission;

<sup>(1)</sup> Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).



- (e) at the request of the Commission, issue opinions to it regarding requests by Member States for non-application of TSIs, in accordance with Article 7 of Directive (EU) 2016/797;
  - (f) issue technical documents, in accordance with Article 4(8) of Directive (EU) 2016/797;
  - (g) issue a decision for approval before any call for tenders relating to ERTMS trackside equipment in order to ensure harmonised implementation of the ERTMS in the Union pursuant to Article 19 of Directive (EU) 2016/797;
  - (h) issue recommendations to the Commission regarding the training and certification of on-board staff with safety-critical tasks;
  - (i) issue detailed guidance concerning standards for the relevant European standardisation bodies to complement the mandate given to them by the Commission;
  - (j) address recommendations to the Commission relating to the working conditions of all staff carrying out safety-critical tasks;
  - (k) address recommendations to the Commission in relation to harmonised standards to be developed by European standardisation bodies and standards relating to interchangeable spare parts which may improve the level of safety and interoperability of the Union rail system;
  - (l) address, where appropriate, recommendations to the Commission in relation to safety-critical components.
2. In drafting recommendations as referred to in points (a), (b), (c), (h), (k) and (l) of paragraph 1, the Agency shall:
- (a) ensure that the TSIs and the specifications for registers are adapted to technical progress, market trends and social requirements;
  - (b) ensure that the development and updating of the TSIs and the development of any European standards which prove necessary for interoperability are coordinated, and maintain relevant contacts with European standardisation bodies;
  - (c) participate, where appropriate, as an observer in the relevant working groups established by recognised standardisation bodies.
3. The Agency may issue guidelines and other non-binding documents to facilitate the implementation of railway interoperability legislation, including assistance to Member States in identifying national rules that can be repealed further to the adoption or revision of TSIs.
4. In cases of non-compliance of interoperability constituents with essential requirements, the Agency shall assist the Commission in accordance with Article 11 of Directive (EU) 2016/797.

#### *Article 20*

### **Authorisations for the placing on the market of vehicles**

The Agency shall issue authorisations for the placing on the market of railway vehicles, and shall be empowered to renew, amend, suspend and revoke authorisations issued by it. For that purpose, the Agency shall cooperate with national safety authorities in accordance with Article 21 of Directive (EU) 2016/797.

#### *Article 21*

### **Authorisations for the placing on the market of vehicle types**

The Agency shall issue authorisations for the placing on the market of vehicle types, and shall be empowered to renew, amend, suspend and revoke authorisations issued by it, in accordance with Article 24 of Directive (EU) 2016/797.

#### *Article 22*

### **Placing in service of trackside control-command and signalling subsystems**

The Agency shall, before any call for tenders relating to ERTMS trackside equipment, check that the technical solutions are fully compliant with the relevant TSIs and are therefore fully interoperable, and take a decision for approval in accordance with Article 19 of Directive (EU) 2016/797.

*Article 23***Telematics applications**

1. The Agency shall act as the system authority to ensure the coordinated development of telematics applications in the Union, in accordance with relevant TSIs. To that end, the Agency shall maintain, monitor and manage the corresponding subsystems requirements.
2. The Agency shall define, publish and apply the procedure for managing requests for changes to specifications for telematics applications. To that end, the Agency shall set up, maintain and update a register of requests for changes to such specifications and their status, accompanied by the relevant justifications.
3. The Agency shall develop and maintain the technical tools for managing the different versions of specifications for telematics applications and endeavour to ensure backward compatibility.
4. The Agency shall assist the Commission in the monitoring of deployment of specifications for telematics applications in accordance with relevant TSIs.

*Article 24***Support for notified conformity assessment bodies**

1. The Agency shall support the activities of notified conformity assessment bodies as referred to in Article 30 of Directive (EU) 2016/797. That support shall include, in particular, the issue of drafting guidelines for assessing the conformity or suitability for use of an interoperability constituent as referred to in Article 9 of Directive (EU) 2016/797 and of guidelines for the 'EC' verification procedure referred to in Articles 10 and 15 of Directive (EU) 2016/797.
2. The Agency may facilitate cooperation between notified conformity assessment bodies, in accordance with Article 44 of Directive (EU) 2016/797, and may, in particular, act as the technical secretariat for their coordination group.

## CHAPTER 5

## TASKS OF THE AGENCY RELATING TO NATIONAL RULES

*Article 25***Examination of draft national rules**

1. The Agency shall, within 2 months of receipt thereof, examine the draft national rules submitted to it in accordance with Article 8(4) of Directive (EU) 2016/798 and Article 14(5) of Directive (EU) 2016/797. If translation is necessary or the draft national rule is long or complex the Agency may extend this time period by up to 3 additional months, subject to the consent of the Member State. However, in exceptional circumstances, the Agency and the Member State concerned may mutually agree to further extend that period.

Within that period, the Agency shall exchange relevant information with the Member State concerned, consult the relevant stakeholders where appropriate, and subsequently inform the Member State of the outcome of the examination.

2. Where, after the examination referred to in paragraph 1, the Agency considers that the draft national rules enable the essential requirements for railway interoperability to be fulfilled, the CSMs and TSIs in force to be respected and the CSTs to be achieved, and that they would not result in arbitrary discrimination or a disguised restriction on rail transport operations between Member States, the Agency shall inform the Commission and the Member State concerned of its positive assessment. In that case, the Commission may validate the rules in the IT system referred to in Article 27. Where the Agency within 2 months of receipt of the draft national rule or within the extended time period agreed in accordance with paragraph 1 does not inform the Commission and the Member State concerned of its assessment, the Member State may proceed with the introduction of the rule without prejudice to Article 26.

3. Where the examination referred to in paragraph 1 leads to a negative assessment, the Agency shall inform the Member State concerned and ask it to state its position regarding that assessment. If, following that exchange of views with the Member State concerned, the Agency maintains its negative assessment, the Agency shall within a maximum period of 1 month:

- (a) issue an opinion addressed to the Member State concerned, stating the reasons why the national rule or rules in question should not enter into force and/or be applied; and
- (b) inform the Commission of its negative assessment, stating the reasons why the national rule or rules in question should not enter into force and/or be applied.

This shall not prejudice the right of a Member State to adopt a new national rule in accordance with point (c) of Article 8(3) of Directive (EU) 2016/798 or with point (b) of Article 14(4) of Directive (EU) 2016/797.

4. The Member State concerned shall inform the Commission of its position on the opinion referred to in paragraph 3 within 2 months, including its reasons in the event of disagreement.

Where the reasons provided are deemed not to be sufficient, or in the absence of such information, and the Member State adopts the national rule in question without paying sufficient heed to the opinion referred to in paragraph 3, the Commission may adopt, by way of implementing acts, a decision addressed to the Member State concerned, requesting it to modify or repeal that rule. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 81(2).

#### Article 26

#### **Examination of existing national rules**

1. The Agency shall, within 2 months of receipt thereof, examine the national rules notified in accordance with Article 14(6) of Directive (EU) 2016/798 and Article 8(6) of Directive (EU) 2016/797. If translation is necessary or the national rule is long or complex the Agency may extend this time period by up to 3 additional months, subject to the consent of the Member State. However, in exceptional circumstances, the Agency and the Member State concerned may mutually agree to further extend that time period.

Within that period, the Agency shall exchange relevant information with the Member State concerned and subsequently inform it of the outcome of the examination.

2. Where, after the examination referred to in paragraph 1, the Agency considers that the national rules enable the essential requirements for railway interoperability to be fulfilled, the CSMs and TSIs in force to be respected and the CSTs to be achieved, and that they would not result in arbitrary discrimination or a disguised restriction on rail transport operations between Member States, the Agency shall inform the Commission and the Member State concerned of its positive assessment. In that case, the Commission may validate the rules in the IT system referred to in Article 27. Where the Agency does not inform the Commission and the Member State concerned within 2 months of receipt of the national rules, or within the extended time period agreed in accordance with paragraph 1, the rule shall remain valid.

3. Where the examination referred to in paragraph 1 leads to a negative assessment, the Agency shall inform the Member State concerned and ask it to state its position regarding that assessment. If, following that exchange of views with the Member State concerned, the Agency maintains its negative assessment, the Agency shall within a maximum period of 1 month:

- (a) issue an opinion addressed to the Member State concerned, stating that the national rule or rules in question has or have been the subject of a negative assessment and the reasons why the rule or rules in question should be modified or repealed; and
- (b) inform the Commission of its negative assessment, stating the reasons why the national rule or rules in question should be modified or repealed.

4. The Member State concerned shall inform the Commission of its position on the opinion referred to in paragraph 3 within 2 months, including its reasons in the event of disagreement. Where the reasons provided are deemed not to be sufficient, or in the absence of such information, the Commission may adopt, by way of implementing acts, a decision addressed to the Member State concerned, requesting it to modify or repeal the national rule in question. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 81(2).

5. By way of derogation from paragraphs 3 and 4, in the case of urgent preventive measures, where the examination referred to in paragraph 1 leads to a negative assessment and if the Member State concerned has not amended or repealed the national rule in question within 2 months of receipt of the opinion of the Agency, the Commission may adopt a decision, by way of implementing acts, requesting the Member State to amend or repeal that rule. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 81(2).

In the case of a positive assessment by the Agency and if the national rule in question has an impact on more than one Member State, the Commission, working in cooperation with the Agency and Member States, shall take the appropriate measures, including the revision of CSMs and TSIs where necessary.

6. The procedure referred to in paragraphs 2, 3 and 4 shall apply, *mutatis mutandis*, in cases where the Agency becomes aware of any national rule, whether or not notified, that is redundant, in conflict with the CSMs, CSTs, TSIs or any other Union legislation in the railway field or creates an unjustified barrier to the single railway market.

#### Article 27

### IT system to be used for notification purposes and classification of national rules

1. The Agency shall manage a dedicated IT system containing national rules as referred to in Articles 25 and 26 and acceptable national means of compliance referred to in point 34 of Article 2 of Directive (EU) 2016/797. The Agency shall make them accessible to stakeholders for the purposes of consultation, where appropriate.

2. Member States shall notify national rules as referred to in Articles 25(1) and 26(1) to the Agency and to the Commission through the IT system referred to in paragraph 1 of this Article. The Agency shall publish those rules in that IT system, including the status of their examination and, when completed, the positive or negative outcome of the assessment, and use that IT system for the purposes of informing the Commission in accordance with Articles 25 and 26.

3. The Agency shall carry out a technical examination of the existing national rules referred to in the available national legislation, which, as of 15 June 2016 are listed in its reference document database. The Agency shall classify notified national rules in accordance with Article 14(10) of Directive (EU) 2016/797. To that end, it shall use the system referred to in paragraph 1 of this Article.

4. The Agency shall classify notified national rules in accordance with Article 8 of, and Annex I to, Directive (EU) 2016/798, taking into account the development of Union legislation. To that end, the Agency shall develop a rule management tool to be used by Member States for simplifying their systems of national rules. The Agency shall use the system referred to in paragraph 1 of this Article to publish the rule management tool.

#### CHAPTER 6

### TASKS OF THE AGENCY RELATING TO THE EUROPEAN RAIL TRAFFIC MANAGEMENT SYSTEM (ERTMS)

#### Article 28

### System authority for the ERTMS

1. The Agency shall act as the system authority to ensure the coordinated development of the ERTMS within the Union, in accordance with relevant TSIs. To that end, the Agency shall maintain, monitor and manage the corresponding subsystem requirements, including the technical specifications for ETCS and GSM-R.

2. The Agency shall define, publish and apply the procedure for managing requests for changes to the ERTMS specifications. To that end, the Agency shall set up, maintain and update a register of requests for changes to ERTMS specifications and their status, accompanied by the relevant justifications.

3. The development of new versions of ERTMS technical specifications shall not be detrimental to the rate of deployment of the ERTMS, the stability of the specifications which is needed to optimise the production of ERTMS equipment, the return on investment for railway undertakings, infrastructure managers and keepers, and efficient planning of the deployment of the ERTMS.
4. The Agency shall develop and maintain the technical tools for managing the different versions of the ERTMS, with the aim of ensuring technical and operational compatibility between networks and vehicles fitted with different versions and of providing incentives for the swift and coordinated implementation of the versions in force.
5. In accordance with Article 5(10) of Directive (EU) 2016/797, the Agency shall ensure that successive versions of ERTMS equipment are technically compatible with earlier versions.
6. The Agency shall draw up and disseminate relevant application guidelines for stakeholders and explanatory documentation relating to the technical specifications for the ERTMS.

#### Article 29

##### **ERTMS group of notified conformity assessment bodies**

1. The Agency shall set up and chair an ERTMS group of notified conformity assessment bodies as referred to in Article 30(7) of Directive (EU) 2016/797.

The group shall check the consistency of application of the procedure for assessing the conformity or suitability for use of an interoperability constituent as referred to in Article 9 of Directive (EU) 2016/797 and of the 'EC' procedures for verification referred to in Article 10 of Directive (EU) 2016/797 and carried out by notified conformity assessment bodies.

2. The Agency shall report every year to the Commission on the activities of the group referred to in paragraph 1, including by means of statistics on attendance of notified conformity assessment bodies' representatives in the group.
3. The Agency shall evaluate the application of the procedure for conformity assessment of interoperability constituents and of the 'EC' verification procedure for ERTMS equipment, and shall submit to the Commission, every 2 years, a report including, where appropriate, recommendations for any improvements.

#### Article 30

##### **Compatibility between ERTMS on-board and trackside subsystems**

1. The Agency shall decide to:
  - (a) without prejudice to Article 21(5) of Directive (EU) 2016/797, and before issuing an authorisation for the placing on the market of a vehicle equipped with an ERTMS on-board subsystem, advise applicants at their request, on the technical compatibility between ERTMS on-board and trackside subsystems;
  - (b) without prejudice to Article 17 of Directive (EU) 2016/798, and after issuing an authorisation for the placing on the market of a vehicle equipped with an ERTMS on-board subsystem, advise railway undertakings at their request, before they use a vehicle equipped with an ERTMS on-board subsystem, on the operational compatibility between ERTMS on-board and trackside subsystems.

For the purposes of this paragraph, the Agency shall cooperate with the relevant national safety authorities.

2. Where, before an authorisation is issued by the national safety authority, the Agency becomes aware or is informed by the applicant through the one-stop shop in accordance with Article 19(6) of Directive (EU) 2016/797 that a project design or specification was changed after the Agency had issued an approval in accordance with Article 19 of Directive (EU) 2016/797 and that there is a risk of a lack of technical and operational compatibility between the ERTMS trackside subsystem and vehicles fitted with ERTMS, it shall cooperate with the parties involved, including the applicant and the relevant national safety authority, in order to find a mutually acceptable solution. If no mutually acceptable solution can be found within 1 month of the beginning of the coordination process, the matter shall be referred to the Board of Appeal for arbitration.

3. Where the Agency finds after an authorisation is issued by the national safety authority that there is a risk of a lack of technical or operational compatibility between the relevant networks and vehicles fitted with ERTMS equipment, the national safety authority and the Agency shall cooperate with all parties involved in order to find, without delay, a mutually acceptable solution. The Agency shall inform the Commission about such cases.

#### Article 31

### Supporting ERTMS deployment and ERTMS projects

1. The Agency shall assist the Commission in monitoring the deployment of the ERTMS in accordance with the European deployment plan in force. At the Commission's request, it shall facilitate the coordination of ERTMS deployment along the Trans-European Transport Corridors and Rail Freight Corridors as provided for in Regulation (EU) No 913/2010 of the European Parliament and of the Council <sup>(1)</sup>.

2. The Agency shall ensure technical follow-up of Union-funded projects for the deployment of the ERTMS, including, where applicable and without causing undue delay to the process, analysis of tendering documents at the time of the call for tenders. The Agency shall also, if necessary, assist the beneficiaries of those Union funds to ensure that the technical solutions implemented within projects are fully compliant with the TSIs relating to control-command and signalling and are therefore fully interoperable.

#### Article 32

### Accreditation of laboratories

1. The Agency shall support, in particular by giving appropriate guidelines to the accreditation bodies, harmonised accreditation of ERTMS laboratories in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council <sup>(2)</sup>.

2. The Agency shall inform Member States and the Commission in cases of non-conformity with the requirements of Regulation (EC) No 765/2008 in relation to the accreditation of ERTMS laboratories.

3. The Agency may participate as an observer in the peer evaluations required by Regulation (EC) No 765/2008.

#### CHAPTER 7

#### TASKS OF THE AGENCY RELATING TO MONITORING THE SINGLE EUROPEAN RAILWAY AREA

#### Article 33

### Monitoring of the performance and decision-making of national safety authorities

1. In order to perform the tasks entrusted to it and to assist the Commission in fulfilling its duties under the TFEU, the Agency shall monitor the performance and decision-making of national safety authorities through audit and inspections, on behalf of the Commission.

<sup>(1)</sup> Regulation (EU) No 913/2010 of the European Parliament and of the Council of 22 September 2010 concerning a European rail network for competitive freight (OJ L 276, 20.10.2010, p. 22).

<sup>(2)</sup> 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).

2. The Agency shall be entitled to audit:
  - (a) the capacity of national safety authorities to execute tasks relating to railway safety and interoperability; and
  - (b) the effectiveness of the monitoring by national safety authorities of safety management systems of actors as referred to in Article 17 of Directive (EU) 2016/798.

The Management Board shall adopt the policy, working methods, procedures and practical arrangements for the application of this paragraph, including, where appropriate, arrangements regarding consultation with Member States before the publication of information.

The Agency shall promote the inclusion in the audit team of qualified auditors from national safety authorities that are not subject to the actual audit. For that purpose, the Agency shall establish a list of qualified auditors and provide them with training when needed.

3. The Agency shall issue audit reports and send them to the national safety authority concerned, to the Member State concerned and to the Commission. Each audit report shall include, in particular, a list of any deficiencies identified by the Agency as well as recommendations for improvement.

4. If the Agency considers that the deficiencies referred to in paragraph 3 prevent the national safety authority concerned from effectively performing its tasks in relation to railway safety and interoperability, the Agency shall recommend to the national safety authority that it take appropriate steps within a mutually agreed time limit, taking into account the seriousness of the deficiency. The Member State concerned shall be kept informed by the Agency about such a recommendation.

5. Where a national safety authority disagrees with the Agency's recommendations referred to in paragraph 4, or does not take the appropriate steps referred to in paragraph 4, or where no answer is given by a national safety authority in response to the Agency's recommendations within 3 months of receipt thereof, the Agency shall inform the Commission.

6. The Commission shall inform the Member State concerned of the issue and ask it to state its position regarding the recommendation referred to in paragraph 4. Where the answers provided are deemed not to be sufficient or, where no answer is given by the Member State within 3 months of the Commission's request, the Commission may within 6 months take appropriate action concerning the steps to be taken as a result of the audit, where relevant.

7. The Agency shall be entitled to conduct pre-announced inspections of national safety authorities, to verify specific areas of their activities and operation, and in particular to review documents, processes and records relating to their tasks as referred to in Directive (EU) 2016/798. The inspections may be conducted on an ad hoc basis or in accordance with a plan developed by the Agency. The duration of an inspection shall not exceed 2 days. The national authorities of the Member States shall facilitate the work of the Agency's staff. The Agency shall provide the Commission, the Member State concerned and the national safety authority concerned with a report on each inspection.

The policy, working methods and procedure for performing the inspections shall be adopted by the Management Board.

#### Article 34

### **Monitoring of notified conformity assessment bodies**

1. For the purposes of Article 41 of Directive (EU) 2016/797, the Agency shall support the Commission in monitoring the notified conformity assessment bodies through the provision of assistance to accreditation bodies and to the relevant national authorities, and through audits and inspections, as provided for in paragraphs 2 to 6.

2. The Agency shall support harmonised accreditation of notified conformity assessment bodies, in particular by giving the accreditation bodies appropriate guidance on evaluation criteria and procedures to assess whether notified bodies meet the requirements referred to in Chapter VI of Directive (EU) 2016/797, via the European accreditation infrastructure recognised pursuant to Article 14 of Regulation (EC) No 765/2008.

3. In the case of notified conformity assessment bodies which are not accredited in accordance with Article 27 of Directive (EU) 2016/797, the Agency may audit their capacity to meet the requirements laid down in Article 30 of Directive (EU) 2016/797. The procedure for performing audits shall be adopted by the Management Board.

4. The Agency shall issue audit reports covering the activities referred to in paragraph 3 and send them to the notified conformity assessment body concerned, to the Member State concerned and to the Commission. Each audit report shall include, in particular, a list of any deficiencies identified by the Agency as well as recommendations for improvement. If the Agency considers that those deficiencies prevent the notified conformity assessment body concerned from effectively performing its tasks in relation to railway interoperability, the Agency shall adopt a recommendation requesting the Member State in which that notified body is established to take appropriate steps, within a mutually agreed time limit, taking into account the seriousness of the deficiency.

5. Where a Member State disagrees with the recommendation referred to in paragraph 4 or does not take the appropriate steps referred to in paragraph 4, or where no answer is given by a notified body in response to the Agency's recommendation within 3 months of receipt thereof, the Agency shall inform the Commission. The Commission shall inform the Member State concerned about the issue and ask it to state its position regarding the recommendation. Where the answers provided are deemed not to be sufficient or where no answer is given by the Member State within 3 months of receipt of the Commission's request, the Commission may adopt a decision within a period of 6 months.

6. The Agency shall be entitled to conduct pre-announced or unannounced inspections of notified conformity assessment bodies, to verify specific areas of their activities and operation, and in particular to review documents, certificates and records relating to their tasks as referred to in Article 41 of Directive (EU) 2016/797. In the case of accredited bodies, the Agency shall cooperate with the relevant national accreditation bodies. In the case of conformity assessment bodies which are not accredited, the Agency shall cooperate with the relevant national authorities that recognised the notified bodies concerned. The inspections may be conducted on an ad hoc basis or in accordance with the policy, working methods and procedures developed by the Agency. The duration of an inspection shall not exceed 2 days. The notified conformity assessment bodies shall facilitate the work of the Agency's staff. The Agency shall provide the Commission and the Member State concerned with a report on each inspection.

#### *Article 35*

### **Monitoring progress of railway safety and interoperability**

1. The Agency, together with the national investigation bodies, shall collect relevant data on accidents and incidents, taking into account the contribution of the national investigation bodies to the safety of the Union rail system.

2. The Agency shall monitor the overall safety performance of the Union rail system. The Agency may in particular seek the assistance of the bodies referred to in Article 38, including assistance in the form of the collection of data and access to the results of the peer review in accordance with Article 22(7) of Directive (EU) 2016/798. The Agency shall also draw on the data collected by Eurostat and shall cooperate with Eurostat to prevent any duplication of work and to ensure methodological consistency between the CSIs and the indicators used in other modes of transport.

3. At the Commission's request, the Agency shall issue recommendations on how to improve the interoperability of the Union rail system, in particular by facilitating coordination between railway undertakings and infrastructure managers, or between infrastructure managers.

4. The Agency shall monitor progress on the safety and interoperability of the Union rail system. Every 2 years it shall present to the Commission, and publish, a report on progress on safety and interoperability in the single European railway area.



