



STATUTORY INSTRUMENTS.

S.I. No. 477 of 2020

EUROPEAN UNION (INTEROPERABILITY OF THE RAIL SYSTEM)
REGULATIONS 2020

EUROPEAN UNION (INTEROPERABILITY OF THE RAIL SYSTEM)
REGULATIONS 2020

CONTENTS

Part 1

Preliminary

1. Citation and commencement
2. Interpretation
3. Scope
4. Safety authority
5. Revocations

Part 2

TSIs

6. Content of TSIs
7. Non-application of TSIs

Part 3

Interoperability constituents

8. Assessment of interoperability constituents
9. Placing on market of interoperability constituents
10. Conformity or suitability for use of interoperability constituents
11. “EC” declaration of conformity or suitability for use
12. Non-compliance of interoperability constituents with essential requirements
13. Conformity with TSIs and national rules

Part 4

Subsystems

14. Free movement of subsystems
15. Notification of national rules
16. “EC” declaration of verification
17. Non-compliance of subsystems with essential requirements

Part 5

Placing on the market and Placing in Service

18. Authorisation for placing in service fixed installations
19. Harmonised implementation of ERTMS in European Union
20. Placing on market of mobile subsystems
21. Vehicle authorisation for placing on market
22. Checks before the use of authorised vehicles
23. Type authorisation of vehicles

- 24. Conformity of vehicles with an authorised vehicle type
- 25. Transitional regime for using vehicles
- 26. Non-compliance of vehicles or vehicle types with essential requirements

Part 6
Conformity Assessment Bodies

- 27. Notifying authority
- 28. Accreditation body
- 29. Conformity assessment bodies
- 30. Impartiality of conformity assessment bodies
- 31. Personnel of conformity assessment bodies
- 32. Presumption of conformity of a conformity assessment body
- 33. Subsidiaries of, and subcontracting, by notified bodies
- 34. Accredited in-house bodies
- 35. Application for notification
- 36. Notification procedure
- 37. Changes to notifications
- 38. Operational obligations of notified bodies
- 39. Appeals against decisions of notified bodies
- 40. Obligation of notified bodies to provide information
- 41. Coordination of notified bodies
- 42. Designated bodies

Part 7
Vehicle Registers

- 43. Vehicle register
- 44. Registration of vehicles authorised to be placed on market
- 45. Vehicle numbering
- 46. Register of infrastructure

Part 8
Enforcement

- 47. Inspectors
- 48. Compliance orders
- 49. Proceedings – summary offences
- 50. Offences by bodies corporate
- 51. Service of notices, etc.

EUROPEAN UNION (INTEROPERABILITY OF THE RAIL SYSTEM)
REGULATIONS 2020

I, EAMON RYAN, Minister for Transport, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Council Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016¹ (as amended by Article 1 of Directive (EU) 2020/700 of the European Parliament and of the Council of 25 May 2020²), hereby make the following regulations:

Part 1
Preliminary

Citation and commencement

1. (1) These Regulations may be cited as the European Union (Interoperability of the Rail System) Regulations 2020.
- (2) These Regulations come into operation on 31 October 2020.

Interpretation

2. (1) In these Regulations —

“acceptable national means of compliance” means non-binding opinions issued by the safety authority to define ways of establishing compliance with national rules;

“accreditation” has the meaning assigned to it in Article 2(10) of Regulation (EC) No 765/2008³;

“accreditation body” means Irish National Accreditation Board;

“Agency” means European Union Agency for Railways;

“applicant” means a person requesting an authorisation, be it a railway undertaking, an infrastructure manager or any other person, such as a manufacturer, an owner or a keeper; for the purpose of —

¹ OJ No. L138, 26.05.2016, p.44

² OJ No. L165, 27.05.2020, p.27

³ OJ No. L218, 13.8.2008, p.30

- (a) Regulation 16, the ‘applicant’ means a contracting entity or a manufacturer, or its authorised representatives, and
- (b) Regulation 19, the ‘applicant’ means a person requesting the Agency’s decision for the approval of the technical solutions envisaged for the ERTMS track-side equipment projects;

“area of use of a vehicle” means a network within the State in which a vehicle is intended to be used;

“authorised representative” means any person established within the European 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;

“conformity assessment” means the process demonstrating whether specified requirements relating to a product, process, service, subsystem, person or body have been fulfilled;

“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) a conformity assessment body is classified as a ‘notified body’ following notification by the notifying authority under Article 37;
- (b) a conformity assessment body is classified as a ‘designated body’ following designation by the safety authority under Regulation 16(3);

“contracting entity” means a public or private entity which orders the design, construction or the renewal or upgrading of a subsystem;

“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;

“Directive” means Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016⁴;

“Directive (EU) 2016/798” means Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016⁵;

⁴ OJ No. L138, 26.05.2016, p.44

⁵ OJ No. L 138, 26.5.2016, p. 102

“‘EC’ declaration of conformity or suitability for use” means a declaration of conformity or suitability for use in accordance with the procedure described in Regulation 11;

“‘EC’ declaration of verification” means a declaration of verification in accordance with the procedure described in Regulation 16;

“ECM” means entity in charge of maintenance;

“entity in charge of maintenance” means an entity in charge of the maintenance of a vehicle, and registered as such in the vehicle register;

“essential requirements” means all the conditions set out in Annex III which must be met by the railway system, the subsystems, and the interoperability constituents, including interfaces;

“European specification” means a specification which falls into one of the following categories:

- (a) a technical specification in the field of ICT laid down in accordance with Articles 13 and 14 of Regulation (EU) No 1025/2012⁶,
- (b) a European technical approval as referred to in European Union (Award of Contracts by Utility Undertakings) Regulations 2016 (S.I. No. 286 of 2016), or
- (c) a standard adopted by a European standardisation organisation;

“EVN”, in relation to a vehicle, means the number, known as a European vehicle number, specified in the TSI on operation and traffic management to be assigned to that vehicle;

“harmonised standard” means a European standard adopted on the basis of a request made by the European Commission for the application of Union harmonisation legislation;

“infrastructure manager” has the meaning assigned to it in the Regulations of 2015;

“inspector” means a person deemed to be an inspector under Regulation 47;

⁶ OJ No. L316, 14.11.2012, p.12

“interoperability” means the ability of a railway system to allow the safe and uninterrupted movement of trains which accomplish the required levels of performance;

“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 railway system depends directly or indirectly, including both tangible and intangible objects;

“keeper” means the 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 the vehicle register;

“light rail” means an urban 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;

“manufacturer” means any 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 or her name or trademark;

“Minister” means Minister for Transport;

“mobile subsystem” means the rolling stock subsystem and the on-board control-command and signalling subsystem;

“national rules” means binding rules adopted in the State, irrespective of the body issuing them, which contain railway safety or technical