5. The Agency shall, at the Commission's request, provide reports on the state of implementation and application of Union legislation on railway safety and interoperability in a given Member State.

6. The Agency shall, at the request of a Member State or the Commission, provide an overview of the safety and interoperability level of the Union rail system and establish a dedicated tool for that purpose, in accordance with Article 53(2) of Directive (EU) 2016/797.

#### CHAPTER 8

##### OTHER TASKS OF THE AGENCY

###### Article 36

###### **Railway staff**

1. The Agency shall perform the appropriate tasks relating to railway staff set out in Articles 4, 22, 23, 25, 28, 33, 34, 35 and 37 of Directive 2007/59/EC of the European Parliament and of the Council <sup>(1)</sup>.

2. The Commission may request the Agency to perform other tasks relating to railway staff in accordance with Directive 2007/59/EC and to issue recommendations relating to railway staff entrusted with safety tasks not covered by Directive 2007/59/EC.

3. The Agency shall consult the national authorities competent with regard to railway staff issues concerning the tasks referred to in paragraphs 1 and 2. The Agency may promote cooperation between those authorities, including by organising appropriate meetings with their representatives.

###### Article 37

###### **Registers and their accessibility**

1. The Agency shall set up and maintain, where relevant in cooperation with the competent national actors:

- (a) the European Vehicle Register in accordance with Article 47 of Directive (EU) 2016/797;
- (b) the European register of authorised vehicle types in accordance with Article 48 of Directive (EU) 2016/797.

2. The Agency shall act as the system authority for all registers and databases referred to in Directive (EU) 2016/797, Directive (EU) 2016/798 and Directive 2007/59/EC. Its actions in that capacity shall include, in particular:

- (a) developing and maintaining specifications of the registers;
- (b) coordinating developments in the Member States in relation to the registers;
- (c) providing guidance on the registers to relevant stakeholders;
- (d) addressing recommendations to the Commission regarding improvements to the specifications of existing registers, where necessary including simplification and deletion of redundant information, and any need to set up new ones, subject to a cost-benefit analysis.

3. The Agency shall make the following documents and registers provided for in Directive (EU) 2016/797 and Directive (EU) 2016/798 publicly available:

- (a) the 'EC' declarations of verification of subsystems;
- (b) the 'EC' declarations of conformity of interoperability constituents and 'EC' declarations of suitability of use of interoperability constituents;
- (c) the licences issued in accordance with Article 24(8) of Directive 2012/34/EU of the European Parliament and of the Council <sup>(2)</sup>;
- (d) the single safety certificates issued in accordance with Article 10 of Directive (EU) 2016/798;
- (e) the investigation reports sent to the Agency in accordance with Article 24 of Directive (EU) 2016/798;
- (f) the national rules notified to the Commission in accordance with Article 8 of Directive (EU) 2016/798 and Article 14 of Directive (EU) 2016/797;

<sup>(1)</sup> Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community (OJ L 315, 3.12.2007, p. 51).

<sup>(2)</sup> 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).

- (g) the vehicle registers referred to in Article 47 of Directive (EU) 2016/797, including via the links to relevant national registers;
- (h) the infrastructure registers, including via the links to relevant national registers;
- (i) the registers relating to entities in charge of maintenance and their certification bodies;
- (j) the European register of authorised types of vehicles in accordance with Article 48 of Directive (EU) 2016/797;
- (k) the register of requests for changes and planned changes to the ERTMS specifications, in accordance with Article 28 (2) of this Regulation;
- (l) the register of requests for changes and planned changes to the TSIs for telematics applications for passengers ('TAPs') and telematics applications for freight ('TAFs'), in accordance with Article 23(2) of this Regulation;
- (m) the register of vehicle keeper markings kept by the Agency in accordance with the TSI on operation and traffic management;
- (n) the quality reports issued in accordance with Article 28(2) of Regulation (EC) No 1371/2007 of the European Parliament and of the Council <sup>(1)</sup>.

4. The practical arrangements for sending the documents referred to in paragraph 3 shall be discussed and agreed by the Commission and the Member States on the basis of a draft prepared by the Agency.

5. When the documents referred to in paragraph 3 are being sent, the bodies concerned may indicate which documents are not to be disclosed to the public for reasons of security.

6. The national authorities responsible for issuing the licences referred to in point (c) of paragraph 3 of this Article shall notify the Agency of each individual decision to issue, renew, amend or revoke those licenses, in accordance with Directive 2012/34/EU.

The national safety authorities responsible for issuing the single safety certificates referred to in point (d) of paragraph 3 of this Article shall notify the Agency, in accordance with Article 10(16) of Directive (EU) 2016/798, of each individual decision to issue, renew, amend, restrict or revoke those certificates.

7. The Agency may include any public document or link relevant to the objectives of this Regulation in the public database, taking into account applicable Union legislation on data protection.

#### Article 38

##### **Cooperation among national safety authorities, investigating bodies and representative bodies**

1. The Agency shall establish a network of the national safety authorities referred to in Article 16 of Directive (EU) 2016/798. The Agency shall provide the network with a secretariat.

2. The Agency shall support the investigating bodies in accordance with Article 22(7) of Directive (EU) 2016/798. To facilitate cooperation among the investigating bodies, the Agency shall provide a secretariat which shall be organised separately from the functions within the Agency relating to safety certification of railway undertakings and authorisations to place vehicles on the market.

3. The objectives of the cooperation between the bodies referred to in paragraph 1 and 2 shall be, in particular:

- (a) exchange of information relating to railway safety and interoperability;
- (b) promotion of good practices and dissemination of relevant knowledge;
- (c) provision to the Agency of data on railway safety, in particular data relating to CSIs.

The Agency shall facilitate cooperation between the national safety authorities and national investigating bodies, in particular by holding joint meetings.

<sup>(1)</sup> Regulation (EC) No 1371/2007 of the European Parliament and of the Council of 23 October 2007 on rail passengers' rights and obligations (OJ L 315, 3.12.2007, p. 14).

4. The Agency may establish a network of representative bodies from the railway sector acting at Union level. The list of those bodies shall be defined by the Commission. The Agency may provide the network with a secretariat. The tasks of the network shall be, in particular:

- (a) exchange of information relating to railway safety and interoperability;
- (b) promotion of good practices and dissemination of relevant knowledge;
- (c) provision to the Agency of data on railway safety and interoperability.

5. The networks and bodies referred to in paragraphs 1, 2 and 4 of this Article may comment on the draft opinions referred to in Article 10(2).

6. The Agency may establish other networks with bodies or authorities having responsibility for a part of the Union rail system.

7. The Commission may participate in the meetings of networks referred to in this Article.

#### *Article 39*

### **Communication and dissemination**

The Agency shall communicate and disseminate to relevant stakeholders information relating to the Union framework of railway law and the development of standards and guidance in accordance with relevant communication and dissemination plans adopted by the Management Board on the basis of a draft prepared by the Agency. Those plans, based on an analysis of needs, shall be regularly updated by the Management Board.

#### *Article 40*

### **Research and promotion of innovation**

1. The Agency shall contribute, at the Commission's request or on its own initiative subject to the procedure referred to in Article 52(4), to railway research activities at Union level, including by providing support to relevant Commission services and representative bodies. Such contributions shall be without prejudice to other research activities at Union level.

2. The Commission may entrust the Agency with the task of promoting innovation aimed at improving railway safety and interoperability, particularly the use of new information technologies, timetable information and tracking and tracing systems.

#### *Article 41*

### **Assistance to the Commission**

The Agency shall, at the Commission's request, assist the Commission with the implementation of Union legislation aimed at enhancing the level of interoperability of railway systems and at developing a common approach to safety on the Union rail system.

Such assistance may include providing technical advice in matters requiring specific knowledge and collecting information through the networks referred to in Article 38.

#### *Article 42*

### **Assistance with the assessment of rail projects**

Without prejudice to the derogations provided for by Article 7 of Directive (EU) 2016/797, the Agency shall, at the Commission's request, examine, from the point of view of railway safety and interoperability, any project involving the design, construction, renewal or upgrading of any subsystem in respect of which an application for Union financial support has been submitted.

Within a period to be agreed with the Commission, which may not exceed 2 months, taking into account the importance of the project and the resources available, the Agency shall give an opinion on whether the project complies with the relevant railway safety and interoperability legislation.

#### *Article 43*

### **Assistance to Member States, candidate countries and stakeholders**

1. At the request of the Commission, Member States, candidate countries or the networks referred to in Article 38, the Agency shall engage in training and other appropriate activities concerning the application and explanation of railway safety and interoperability legislation and related products of the Agency such as registers, implementation guides and recommendations.
2. The nature and extent of the activities referred to in paragraph 1, including the possible impact on resources, shall be decided by the Management Board and included in the Agency's programming document. The costs of such assistance shall be borne by the requesting parties unless otherwise agreed.

#### *Article 44*

### **International relations**

1. In so far as is necessary in order to achieve the objectives set out in this Regulation, and without prejudice to the respective competences of the Member States, the institutions of the Union and the European External Action Service, the Agency may strengthen coordination with international organisations on the basis of concluded agreements and develop contacts and enter into administrative arrangements with supervisory authorities, international organisations and the administrations of third countries competent in matters covered by Agency activities in order to keep up with scientific and technical developments and to ensure promotion of the Union railways legislation and standards.
2. The arrangements referred to in paragraph 1 shall not create legal obligations incumbent on the Union and its Member States, nor shall they prevent Member States and their competent authorities from concluding bilateral or multilateral arrangements with the supervisory authorities, international organisations and the administrations of third countries referred to in paragraph 1. Such bilateral or multilateral arrangements and cooperation shall be subject to prior discussion with the Commission and periodical reporting to it. The Management Board shall be duly informed of those bilateral or multilateral arrangements.
3. The Management Board shall adopt a strategy for relations with third countries or international organisations concerning matters for which the Agency is competent. That strategy shall be included in the programming document of the Agency, with a specification of associated resources.

#### *Article 45*

### **Coordination regarding spare parts**

The Agency shall contribute to the identification of potential interchangeable spare parts to be standardised, including main interfaces to such spare parts. To that end, the Agency may establish a working party to coordinate the activities of relevant stakeholders and may establish contacts with the European standardisation bodies. The Agency shall present to the Commission appropriate recommendations.

#### CHAPTER 9

#### ORGANISATION OF THE AGENCY

#### *Article 46*

### **Administrative and management structure**

The Agency's administrative and management structure shall comprise:

- (a) a Management Board, which shall exercise the functions set out in Article 51;
- (b) an Executive Board, which shall exercise the functions set out in Article 53;

- (c) an Executive Director, who shall exercise the duties set out in Article 54;
- (d) one or more Boards of Appeal, which shall exercise the functions set out in Articles 58 to 62.

#### Article 47

### Composition of the Management Board

1. The Management Board shall be composed of one representative from each Member State and two representatives of the Commission, all with a right to vote.

The Management Board shall also include six representatives, without a right to vote, representing, at European level, the following stakeholders:

- (a) railway undertakings;
- (b) infrastructure managers;
- (c) the railway industry;
- (d) trade-union organisations;
- (e) passengers;
- (f) freight customers.

For each of those stakeholders, the Commission shall appoint a representative and an alternate from a shortlist of four names submitted by their respective European organisations.

- 2. Board members and their alternates shall be appointed in light of their knowledge of the Agency's core business, taking into account relevant managerial, administrative and budgetary skills. All parties shall make efforts to limit turnover of their representatives on the Management Board, in order to ensure continuity of the Management Board's work. All parties shall aim to achieve a balanced gender representation on the Management Board.
- 3. Member States and the Commission shall appoint members of the Management Board and their respective alternates who shall replace the members in their absence.
- 4. The term of office of the members shall be 4 years and may be renewed.
- 5. Where appropriate, the participation of representatives of third countries and the conditions of such participation shall be established in the arrangements referred to in Article 75.

#### Article 48

### Chairperson of the Management Board

1. The Management Board shall elect, by a two-thirds majority of its members entitled to vote, a chairperson from among the representatives of the Member States and a deputy chairperson from among its members.

The deputy chairperson shall replace the chairperson in the event of the chairperson being unable to attend to his or her duties.

2. The term of office of the chairperson and deputy chairperson shall be 4 years and may be renewed once. If, however, their membership of the Management Board ends at any time during their term of office, their term of office shall automatically also expire on that date.

#### Article 49

### Meetings

1. Meetings of the Management Board shall be conducted in accordance with its rules of procedure and convened by its chairperson. The Executive Director of the Agency shall participate in the meetings, except when his or her participation may lead to a conflict of interests, as decided by the chairperson, or when the Management Board is to take a decision relating to Article 70, in accordance with point (i) of Article 51(1).

The Management Board may invite any person whose opinion may be of interest to attend specific agenda items of its meetings as an observer.

2. The Management Board shall meet at least twice a year. It shall also meet on the initiative of the chairperson or at the request of the Commission, of a majority of its members, or of one-third of the Member States' representatives on the Board.

3. When a matter of confidentiality or a conflict of interest arises, the Management Board may decide to examine specific items on its agenda without the members concerned being present. This does not affect the right of the Member States and of the Commission to be represented by an alternate or by any other person. Detailed rules for the application of this provision shall be laid down in the Management Board's rules of procedure.

#### Article 50

#### Voting

Unless stated otherwise in this Regulation, the Management Board shall take its decisions by an absolute majority of its members entitled to vote. Each member entitled to vote shall have one vote.

#### Article 51

#### Functions of the Management Board

1. In order to ensure that the Agency carries out its tasks, the Management Board shall:
  - (a) adopt the annual report on the Agency's activities for the previous year, send it by 1 July to the European Parliament, the Council, the Commission and the Court of Auditors, and make it public;
  - (b) adopt each year, by a two-thirds majority of its members entitled to vote, after having received the opinion of the Commission and in accordance with Article 52, the programming document of the Agency;
  - (c) adopt, by a two-thirds majority of its members entitled to vote, the annual budget of the Agency and exercise other functions in relation to the Agency's budget, in accordance with Chapter 10;
  - (d) establish procedures for decision-making by the Executive Director;
  - (e) adopt a policy, working methods and procedures in relation to visits, audits and inspections pursuant to Articles 11, 33 and 34;
  - (f) establish its rules of procedure;
  - (g) adopt and update the communication and dissemination plans referred to in Article 39;
  - (h) subject to paragraph 2, exercise, with respect to the staff of the Agency, the powers conferred by the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the Union ('Staff Regulations' and the 'Conditions of Employment of Other Servants') laid down in Regulation (EEC, Euratom, ECSC) No 259/68<sup>(1)</sup> on the appointing authority and on the authority empowered to conclude contracts of employment;
  - (i) take duly reasoned decisions in relation to waiver of immunity in accordance with Article 17 of Protocol No 7 on the privileges and immunities of the European Union;
  - (j) submit to the Commission, for its agreement, rules for the implementation of the Staff Regulations and the Conditions of Employment of Other Servants if they are different from those adopted by the Commission, in accordance with the procedure provided for in Article 110 of the Staff Regulations;
  - (k) appoint the Executive Director and, where appropriate, extend his or her term of office or remove him or her from the office, by a two-thirds majority of its members entitled to vote, in accordance with Article 68;
  - (l) appoint the members of the Executive Board, by a two-third majority of its members entitled to vote, in accordance with Article 53;

<sup>(1)</sup> Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Communities and instituting special measures temporarily applicable to officials of the Commission (OJ L 56, 4.3.1968, p. 1).

- (m) adopt a mandate for the tasks of the Executive Board referred to in Article 53;
- (n) adopt decisions relating to the arrangements referred to in Article 75(2);
- (o) appoint and remove the members of the Boards of Appeal, by a two-thirds majority of its members entitled to vote, in accordance with Article 55 and Article 56(4);
- (p) adopt a decision laying down rules on the secondment to the Agency of national experts, in accordance with Article 69;
- (q) adopt an anti-fraud strategy proportionate to the risks of fraud, having regard to a cost-benefit analysis of the measures to be implemented;
- (r) ensure adequate follow-up to the findings and recommendations stemming from investigations of the European Anti-fraud Office (OLAF) and the various internal or external audit reports and evaluations, verifying that appropriate actions are taken by the Executive Director;
- (s) adopt rules for the prevention and management of conflicts of interest in respect of members of the Management Board and of the Boards of Appeal, and of participants in working parties and groups referred to in Article 5(2) and other staff not covered by the Staff Regulations. Such rules shall include provisions on declarations of interest and, where appropriate, post-employment;
- (t) adopt guidelines and the list of the main elements to be included in the cooperation agreements to be concluded between the Agency and the national safety authorities, taking into account the provisions of Article 76;
- (u) adopt a framework model for the financial apportionment of the fees and charges payable by applicants as referred to in Article 76(2), for the purposes of Articles 14, 20 and 21;
- (v) establish procedures for cooperation by the Agency and its staff in national judicial proceedings;
- (w) adopt rules of procedure of working parties and groups, and scales relating to travel and subsistence expenses of their members as referred to in Article 5(5) and (9);
- (x) appoint an observer from amongst its members to follow the selection procedure applied by the Commission for the appointment of the Executive Director;
- (y) adopt appropriate rules for the implementation of Regulation No 1 <sup>(1)</sup>, in accordance with the voting rules defined in Article 74(1).

2. The Management Board shall adopt, in accordance with the procedure provided for in Article 110 of the Staff Regulations, a decision in application of Article 2(1) of the Staff Regulations and of Article 6 of the Conditions of Employment of Other Servants delegating the relevant appointing authority powers to the Executive Director and laying down the conditions under which that delegation of powers may be suspended. The Executive Director shall be authorised to subdelegate those powers. The Executive Director shall inform the Management Board of such subdelegations.

In application of the first subparagraph, where exceptional circumstances so require, the Management Board may, by way of a decision, suspend temporarily the delegation of appointing authority powers to the Executive Director and those subdelegated by the latter and exercise them itself or delegate them to one of its members or to a staff member other than the Executive Director. The delegate shall report to the Management Board on the exercise of such a delegation.

#### Article 52

#### Programming document

1. The Management Board shall adopt the programming document containing annual and multi-annual programmes by 30 November each year, taking into account the opinion of the Commission, and shall forward it to the Member States, the European Parliament, the Council and the Commission and to the networks referred to in Article 38. The annual work programme shall lay down the actions that the Agency is to perform during the coming year.

<sup>(1)</sup> Regulation No 1 of 15 April 1958 determining the languages to be used in the European Economic Community (OJ 17, 6.10.1958, p. 385).

The Management Board shall establish appropriate procedures to be applied for the adoption of the programming document, including for the consultation of relevant stakeholders.

2. The programming document shall become definitive after final adoption of the Union general budget and, if necessary, shall be adjusted accordingly.

If, within 15 days of the date of adoption of the programming document, the Commission expresses its disagreement with such document, the Management Board shall re-examine the programme and adopt it, as amended if necessary, within a period of 2 months, in second reading either by a two-thirds majority of its members entitled to vote, including all Commission representatives, or by unanimity of the representatives of the Member States.

3. The Agency's annual work programme shall identify the objectives of each activity. As a general rule, each activity shall be clearly linked with the budgetary and human resources required to carry it out, in accordance with the principles of activity-based budgeting and management and the early impact-assessment procedure provided for in Article 8(2).

4. The Management Board shall, if necessary, amend the adopted programming document when a new task is assigned to the Agency. The inclusion of such a new task shall be subject to an analysis of the human and budgetary resources implications in accordance with Article 8(2), and may be subject to a decision to postpone other tasks.

5. The Agency's multi-annual work programme shall set out overall strategic programming, including objectives, expected results and performance indicators. It shall also set out resource programming, including the multiannual budget and staff. The European Parliament shall be consulted on the draft multi-annual work programme.

The resource programming shall be updated annually. The strategic programming shall be updated where appropriate, in particular to address the outcome of the evaluation and review referred to in Article 82.

#### *Article 53*

#### **Executive Board**

1. The Management Board shall be assisted by an Executive Board.

2. The Executive Board shall prepare decisions to be adopted by the Management Board. Where necessary, on grounds of urgency, it shall take certain provisional decisions on behalf of the Management Board, in particular on administrative and budgetary matters, subject to a mandate received from the Management Board.

Together with the Management Board, the Executive Board shall ensure adequate follow-up to the findings and recommendations stemming from investigations by OLAF and the various internal or external audit reports and evaluations, including by means of appropriate actions of the Executive Director.

Without prejudice to the responsibilities of the Executive Director, as set out in Article 54, the Executive Board shall assist and advise the Executive Director in the implementation of decisions of the Management Board, with a view to reinforcing supervision of administrative and budgetary management.

3. The Executive Board shall be composed of the following members:

- (a) the chairperson of the Management Board;
- (b) four of the other representatives of Member States on the Management Board; and
- (c) one of the representatives of the Commission on the Management Board.

The chairperson of the Management Board shall act as the chairperson of the Executive Board.



The four representatives of the Member States, and their alternates, shall be appointed by the Management Board on the basis of their relevant competence and experience. When appointing them, the Management Board shall aim to achieve a balanced gender representation on the Executive Board.

4. The term of office of members of the Executive Board shall be the same as that of members of the Management Board unless the Management Board decides that it is to be shorter.

5. The Executive Board shall meet at least once every 3 months and, where possible, not less than 2 weeks prior to the meeting of the Management Board. The chairperson of the Executive Board shall convene additional meetings at the request of its members or of the Management Board.

6. The Management Board shall lay down the rules of procedure of the Executive Board, shall be periodically informed of the work of the Executive Board, and shall have access to its documents.

#### Article 54

##### **Duties of the Executive Director**

1. The Agency shall be managed by its Executive Director, who shall be completely independent in the performance of his or her duties. The Executive Director shall be accountable to the Management Board for his or her activities.

2. Without prejudice to the powers of the Commission, the Management Board or the Executive Board, the Executive Director shall neither seek nor take instructions from any government or from any other body.

3. Upon being requested to do so by the European Parliament or the Council, the Executive Director shall report on the performance of his or her duties to the institution concerned.

4. The Executive Director shall be the legal representative of the Agency and shall adopt decisions, recommendations, opinions and other formal acts of the Agency.

5. The Executive Director shall be responsible for the administrative management of the Agency and for the implementation of the tasks assigned to it by this Regulation. In particular, the Executive Director shall be responsible for:

- (a) the day-to-day administration of the Agency;
- (b) implementing the decisions adopted by the Management Board;
- (c) preparing the programming document and submitting it to the Management Board after consultation of the Commission;
- (d) implementing the programming document and, as far as possible, responding to requests for assistance from the Commission in relation to the tasks of the Agency in accordance with this Regulation;
- (e) preparing the consolidated annual report on the Agency's activities, including the declaration of the authorising officer stating whether he or she has a reasonable assurance in accordance with point (b) of Article 47(1) of Delegated Regulation (EU) No 1271/2013 and point (a) of Article 51(1) of this Regulation, and presenting it to the Management Board for assessment and adoption;
- (f) taking the necessary steps, in particular the issuing of internal administrative instructions and the publication of orders, to ensure that the Agency operates in accordance with this Regulation;
- (g) establishing an effective monitoring system enabling the Agency's results to be compared with its operational objectives and establishing a regular assessment system corresponding to recognised professional standards;
- (h) preparing on a yearly basis a draft general report on the basis of the monitoring and assessment systems referred to in point (g), and submitting it to the Management Board;
- (i) preparing the Agency's draft statement of estimates of the revenue and expenditure of the Agency pursuant to Article 64 and implementing the budget pursuant to Article 65;
- (j) taking the necessary steps to follow the work of the networks of national safety authorities, investigating bodies and representative bodies referred to in Article 38;

- (k) preparing an action plan following up on the conclusions of the internal or external audit reports and evaluations, as well as investigations by OLAF, and reporting on progress bi-annually to the Commission and regularly to the Management Board;
- (l) protecting the financial interests of the Union by the application of measures to prevent fraud, corruption and any other illegal activities, by effective checks and, where irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by the imposition of effective, proportionate and dissuasive administrative and financial penalties;
- (m) preparing an anti-fraud strategy of the Agency and presenting it to the Management Board for approval;
- (n) preparing the Agency's draft financial regulation for adoption by the Management Board under Article 66, and its implementing rules;
- (o) concluding, on behalf of the Agency, cooperation agreements with national safety authorities in accordance with Article 76.

#### Article 55

### **Establishment and composition of the Boards of Appeal**

1. By decision of the Management Board, the Agency shall establish one or more Boards of Appeal which shall be in charge of the appeals and arbitration procedures referred to in Articles 58 and 61.
2. Each Board of Appeal shall be composed of a chairperson and two other members. They shall have alternates to represent them in their absence, or where any conflicts of interest arise.
3. The establishment and composition of Boards of Appeal shall be decided on a case-by-case basis. Alternatively, a Board of Appeal may be established as a permanent body for a maximum period of 4 years. In both cases, the following procedure applies:
  - (a) the Commission shall draw up a list of qualified experts based on relevant competence and experience, and following an open selection procedure;
  - (b) the Management Board shall appoint the chairperson, the other members and their alternates from the list referred to in point (a). Where the Board of Appeal is not established as a permanent body, the Management Board shall take into account the nature and content of the appeal or arbitration, and avoid any conflict of interest in accordance with Article 57.
4. Where the Board of Appeal considers that the nature of the appeal so requires, it may request the Management Board to appoint two additional members and their alternates from the list referred to in point (a) of paragraph 3.
5. On a proposal by the Agency, and after consulting the Management Board, the Commission shall establish the rules of procedure of the Boards of Appeal, including the voting rules the procedures for filing an appeal and the conditions for reimbursement of expenses of their members. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).
6. The Boards of Appeal may request the opinion of experts from the Member States concerned, in particular with a view to clarifying the national legislation concerned, during the initial examination phase of the procedure.

#### Article 56

### **Members of the Boards of Appeal**

1. In the case of a permanent Board of Appeal, the term of office of its members and alternates shall be limited to 4 years and may be renewed once. In other cases, the term of office shall be limited to the duration of the appeal or arbitration.
2. Members of Boards of Appeal shall be independent from all parties involved in the appeal or arbitration and may not perform any other duties within the Agency. In their deliberations and decisions they shall not be bound by any instructions and shall be free from any conflict of interest.

3. Members of Boards of Appeal shall not be part of the Agency's staff and shall be remunerated for their actual involvement in a given appeal or arbitration.
4. Members of Boards of Appeal may not be removed from office during their term of office, unless there are serious grounds for such removal and the Management Board takes a decision to that effect.
5. Members of Boards of Appeal may not be removed from the list of qualified experts during their term of office, unless there are serious grounds for such removal and the Commission takes a decision to that effect.

#### Article 57

##### **Exclusion and objection**

1. Members of Boards of Appeal may not take part in any appeal or arbitration proceedings if they have any personal interest in the proceedings, if they have previously been involved as representatives of one of the parties to the proceedings, or if they participated in the taking of the decision appealed against.
2. Where a member of a Board of Appeal considers that it is not appropriate for him or her or any other member to take part in any appeal or arbitration proceeding, on any of the grounds referred to in paragraph 1 or for any other reason, that member shall inform the Board of Appeal, which shall decide on the exclusion of the person concerned on the basis of the rules adopted by the Management Board pursuant to point (s) of Article 51(1).
3. Any party to the appeal or arbitration proceedings may object, in accordance with the rules of procedure established pursuant to Article 55(5), to any member of the Board of Appeal on any of the grounds referred to in paragraph 1 of this Article, or if that member is suspected of partiality. No objection may be based on the nationality of the member concerned.
4. An objection under paragraph 3 shall only be admissible if it is made prior to the start of proceedings before the Board of Appeal, or, where the information constituting the grounds for the objection becomes known after the proceedings have started, within the deadlines laid down in the Board of Appeal's rules of procedure. The Board of Appeal member concerned shall be notified of the objection and shall state whether he or she agrees to be excluded. If he or she does not agree, the Board of Appeal shall take a decision within the deadlines laid down in its rules of procedure or, where there is no response, after expiry of the deadline set for issuing a response.
5. The Boards of Appeal shall decide as to the action to be taken in the cases specified in paragraphs 2, 3 and 4 without the participation of the member concerned. For the purpose of taking that decision, the member concerned shall be replaced on the Board of Appeal by his or her alternate. The Management Board shall be informed of the decisions taken by the Board of Appeal.

#### Article 58

##### **Appeals against decisions and failures to act**

1. An appeal may be brought before a Board of Appeal against a decision taken by the Agency pursuant to Articles 14, 20, 21 and 22 or if the Agency fails to act within the applicable time limits, following completion of the interlocutory revision referred to in Article 60.
2. An appeal lodged pursuant to paragraph 1 shall not have suspensory effect. However, upon request by the parties involved, the Board of Appeal may decide that the appeal in question is to have suspensory effect, if it considers that circumstances, such as impact on safety, so permit. In such a case, the Board of Appeal shall provide a statement of reasons for its decision.

#### Article 59

##### **Persons entitled to appeal, time limit and form**

1. Any natural or legal person may appeal against a decision of the Agency addressed to that person, or of direct and individual concern to that person, pursuant to Articles 14, 20 and 21, or if the Agency fails to act within the applicable time limits.

2. The appeal, together with the statement of grounds thereof, shall be filed in writing in accordance with the rules of procedure referred to in Article 55(5) within 2 months of notification of the measure to the person concerned, or, if the person is not notified of the measure, within 2 months of the day on which it came to the knowledge of that person.

Appeals regarding a failure to act shall be filed at the Agency in writing within 2 months of the expiry of the time limit set out in the relevant Article.

#### *Article 60*

##### **Interlocutory revision**

1. If the Agency considers the appeal to be admissible and well founded, it shall rectify the decision or failure to act referred to in Article 58(1). This shall not apply where the decision appealed against affects another party involved in the appeal proceedings.

2. If the decision is not rectified within 1 month after receipt of the appeal, the Agency shall forthwith decide whether or not to suspend the application of its decision and shall refer the appeal to one of the Boards of Appeal.

#### *Article 61*

##### **Arbitration procedure**

In the event of a disagreement between the Agency and a national safety authority or authorities pursuant to Article 21(7) and Article 24 of Directive (EU) 2016/797 and Article 10(7) and Article 17(5) and (6) of Directive (EU) 2016/798, the Board of Appeal assigned to the matter shall act as an arbitrator upon request of the national safety authority or authorities concerned. In such a case, the Board of Appeal shall decide whether to uphold the Agency's position.

#### *Article 62*

##### **Examination and decisions on appeals and arbitration**

1. The Board of Appeal shall decide within 3 months of the appeal being filed whether to grant or refuse that appeal. When examining an appeal or acting as arbitrator, the Board of Appeal shall act within the deadlines laid down in its rules of procedure. It shall, as often as necessary, invite the parties to the appeal proceedings to file, within specified time limits, observations on its notifications or on communications from other parties to the appeal proceedings. Parties to the appeal proceedings shall be entitled to make oral representations.

2. As regards arbitration, the Agency shall take its final decision in accordance with the procedures referred to in Article 21(7) of Directive (EU) 2016/797 and Article 10(7) of Directive (EU) 2016/798.

3. Where the Board of Appeal finds that the grounds for appeal are founded, it shall remit the case to the Agency. The Agency shall take its final decision in compliance with the findings of the Board of Appeal and shall provide a statement of reasons for that decision. The Agency shall inform the parties to the appeal proceedings accordingly.

#### *Article 63*

##### **Actions before the Court of Justice of the European Union**

1. Actions for the annulment of Agency decisions taken pursuant to Articles 14, 20 and 21, or for failure to act within the applicable time limits, may be brought before the Court of Justice of the European Union only after the appeal procedure within the Agency in accordance with Article 58 has been exhausted.

2. The Agency shall take all necessary measures to comply with the judgment of the Court of Justice of the European Union.

## CHAPTER 10

## FINANCIAL PROVISIONS

*Article 64***Budget**

1. Estimates of all the revenue and expenditure of the Agency shall be prepared for each financial year, corresponding to the calendar year, and shall be set out in the budget of the Agency.
2. Without prejudice to other resources, the revenue of the Agency shall consist of:
  - (a) a contribution from the Union and grants from Union bodies;
  - (b) any contribution from third countries participating in the work of the Agency, as provided for in Article 75;
  - (c) the fees paid by applicants for, and holders of, certificates and authorisations issued by the Agency in accordance with Articles 14, 20 and 21;
  - (d) charges for publications, training and any other services provided by the Agency;
  - (e) any voluntary financial contribution from Member States, third countries or other entities, provided such contribution is transparent, is clearly identified in the budget and does not compromise the independence and impartiality of the Agency.
3. The expenditure of the Agency shall include staff, administrative, infrastructure and operational expenses.
4. Revenue and expenditure shall be kept in balance.
5. Each year, the Management Board, on the basis of a draft drawn up by the Executive Director in accordance with the principle of activity-based budgeting, shall produce a statement of estimates of revenue and expenditure for the Agency for the following financial year. That statement of estimates, which shall include a draft establishment plan, shall be forwarded by the Management Board to the Commission by 31 January at the latest.
6. The statement of estimates shall be forwarded by the Commission to the European Parliament and the Council together with the preliminary draft general budget of the Union.
7. On the basis of the statement of estimates, the Commission shall enter in the preliminary draft general budget of the Union the estimates it considers necessary for the establishment plan and the amount of the contribution to be charged to the general budget, which it shall place before the European Parliament and the Council in accordance with Article 314 TFEU, together with a description of and justification for any difference between the Agency's statement of estimates and the subsidy to be charged to the general budget.
8. The European Parliament and the Council shall authorise the appropriations for the contribution to the Agency. The European Parliament and the Council shall adopt the establishment plan for the Agency.
9. The budget shall be adopted by the Management Board, by a two-thirds majority of its members entitled to vote. The budget of the Agency shall become final following final adoption of the general budget of the Union. Where appropriate, it shall be adjusted accordingly.
10. For any property-related project likely to have significant implications for the budget of the Agency, Article 203 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council <sup>(1)</sup> shall apply.

*Article 65***Implementation and control of the budget**

1. The Executive Director shall implement the budget of the Agency.

<sup>(1)</sup> Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

2. By 1 March following each financial year, the Agency's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 147 of Regulation (EU, Euratom) No 966/2012.

3. By 31 March following each financial year, the Commission's accounting officer shall forward the Agency's provisional accounts to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report on the budgetary and financial management for the financial year shall also be forwarded to the European Parliament and the Council.

The Court of Auditors shall examine those accounts in accordance with Article 287 TFEU. It shall publish a report on the Agency's activities every year.

4. On receipt of the Court of Auditors' observations on the Agency's provisional accounts, pursuant to Article 148 of Regulation (EU, Euratom) No 966/2012, the accounting officer shall draw up the Agency's final accounts. The Executive Director shall submit them to the Management Board for its opinion.

5. The Management Board shall deliver an opinion on the Agency's final accounts.

6. The accounting officer shall, by 1 July following each financial year, forward the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.

7. The final accounts of the Agency shall be published.

8. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September following each financial year. He or she shall also send that reply to the Management Board and to the Commission.

9. The Executive Director shall submit to the European Parliament, at the latter's request, all information necessary for the smooth application of the discharge procedure for the financial year in question, in accordance with Article 165 (3) of Regulation (EU, Euratom) No 966/2012.

10. The European Parliament, on a recommendation from the Council acting by a qualified majority, shall, before 15 May of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.

#### *Article 66*

### **Financial rules**

The financial rules applicable to the Agency shall be adopted by the Management Board after the Commission has been consulted. They may not depart from Delegated Regulation (EU) No 1271/2013 unless such a departure is specifically required for the Agency's operation and the Commission has given its prior consent thereto.

#### CHAPTER 11

#### STAFF

#### *Article 67*

### **General provisions**

1. The Staff Regulations and the Conditions of Employment of Other Servants, and the rules adopted by agreement between the institutions of the Union for giving effect to those Staff Regulations, shall apply to the staff of the Agency.

2. Without prejudice to point (j) of Article 51(1) of this Regulation, implementing rules adopted by the Commission to give effect to the Staff Regulations and the Conditions of Employment of Other Servants, including the general implementing provisions, shall apply by analogy to the Agency, in accordance with Article 110 of the Staff Regulations.

3. The Agency shall take appropriate administrative measures, inter alia, through training and prevention strategies, to organise its services in such a way as to avoid any conflict of interest.

#### Article 68

##### **Executive Director**

1. The Executive Director shall be engaged as a temporary agent of the Agency under point (a) of Article 2 of the Conditions of Employment of Other Servants.

2. The Executive Director shall be appointed by the Management Board on the grounds of merit, documented administrative and managerial skills, and relevant knowledge and experience of the transport sector, from a list of at least three candidates proposed by the Commission, after an open and transparent selection procedure, following publication of the vacancy notice in the *Official Journal of the European Union* and elsewhere, as appropriate. Before the decision of the Management Board is taken, the observer referred to in point (x) of Article 51(1) shall report on the procedure.

For the purposes of concluding the contract of engagement of the Executive Director, the Agency shall be represented by the chair of the Management Board.

Before being appointed, the candidate selected by the Management Board may be invited to make a statement before the competent committee of the European Parliament and to answer questions put by its members.

3. The term of office of the Executive Director shall be 5 years. By the end of that period, the Commission shall undertake an assessment of the performance of the Executive Director and of the Agency's future tasks and challenges.

4. The Management Board, acting on a proposal from the Commission taking into account the assessment referred to in paragraph 3, may extend the term of office of the Executive Director once, for no more than 5 years.

5. The Management Board shall inform the European Parliament of its intention to extend the Executive Director's term of office. Within 1 month before any such extension, the Executive Director may be invited to make a statement before the competent committee of the European Parliament and to answer questions put by its members.

6. An Executive Director whose term of office has been extended may not participate in another selection procedure for the same post following such an extension of term of office.

7. The Executive Director may be removed from office only upon a decision of the Management Board acting on a request from the Commission or from one third of its members.

#### Article 69

##### **Seconded national experts and other staff**

The Agency may make use of seconded national experts or other staff who are not employed by the Agency under the Staff Regulations and the Conditions of Employment of Other Servants.

Without prejudice to the rules laid down in the relevant Commission Decision on the secondment of national experts, which apply to the Agency, the Management Board shall adopt a decision laying down rules on the secondment to the Agency of national experts, including rules on the prevention and management of conflicts of interest and on relevant restrictions for cases in which national experts' independence and impartiality could be undermined.

#### CHAPTER 12

##### GENERAL PROVISIONS

#### Article 70

##### **Privileges and immunities**

Protocol No 7 on the privileges and immunities of the European Union shall apply to the Agency and its staff.

*Article 71***Headquarters agreement and operating conditions**

1. Where the necessary arrangements concerning the accommodation to be provided for the Agency in the host Member State and the facilities to be made available by that Member State together with the specific rules applicable in that Member State to the Executive Director, members of the Management Board, Agency staff and members of their families are not yet in place or not yet provided for in a written agreement, an agreement between the Agency and the host Member State on all these elements shall be concluded, in accordance with the legal order of the host Member State, and after the approval of the Management Board, no later than 16 June 2017. That agreement may take the form of a headquarters agreement.
2. The host Member State shall provide the best possible conditions to ensure the proper functioning of the Agency, including multilingual, European-oriented schooling and appropriate transport connections.

*Article 72***Liability**

1. The contractual liability of the Agency shall be governed by the law applicable to the contract in question.
2. The Court of Justice of the European Union shall have jurisdiction to adjudicate pursuant to any arbitration clause contained in a contract concluded by the Agency.
3. In the event of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its departments or by its staff in the performance of their duties.
4. The Court of Justice of the European Union shall have jurisdiction in disputes relating to compensation for damage as referred to in paragraph 3.
5. The personal liability of its staff towards the Agency shall be governed by the provisions laid down in the Staff Regulations or the Conditions of Employment of Other Servants applicable to them.

*Article 73***Cooperation with national judicial authorities**

In the case of national judicial proceedings involving the Agency by reason of the Agency having exercised its tasks in accordance with Article 19 and Article 21(6) of Directive (EU) 2016/797 and 10(6) of Directive (EU) 2016/798, the Agency and its staff shall cooperate without undue delay with the competent national judicial authorities. Appropriate procedures to be applied in such situations shall be established by the Management Board in accordance with point (v) of Article 51(1).

*Article 74***Language arrangements**

1. Regulation No 1 shall apply to the Agency. If necessary, the Management Board shall adopt appropriate rules for the implementation of that Regulation.

At the request of a member of the Management Board, the decision in that regard shall be taken by unanimity.

2. The translation services required for the functioning of the Agency shall be provided by the Translation Centre for the Bodies of the European Union.

*Article 75***Participation by third countries in the work of the Agency**

1. Without prejudice to Article 44, the Agency shall be open to participation by third countries, in particular by countries within the scope of the European Neighbourhood Policy, the Enlargement policy countries and EFTA countries which have concluded agreements with the Union under which the countries concerned have adopted and are applying Union law, or equivalent national measures, in the field covered by this Regulation, in accordance with the procedure laid down in Article 218 TFEU.



2. In accordance with the relevant provisions of the agreements referred to in paragraph 1, arrangements shall be made between the Agency and the third countries concerned, setting out detailed rules for participation by those third countries in the work of the Agency, in particular the nature and extent of such participation. Those arrangements shall include provisions on financial contributions and staff. They may provide for representation of the third countries concerned, without the right to vote, on the Management Board.

The Agency shall sign the arrangements after having received the agreement of the Commission and of the Management Board.

#### Article 76

### Cooperation with national authorities and bodies

1. The Agency and the national safety authorities shall conclude cooperation agreements in relation to the implementation of Articles 14, 20 and 21, taking into account point (t) of Article 51(1).
2. The cooperation agreements may be specific or framework agreements, and may involve one or more national safety authorities. They shall contain a specified description of tasks and conditions for deliverables, lay down the time limits applying to their delivery, and determine the manner in which the fees payable by applicants are to be apportioned as between the Agency and the national safety authorities. Such apportionment shall take into account the framework model referred to in point (u) of Article 51(1).
3. The cooperation agreements 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 efficient and proportionate allocation of resources.
4. 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, a multilateral cooperation agreement shall involve all the national safety authorities concerned in those Member States as provided for in Article 21(15) of Directive (EU) 2016/797 and Article 11(3) of Directive (EU) 2016/798.
5. The cooperation agreements shall be in place before the Agency carries out its tasks in accordance with Article 83(4).
6. The Agency may conclude cooperation agreements with other national authorities and competent bodies in relation to the implementation of Articles 14, 20 and 21.
7. The cooperation agreements shall be without prejudice to the overall responsibility of the Agency for the performance of its tasks as provided for in Articles 14, 20 and 21.
8. The Agency and the national safety authorities may work together and share best practices in relation to the implementation of Directive (EU) 2016/797 and of Directive (EU) 2016/798.

#### Article 77

### Transparency

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council <sup>(1)</sup> shall apply to documents held by the Agency.

The Management Board shall adopt practical measures for the implementation of Regulation (EC) No 1049/2001 by 16 June 2017.

<sup>(1)</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Decisions taken by the Agency pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice of the European Union under Articles 228 and 263 TFEU respectively.

2. The Agency shall publish its recommendations, opinions, studies, reports and outcomes of impact assessments on its website, without prejudice to paragraph 1 and after all confidential material has been removed therefrom.

3. The Agency shall make public the declarations of interests of the members of the Agency's management and administrative structure listed in Article 46.

The processing of personal data by the Agency shall be subject to Regulation (EC) No 45/2001 of the European Parliament and of the Council <sup>(1)</sup>.

4. The Management Board shall adopt measures to ensure that the Agency provides efficient, user-friendly and easily accessible information on its website about railway interoperability and safety processes and about other relevant railway documents.

#### Article 78

### Security rules for protecting classified or sensitive information

The Agency shall apply the principles contained in the Commission's security rules for protecting European Union Classified Information (EUCI) and sensitive non-classified information, as set out in Commission Decision (EU, Euratom) 2015/444 <sup>(2)</sup>. This shall cover, inter alia, provisions for exchanging, processing and storing such information.

#### Article 79

### Combating fraud

1. In order to facilitate the fight against fraud, corruption and other unlawful activities under Regulation (EC) No 1073/1999, the Agency shall by 16 December 2016 accede to the Inter-institutional Agreement of 25 May 1999 concerning internal investigations by OLAF and adopt the appropriate provisions applicable to all employees of the Agency, using the template set out in the Annex to that Agreement.

2. The Court of Auditors shall have the power of audit, on the basis of documents and on the spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds from the Agency.

3. OLAF may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Regulation (EU) No 883/2013 and in Council Regulation (Euratom, EC) No 2185/96 <sup>(3)</sup>, with a view to establishing whether there has been any fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant or contract funded by the Agency.

4. Without prejudice to paragraphs 1, 2 and 3, cooperation agreements with third countries and international organisations, contracts, grant agreements and grant decisions of the Agency shall contain provisions expressly empowering the Court of Auditors and OLAF to conduct such audits and investigations in accordance with their respective competences.

<sup>(1)</sup> Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

<sup>(2)</sup> Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

<sup>(3)</sup> Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

## CHAPTER 13

## FINAL PROVISIONS

*Article 80***Implementing acts relating to fees and charges**

1. The Commission shall adopt, on the basis of the principles set out in paragraphs 2 and 3, implementing acts specifying:

- (a) the fees and charges payable to the Agency, in particular in application of Articles 14, 20, 21 and 22; and
- (b) the conditions of payment.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3).

2. Fees and charges shall be levied for:

- (a) the issuing and renewal of authorisations for the placing on the market of vehicles and types of vehicles;
- (b) the issuing and renewal of single safety certificates;
- (c) the provision of services; the fees and charges payable in this regard shall reflect the actual cost of each individual provision;
- (d) the issuing of decisions for approval in accordance with Article 19 of Directive (EU) 2016/797.

Fees and charges may be levied for the processing of appeals.

All fees and charges shall be expressed, and payable, in euro.

Fees and charges shall be set in a transparent, fair and uniform manner, taking into account the competitiveness of the European railway sector. They shall not lead to the imposition of unnecessary financial burdens on applicants. The specific needs of small and medium-sized enterprises, including the possibility of splitting payments into several instalments and phases, shall be taken into account, as appropriate.

The fee for issuing the decision for approval shall be set in a proportionate manner, taking into account the different stages of the authorisation process for ERTMS trackside projects and the workload required for each of the stages. The apportionment of the fees shall be clearly identified in the accounts.

Reasonable deadlines shall be set for the payment of fees and charges, taking due account of the deadlines for the procedures provided for in Articles 19 and 21 of Directive (EU) 2016/797 and Article 10 of Directive (EU) 2016/798.

3. The amount of the fees and charges shall be fixed at such a level as to ensure that the revenue in respect thereof is sufficient to cover the full cost of the services provided, including the relevant costs resulting from the tasks assigned to the national safety authorities in accordance with Article 76(2) and (3). All expenditure of the Agency attributed to staff involved in the activities referred to in paragraph 2 of this Article, including the employer's pro-rata contribution to the pension scheme, shall in particular be reflected in that cost. Should a significant imbalance resulting from the provision of the services covered by fees and charges become recurrent, the level of those fees and charges shall be revised. Those fees and charges shall be assigned revenues for the Agency.

When setting the levels of fees and charges, the Commission shall take into account:

- (a) the area of operation of certificates;
- (b) the area of use of authorisations; and
- (c) the type and extent of railway operations.

*Article 81***Committee procedure**

1. The Commission shall be assisted by the committee established by Article 51 of Directive (EU) 2016/797. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third paragraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

*Article 82***Evaluation and review**

1. No later than 16 June 2020 and every 5 years thereafter, the Commission shall commission an evaluation to assess, in particular, the impact, effectiveness and efficiency of the Agency and its working practices, taking into account all relevant work by the Court of Auditors as well as the views and recommendations of relevant stakeholders, including national safety authorities, representatives of the railway sector, social partners and consumer organisations. The evaluation shall address, in particular, any need to amend the mandate of the Agency and the financial implications of any such amendment.
2. By 16 June 2023, the Commission, in order to identify whether improvements are needed, shall assess the functioning of the dual system for vehicle authorisation and safety certification, the one-stop shop related thereto and the harmonised implementation of ERTMS in the Union.
3. The Commission shall forward the evaluation report together with its conclusions thereon to the European Parliament, the Council and the Management Board. The findings of the evaluation shall be made public.
4. On the occasion of every second evaluation, there shall also be an assessment of the results achieved by the Agency, having regard to its objectives, mandate and tasks.

*Article 83***Transitional provisions**

1. The Agency replaces and succeeds the European Railway Agency established by Regulation (EC) No 881/2004 as regards all ownership, agreements, legal obligations, employment contracts, financial commitments and liabilities.
2. By way of derogation from Article 47, the members of the Administrative Board appointed under Regulation (EC) No 881/2004 before 15 June 2016 shall remain in office as members of the Management Board until the expiry date of their term of office, without prejudice to the right of each Member State to appoint a new representative.

By way of derogation from Article 54, the Executive Director appointed in accordance with Regulation (EC) No 881/2004 shall remain in office until the expiry date of his or her term of office.

3. By way of derogation from Article 67, all employment contracts in force on 15 June 2016 shall be honoured until their expiry date.
4. The Agency shall carry out the certification and authorisation tasks pursuant to Articles 14, 20 and 21 and the tasks referred to in Article 22 from 16 June 2019 at the latest, subject to Article 54(4) of Directive (EU) 2016/797 and Article 31(3) of Directive (EU) 2016/798.

Article 84

**Repeal**

Regulation (EC) No 881/2004 is hereby repealed.

Article 85

**Entry into force**

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 11 May 2016.

*For the European Parliament*

*The President*

M. SCHULZ

*For the Council*

*The President*

J. A. HENNIS-PLASSCHAERT

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# DIRECTIVES

## DIRECTIVE (EU) 2016/797 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 May 2016

on the interoperability of the rail system within the European Union

(recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91(1) and Articles 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 <sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(3)</sup>,

Whereas:

- (1) Directive 2008/57/EC of the European Parliament and of the Council <sup>(4)</sup> 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.
- (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.

<sup>(1)</sup> OJ C 327, 12.11.2013, p. 122.

<sup>(2)</sup> OJ C 356, 5.12.2013, p. 92.

<sup>(3)</sup> 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 (OJ C 57, 12.2.2016, p. 1). Position of the European Parliament of 28 April 2016 (not yet published in the Official Journal).

<sup>(4)</sup> 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).

- (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) 2016/796 of the European Parliament and of the Council <sup>(1)</sup> 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 <sup>(2)</sup>. 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.
- (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.

<sup>(1)</sup> Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (see page 1 of this Official Journal).

<sup>(2)</sup> 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).

- (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) 2016/796, 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 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 be progressively 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 <sup>(1)</sup>, 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) 2016/798 of the European Parliament and of the Council <sup>(2)</sup>, 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

<sup>(1)</sup> 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).

<sup>(2)</sup> Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (see page 102 of this Official Journal).

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 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) 2016/796, 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.

- (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 <sup>(1)</sup>, 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.

<sup>(1)</sup> 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 <sup>(1)</sup>.
- (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,

<sup>(1)</sup> 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) 2016/798 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;
  - (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');

- (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 track-side 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) 2016/798;
- (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) 2016/798;
- (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;
- (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 <sup>(1)</sup>;
- (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.

<sup>(1)</sup> 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).

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.

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 <sup>(1)</sup>;
- (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.

<sup>(1)</sup> 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) 2016/798. 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) 2016/796 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) 2016/796, 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 <sup>(1)</sup>. 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 (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.
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) 2016/796 may make the Commission aware of possible TSI deficiencies.

<sup>(1)</sup> 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).

*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.
  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 15 June 2016. In that case, they shall be notified by 16 December 2016;
- (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.

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) 2016/796.

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) 2016/796, 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) 2016/796 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) 2016/796.
  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) 2016/796.
  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) 2016/796 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) 2016/796.
  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 <sup>(1)</sup>.
  13. National rules not notified in accordance with this Article shall not apply for the purposes of this Directive.

#### Article 15

#### **Procedure for establishing the 'EC' declaration of verification**

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.

<sup>(1)</sup> 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).

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) 2016/798;
  - (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) 2016/796.
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.

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) 2016/796. 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 pre-determined, 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) 2016/798.

#### 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 track-side 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.

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) 2016/796.

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) 2016/796.

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) 2016/796. In that case, 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.
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 CSMs referred to in Article 6 of Directive (EU) 2016/798;
  - (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) 2016/798.

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) 2016/796.

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.

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) 2016/796. 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 16 June 2018, the Commission shall adopt by means of implementing acts practical arrangements specifying:
- 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;
  - the details of the authorisation process, such as procedural stages and timeframes for each stage of the process;
  - 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:
- the area(s) of use;
  - 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;
  - the vehicle's compliance with the relevant TSIs and sets of national rules, relating to the parameters referred to in point (b);
  - 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) 2016/796.

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) 2016/798 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.

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) 2016/796. 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) 2016/798.



*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:
  - (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) 2016/798 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) 2016/796.
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 No 768/2008/EC of the European Parliament and of the Council <sup>(1)</sup>.
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.

#### 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) 2016/798, 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) 2016/798. 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.

<sup>(1)</sup> 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).

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.

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) 2016/796 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) 2016/798. 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.

#### 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) 2016/796. 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;

- (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 No 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 practices 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) 2016/796.

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.

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) 2016/798; 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) references to 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 16 June 2018, 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.

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 16 June 2021.

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).

## 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 15 June 2016. 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 <sup>(1)</sup>. 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.

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<sup>(1)</sup> 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).

*Article 53***Reports and information**

1. By 16 June 2018, 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 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 15 June 2016 and 16 June 2019 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 15 June 2016, 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. At the latest from 16 June 2019 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 16 June 2020.

*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 15 June 2016 and 16 June 2019.
3. Projects which have completed the tendering or contracting phase prior to 16 June 2019 are not subject to the pre-authorisation by the Agency referred to in Article 19.
4. Until 16 June 2031 options included in contracts which were signed before 15 June 2016 shall not be subject to the pre-authorisation by the Agency referred to in Article 19, even if they are exercised after 15 June 2016.

5. Before authorising the placing in service of any ERTMS track-side 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) 2016/796.

#### Article 56

### Recommendations and opinions of the Agency

The Agency shall provide recommendations and opinions in accordance with Article 19 of Regulation (EU) 2016/796 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 16 June 2019. 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 16 December 2018, 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 16 June 2020, 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.

#### 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 Strasbourg, 11 May 2016.

*For the European Parliament*  
*The President*  
M. SCHULZ

*For the Council*  
*The President*  
J. A. HENNIS-PLASSCHAERT

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## 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.

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## 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.

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## 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.

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## 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 CSMs on risk assessment referred to in Article 6(3) of Directive 2004/49/EC <sup>(1)</sup>.

#### 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.

<sup>(1)</sup> Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) (OJ L 164, 30.4.2004, p. 44).

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.

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## 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
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

Directive 2008/57/EC	This Directive
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

**Statement by the Commission on explanatory documents**

The Commission recalls that the European Parliament, the Council and the Commission acknowledged in their Joint Political Declaration of 27 October 2011 on explanatory documents that the information Member States supply to the Commission as regards the transposition of directives in national law 'must be clear and precise' in order to facilitate the achievement by the Commission of its task of overseeing the application of Union law. In the present case, explanatory documents could have been useful to this end. The Commission regrets that the final text does not contain provisions to this effect.

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**DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**of 11 May 2016**  
**on railway safety**  
**(recast)**  
**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91(1) 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 <sup>(1)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(2)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(3)</sup>,

Whereas:

- (1) Directive 2004/49/EC of the European Parliament and of the Council <sup>(4)</sup> has been substantially amended. Since further amendments are to be made, it should be recast in the interests of clarity.
- (2) Directive 2004/49/EC established a common regulatory framework for railway safety through harmonisation of the content of safety rules, the safety certification of railway undertakings, the tasks and roles of the national safety authorities and the investigation of accidents. Nevertheless, in order to pursue efforts to further develop a single European railway area, it is necessary to thoroughly revise Directive 2004/49/EC.
- (3) Metros, trams and other light rail systems are subject in many Member States to local technical requirements and are excluded from the scope of Directive (EU) 2016/797 of the European Parliament and of the Council <sup>(5)</sup>. In order to facilitate the implementation of this Directive and of Directive (EU) 2016/797, both Directives should have the same scope. Therefore, such local systems should be excluded from the scope of this Directive.
- (4) Insofar as some concepts referred to in this Directive may be usefully applied to metros and other local systems, Member States should be permitted to decide, without prejudice to the scope of this Directive, to apply certain provisions of this Directive that they consider to be appropriate. In such cases, Member States should be allowed not to apply obligations such as the notification of national rules and reporting.
- (5) Safety levels in the Union rail system are generally high especially when compared to road transport. Railway safety should be generally maintained and, when practicable, continuously improved, taking into account technical and scientific progress, and the development of Union and international law. Priority should be given to the prevention of accidents. The impact of human factors should also be taken into consideration.

<sup>(1)</sup> OJ C 327, 12.11.2013, p. 122.

<sup>(2)</sup> OJ C 356, 5.12.2013, p. 92.

<sup>(3)</sup> 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 (OJ C 57, 12.2.2016, p. 64). Position of the European Parliament of 28 April 2016 (not yet published in the Official Journal).

<sup>(4)</sup> Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (OJ L 164, 30.4.2004, p. 44).

<sup>(5)</sup> Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (see page 44 of this Official Journal).



- (6) If a Member State introduces a higher level of safety, it should ensure that the rule adopted does not create a barrier to interoperability or result in discrimination.
- (7) The main actors in the Union rail system, infrastructure managers and railway undertakings should bear full responsibility for the safety of the system, each for their own part. Whenever appropriate, they should cooperate in implementing risk control measures.
- (8) Without prejudice to the responsibility of infrastructure managers and railway undertakings for developing and improving railway safety, the other actors, such as entities in charge of maintenance, manufacturers, carriers, consignors, consignees, fillers, unfillers, loaders, unloaders, maintenance suppliers, keepers, service providers and contracting entities, should not be precluded from assuming responsibility for their products, services and processes. Each actor in the Union rail system should be responsible, vis-à-vis the other actors, for complete and truthful communication of all relevant information to check whether vehicles are fit to run. This concerns, in particular, information on the status and history of a given vehicle, maintenance files, traceability of loading operations, and consignment notes.
- (9) Each railway undertaking, infrastructure manager and entity in charge of maintenance should ensure that its contractors and other parties implement risk control measures. To that end, each railway undertaking, infrastructure manager and entity in charge of maintenance should apply the methods for monitoring set out in the common safety methods ('CSMs'). Their contractors should apply this process through contractual arrangements. In view of the fact that such arrangements are an essential part of the safety management system of railway undertakings and infrastructure managers, railway undertakings and infrastructure managers should disclose their contractual arrangements on request of the European Union Agency for Railways ('the Agency') established by Regulation (EU) 2016/796 of the European Parliament and of the Council <sup>(1)</sup> or the national safety authority in the context of supervision activities.
- (10) Member States should promote a culture of mutual trust, confidence and learning in which the staff of railway undertakings and infrastructure managers are encouraged to contribute to the development of safety while confidentiality is ensured.
- (11) Common safety targets ('CSTs') and CSMs have been gradually introduced to ensure that safety is maintained at a high level and, when necessary and where reasonably practicable, improved. They should provide tools for the assessment of the safety and performance of operators at Union level as well as in the Member States. Common safety indicators ('CSIs') have been established in order to assess whether systems comply with the CSTs and to facilitate the monitoring of railway safety performance.
- (12) National rules, which are often based on national technical standards, are being gradually replaced by rules based on common standards, established by CSTs, CSMs and technical specifications for interoperability ('TSIs'). In order to eliminate the obstacles to interoperability, the volume of national rules, including operating rules, should be reduced as a consequence of extending the scope of the TSIs to the whole of the Union rail system and of closing open points in the TSIs. For that purpose, Member States should keep their system of national rules updated, delete obsolete rules and inform the Commission and the Agency thereof without delay.
- (13) National rules should be drafted and published in such a way that any potential user of a national network can understand them. However, 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. It is appropriate, therefore, that the obligation of publication should not apply to any documents referred to directly or indirectly in the national rule.
- (14) National rules often include requirements which are partly relevant for both interoperability and safety purposes. Safety being an essential requirement of Directive (EU) 2016/797, a national rule may be relevant for Directive (EU) 2016/797 and for this Directive. The distinction between the terms 'national safety rules' and 'national technical rules' as defined in Directive 2004/49/EC and Directive 2008/57/EC of the European Parliament and of

<sup>(1)</sup> Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (see page 1 of this Official Journal).

the Council <sup>(1)</sup> respectively should therefore be removed and replaced by the concept of 'national rules' which are to be notified under Directive (EU) 2016/797 and/or this Directive. National rules are to be notified under Directive (EU) 2016/797 mainly when they relate to the placing on the market or placing in service of structural subsystems. They should be notified under this Directive when they relate to the operation of the Union rail system, or to the specific subjects of this Directive, including the role of the actors, safety certification, safety authorisation and accident investigation.

- (15) 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 except in the specific situations as provided for in this Directive. The safety management system is the recognised tool for controlling risks, whereas infrastructure managers and railway undertakings are responsible for taking immediate corrective action to prevent recurrence of accidents. Member States should avoid establishing new national rules immediately after an accident, unless such new rules are required as an urgent preventive measure.
- (16) Train control and signalling systems play a critical role in ensuring railway safety. In this regard, the deployment of the European Rail Traffic Management System (ERTMS) on the Union railway network constitutes an important contribution to improving safety levels.
- (17) In carrying out their duties and fulfilling their responsibilities, infrastructure managers and railway undertakings should implement a safety management system meeting Union requirements and containing common elements. Information on safety and on the implementation of the safety management system should be submitted to the Agency and to the national safety authority in the Member State concerned.
- (18) Through its processes, the safety management system should ensure that human capabilities and limitations and the influences on human performance are addressed by applying human factors knowledge and using recognised methods.
- (19) Rail freight services should also encompass the transport of dangerous goods. However, a distinction should be made between the objective of this Directive, which is to maintain and, where possible, improve the safety of the Union rail system, and that of Directive 2008/68/EC of the European Parliament and of the Council <sup>(2)</sup>, which is, mainly, to regulate the classification of substances and the specification of their containments, including the safe loading, unloading and use of the containments within the existing railway system. Consequently, without prejudice to Directive 2008/68/EC, the safety management system of the railway undertakings and of the infrastructure managers should duly take into consideration the potential additional risks generated by carrying dangerous goods containments.
- (20) All railway undertakings should be subject to the same safety requirements in order to ensure a high level of railway safety and equal conditions. A railway undertaking should hold a safety certificate as a condition of being allowed to obtain access to the railway infrastructure. The safety certificate should provide evidence that the railway undertaking has established its safety management system and that it is able to comply with the relevant safety standards and rules for the relevant area of operation. When the Agency issues a single safety certificate to a railway undertaking having an area of operation in one or more Member States, it should be the only authority to assess whether the railway undertaking has correctly established its safety management system. The national safety authorities concerned by the intended area of operation should be involved in assessing the requirements laid down in the relevant national rules.
- (21) Harmonised methods based on Directive 2004/49/EC have been established, to be applied to the actors in the Union rail system and the national safety authorities, on monitoring, conformity assessment, supervision and risk evaluation and assessment. That regulatory framework is sufficiently mature to move progressively towards a 'single safety certificate' valid within the area of operation of the railway undertaking concerned.

<sup>(1)</sup> 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).

<sup>(2)</sup> Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

- (22) In order to make the procedures for issuing single safety certificates to railway undertakings more efficient and coherent, it is necessary to assign the Agency a central role in the issuing of such certificates. Where the area of operation is limited to one Member State, the applicant should have the possibility of choosing whether to submit its application for a single safety certificate, through the one-stop shop referred to in Regulation (EU) 2016/796, 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. This new regime should make the Union rail system more effective and efficient by reducing administrative burdens for railway undertakings.
- (23) The Agency and the national safety authorities should cooperate and share competences as appropriate for the issuing of single safety certificates. Clear procedural and arbitration 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 single safety certificates.
- (24) The new allocation of functions and tasks between national safety authorities and the Agency concerning the issuing of safety certificates should be done efficiently. To that end, cooperation agreements between the Agency and the national safety authorities should be established.
- (25) In particular, cooperation agreements are required to take account of the specific geographical and historical situation of certain Member States, while ensuring the proper functioning of the internal market. 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 purposes of reducing administrative burdens and costs, it should be possible for the cooperation agreements to be concluded between the Agency and the relevant national safety authorities to provide for an appropriate allocation of tasks, without prejudice to the ultimate responsibility of the Agency in issuing the single safety certificate.
- (26) The railway networks located in the Baltic States (Estonia, Latvia and Lithuania) have 1520 mm track gauge, which is the same as in neighbouring third countries, but 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 safety certificate issued in one of these Member States might be extended to the rest of these networks. To facilitate the efficient and proportionate allocation of resources for safety certification, 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.
- (27) This Directive should not lead to a reduced level of safety and should not increase costs in the Union's railway sector. To that end, the Agency and the national safety authorities should take full responsibility for the single safety certificates they issue, assuming in particular contractual and non-contractual liabilities in that regard. In the event of a judicial inquiry involving the Agency or its staff, the Agency should cooperate fully with the competent authorities of the Member State or States concerned.
- (28) A clear distinction should be drawn between, on the one hand, the immediate responsibility of the Agency and the national safety authorities for safety deriving from the issuing of the safety certificates and safety authorisations and, on the other, the national safety authorities' task of providing a national regulatory framework and supervising the performance of all parties concerned on a continuous basis. Each national safety authority should oversee continued compliance with the legal obligation imposed on a railway undertaking or infrastructure manager to establish a safety management system. Establishing evidence of such compliance may require not only on-site inspections of the railway undertaking or infrastructure manager concerned, but also supervision tasks to be carried out by the national safety authorities in order to assess that the railway undertaking or infrastructure manager continue to duly apply their safety management system after having been granted a safety certificate or a safety authorisation. National safety authorities should coordinate their supervision activities in relation to railway undertakings established in different Member States, and should share information among themselves and, where appropriate, with the Agency. The Agency should assist the national safety authorities in their cooperation. In that context, necessary arrangements should be established by the Agency and the national safety authorities to facilitate the exchange of information between them.

- (29) The Agency and the national safety authorities should cooperate closely in cases where a national safety authority concludes that a holder of a single safety certificate issued by the Agency no longer satisfies the conditions for certification. In such a case, it should ask the Agency to restrict or revoke that certificate. An arbitration procedure should be established to deal with cases of disagreement between the Agency and the national safety authority. If a national safety authority identifies a serious safety risk during supervision, it should inform the Agency and any other national safety authority concerned in the area of operation of the railway undertaking. The national safety authorities concerned should be allowed to apply temporary safety measures, including immediately restricting or suspending the relevant operations. A serious safety risk in this context should be understood as being a serious instance of non-compliance with legal obligations or safety requirements that may in itself, or in a series of consequential events, cause an accident or a serious accident.
- (30) The Agency should be able to establish a tool that facilitates the exchange of information among the relevant actors who identify or are informed of a safety risk relating to defects and construction non-conformities or malfunctions of technical equipment.
- (31) The single safety certificate should be issued on the basis of evidence that a railway undertaking has established its safety management system.
- (32) Infrastructure managers should have a key responsibility for the safe design, maintenance and operation of their rail network. Infrastructure managers should be subject to a safety authorisation by the national safety authority concerning their safety management system and to other provisions so as to meet safety requirements.
- (33) The certification of train staff might create difficulties for new entrants. Member States should ensure that facilities for the training and certification of train staff necessary to meet requirements under national rules are available to railway undertakings intending to operate on the relevant network.
- (34) The entity in charge of maintenance should be certified for freight wagons. Where the entity in charge of maintenance is an infrastructure manager, this certification should be included in the procedure for safety authorisation. The certificate issued to such an entity should guarantee that the maintenance requirements of this Directive are met for any freight wagon for which it is responsible. That certificate should be valid throughout the Union and should be issued by a body able to audit the maintenance system established by the entity. As freight wagons are frequently used in international traffic, and as the entity in charge of maintenance may want to use workshops established in more than one Member State, the certification body should be able to implement its controls throughout the Union. The Agency should evaluate the system of certification of the entity in charge of maintenance for freight wagons and should, if appropriate, recommend its extension to all rail vehicles.
- (35) The national safety authorities should be fully independent in their organisation, legal structure and decision-making from any railway undertaking, infrastructure manager, applicant, contracting entity or entity which awards public service contracts. They should carry out their tasks in an open and non-discriminatory way and should cooperate with the Agency to create a single European railway area and coordinate their decision-making criteria. It should be possible, where necessary, for Member States to decide to include their national safety authority within the national ministry responsible for transport matters, provided that the independence of the national safety authority is respected. In order to fulfil their tasks, the national safety authorities should have the necessary internal and external organisational capacity in terms of human and material resources.
- (36) The national investigating bodies play a core role in the safety investigation process. Their work is of the utmost importance in determining the causes of an accident or incident. It is therefore essential that they should possess the financial and human resources required to conduct effective and efficient investigations. The national investigating bodies should cooperate with a view to exchanging information and best practices. They should establish a programme of peer reviews in order to monitor the effectiveness of their investigations. The peer-review reports should be provided to the Agency in order to allow it to monitor the overall safety performance of the Union rail system.

- (37) Serious accidents on the railways are rare. However, they can have disastrous consequences and raise concern among the public about the safety performance of the Union rail system. All such accidents should therefore be investigated from a safety perspective to avoid recurrence with the results of the investigations being made publicly available. Other accidents and incidents should also be subject to safety investigations when they involve significant precursors to a serious accident.
- (38) A safety investigation should be kept separate from any judicial inquiry into the same incident, and those conducting it should be granted access to evidence and witnesses. It should be carried out by a permanent body that is independent of the actors in the Union rail system. The body should function in a way which avoids any conflict of interest and any possible involvement in the causes of the occurrences that are investigated. In particular, its functional independence should not be affected if it is closely linked, for organisational and legal structure purposes, to the national safety authority, the Agency or the regulator of railways. Its investigations should be carried out with as much openness as possible. For each occurrence, the investigating body should establish the relevant investigation group possessing the expertise needed to find the immediate and underlying causes.
- (39) An investigation after a serious accident should be carried out in such a way that all parties are given the possibility to be heard and to share the results. In particular, during the investigation, the investigating body should update the parties whom it judges as having safety-related responsibility on the progress of the investigation, and should take account of their views and opinions. This will allow the investigating body to receive any additional relevant information and to be aware of different opinions on its work so that it can complete its investigation in the most appropriate manner. Such consultation should in no case lead to apportioning blame or liability but, rather, to collecting factual evidence and learning lessons for the future improvement of safety. The investigating body should, however, be free to choose the information it intends to share with such parties in order to avoid any undue pressure, except when this is requested by those conducting the judicial procedure. The investigating body should also take account of the reasonable information needs of any victims and of their relatives.
- (40) In order to improve the efficiency of their activities and to facilitate the discharge of their duties, investigating bodies should have timely access to the site of an accident, where necessary in good cooperation with any judicial authority involved in the matter. The reports on investigations and any findings and recommendations provide crucial information for the further improvement of railway safety and should be made publicly available at Union level. Safety recommendations should be acted upon by the addressees and actions reported back to the investigating body.
- (41) In the event that the direct cause of an accident or incident seems to be related to human actions, attention should be paid to the particular circumstances and the manner in which routine activities are performed by staff during normal operations, including the design of the man-machine interface, the suitability of procedures, conflicting objectives, workload and any other circumstances which may have influence on the occurrence, including physical and work-related stress, fatigue or psychological fitness.
- (42) Efforts should be made to ensure that a high level of training and advanced qualifications is available across the Union.
- (43) In order to supplement and amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of CSMs and CSTs, and their revision. 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.
- (44) Implementing powers should be conferred on the Commission in order to ensure uniform conditions for the implementation of this Directive with regard to the mandate of the Agency to draft CSMs and CSTs and their amendments and to make the relevant recommendations to the Commission; practical arrangements for the purpose of safety certification; detailed provisions identifying which of the requirements set out in Annex III are

to apply for the purpose of maintenance functions carried out by maintenance workshops, including detailed provisions to ensure the uniform implementation of certification of maintenance workshops, in compliance with the relevant CSM and TSIs; detailed provisions identifying which of the requirements set out in Annex III are to apply for the purpose of certification of entities in charge of maintenance of the vehicles other than freight wagons, on the basis of the technical characteristics of such vehicles, including detailed provisions to ensure uniform implementation of certification conditions for the entity in charge of maintenance for vehicles other than freight wagons, in compliance with the relevant CSM and TSIs and the reporting structure of the accident and incident investigation report. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council <sup>(1)</sup>.

- (45) The Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.
- (46) Since the objectives of this Directive, namely coordinating activities in the Member States in order to regulate and supervise safety, investigating accidents and establishing CSTs, CSMs, CSIs and common requirements for single safety certificates, cannot be sufficiently achieved by the Member States but can rather, by reason of their 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 those objectives.
- (47) The obligation to transpose this Directive into national law should be confined to those provisions representing a substantive amendment as compared to Directive 2004/49/EC. The obligation to transpose the provisions that are unchanged arises under that Directive.
- (48) This Directive should be without prejudice to the obligation of the Member States relating to the time limits for transposition into national law of the Directives set out in Part B of Annex IV,

HAVE ADOPTED THIS DIRECTIVE:

#### CHAPTER I

#### GENERAL PROVISIONS

#### *Article 1*

#### **Subject matter**

This Directive lays down provisions to ensure the development and improvement of the safety of the Union rail system and improved access to the market for rail transport services by:

- (a) harmonising the regulatory structure in the Member States;
- (b) defining responsibilities between the actors in the Union rail system;
- (c) developing common safety targets ('CSTs') and common safety methods ('CSMs') with a view to gradually removing the need for national rules;
- (d) setting out the principles for issuing, renewing, amending and restricting or revoking safety certificates and authorisations;
- (e) requiring the establishment, for each Member State, of a national safety authority and an accident and incident investigating body; and
- (f) defining common principles for the management, regulation and supervision of railway safety.

<sup>(1)</sup> 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).

*Article 2***Scope**

1. This Directive applies to the rail system in the Member States, which may be broken down into subsystems for structural and functional areas. It covers safety requirements for the system as a whole, including the safe management of infrastructure and of traffic operation and the interaction between railway undertakings, infrastructure managers and other actors in the Union rail system.
2. This Directive shall not apply to:
  - (a) metros;
  - (b) trams and light rail vehicles, and infrastructure used exclusively by those vehicles; or
  - (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.
3. Member States may exclude from the scope of the measures implementing this Directive:
  - (a) privately owned railway infrastructure, including sidings, used by the 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 strictly local, historical or tourist 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.
4. Notwithstanding paragraph 2, Member States may decide to apply, where appropriate, provisions of this Directive to metros and other local systems in accordance with national law.

*Article 3***Definitions**

For the purposes of this Directive, the following definitions apply:

- (1) 'Union rail system' means the Union rail system as defined in point (1) of Article 2 of Directive (EU) 2016/797;
- (2) '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 <sup>(1)</sup>;
- (3) '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, including undertakings which provide traction only;
- (4) 'technical specification for interoperability' (TSI) means a specification adopted in accordance with Directive (EU) 2016/797 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;
- (5) 'common safety targets' (CSTs) means the minimum safety levels that are to be reached by the system as a whole, and where feasible, by different parts of the Union rail system (such as the conventional rail system, the high-speed rail system, long railway tunnels or lines solely used for freight transport);

<sup>(1)</sup> 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).

- (6) 'common safety methods' (CSMs) means the methods describing the assessment of safety levels and achievement of safety targets and compliance with other safety requirements;
- (7) 'national safety authority' means the national body entrusted with the tasks regarding railway safety in accordance with this Directive or any body entrusted by several Member States with those tasks in order to ensure a unified safety regime;
- (8) '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, and which are applicable within that Member State to railway undertakings, infrastructure managers or third parties;
- (9) 'safety management system' means the organisation, arrangements and procedures established by an infrastructure manager or a railway undertaking to ensure the safe management of its operations;
- (10) 'investigator-in-charge' means a person responsible for the organisation, conduct and control of an investigation;
- (11) 'accident' means an unwanted or unintended sudden event or a specific chain of such events which have harmful consequences; accidents are divided into the following categories: collisions; derailments; level crossing accidents; accidents to persons involving rolling stock in motion; fires and others;
- (12) 'serious accident' means any train collision or derailment of trains resulting in the death of at least one person or serious injuries to five or more persons or extensive damage to rolling stock, the infrastructure or the environment, and any other accident with the same consequences which has an obvious impact on railway safety regulation or the management of safety; 'extensive damage' means damage that can be immediately assessed by the investigating body to cost at least EUR 2 million in total;
- (13) 'incident' means any occurrence, other than an accident or serious accident, affecting the safety of railway operations;
- (14) 'investigation' means a process conducted for the purpose of accident and incident prevention which includes the gathering and analysis of information, the drawing of conclusions, including the determination of causes and, when appropriate, the making of safety recommendations;
- (15) 'causes' means actions, omissions, events or conditions, or a combination thereof, which led to an accident or incident;
- (16) '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;
- (17) '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;
- (18) 'interoperability constituents' means the interoperability constituents as defined in point (7) of Article 2 of Directive (EU) 2016/797;
- (19) '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 of Directive (EU) 2016/797;
- (20) 'entity in charge of maintenance' ('ECM') means an entity in charge of the maintenance of a vehicle, and registered as such in a vehicle register referred to in Article 47 of Directive (EU) 2016/797;
- (21) '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;



- (22) 'manufacturer' means the manufacturer as defined in point (36) of Article 2 of Directive (EU) 2016/797;
- (23) 'consignor' means an enterprise which consigns goods either on its own behalf or for a third party;
- (24) 'consignee' means any natural or legal person who receives goods pursuant to a contract of carriage; if the transport operation takes place without a contract of carriage, any natural or legal person that takes charge of the goods on arrivals shall be deemed to be the consignee;
- (25) 'loader' means an enterprise which loads packaged goods, small containers or portable tanks into or onto a wagon or a container, or which loads a container, bulk-container, multiple-element gas container, tank-container or portable tank onto a wagon;
- (26) 'unloader' means an enterprise which removes a container, bulk-container, multiple-element gas container, tank-container or portable tank from a wagon, or any enterprise which unloads packaged goods, small containers or portable tanks out of or from a wagon or a container, or any enterprise which discharges goods from a tank (tank-wagon, demountable tank, portable tank or tank-container), or from a battery-wagon or multiple-element gas container, or from a wagon, large container or small container for carriage in bulk or a bulk-container;
- (27) 'filler' means an enterprise that loads goods into a tank (including a tank-wagon, wagon with demountable tank, portable tank or tank-container), into a wagon, large container or small container for carriage in bulk, or into a battery-wagon or multiple-element gas container;
- (28) 'unfiller' means an enterprise that removes goods from a tank (including a tank-wagon, wagon with demountable tank, portable tank or tank-container), a wagon, a large container or small container for carriage in bulk, or from a battery-wagon or multiple-element gas container;
- (29) 'carrier' means an enterprise which carries out a transport operation pursuant to a contract of carriage;
- (30) 'contracting entity' means a public or private entity which orders the design and/or construction or the renewal or upgrading of a subsystem;
- (31) 'type of operation' means the type characterised by passenger transport, including or excluding high-speed services, freight transport, including or excluding dangerous goods services, and shunting services only;
- (32) 'extent of operation' means the extent characterised by the number of passengers and/or volume of goods and the estimated size of a railway undertaking in terms of number of employees working in the railway sector (i.e., as a micro, small, medium-sized or large enterprise);
- (33) 'area of operation' means a network or networks within one or more Member States where a railway undertaking intends to operate.

## CHAPTER II

### DEVELOPMENT AND MANAGEMENT OF RAILWAY SAFETY

#### *Article 4*

#### **Role of actors in the Union rail system in developing and improving railway safety**

1. With the aim of developing and improving railway safety, Member States, within the limits of their competences, shall:
- (a) ensure that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Union law and international rules and of technical and scientific progress, and giving priority to the prevention of accidents;
- (b) ensure that all applicable legislation is enforced in an open and non-discriminatory manner, fostering the development of a single European rail transport system;
- (c) ensure that measures to develop and improve railway safety take account of the need for a system-based approach;

- (d) ensure that the responsibility for the safe operation of the Union rail system and the control of risks associated with it is laid upon the infrastructure managers and railway undertakings, each for its part of the system, obliging them to:
  - (i) implement necessary risk control measures as referred to in point (a) of Article 6(1), where appropriate in cooperation with each other;
  - (ii) apply Union and national rules;
  - (iii) establish safety management systems in accordance with this Directive;
- (e) without prejudice to civil liability in accordance with the legal requirements of the Member States, ensure that each infrastructure manager and each railway undertaking is made responsible for its part of the system and its safe operation, including supply of materials and contracting of services vis-à-vis users, customers, the workers concerned and other actors referred to in paragraph 4;
- (f) develop and publish annual safety plans setting out the measures envisaged to achieve the CSTs; and
- (g) where appropriate, support the Agency in its work to monitor the development of railway safety at Union level.

2. The Agency shall ensure, within the limits of its competences, that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Union law and of technical and scientific progress and giving priority to the prevention of serious accidents.

3. Railway undertakings and infrastructure managers shall:

- (a) implement the necessary risk control measures referred to in point (a) of Article 6(1), where appropriate in cooperation with each other and with other actors;
- (b) take account in their safety management systems of the risks associated with the activities of other actors and third parties;
- (c) where appropriate, contractually oblige the other actors referred to in paragraph 4 having a potential impact on the safe operation of the Union rail system to implement risk control measures; and
- (d) ensure that their contractors implement risk control measures through the application of the CSMs for monitoring processes set out in the CSMs on monitoring referred to in point (c) of Article 6(1), and that this is stipulated in contractual arrangements to be disclosed on request of the Agency or of the national safety authority.

4. Without prejudice to the responsibilities of railway undertakings and infrastructure managers referred to in paragraph 3, entities in charge of maintenance and all other actors having a potential impact on the safe operation of the Union rail system, including manufacturers, maintenance suppliers, keepers, service providers, contracting entities, carriers, consignors, consignees, loaders, unloaders, fillers and unfillers, shall:

- (a) implement the necessary risk control measures, where appropriate in cooperation with other actors;
- (b) ensure that subsystems, accessories, equipment and services supplied by them comply with specified requirements and conditions for use so that they can be safely operated by the railway undertaking and/or the infrastructure manager concerned.

5. Railway undertakings, infrastructure managers and any actor referred to in paragraph 4 who identifies or is informed of a safety risk relating to defects and construction non-conformities or malfunctions of technical equipment, including those of structural subsystems, shall, within the limits of their respective competence:

- (a) take any necessary corrective measure to tackle the safety risk identified;

(b) report those risks to the relevant parties involved, in order to enable them to take any necessary further corrective action to ensure continuous achievement of the safety performance of the Union rail system. The Agency may establish a tool that facilitates this exchange of information among the relevant actors, taking into account the privacy of the users involved, the results of a cost-benefit analysis as well as the IT applications and registers already set up by the Agency.

6. In the case of exchange of vehicles between railway undertakings, any involved actor shall exchange all information relevant to safe operation including, but not limited to, the status and history of the vehicle concerned, elements of the maintenance files for the purpose of traceability, traceability of loading operations and consignment notes.

#### Article 5

### Common safety indicators ('CSIs')

1. In order to facilitate assessment of the achievement of the CSTs and to provide for the monitoring of the general development of railway safety, Member States shall collect information on CSIs through the annual reports of the national safety authorities referred to in Article 19.

2. The CSIs are set out in Annex I.

#### Article 6

### Common safety methods ('CSMs')

1. The CSMs shall describe how the safety levels, the achievement of safety targets and compliance with other safety requirements are assessed, including, where appropriate, through an independent assessment body, by elaborating and defining:

- (a) the risk evaluation and assessment methods;
- (b) the methods for assessing conformity with requirements in safety certificates and safety authorisations issued in accordance with Articles 10 and 12;
- (c) the methods for supervision to be applied by national safety authorities and the methods for monitoring to be applied by railway undertakings, infrastructure managers and entities in charge of maintenance;
- (d) the methods for assessing the safety level and the safety performance of railway operators at national and Union level;
- (e) the methods for assessing the achievement of safety targets at national and Union level; and
- (f) any other methods covering a process of the safety management system which need to be harmonised at Union level.

2. The Commission shall, by means of implementing acts, give a mandate to the Agency to draft CSMs and amendments thereto and to make the relevant recommendations to the Commission, on the basis of a clear justification of the need for a new or amended CSM and its impact on existing rules and on the level of safety of the Union rail system. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3). Where the committee referred to in Article 28 ('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.

The drafting, adoption and review of CSMs shall take account of the opinions of users, the national safety authorities and stakeholders, including social partners, where appropriate. The recommendations shall enclose a report on the results of that consultation and a report assessing the impact of the new or amended CSM to be adopted.

3. During the exercise of the mandate referred to in paragraph 2, the committee shall be kept systematically and regularly informed by the Agency or by the Commission of the preparatory work on the CSMs. During that work, the Commission may address to the Agency any useful recommendations concerning the CSMs and a cost-benefit analysis. In particular, the Commission may require that alternative solutions be examined by the Agency and that the assessment of the costs and benefits of those alternative solutions be set out in the report annexed to the draft CSMs.

The Commission shall be assisted by the committee for the tasks mentioned in the first subparagraph.

4. The Commission shall examine the recommendation issued by the Agency with a view to verifying that the mandate referred to in paragraph 2 is fulfilled. Where the mandate is not fulfilled, the Commission shall request the Agency to review its recommendation by indicating the points of the mandate which were not fulfilled. For justified reasons, the Commission may decide to modify the mandate given to the Agency in accordance with the procedure set out in paragraph 2.

The Commission shall be assisted by the committee for the tasks mentioned in the first subparagraph.

5. The CSMs shall be revised at regular intervals, taking into account the experience gained from their application and the global development of railway safety and with the objective of generally maintaining and, where reasonably practicable, continuously improving safety.

6. On the basis of the recommendation issued by the Agency and after the examination referred to in paragraph 4 of this Article, the Commission shall be empowered to adopt delegated acts in accordance with Article 27 concerning the content of CSMs, and of any amendments thereto.

7. Member States shall make any necessary amendments to their national rules in the light of the adoption of CSMs and amendments thereto without delay.

#### Article 7

#### **Common safety targets ('CSTs')**

1. The CSTs shall establish the minimum safety levels to be reached by the system as a whole, and where feasible, by different parts of the rail system in each Member State and in the Union. The CSTs may be expressed in terms of risk acceptance criteria or target safety levels and shall take into consideration, in particular:

- (a) individual risks relating to passengers, staff including employees or contractors, level crossing users and others, and, without prejudice to existing national and international liability rules, individual risks relating to trespassers;
- (b) societal risks.

2. The Commission shall, by means of implementing acts, give a mandate to the Agency to draft CSTs and amendments thereto and to make the relevant recommendations to the Commission, on the basis of a clear justification of the need for a new or amended CST and its impact on existing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3). 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.

3. During the exercise of the mandate referred to in paragraph 2, the committee shall be kept systematically and regularly informed by the Agency or by the Commission of the preparatory work on the CSTs. During that work, the Commission may address to the Agency any useful recommendations concerning the CSTs and a cost-benefit analysis. In particular, the Commission may require that alternative solutions be examined by the Agency and that the assessment of the cost and benefits of those alternative solutions be set out in the report annexed to the draft CSTs.

The Commission shall be assisted by the committee for the tasks mentioned in the first subparagraph.

4. The Commission shall examine the recommendation issued by the Agency with a view to verifying that the mandate referred to in paragraph 2 is fulfilled. Where the mandate is not fulfilled, the Commission shall request the Agency to review its recommendation by indicating the points of the mandate which were not fulfilled. For justified reasons, the Commission may decide to modify the mandate given to the Agency in accordance with the procedure set out in paragraph 2.

The Commission shall be assisted by the committee for the tasks mentioned in the first subparagraph.

5. The CSTs shall be revised at regular intervals, taking into account the global development of railway safety. The revised CSTs shall reflect any priority area where safety needs to be further improved.
6. On the basis of the recommendation issued by the Agency and after the examination referred to in paragraph 4 of this Article, the Commission shall be empowered to adopt delegated acts in accordance with Article 27 concerning the content of CSTs, and of any amendments thereto.
7. Member States shall make any necessary amendments to their national rules in order to achieve at least the CSTs, and any revised CSTs, in accordance with the implementation timetables attached to them. Those amendments shall be taken into account in the annual safety plans referred to in point (f) of Article 4(1). Member States shall notify those rules to the Commission in accordance with Article 8.

#### Article 8

##### **National rules in the field of safety**

1. National rules notified by 15 June 2016 pursuant to Directive 2004/49/EC shall apply if they:
  - (a) fall into one of the types identified under Annex II; and
  - (b) comply with Union law, including in particular TSIs, CSTs and CSMs; and
  - (c) would not result in arbitrary discrimination or a disguised restriction on rail transport operation between Member States.
2. By 16 June 2018, Member States shall review the national rules referred to in paragraph 1 and repeal:
  - (a) any national rule which was not notified or which does not meet the criteria specified in paragraph 1;
  - (b) any national rule which has been made redundant by Union law, including in particular TSIs, CSTs and CSMs.

To that end, Member States may use the rule management tool referred to in Article 27(4) of Regulation (EU) 2016/796 and may request Agency to examine specific rules against the criteria specified in this paragraph.

3. Member States may lay down new national rules pursuant to this Directive only in the following cases:
  - (a) where rules concerning existing safety methods are not covered by a CSM;
  - (b) where operating rules of the railway network are not yet covered by TSIs;
  - (c) as an urgent preventive measure, in particular following an accident or an incident;
  - (d) where an already notified rule needs to be revised;
  - (e) where rules concerning requirements in respect of staff executing safety-critical tasks, including selection criteria, physical and psychological fitness and vocational training are not yet covered by a TSI or by Directive 2007/59/EC of the European Parliament and of the Council <sup>(1)</sup>.

4. Member States shall submit the draft of a new national rule to the Agency and the Commission for consideration in due time and within the deadlines referred to in Article 25(1) of Regulation (EU) 2016/796, before the expected introduction into the national legal system of the proposed new rule, providing justification for its introduction, through the appropriate IT system in accordance with Article 27 of Regulation (EU) 2016/796. 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) 2016/796.

5. In the case of urgent preventive measures, Member States may adopt and apply a new rule immediately. That rule shall be notified in accordance with Article 27(2) of Regulation (EU) 2016/796 and subject to the assessment of the Agency in accordance with Article 26(1), (2) and (5) of Regulation (EU) 2016/796.

6. If the Agency becomes aware of any national rule, whether notified or not, which has become redundant or is in conflict with the CSMs or any other Union law adopted after the application of the national rule concerned, the procedure provided for in Article 26 of Regulation (EU) 2016/796 shall apply.

<sup>(1)</sup> Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community (OJ L 315, 3.12.2007, p. 51).

7. Member States shall notify to the Agency and to the Commission the national rules adopted. They shall use the appropriate IT system in accordance with Article 27 of Regulation (EU) 2016/796. Member States shall ensure that existing national rules 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 their national rules.
8. 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 of Directive (EU) 2016/797 or indicate in the network statement referred to in Article 27 of Directive 2012/34/EU where those rules and restrictions are published.
9. National rules notified in accordance with this Article shall not be subject to the notification procedure provided for by Directive (EU) 2015/1535 of the European Parliament and the Council <sup>(1)</sup>.
10. Draft national rules and existing national rules shall be examined by the Agency in accordance with the procedures laid down in Articles 25 and 26 of Regulation (EU) 2016/796.
11. Without prejudice to paragraph 8, national rules not notified in accordance with this Article shall not apply for the purposes of this Directive.

#### Article 9

#### **Safety management systems**

1. Infrastructure managers and railway undertakings shall establish their respective safety management systems to ensure that the Union rail system can achieve at least the CSTs, that it is in conformity with the safety requirements laid down in TSIs, and that the relevant parts of CSMs and national rules notified in accordance with Article 8 are applied.
2. The safety management system shall be documented in all relevant parts and shall in particular describe the distribution of responsibilities within the organisation of the infrastructure manager or the railway undertaking. It shall show how control is ensured by the management on different levels, how staff and their representatives on all levels are involved and how continuous improvement of the safety management system is ensured. There shall be a clear commitment to consistently apply human factors knowledge and methods. Through the safety management system, infrastructure managers and railway undertakings shall promote a culture of mutual trust, confidence and learning in which staff are encouraged to contribute to the development of safety while ensuring confidentiality.
3. The safety management system shall contain the following basic elements:
  - (a) a safety policy approved by the organisation's chief executive and communicated to all staff;
  - (b) qualitative and quantitative targets of the organisation for the maintenance and enhancement of safety, and plans and procedures for reaching these targets;
  - (c) procedures to meet existing, new and altered technical and operational standards or other prescriptive conditions as laid down in TSIs, national rules referred to in Article 8 and Annex II, other relevant rules or authority decisions;
  - (d) procedures to assure compliance with the standards and other prescriptive conditions throughout the life cycle of equipment and operations;
  - (e) procedures and methods for identifying risks, carrying out risk evaluation and implementing risk-control measures whenever a change of operating conditions or the introduction of new material imposes new risks on the infrastructure or the man-machine-organisation interface;
  - (f) the provision of programmes for the training of staff and systems to ensure that the staff's competence is maintained and that tasks are carried out accordingly, including arrangements with regard to physical and psychological fitness;

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

- (g) arrangements for the provision of sufficient information within the organisation and, where appropriate, between organisations of the railway system;
- (h) procedures and formats for the documentation of safety information and designation of procedure for the configuration control of vital safety information;
- (i) procedures to ensure that accidents, incidents, near misses and other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken;
- (j) the provision of actions plans, alerts and information in the event of an emergency, agreed upon with the appropriate public authorities; and
- (k) provisions for recurrent internal auditing of the safety management system.

Infrastructure managers and railway undertakings shall include any other element necessary to cover safety risks, in accordance with the assessment of risks arising from their own activity.

4. The safety management system shall be adapted to the type, extent, area of operations and other conditions of the activity pursued. It shall ensure the control of all risks associated with the activity of the infrastructure manager or railway undertaking, including the supply of maintenance, without prejudice to Article 14, and material, and the use of contractors. Without prejudice to existing national and international liability rules, the safety management system shall also take into account, where appropriate and reasonable, the risks arising as a result of activities by other actors referred to in Article 4.

5. The safety management system of any infrastructure manager shall take into account the effects of operations by different railway undertakings on the network and shall provide for all railway undertakings to be able to operate in accordance with TSIs and national rules and with the conditions laid down in their safety certificate.

Safety management systems shall be developed with the aim of coordinating the emergency procedures of the infrastructure manager with all railway undertakings that operate on its infrastructure, and with the emergency services, so as to facilitate the rapid intervention of rescue services, and with any other party that could be involved in an emergency situation. For cross-border infrastructure, the cooperation between the relevant infrastructure managers shall facilitate the necessary coordination and preparedness of the competent emergency services on both sides of the border.

Following a serious accident, the railway undertaking shall provide assistance to victims helping them in complaints procedures under Union law, in particular Regulation (EC) No 1371/2007 of the European Parliament and of the Council<sup>(1)</sup>, without prejudice to the obligations of other parties. Such assistance shall use channels for communicating with victims' families and include psychological support for accident victims and their families.

6. Before 31 May of each year, all infrastructure managers and railway undertakings shall submit to the national safety authority an annual safety report concerning the preceding calendar year. The safety report shall contain:

- (a) information on how the organisation's corporate safety targets are met and the results of safety plans;
- (b) an account of the development of national safety indicators, and of the CSIs referred to in Article 5, in so far as it is relevant to the reporting organisation;
- (c) the results of internal safety auditing;
- (d) observations on deficiencies and malfunctions of railway operations and infrastructure management that might be relevant for the national safety authority, including a summary of information provided by the relevant actors in accordance with point (b) of Article 4(5); and
- (e) a report on the application of the relevant CSMs.

<sup>(1)</sup> Regulation (EC) No 1371/2007 of the European Parliament and of the Council of 23 October 2007 on rail passengers' rights and obligations (OJ L 315, 3.12.2007, p. 14).

7. On the basis of the information provided by the national safety authorities in accordance with Articles 17 and 19, the Agency may address a recommendation to the Commission for a CSM covering elements of the safety management system which need to be harmonised at Union level, including through harmonised standards, as referred to in point (f) of Article 6(1). In such case, Article 6(2) shall apply.

### CHAPTER III

#### SAFETY CERTIFICATION AND AUTHORISATION

##### Article 10

#### **Single safety certificate**

1. Without prejudice to paragraph 9, access to the railway infrastructure shall be granted only to railway undertakings which hold the single safety certificate issued by the Agency in accordance with paragraphs 5 to 7 or by a national safety authority in accordance with paragraph 8.

The purpose of the single safety certificate is to provide evidence that the railway undertaking concerned has established its safety management system and that it is able to operate safely in the intended area of operation.

2. In its application for a single safety certificate, the railway undertaking shall specify the type and extent of the railway operations covered and the intended area of operation.

3. The application for a single safety certificate shall be accompanied by a file including documentary evidence that:

- (a) the railway undertaking has established its safety management system in accordance with Article 9 and that it meets the requirements laid down in TSIs, CSMs and CSTs and in other relevant legislation in order to control risks and provide transport services safely on the network; and
- (b) the railway undertaking, where applicable, meets the requirements laid down in the relevant national rules notified in accordance with Article 8.

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) 2016/796.

4. The Agency, or in the cases provided for by paragraph 8 the national safety authority, shall issue the single safety certificate, or inform the applicant of its negative decision, within a predetermined and reasonable time, and, in any case, not more than 4 months after all information required and any supplementary information requested have been submitted by the applicant. The Agency, or in the cases provided for by paragraph 8 the national safety authority, shall apply the practical arrangements on the certification procedure to be established in an implementing act, as referred to in paragraph 10.

5. The Agency shall issue a single safety certificate to railway undertakings having an area of operation in one or more Member States. In order to issue such a certificate, the Agency shall:

- (a) assess the elements set out in point (a) of paragraph 3; and
- (b) immediately refer the railway undertaking's file in its entirety to the national safety authorities concerned by the intended area of operation for an assessment of the elements set out in point (b) of paragraph 3.

As part of the above assessments, the Agency or the national safety authorities shall be authorised to undertake visits and inspections on the sites of the railway undertaking and audits, and may request relevant supplementary information. The Agency and the national safety authorities shall coordinate the organisation of such visits, audits and inspections.

6. Within 1 month of receipt of an application for a single safety certificate, the Agency shall inform the railway undertaking 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 set out in point (b) of paragraph 3.



The Agency shall take full account of the assessments under paragraph 5 before taking its decision on the issuing of the single safety certificate.

The Agency shall take full responsibility for any single safety certificates it issues.

7. Where 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 that 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, the Agency and the national safety authority or authorities may decide to involve the railway undertaking. If no mutually acceptable assessment can be agreed on within 1 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) 2016/796. The Board of Appeal shall decide whether to confirm the Agency's draft decision within 1 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 grant a single safety certificate with an area of operations 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, the Agency and the national safety authority or authorities may decide to involve the applicant. If no mutually acceptable assessment can be agreed on within 1 month after the Agency has informed the national safety authority or authorities of its disagreement, the Agency shall take its final decision.

8. Where the area of operation is limited to one Member State, the national safety authority of that Member State may, under its own responsibility and when the applicant so requests, issue a single safety certificate. In order to issue such certificates, the national safety authority shall assess the file in relation to all the elements specified in paragraph 3 and shall apply the practical arrangements to be established in the implementing acts referred to in paragraph 10. As part of the above assessments, the national safety authority shall be authorised to undertake visits and inspections on the sites of the railway undertaking and audits. Within 1 month of receipt of the application, the national safety authority shall inform the applicant that the file is complete or ask for relevant supplementary information. The single safety certificate shall also be valid without an extension of the area of operations for railway undertakings travelling to stations in neighbouring Member States with similar network characteristics and similar operating rules, 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 Member States or national safety authorities.

The national safety authority shall take full responsibility for any single safety certificates it issues.

9. A Member State may allow third-country operators to reach a station in its territory designated for cross-border operations and close to the border of that Member State without requiring a single safety certificate, provided that an appropriate level of safety is ensured through:

- (a) cross-border agreement between the Member State concerned and the neighbouring third country; or
- (b) contractual arrangements between the third-country operator and the railway undertaking or infrastructure manager that has a single safety certificate or safety authorisation to operate on that network, provided that the safety-related aspects of those arrangements have been duly reflected in their safety management system.

10. By 16 June 2018, the Commission shall adopt, by means of implementing acts, practical arrangements specifying:

- (a) how the requirements for the single safety certificate laid down in this Article shall be fulfilled by the applicant and listing the documents required;
- (b) the details of the certification process, such as procedural stages and timeframes for each stage of the process;
- (c) how the requirements laid down in this Article shall to be complied with by the Agency and the national safety authority through the different stages of the application and certification process, including in the assessment of applicants' files; and
- (d) the period of validity of single safety certificates issued by the Agency or by the national safety authorities, in particular in the case of updates of any single safety certificate resulting from changes to type, extent and area of operation.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3). They shall take into account the experience gained during the implementation of Commission Regulation (EC) No 653/2007 <sup>(1)</sup> and of Commission Regulation (EU) No 1158/2010 <sup>(2)</sup> and the experience gained during the preparation of the cooperation agreements referred to in Article 11(1).

11. Single safety certificates shall specify the type and extent of the railway operations covered and the area of operation. A single safety certificate may also cover sidings owned by the railway undertaking if these are included in its safety management system.

12. Any decision refusing the issuing of a single safety certificate 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 1 month of receipt of the decision, request that the Agency or the national safety authority, as appropriate, review the decision. The Agency or the national safety authority shall have 2 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) 2016/796.

If the negative decision of a national safety authority is confirmed, the applicant may bring an appeal before an appeal body in accordance with national law. Member States may designate the regulatory body referred to in Article 56 of Directive 2012/34/EU for the purpose of this appeal procedure. In that case, Article 18(3) of this Directive shall apply.

13. A single safety certificate issued either by the Agency or by a national safety authority under this Article shall be renewed upon application by the railway undertaking at intervals not exceeding 5 years. It shall be fully or partly updated whenever the type or extent of the operation is substantially altered.

14. Where an applicant already has a single safety certificate issued in accordance with paragraphs 5 to 7 and wishes to extend its area of operations, or where it already has a single safety certificate issued in accordance with paragraph 8 and wishes to extend its area of operations to another Member State, it shall supplement the file with the relevant documents referred to in paragraph 3 concerning the additional area of operation. The railway undertaking shall submit the file to the Agency, which shall, after following the procedures laid down in paragraphs 4 to 7, issue an updated single safety certificate covering the extended area of operation. In that case, only the national safety authorities concerned by the extension of operation shall be consulted for the purposes of assessing the file as provided for in point (b) of paragraph 3.

<sup>(1)</sup> Commission Regulation (EC) No 653/2007 of 13 June 2007 on the use of a common European format for safety certificates and application documents in accordance with Article 10 of Directive 2004/49/EC of the European Parliament and of the Council and on the validity of safety certificates delivered under Directive 2001/14/EC (OJ L 153, 14.6.2007, p. 9).

<sup>(2)</sup> Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates (OJ L 326, 10.12.2010, p. 11).

If the railway undertaking has a single safety certificate in accordance with paragraph 8 and wishes to extend the area of operation within that Member State, it shall supplement the file with the relevant documents referred to in paragraph 3 concerning the additional area of operation. It shall submit the file, through the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796, to the national safety authority, which shall, after following the procedures laid down in paragraph 8, issue an updated single safety certificate covering the extended area of operation.

15. The Agency and the competent national safety authorities may require the revision of single safety certificates issued by them following substantial changes to the safety regulatory framework.

16. The Agency shall inform the competent national safety authorities without delay, and in any case within 2 weeks, of the issue of a single safety certificate. The Agency shall inform the competent national safety authorities immediately in the case of renewal, amendment or revocation of a single safety certificate. It shall state the name and address of the railway undertaking, the issue date, the type, extent, validity and area of operation of the single safety certificate and, in the case of revocation, the reasons for its decision. In the case of single safety certificates issued by national safety authorities, the same information shall be provided by the competent national safety authority or authorities to the Agency within the same timeframe.

#### Article 11

### Cooperation between the Agency and national safety authorities on issuing single safety certificates

1. For the purposes of Article 10(5) and (6) of this Directive, the Agency and the national safety authorities shall conclude cooperation agreements in accordance with Article 76 of Regulation (EU) 2016/796. The cooperation agreements shall be specific or framework agreements, and shall involve one or more national safety authorities. The cooperation agreements 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.

2. The cooperation agreements 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 efficient and proportionate allocation of resources for certification. Those cooperation agreements shall be in place before the Agency carries out the certification tasks in accordance with Article 31(3).

3. 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 2 all the national safety authorities concerned in those Member States shall conclude with the Agency a multilateral agreement which shall include the conditions to facilitate the extension of the area of operation of safety certificates in the Member States concerned, where relevant.

#### Article 12

### Safety authorisation of infrastructure managers

1. In order to be allowed to manage and operate a rail infrastructure, the infrastructure manager shall obtain a safety authorisation from the national safety authority in the Member State where the rail infrastructure is located.

The safety authorisation shall comprise an authorisation confirming acceptance of the infrastructure manager's safety management system as provided for in Article 9, and shall include the procedures and provisions fulfilling the requirements necessary for the safe design, maintenance and operation of the railway infrastructure, including, where appropriate, the maintenance and operation of the traffic control and signalling system.

The national safety authority shall explain the requirements for the safety authorisations and the documents required, where appropriate in the form of an application guidance document.

2. The safety authorisation shall be valid for 5 years and may be renewed upon application by the infrastructure manager. It shall be wholly or partly revised whenever substantial changes are made to the infrastructure, signalling or energy subsystems or to the principles of their operation and maintenance. The infrastructure manager shall inform the national safety authority of all such changes without delay.

The national safety authority may require that the safety authorisation be revised following substantial changes to the safety regulatory framework.

3. The national safety authority shall take a decision on an application for safety authorisation without delay and in any event not more than 4 months after all the information required and any supplementary information requested has been submitted by the applicant.

4. The national safety authority shall inform the Agency without delay, and in any event within 2 weeks, of the safety authorisations that have been issued, renewed, amended or revoked. It shall state the name and address of the infrastructure manager, the issue date, scope and period of validity of the safety authorisation and, in the event of revocation, the reasons for its decision.

5. In the case of cross-border infrastructure, the competent national safety authorities shall cooperate in order to issue the safety authorisations.

#### *Article 13*

#### **Access to training facilities**

1. Member States shall ensure that railway undertakings and infrastructure managers and their staff performing safety-critical tasks have fair and non-discriminatory access to training facilities for train drivers and staff accompanying trains, whenever such training is necessary for operating services on their network.

The training services shall include training on necessary route knowledge, operating rules and procedures, the signalling and control-command system and emergency procedures applied on the routes operated.

If the training services do not include examinations and granting of certificates, Member States shall ensure that staff of railway undertakings and infrastructure managers have access to such certificates.

The national safety authority shall ensure that the training services meet the requirements laid down respectively in Directive 2007/59/EC, in TSIs or in the national rules referred to in point (e) of Article 8(3) of this Directive.

2. If the training facilities are available only through a single railway undertaking or the infrastructure manager, Member States shall ensure that they are made available to other railway undertakings at a reasonable and non-discriminatory price which is cost-related and which may include a profit margin.

3. When recruiting new train drivers, staff on board trains and staff performing safety-critical tasks, railway undertakings may take into account any training, qualifications and experience acquired previously from other railway undertakings. For that purpose, such members of staff shall be entitled to have access to, obtain copies of, and communicate all documents attesting to their training, qualifications and experience.

4. Railway undertakings and infrastructure managers shall be responsible for the level of training and qualifications of their staff carrying out safety-critical work.

#### *Article 14*

#### **Maintenance of vehicles**

1. Each vehicle, before it is being used on the network, shall have an entity in charge of maintenance assigned to it and this entity shall be registered in the vehicle register in accordance with Article 47 of Directive (EU) 2016/797.

2. Without prejudice to the responsibility of the railway undertakings and infrastructure managers for the safe operation of a train as provided for in Article 4, the entity in charge of maintenance shall ensure that the vehicles for the maintenance of which it is in charge are in a safe state of running. To that end, the entity in charge of maintenance shall establish a maintenance system for those vehicles and shall by means of that system:

- (a) ensure that vehicles are maintained in accordance with the maintenance file of each vehicle and the requirements in force, including maintenance rules and relevant TSI provisions;
- (b) implement the necessary risk evaluation and assessment methods established in the CSMS as referred to in point (a) of Article 6(1), where appropriate in cooperation with other actors;
- (c) ensure that its contractors implement risk control measures through the application of the CSM on monitoring referred to in point (c) of Article 6(1) and that this is stipulated in contractual arrangements to be disclosed on request of the Agency or the national safety authority; and
- (d) ensure the traceability of the maintenance activities.

3. The maintenance system shall be composed of the following functions:

- (a) a management function to supervise and coordinate the maintenance functions referred to in points (b) to (d) and to ensure the safe state of the vehicle in the railway system;
- (b) a maintenance development function responsible to manage the maintenance documentation, including the configuration management, based on design and operational data as well as on performance and return on experience;
- (c) a fleet-maintenance management function to manage the vehicle's removal for maintenance and its return to operation after maintenance;
- (d) a maintenance delivery function to deliver the required technical maintenance of a vehicle or parts of it, including the release to service documentation.

The entity in charge of maintenance shall carry out the management function itself, but may outsource the maintenance functions referred to in points (b) to (d), or parts thereof, to other contracting parties such as maintenance workshops.

The entity in charge of maintenance shall ensure that all the functions set out in points (a) to (d) comply with the requirements and assessment criteria set out in Annex III.

Maintenance workshops shall apply relevant sections of Annex III as identified in the implementing acts adopted pursuant to point (a) of paragraph 8, which correspond to the functions and activities to be certified.

4. In the case of freight wagons, and after the adoption of the implementing acts referred to in point (b) of paragraph 8 in the case of other vehicles, each entity in charge of maintenance shall be certified and be awarded an entity in charge of maintenance certificate (ECM certificate) by an accredited or recognised body or by a national safety authority in accordance with the following conditions:

- (a) the accreditation and recognition processes of certification processes shall be based on criteria of independence, competence and impartiality;
- (b) the system of certification shall provide evidence that an entity in charge of maintenance has established the maintenance system to ensure the safe state of running of any vehicle for which it is in charge of maintenance;
- (c) the ECM certification shall be based on an assessment of the ability of the entity in charge of maintenance to meet the relevant requirements and assessment criteria set out in Annex III and to apply them consistently. It shall include a system of surveillance to ensure continuing compliance with those requirements and assessment criteria after award of the ECM certificate;
- (d) the certification of maintenance workshops shall be based on the compliance with the relevant sections in Annex III applied to the corresponding functions and activities to be certified.

Where the entity in charge of maintenance is a railway undertaking or an infrastructure manager, compliance with the conditions set out in the first subparagraph may be checked by the national safety authority pursuant to the procedures referred to in Article 10 or 12 and may be confirmed on the certificates issued in accordance with those procedures.

5. The certificates issued in accordance with paragraph 4 shall be valid throughout the Union.

6. On the basis of the recommendation of the Agency, the Commission shall, by means of implementing acts, adopt detailed provisions on the certification conditions referred to in the first subparagraph of paragraph 4 for the entity in charge of maintenance of freight wagons, including the requirements set out in Annex III in compliance with the relevant CSM and TSIs, and, when necessary, shall amend those provisions.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3).

The certification system applicable to freight wagons adopted by Commission Regulation (EU) No 445/2011 <sup>(1)</sup> shall continue to apply until the implementing acts referred to in this paragraph apply.

7. By 16 June 2018, the Agency shall evaluate the system of certification of the entity in charge of maintenance for freight wagons, consider the expediency of extending that system to all vehicles and the mandatory certification of maintenance workshops and submit its report to the Commission.

8. On the basis of the evaluation carried out by the Agency pursuant to paragraph 7, the Commission shall, by means of implementing acts, adopt, if appropriate, and, when necessary, subsequently amend detailed provisions identifying which of the requirements set out in Annex III shall apply for the purpose of:

- (a) maintenance functions carried out by maintenance workshops, including detailed provisions to ensure the uniform implementation of the certification of maintenance workshops, in compliance with the relevant CSM and TSIs;
- (b) the certification of entities in charge of maintenance of vehicles other than freight wagons, on the basis of the technical characteristics of such vehicles, including detailed provisions to ensure the uniform implementation of the certification conditions by the entity in charge of maintenance for vehicles other than freight wagons, in compliance with the relevant CSM and TSIs.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3).

#### Article 15

#### **Derogations from the system of certification of entities in charge of maintenance**

1. Member States may fulfil the obligation to identify the entity in charge of maintenance through alternative measures with respect to the maintenance system established in Article 14, in the following cases:

- (a) vehicles registered in a third country and maintained in accordance with the law of that country;
- (b) vehicles used on networks or lines the track gauge of which is different from that of the main rail network within the Union and in respect of which fulfilment of the requirements laid down in Article 14(2) is ensured by international agreements with third countries;
- (c) freight wagons and 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;
- (d) vehicles used on the networks referred to in Article 2(3), and military equipment and special transport requiring an ad hoc national safety authority permit to be delivered prior to their entry into service. In this case derogations shall be granted for periods not longer than 5 years.

<sup>(1)</sup> Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 (OJ L 122, 11.5.2011, p. 22).

2. The alternative measures referred to in paragraph 1 shall be implemented through derogations to be granted by the relevant national safety authority or by the Agency when:
  - (a) registering vehicles pursuant to Article 47 of Directive (EU) 2016/797, as far as the identification of the entity in charge of maintenance is concerned;
  - (b) delivering single safety certificates and safety authorisations to railway undertakings and infrastructure managers pursuant to Articles 10 and 12 of this Directive, as far as the identification or certification of the entity in charge of maintenance is concerned.
3. Derogations shall be identified and justified in the annual report referred to in Article 19. Where it appears that undue safety risks are being taken on the Union rail system, the Agency shall immediately inform the Commission thereof. The Commission shall make contact with the parties concerned and, where appropriate, request the Member State concerned to withdraw its derogation decision.

#### CHAPTER IV

#### NATIONAL SAFETY AUTHORITIES

#### Article 16

#### Tasks

1. Each Member State shall establish a national safety authority. Member States shall ensure that the national safety authority has the necessary internal and external organisational capacity in terms of human and material resources. That authority shall be independent in its organisation, legal structure and decision-making from any railway undertaking, infrastructure manager, applicant or contracting entity and from any entity awarding public service contracts. Provided that such independence is guaranteed, that authority may be a department within the national ministry responsible for transport matters.
2. The national safety authority shall be entrusted with at least the following tasks:
  - (a) authorising the placing in service of the trackside control-command and signalling, energy and infrastructure subsystems constituting the Union rail system in accordance with Article 18(2) of Directive (EU) 2016/797;
  - (b) issuing, renewing, amending and revoking vehicle authorisations for placing on the market in accordance with Article 21(8) of Directive (EU) 2016/797;
  - (c) supporting the Agency in the issuing, renewal, amendment and revocation of vehicle authorisations for placing on the market in accordance with Article 21(5) of Directive (EU) 2016/797 and type authorisations of vehicle in accordance with Article 24 of Directive (EU) 2016/797;
  - (d) supervising, in its territory, that interoperability constituents are in compliance with the essential requirements as required by Article 8 of Directive (EU) 2016/797;
  - (e) ensuring that a vehicle number has been assigned in accordance with Article 46 of Directive (EU) 2016/797, without prejudice to Article 47(4) of that Directive;
  - (f) supporting the Agency in the issuing, renewal, amendment and revocation of single safety certificates granted in accordance with Article 10(5);
  - (g) issuing, renewing, amending and revoking single safety certificates granted in accordance with Article 10(8);
  - (h) issuing, renewing, amending and revoking safety authorisations granted in accordance with Article 12;
  - (i) monitoring, promoting, and, where appropriate, enforcing and updating the safety regulatory framework including the system of national rules;
  - (j) supervising railway undertakings and infrastructure managers in accordance with Article 17;
  - (k) where relevant, and in accordance with national law, issuing, renewing, amending and revoking train driving licences in accordance with Directive 2007/59/EC;
  - (l) where relevant, and in accordance with national law, issuing, renewing, amending and revoking certificates granted to entities in charge of maintenance.

3. The tasks referred to in paragraph 2 may not be transferred or subcontracted to any infrastructure manager, railway undertaking or contracting entity.

#### Article 17

### Supervision

1. National safety authorities shall oversee continued compliance with the legal obligation incumbent on railway undertakings and infrastructure managers to use a safety management system as referred to in Article 9.

For that purpose, the national safety authorities shall apply the principles set out in the relevant CSMs for supervision referred to in point (c) of Article 6(1), ensuring that supervision activities include, in particular, checking the application by railway undertakings and infrastructure managers of:

- (a) the safety management system to monitor its effectiveness;
- (b) the individual or partial elements of the safety management system, including operational activities, the supply of maintenance and material and the use of contractors to monitor their effectiveness; and
- (c) the relevant CSMs referred to in Article 6. The supervision activities relating to this point shall also apply to entities in charge of maintenance, where appropriate.

2. Railway undertakings shall inform the relevant national safety authorities at least 2 months before starting any new rail transport operation, in order to allow the latter to plan the supervision activities. Railway undertakings shall also provide a breakdown of the categories of staff and the types of vehicles.

3. The holder of a single safety certificate shall inform the competent national safety authorities without delay of any major changes to the information referred to in paragraph 2.

4. The monitoring of compliance with applicable working, driving and rest-time rules for train drivers shall be ensured by competent authorities designated by Member States. Where the monitoring of compliance is not ensured by national safety authorities, the competent authorities shall cooperate with the national safety authorities with a view to allowing the national safety authorities to fulfil their role of supervision of railway safety.

5. If a national safety authority finds that a holder of a single safety certificate no longer satisfies the conditions for certification, it shall ask the Agency to restrict or revoke that certificate. The Agency shall immediately inform all the competent national safety authorities. If the Agency decides to restrict or revoke the single safety certificate, it shall give reasons for its decision.

In the event of disagreement between the Agency and the national safety authority, the arbitration procedure indicated in Article 10(7) shall apply. If the result of that arbitration procedure is that the single safety certificate is to be neither restricted nor revoked, the temporary safety measures referred to in paragraph 6 of this Article shall be suspended.

Where the national safety authority has itself issued the single safety certificate in accordance with Article 10(8), it may restrict or revoke the certificate, giving reasons for its decision, and shall inform the Agency.

The holder of a single safety certificate whose certificate has been restricted or revoked either by the Agency or by the national safety authority shall have the right to appeal in accordance with Article 10(12).

6. If, during supervision, a national safety authority identifies a serious safety risk, it may at any time apply temporary safety measures, including immediately restricting or suspending the relevant operations. If the single safety certificate was issued by the Agency, the national safety authority shall immediately inform the Agency thereof and provide supporting evidence for its decision.



If the Agency finds that the holder of a single safety certificate no longer satisfies the conditions for certification, it shall immediately restrict or revoke that certificate.

If the Agency finds that the measures applied by the national safety authority are disproportionate, it may ask the national safety authority to withdraw or adapt those measures. The Agency and the national safety authority shall cooperate with a view to reaching a mutually acceptable solution. Where necessary, this process shall also involve the railway undertaking. If the latter procedure fails, the decision of the national safety authority to apply temporary measures shall remain in force.

The decision of the national safety authority relating to temporary safety measures shall be subject to national judicial review as referred to in Article 18(3). In such a case, the temporary safety measures may apply until the end of the judicial review, without prejudice to paragraph 5.

If the duration of a temporary measure is longer than 3 months, the national safety authority shall ask the Agency to restrict or revoke the single safety certificate and the procedure set out in paragraph 5 shall apply.

7. The national safety authority shall supervise the trackside, control-command and signalling, energy and infrastructure subsystems and ensure that they are in compliance with the essential requirements. In the case of cross-border infrastructures, it will perform its activities of supervision in cooperation with other relevant national safety authorities. If the national safety authority finds that an infrastructure manager no longer satisfies the conditions for its safety authorisation, it shall restrict or revoke that authorisation, giving reasons for its decision.

8. When supervising the effectiveness of the safety management systems of infrastructure managers and railway undertakings, the national safety authorities may take into account the safety performance of actors as referred to in Article 4(4) of this Directive, and, where appropriate, the training centres referred to in Directive 2007/59/EC as long as their activities have an impact on railway safety. This paragraph applies without prejudice to the responsibility of the railway undertakings and infrastructure managers referred to in Article 4(3) of this Directive.

9. The national safety authorities of Member States where a railway undertaking operates shall cooperate in coordinating their supervision activities concerning that railway undertaking to ensure that any key information on the specific railway undertaking is shared, particularly on known risks and its safety performance. The national safety authority shall also share information with other relevant national safety authorities and the Agency if it finds that the railway undertaking is not taking the necessary risk control measures.

That cooperation shall ensure that the supervision has sufficient coverage and that the duplication of inspections and audits is avoided. The national safety authorities may develop a common supervision plan in order to ensure that audits and other inspections are carried out periodically, taking into account the type and extent of transport operations in each of the Member States concerned.

The Agency shall assist such coordination activities by developing guidelines.

10. National safety authorities may address notices to warn infrastructure managers and railway undertakings in cases of non-compliance with their obligations set out in paragraph 1.

11. National safety authorities shall use information gathered by the Agency during the assessment of the file referred to in point (a) of Article 10(5) for the purposes of supervision of a railway undertaking after issuing its single safety certificate. They shall use the information gathered during the process of safety authorisation in accordance with Article 12 for the purposes of supervision of the infrastructure manager.

12. For the purpose of renewing single safety certificates, the Agency, or the competent national safety authorities in the case of a safety certificate issued in accordance with Article 10(8), shall use information gathered during the supervision activities. For the purpose of renewing safety authorisations, the national safety authority shall also use information gathered during its supervision activities.

13. The Agency and the national safety authorities shall make the necessary arrangements to coordinate and ensure the full exchange of information referred to in paragraphs 10, 11 and 12.

*Article 18***Decision-making principles**

1. The Agency, when considering applications for a single safety certificate in accordance with Article 10(1), and the national safety authorities shall carry out their tasks in an open, non-discriminatory and transparent way. In particular, they shall allow all interested parties to be heard and give reasons for their decisions.

They shall promptly respond to requests and applications and communicate their requests for information without delay and adopt all their decisions within 4 months after all relevant information has been provided by the applicant. They may at any time request the technical assistance of infrastructure managers and railway undertakings or other qualified bodies when they are carrying out the tasks referred to in Article 16.

In the process of developing the national regulatory framework, the national safety authorities shall consult all actors and interested parties, including infrastructure managers, railway undertakings, manufacturers and maintenance providers, users and staff representatives.

2. The national safety authorities shall be free to carry out all inspections, audits and investigations that are needed for the accomplishment of their tasks, and they shall be granted access to all relevant documents and to premises, installations and equipment of infrastructure managers and railway undertakings and, where necessary, of any actor referred to in Article 4. The Agency shall have the same rights in relation to railway undertakings when it carries out its safety certification tasks in accordance with Article 10(5).

3. Member States shall take the measures necessary to ensure that decisions taken by the national safety authorities are subject to judicial review.

4. The national safety authorities shall conduct an active exchange of views and experience, in particular within the network established by the Agency in order to harmonise their decision-making criteria across the Union.

*Article 19***Annual report**

National safety authorities shall publish an annual report concerning their activities in the preceding year and send them to the Agency by 30 September. The report shall contain information on:

- (a) the development of railway safety, including an aggregation at Member State level of the CSIs, in accordance with Article 5(1);
- (b) important changes in legislation and regulation concerning railway safety;
- (c) the development of safety certification and safety authorisation;
- (d) the results of, and experience relating to, the supervision of infrastructure managers and railway undertakings, including the number and outcome of inspections and audits;
- (e) the derogations decided in accordance with Article 15; and
- (f) the experience of the railway undertakings and infrastructure managers on the application of the relevant CSMs.

## CHAPTER V

## ACCIDENT AND INCIDENT INVESTIGATION

*Article 20***Obligation to investigate**

1. Member States shall ensure that an investigation is carried out by the investigating body referred to in Article 22 after any serious accident on the Union rail system. The objective of the investigation shall be to improve, where possible, railway safety and the prevention of accidents.

2. The investigating body referred to in Article 22 may also investigate those accidents and incidents which under slightly different conditions might have led to serious accidents, including technical failures of the structural subsystems or of interoperability constituents of the Union rail system.

The investigating body may decide whether or not an investigation of such an accident or incident is to be undertaken. In making its decision it shall take into account:

- (a) the seriousness of the accident or incident;
- (b) whether it forms part of a series of accidents or incidents relevant to the system as a whole;
- (c) its impact on railway safety; and
- (d) requests from infrastructure managers, railway undertakings, the national safety authority or the Member States.

3. The extent of investigations and the procedure to be followed in carrying out investigations shall be determined by the investigating body, taking into account Articles 21 and 23 and depending on the lessons it expects to draw from the accident or incident for the improvement of safety.

4. The investigation shall in no case be concerned with apportioning blame or liability.

#### *Article 21*

#### **Status of investigation**

1. Member States shall define, within the framework of their respective legal system, the legal status of the investigation that is to enable the investigators-in-charge to carry out their task in the most efficient way and within the shortest time.

2. In accordance with their national legislation, Member States shall ensure full cooperation by the authorities responsible for any judicial inquiry, and shall ensure that the investigators are given access as soon as possible to information and evidence relevant for the investigation. In particular, they shall be granted:

- (a) immediate access to the site of the accident or incident as well as to the rolling stock involved, the related infrastructure and traffic control and signalling installations;
- (b) the right to an immediate listing of evidence and controlled removal of wreckage, infrastructure installations or components for examination or analysis purposes;
- (c) unrestricted access to, and use of, the contents of on-board recorders and equipment for the recording of verbal messages and registration of the operation of the signalling and traffic control system;
- (d) access to the results of examination of the bodies of victims;
- (e) access to the results of examinations of the train staff and other railway staff involved in the accident or incident;
- (f) the opportunity to question the railway staff involved in the accident or incident and other witnesses; and
- (g) access to any relevant information or records held by the infrastructure manager, railway undertakings, entities in charge of maintenance and national safety authority concerned.

3. The Agency shall cooperate with the investigating body when the investigation involves vehicles authorised by the Agency or railway undertakings certified by the Agency. It shall as soon as possible submit all requested information or records to the investigating body and provide explanations, where requested.

4. The investigation shall be carried out independently of any judicial inquiry.

*Article 22***Investigating body**

1. Each Member State shall ensure that investigations of the accidents and incidents referred to in Article 20 are conducted by a permanent body, which shall comprise at least one investigator able to perform the function of investigator-in-charge in the event of an accident or incident. That body shall be independent in its organisation, legal structure and decision-making from any infrastructure manager, railway undertaking, charging body, allocation body and conformity assessment body and from any party whose interests could conflict with the tasks entrusted to the investigating body. It shall, furthermore, be functionally independent from the national safety authority, from the Agency and from any regulator of railways.

2. The investigating body shall perform its tasks independently of the other entities referred to in paragraph 1 and shall be able to obtain sufficient resources to do so. Its investigators shall be afforded status giving them the necessary guarantees of independence.

3. Member States shall provide for railway undertakings, infrastructure managers and, where appropriate, the national safety authority to be obliged to immediately notify the accidents and incidents referred to in Article 20 to the investigating body and to provide all available information. Where appropriate, this notification shall be updated as soon as any missing information becomes available.

The investigating body shall decide, without delay and in any event no later than 2 months after receipt of the notification concerning the accident or incident, whether or not to start the investigation.

4. The investigating body may combine its tasks under this Directive with the work of investigating occurrences other than railway accidents and incidents as long as such other investigations do not endanger its independence.

5. If necessary, and provided it does not undermine the independence of the investigating body as provided for in paragraph 1, the investigating body may request the assistance of investigating bodies from other Member States or from the Agency to supply expertise or to carry out technical inspections, analyses or evaluations.

6. Member States may entrust the investigating body with the task of carrying out investigations of railway accidents and incidents other than those referred to in Article 20.

7. The investigating bodies shall conduct an active exchange of views and experience for the purposes of the development of common investigation methods, drawing up common principles for follow up of safety recommendations and adaptation to the development of technical and scientific progress.

Without prejudice to paragraph 1, the Agency shall support the investigating bodies in the performance of this task in accordance with Article 38(2) of Regulation (EU) 2016/796.

The investigating bodies, with the support of the Agency in accordance with Article 38(2) of Regulation (EU) 2016/796, shall establish a programme of peer reviews where all investigating bodies are encouraged to participate so as to monitor their effectiveness and independence. The investigating bodies, with the support of the secretariat referred to in Article 38(2) of Regulation (EU) 2016/796, shall publish:

- (a) the common peer-review programme and the review criteria; and
- (b) an annual report on the programme, highlighting identified strengths and suggestions for improvements.

The peer review reports shall be provided to all investigating bodies and to the Agency. Those reports shall be published on a voluntary basis.

*Article 23***Investigation procedure**

1. An accident or incident referred to in Article 20 shall be investigated by the investigating body of the Member State in which it occurred. If it is not possible to establish in which Member State it occurred or if it occurred on or close to a border installation between two Member States, the relevant investigating bodies shall agree which of them is to carry out the investigation or agree to carry it out in cooperation with each other. The other investigating body shall, in the first case, be allowed to participate in the investigation and fully share its results.

Investigating bodies from other Member States shall be invited, if appropriate, to participate in an investigation where:

- (a) a railway undertaking established and licensed in one of those Member States is involved in the accident or incident;  
or
- (b) a vehicle registered or maintained in one of those Member States is involved in the accident or incident.

Investigating bodies from invited Member States shall be provided with the powers necessary to enable them, when requested, to assist in the collection of evidence for another Member State's investigating body.

Investigating bodies from invited Member States shall be provided with access to the information and evidence necessary to enable them to participate effectively in the investigation with due respect for national laws relating to judicial proceedings.

This paragraph shall not preclude Member States from agreeing that the relevant bodies shall carry out investigations in cooperation with each other in other circumstances.

2. For each accident or incident the body responsible for the investigation shall arrange for the appropriate means, comprising the necessary operational and technical expertise, to carry out the investigation. The expertise may be obtained from inside or outside the body, depending on the character of the accident or incident to be investigated.

3. The investigation shall be carried out with as much openness as possible, so that all parties can be heard and can share the results. The relevant infrastructure manager and railway undertakings, the national safety authority, the Agency, victims and their relatives, owners of damaged property, manufacturers, the emergency services involved and representatives of staff and users shall be given an opportunity to provide relevant technical information in order to improve the quality of the investigation report. The investigating body shall also take account of the reasonable needs of the victims and their relatives and keep them informed of the progress made in the investigation.

4. The investigating body shall conclude its examinations at the accident site in the shortest possible time in order to enable the infrastructure manager to restore the infrastructure and open it to rail transport services as soon as possible.

#### *Article 24*

#### **Reports**

1. An investigation of an accident or incident referred to in Article 20 shall be the subject of reports in a form appropriate to the type and seriousness of the accident or incident and the relevance of the investigation findings. The reports shall state the objectives of the investigations as referred to in Article 20(1) and shall contain, where appropriate, safety recommendations.

2. The investigating body shall make public the final report in the shortest possible time and normally not later than 12 months after the date of the occurrence. If the final report cannot be made public within 12 months, the investigating body shall release an interim statement at least on each anniversary of the accident, detailing the progress of the investigation and any safety issues raised. The report, including the safety recommendations, shall be communicated to the relevant parties referred to in Article 23(3) and to bodies and parties concerned in other Member States.

Taking into account experience gained by the investigating bodies, the Commission shall establish, by means of implementing acts, the reporting structure to be followed as closely as possible for accident and incident investigation reports. This reporting structure shall include the following elements:

- (a) a description of the occurrence and its background;
- (b) a record of the investigations and inquiries, including on the safety management system, the rules and regulations applied, the functioning of rolling stock and technical installations, the organisation of man power, the documentation on the operating system and previous occurrences of a similar character;

- (c) analysis and conclusions with regard to the causes of the occurrence, including contributory factors, relating to:
- (i) actions taken by persons involved;
  - (ii) the condition of rolling stock or technical installations;
  - (iii) skills of the staff, procedures and maintenance;
  - (iv) the regulatory framework conditions; and
  - (v) the application of the safety management system.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 28(3).

3. By 30 September every year the investigating body shall publish an annual report accounting for the investigations carried out in the preceding year, the safety recommendations that were issued and actions taken in accordance with recommendations issued previously.

#### *Article 25*

### **Information to be sent to the Agency**

1. Within 7 days of the decision to open an investigation, the investigating body shall inform the Agency thereof. The information shall indicate the date, time and place of the occurrence, as well as its type and its consequences as regards fatalities, injuries and material damage.
2. The investigating body shall send the Agency a copy of the final report referred to in Article 24(2) and of the annual report referred to in Article 24(3).

#### *Article 26*

### **Safety recommendations**

1. A safety recommendation issued by an investigating body shall in no case create a presumption of blame or liability for an accident or incident.
2. Recommendations shall be addressed to the national safety authority and, where needed by reason of the character of the recommendation, to the Agency, to other bodies or authorities in the Member State concerned or to other Member States. Member States, their national safety authorities and the Agency shall, within the limits of their competence, take the necessary measures to ensure that the safety recommendations issued by the investigating bodies are duly taken into consideration, and, where appropriate, acted upon.
3. The Agency, the national safety authority and other authorities or bodies or, where appropriate, other Member States to which recommendations have been addressed, shall report back periodically to the investigating body on measures that are taken or planned as a consequence of a given recommendation.

## CHAPTER VI

### TRANSITIONAL AND FINAL PROVISIONS

#### *Article 27*

### **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 6(6) and Article 7(6) shall be conferred on the Commission for a period of 5 years from 15 June 2016. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-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 3 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 6(6) and Article 7(6) 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 6(6) and Article 7(6) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 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 2 months at the initiative of the European Parliament or of the Council.

#### Article 28

##### Committee procedure

1. The Commission shall be assisted by the committee referred to in Article 51 of Directive (EU) 2016/797. 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 29

##### Report and further Union action

1. The Commission shall submit to the European Parliament and to the Council by 16 June 2021, and every 5 years thereafter, a report on the implementation of this Directive, in particular to monitor the effectiveness of the measures for the issuing of single safety certificates.

The report shall be accompanied where necessary by proposals for further Union action.

2. The Agency shall evaluate the development of a safety culture including occurrence reporting. It shall submit to the Commission, by 16 June 2024, a report containing, where appropriate, improvements to be made to the system. The Commission shall take appropriate measures on the basis of these recommendations and shall propose, if necessary, amendments to this Directive.
3. By 16 December 2017, the Commission shall report to the European Parliament and to the Council on the actions taken with a view to achieving the following objectives:
  - (a) the obligation for manufacturers to mark with an identification code the safety-critical components circulating on the European rail networks, ensuring that the identification code clearly identifies the component, the name of the manufacturer and the significant production data;
  - (b) the full traceability of the safety-critical components, the traceability of their maintenance activities and the identification of their operational life; and
  - (c) the identification of common mandatory principles for the maintenance of those components.

#### Article 30

##### Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, non-discriminatory and dissuasive. The Member States shall notify those rules to the Commission by the date specified in Article 33(1) and shall notify it without delay of any subsequent amendment affecting them.

*Article 31***Transitional provisions**

1. Annex V to Directive 2004/49/EC shall apply until the date of application of the implementing acts referred to in Article 24(2) of this Directive.
2. Without prejudice to paragraph 3 of this Article, railway undertakings which need to be certified between 15 June 2016 and 16 June 2019, shall be subject to Directive 2004/49/EC. Such safety certificates shall be valid until their date of expiry.
3. At the latest from 16 June 2019 the Agency shall carry out the certification tasks pursuant to Article 10 in respect of areas of operation in the Member States that have not notified the Agency or the Commission in accordance with Article 33(2). By way of derogation from Article 10, national safety authorities of the Member States which have notified the Agency and the Commission pursuant to Article 33(2) may continue to issue certificates in accordance with Directive 2004/49/EC until 16 June 2020.

*Article 32***Recommendations and opinions of the Agency**

The Agency shall provide recommendations and opinions in accordance with Article 13 of Regulation (EU) 2016/796 for the purpose of the application of this Directive. Those recommendations and opinions may be taken into account when the Union adopts legal acts pursuant to this Directive.

*Article 33***Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 2, 3, 4, Articles 8 to 11, Article 12(5), Article 15(3), Articles 16 to 19, Article 21(2), Article 23(3) and (7), Article 24(2), Article 26(3) and Annexes II and III by 16 June 2019. 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 1 year. For that purpose, by 16 December 2018, 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 an extension.
3. When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such 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 Directive 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. The obligation to transpose and implement 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 this Directive within 2 years of the receipt of the application.

*Article 34***Repeal**

Directive 2004/49/EC, as amended by the Directives listed in Annex IV, Part A, is repealed with effect from 16 June 2020, without prejudice to the obligations of the Member States concerning the time limits for transposition into national law and application of the Directives set out in Annex IV, Part B.



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

*Article 35*

**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 36*

**Addressees**

This Directive is addressed to the Member States.

Done at Strasbourg, 11 May 2016.

*For the European Parliament*  
*The President*  
M. SCHULZ

*For the Council*  
*The President*  
J.A. HENNIS-PLASSCHAERT

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## ANNEX I

**COMMON SAFETY INDICATORS**

Common safety indicators (CSIs) shall be reported annually by the national safety authorities.

If new facts or errors are discovered after the submission of the report, the indicators for one particular year shall be amended or corrected by the national safety authority at the first convenient opportunity and at the latest in the next annual report.

Common definitions for the CSIs and methods to calculate the economic impact of accidents are laid down in the Appendix.

**1. Indicators relating to accidents****1.1. Total and relative (to train-kilometres) number of serious accidents and a break-down for the following types of accidents:**

- collision of train with rail vehicle,
- collision of train with obstacle within the clearance gauge,
- derailment of train,
- level crossing accident, including accident involving pedestrians at level crossing, and a further break-down for the five types of level crossings defined in point 6.2,
- accident to persons involving rolling stock in motion, with the exception of suicides and attempted suicides,
- fire in rolling stock,
- other.

Each significant accident shall be reported under the type of the primary accident, even if the consequences of the secondary accident are more severe (e.g. a derailment followed by a fire).

**1.2. Total and relative (to train-kilometres) number of persons seriously injured and killed by type of accident divided into the following categories:**

- passenger (also relative to total passenger-kilometres and passenger train-kilometres),
- employee or contractor,
- level crossing user,
- trespasser,
- other person at a platform,
- other person not at a platform.

**2. Indicators relating to dangerous goods**

Total and relative (to train-kilometres) number of accidents involving the transport of dangerous goods by rail divided into the following categories:

- accident involving at least one railway vehicle transporting dangerous goods, as defined in the Appendix,
- number of such accidents in which dangerous goods are released.

**3. Indicators relating to suicides**

Total and relative (to train-kilometres) number of suicides and attempted suicides

**4. Indicators relating to precursors of accidents**

Total and relative (to train-kilometres) number of precursors to accidents and a break down on the following types of precursor:

- broken rail,
- track buckle and other track misalignment,
- wrong-side signalling failure,

- signal passed at danger when passing a danger point,
- signal passed at danger without passing a danger point,
- broken wheel on rolling stock in service,
- broken axle on rolling stock in service.

All precursors are to be reported, both those resulting and those not resulting in accidents. (A precursor resulting in a significant accident shall also be reported under indicators relating to precursors; a precursor not resulting in a significant accident shall only be reported under indicators relating to precursors).

**5. Indicators to calculate the economic impact of accidents**

Total in euro and relative (to train-kilometres):

- number of deaths and serious injuries multiplied by the Value of Preventing a Casualty (VPC),
- cost of damages to environment,
- cost of material damages to rolling stock or infrastructure,
- cost of delays as a consequence of accidents.

National safety authorities shall report the economic impact of significant accidents.

The VPC is the value society attributes to the prevention of a casualty and as such shall not form a reference for compensation between parties involved in accidents.

**6. Indicators relating to technical safety of infrastructure and its implementation**

**6.1. Percentage of tracks with Train Protection Systems (TPSs) in operation and percentage of train-kilometres using on-board TPSs, where these systems provide:**

- warning,
- warning and automatic stop,
- warning and automatic stop and discrete supervision of speed,
- warning and automatic stop and continuous supervision of speed.

**6.2. Number of level crossings (total, per line kilometre and track kilometre) by the following five types:**

- (a) passive level crossing
- (b) active level crossing:
  - (i) manual,
  - (ii) automatic with user-side warning,
  - (iii) automatic with user-side protection,
  - (iv) rail-side protected.

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*Appendix***Common definitions for the CSIs and methods of calculating the economic impact of accidents****1. Indicators relating to accidents**

- 1.1. 'significant accident' means any accident involving at least one rail vehicle in motion, resulting in at least one killed or seriously injured person, or in significant damage to stock, track, other installations or environment, or extensive disruptions to traffic, excluding accidents in workshops, warehouses and depots;
- 1.2. 'significant damage to stock, track, other installations or environment' means damage that is equivalent to EUR 150 000 or more;
- 1.3. 'extensive disruptions to traffic' means that train services on a main railway line are suspended for six hours or more;
- 1.4. 'train' means one or more railway vehicles hauled by one or more locomotives or railcars, or one railcar travelling alone, running under a given number or specific designation from an initial fixed point to a terminal fixed point, including a light engine, i.e. a locomotive travelling on its own;
- 1.5. 'collision of train with rail vehicle' means a front to front, front to end or a side collision between a part of a train and a part of another train or rail vehicle, or with shunting rolling stock;
- 1.6. 'collision of train with obstacle within the clearance gauge' means a collision between a part of a train and objects fixed or temporarily present on or near the track (except at level crossings if lost by a crossing vehicle or user), including collision with overhead contact lines;
- 1.7. 'derailment of train' means any case in which at least one wheel of a train leaves the rails;
- 1.8. 'level crossing accident' means any accident at level crossings involving at least one railway vehicle and one or more crossing vehicles, other crossing users such as pedestrians or other objects temporarily present on or near the track if lost by a crossing vehicle or user;
- 1.9. 'accident to persons involving rolling stock in motion' means accidents to one or more persons who are either hit by a railway vehicle or by an object attached to, or that has become detached from, the vehicle, this includes persons who fall from railway vehicles as well as persons who fall or are hit by loose objects when travelling on board vehicles;
- 1.10. 'fire in rolling stock' means a fire or explosion that occurs in a railway vehicle (including its load) when it is running between the departure station and the destination, including when stopped at the departure station, the destination or intermediate stops, as well as during re-marshalling operations;
- 1.11. 'other (accident)' means any accident other than a collision of train with rail vehicle, collision of train with obstacle within the clearance gauge, derailment of train, level crossing accident, an accident to person involving rolling stock in motion or a fire in rolling stock;
- 1.12. 'passenger' means any person, excluding a member of the train crew, who makes a trip by rail, including a passenger trying to embark onto or disembark from a moving train for accident statistics only;
- 1.13. 'employee or contractor' means any person whose employment is in connection with a railway and is at work at the time of the accident, including the staff of contractors, self-employed contractors, the crew of the train and persons handling rolling stock and infrastructure installations;
- 1.14. 'level crossing user' means any person using a level crossing to cross the railway line by any means of transport or by foot;
- 1.15. 'trespasser' means any person present on railway premises where such presence is forbidden, with the exception of a level crossing user;
- 1.16. 'other person at a platform' means any person at a railway platform who is not defined as 'passenger', 'employee or contractor', 'level crossing user', 'other person not at a platform' or 'trespasser';

- 1.17. 'other person not at a platform' means any person not at a railway platform who is not defined as 'passenger', 'employee or contractor', 'level crossing user', 'other person at a platform' or 'trespasser';
- 1.18. 'death (killed person)' means any person killed immediately or dying within 30 days as a result of an accident, excluding any suicide;
- 1.19. 'serious injury (seriously injured person)' means any person injured who was hospitalised for more than 24 hours as a result of an accident, excluding any attempted suicide.

## 2. Indicators relating to dangerous goods

- 2.1. 'accident involving the transport of dangerous goods' means any accident or incident that is subject to reporting in accordance with RID <sup>(1)</sup>/ADR section 1.8.5;
- 2.2. 'dangerous goods' means those substances and articles the carriage of which is prohibited by RID, or authorised only under the conditions prescribed therein.

## 3. Indicators relating to suicides

- 3.1. 'suicide' means an act to deliberately injure oneself resulting in death, as recorded and classified by the competent national authority;
- 3.2. 'attempted suicide' means an act to deliberately injure oneself resulting in serious injury.

## 4. Indicators relating to precursors of accidents

- 4.1. 'broken rail' means any rail which is separated in two or more pieces, or any rail from which a piece of metal becomes detached, causing a gap of more than 50 mm in length and more than 10 mm in depth on the running surface;
- 4.2. 'track buckle or other track misalignment' means any fault related to the continuum and the geometry of track, requiring track to be placed out of service or immediate restriction of permitted speed;
- 4.3. 'wrong side signalling failure' means any technical failure of a signalling system (either to infrastructure or to rolling stock), resulting in signalling information less restrictive than that demanded;
- 4.4. 'Signal Passed at Danger when passing a danger point' means any occasion when any part of a train proceeds beyond its authorised movement and travels beyond the danger point;
- 4.5. 'Signal Passed at Danger without passing a danger point' means any occasion when any part of a train proceeds beyond its authorised movement but does not travel beyond the danger point.

Unauthorised movement as referred to in points 4.4 and 4.5 above means to pass:

- a trackside colour light signal or semaphore at danger, or an order to STOP where a Train Protection system (TPS) is not operational,
- the end of a safety related movement authority provided in a TPS,
- a point communicated by verbal or written authorisation laid down in regulations,
- stop boards (buffer stops are not included) or hand signals.

Any case in which a vehicle without any traction unit attached or a train that is unattended runs away past a signal at danger is not included. Any case in which, for any reason, the signal is not turned to danger in time to allow the driver to stop the train before the signal is not included.

National safety authorities may report separately on the four indices of unauthorised movement listed in the indents in this point and shall report at least an aggregate indicator containing data on all four items indices.

- 4.6. 'broken wheel on rolling stock in service' means a break affecting the wheel and creating a risk of accident (derailment or collision);

<sup>(1)</sup> RID, Regulations concerning the International Carriage of Dangerous Goods by Rail, as adopted under Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

4.7. 'broken axle on rolling stock in service' means a break affecting the axle and creating a risk of accident (derailment or collision).

## 5. Common methodologies to calculate the economic impact of accidents

5.1. The Value of Preventing a Casualty (VPC) is composed of:

(1) Value of safety per se: Willingness to Pay (WTP) values based on stated preference studies carried out in the Member State for which they are applied.

(2) Direct and indirect economic costs: cost values appraised in the Member State, composed of:

- medical and rehabilitation cost,
- legal court cost, cost for police, private crash investigations, the emergency service and administrative costs of insurance,
- production losses: value to society of goods and services that could have been produced by the person if the accident had not occurred.

When calculating the costs of casualties, fatalities and serious injuries shall be considered separately (different VPC for fatality and serious injury).

5.2. Common principles to appraise the value of safety per se and direct and/or indirect economic costs:

For the value of safety per se, the assessment of whether available estimates are appropriate or not shall be based on the following considerations:

- estimates shall relate to a system for valuation of mortality risk reduction in the transport sector and follow a WTP approach according to stated preference methods,
- the respondent sample used for the values shall be representative of the population concerned. In particular, the sample has to reflect the age/income distribution along with other relevant socioeconomic and/or demographic characteristics of the population,
- method for eliciting WTP values: survey design shall be such that questions are clear/meaningful to respondents.

Direct and indirect economic costs shall be appraised on the basis of the real costs borne by society.

5.3. Definitions

5.3.1. 'Cost of damage to environment' means costs that are to be met by Railway Undertakings and Infrastructure Managers, appraised on the basis of their experience, in order to restore the damaged area to its state before the railway accident.

5.3.2. 'Cost of material damage to rolling stock or infrastructure' means the cost of providing new rolling stock or infrastructure, with the same functionalities and technical parameters as that damaged beyond repair, and the cost of restoring repairable rolling stock or infrastructure to its state before the accident, to be estimated by Railway Undertakings and Infrastructure Managers on the basis of their experience, including also costs related to the leasing of rolling stock, as a consequence of non-availability due to damaged vehicles.

5.3.3. 'Cost of delays as a consequence of accidents' means the monetary value of delays incurred by users of rail transport (passengers and freight customers) as a consequence of accidents, calculated by the following model:

VT = monetary value of travel time savings

Value of time for a passenger of a train (an hour)

$$VT_p = [VT \text{ of work passengers}] * [\text{Average percentage of work passengers per year}] + [VT \text{ of non-work passengers}] * [\text{Average percentage of non-work passengers per year}]$$

VT<sub>p</sub> is measured in EUR per passenger per hour

'Work passenger' means a passenger travelling in connection with their professional activities excluding commuting.

Value of time for a freight train (an hour)

$$VT_f = [VT \text{ of freight trains}] * [(\text{Tonne-km}) / (\text{Train-km})]$$

VT<sub>f</sub> is measured in EUR per freight tonne per hour

Average tonnes of goods transported per train in 1 year = (Tonne-km)/(Train-km)

CM = Cost of 1 minute of delay of a train

Passenger train

$$CM_p = K1 * (VT_p / 60) * [(Passenger-km) / (Train-km)]$$

Average number of passengers per train in 1 year = (Passenger-km)/(Train-km)

Freight train

$$CM_f = K2 * (VT_f / 60)$$

Factors K1 and K2 are between the value of time and the value of delay, as estimated by stated preference studies, to take into account that the time lost as a result of delays is perceived significantly more negatively than normal travel time.

Cost of delays of an accident =  $CM_p$  \*(Minutes of delay of passenger trains) +  $CM_f$  \*(Minutes of delay of freight trains)

Scope of the model

Cost of delays is to be calculated for significant accidents, as follows:

- real delays on the railway lines where accidents occurred as measured at terminal station
- real delays or, if not possible, estimated delays on the other affected lines.

## 6. Indicators relating to technical safety of infrastructure and its implementation

- 6.1. 'Train Protection System (TPS)' means a system that helps to enforce obedience to signals and speed restrictions.
- 6.2. 'On-board systems' mean systems assisting the driver to observe line-side signalling and in cab signalling and thus providing protection of danger points and enforcement of speed limits. On-board TPSs are described as follows:
  - (a) Warning, providing automatic warning to driver.
  - (b) Warning and automatic stop, providing automatic warning to driver and automatic stop when passing a signal at danger.
  - (c) Warning and automatic stop and discrete supervision of speed, providing protection of danger points, where 'discrete supervision of speed' means supervision of speed at certain locations (speed traps) at the approach of a signal.
  - (d) Warning and automatic stop and continuous supervision of speed, providing protection of danger points and continuous supervision of the speed limits of the line, where 'continuous supervision of speed' means continuous indication and enforcement of the maximal allowed target speed on all sections of the line.

Type (d) is regarded as Automatic Train Protection (ATP) system.

- 6.3. 'level crossing' means any level intersection between a road or passage and a railway, as recognised by the infrastructure manager and open to public or private users. Passages between platforms within stations are excluded, as well as passages over tracks for the sole use of employees.
- 6.4. 'road' means, for the purpose of railway accident statistics, any public or private road, street or highway, including adjacent footpaths and bicycle lanes.
- 6.5. 'passage' means any route, other than a road, provided for the passage of people, animals, vehicles or machinery.
- 6.6. 'passive level crossing' means a level crossing without any form of warning system or protection activated when it is unsafe for the user to traverse the crossing.
- 6.7. 'active level crossing' means a level crossing where the crossing users are protected from or warned of the approaching train by devices activated when it is unsafe for the user to traverse the crossing.
  - Protection by the use of physical devices includes:
    - half or full barriers,
    - gates.

- Warning by the use of fixed equipment at level crossings:
  - visible devices: lights,
  - audible devices: bells, horns, klaxons, etc.

Active level crossings are classified as:

- (a) Manual: a level crossing where user-side protection or warning is manually activated by a railway employee.
- (b) Automatic with user-side warning: a level crossing where user-side warning is activated by the approaching train.
- (c) Automatic with user-side protection: a level crossing where user-side protection is activated by the approaching train. This shall include a level crossing with both user-side protection and warning.
- (d) Rail-side protected: a level crossing where a signal or other train protection system permits a train to proceed once the level crossing is fully user-side protected and is free from incursion.

#### 7. **Definitions of the scaling bases**

- 7.1. 'train-km' means the unit of measure representing the movement of a train over one kilometre. The distance used is the distance actually run, if available, otherwise the standard network distance between the origin and destination shall be used. Only the distance on the national territory of the reporting country shall be taken into account.
  - 7.2. 'passenger-km' means the unit of measure representing the transport of one passenger by rail over a distance of one kilometre. Only the distance on the national territory of the reporting country shall be taken into account.
  - 7.3. 'line km' means the length measured in kilometres of the railway network in Member States, whose scope is laid down in Article 2. For multiple-track railway lines, only the distance between origin and destination is to be counted.
  - 7.4. 'track km' means the length measured in kilometres of the railway network in Member States, whose scope is laid down in Article 2. Each track of a multiple-track railway line is to be counted.
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## ANNEX II

**NOTIFICATION OF NATIONAL SAFETY RULES**

National safety rules notified in accordance with point (a) of Article 8(1) include:

1. rules concerning existing national safety targets and safety methods;
  2. rules concerning requirements in respect of safety management systems and safety certification of railway undertakings;
  3. common operating rules of the railway network that are not yet covered by TSIs, including rules relating to the signalling and traffic management system;
  4. rules laying down requirements in respect of additional internal operating rules (company rules) that must be established by infrastructure managers and railway undertakings;
  5. rules concerning requirements in respect of staff executing safety-critical tasks, including selection criteria, medical fitness and vocational training and certification, in so far as they are not yet covered by a TSI;
  6. rules concerning the investigation of accidents and incidents.
-

## ANNEX III

**REQUIREMENTS AND ASSESSMENT CRITERIA FOR ORGANISATIONS APPLYING FOR AN ECM CERTIFICATE OR FOR A CERTIFICATE IN RESPECT OF MAINTENANCE FUNCTIONS OUTSOURCED BY AN ENTITY IN CHARGE OF MAINTENANCE**

The organisation management must be documented in all relevant parts and shall in particular describe the distribution of responsibilities within the organisation and with subcontractors. It shall show how control by the management on different levels is secured, how staff and their representatives on all levels are involved and how continuous improvement is ensured.

The following basic requirements shall be applied to the four functions of an entity in charge of maintenance (ECM) to be covered by the organisation itself or through contracting arrangements:

1. Leadership — commitment to the development and implementation of the maintenance system of the organisation and to the continuous improvement of its effectiveness;
2. Risk assessment — a structured approach to assess risks associated with the maintenance of vehicles, including those directly arising from operational processes and the activities of other organisations or persons, and to identify the appropriate risk control measures;
3. Monitoring — a structured approach to ensure that risk control measures are in place, working correctly and achieving the organisation's objectives;
4. Continuous improvement — a structured approach to analyse the information gathered through regular monitoring, auditing, or other relevant sources and to use the results to learn and to adopt preventive or corrective measures in order to maintain or improve the level of safety;
5. Structure and responsibility — a structured approach to define the responsibilities of individuals and teams for secure delivery of the organisation's safety objectives;
6. Competence management — a structured approach to ensure that employees have the competences required in order to achieve the organisation's objectives safely, effectively and efficiently in all circumstances;
7. Information — a structured approach to ensure that important information is available to those making judgments and decisions at all levels of the organisation and to ensure the completeness and appropriateness of the information;
8. Documentation — a structured approach to ensure the traceability of all relevant information;
9. Contracting activities — a structured approach to ensure that subcontracted activities are managed appropriately in order for the organisation's objectives to be achieved and all competences and requirements are covered;
10. Maintenance activities — a structured approach to ensure:
  - that all maintenance activities affecting safety and safety-critical components are identified and correctly managed and that all the necessary changes to those maintenance activities affecting safety are identified, properly managed based upon the return of experience and the application of Common Safety Methods for risk assessment in accordance with point (a) of Article 6(1) and properly documented;
  - conformity with the essential requirements for interoperability;
  - the implementation and check of maintenance facilities, equipment and tools specifically developed and required for maintenance delivery;
  - the analysis of the initial documentation related to the vehicle for providing the first maintenance file and to ensure its correct implementation through the development of maintenance orders;
  - that components (including spare parts) and materials are used as specified in the maintenance orders and supplier documentation; they are stored, handled and transported in an appropriate manner as specified in the maintenance orders and supplier documentation and comply with relevant national and international rules as well as with the requirements of relevant maintenance orders;

- that suitable and adequate facilities, equipment and tools are determined, identified, provided, recorded and kept available to enable to deliver the maintenance services in accordance with maintenance orders and other applicable specifications, ensuring the safe delivery of maintenance, ergonomics and health protection;
- that the organisation have processes to ensure that its measuring equipment, all facilities, equipment and tools are correctly used, calibrated, preserved and maintained in accordance with documented processes;

11. Control activities — a structured approach to ensure:

- that vehicles are removed from operation for scheduled, conditional or corrective maintenance in due time, or whenever defects or other needs have been identified;
  - the necessary quality control measures;
  - that maintenance tasks are performed in accordance with the maintenance orders and to issue the notice to return to operation that includes eventual restrictions of use;
  - that possible instance of non-compliance in the application of the management system that might result in accidents, incidents, near-misses or other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken in compliance with the common safety method for monitoring provided in point (c) of Article 6(1);
  - recurrent internal auditing and monitoring process compliant with the common safety method for monitoring provided in point (c) of Article 6(1).
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## ANNEX IV

## PART A

**Repealed Directive with a list of the successive amendments thereto**

(referred to in Article 34)

Directive 2004/49/EC	(OJ L 164, 30.4.2004, p. 44)
Directive 2008/57/EC	(OJ L 191, 18.7.2008, p. 1)
Directive 2008/110/EC	(OJ L 345, 23.12.2008, p. 62)
Commission Directive 2009/149/EC	(OJ L 313, 28.11.2009, p. 65)
Corrigendum, 2004/49/EC	(OJ L 220, 21.6.2004, p. 16)
Commission Directive 2014/88/EU	(OJ L 201, 10.7.2014, p. 9)

## PART B

**Time limits for transposition into national law**

(referred to in Article 34)

Directive	Deadline for transposition
2004/49/EC	30 April 2006
2008/57/EC	19 July 2010
2008/110/EC	24 December 2010
Commission Directive 2009/149/EC	18 June 2010
Commission Directive 2014/88/EU	30 July 2015

## ANNEX V

**Correlation table**

Directive 2004/49/EC	This Directive
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article 5
Article 6	Article 6
Article 7	Article 7
Article 8	Article 8
Article 9	Article 9
Article 10	Article 10
—	Article 11
Article 11	Article 12
Article 12	—
Article 13	Article 13
Article 14a(1) to (7)	Article 14
Article 14a(8)	Article 15
Article 15	—
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Directive 2004/49/EC	This Directive
—	Article 34
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Annex I	Annex I
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Annex V	—
—	Annex III

**Statement by the Commission on explanatory documents**

The Commission recalls that the European Parliament, the Council and the Commission acknowledged in their Joint Political Declaration of 27 October 2011 on explanatory documents that the information Member States supply to the Commission as regards the transposition of directives in national law 'must be clear and precise' in order to facilitate the achievement by the Commission of its task overseeing the application of Union law. In the present case, explanatory documents could have been useful to this end. The Commission regrets that the final text does not contain provisions to this effect.

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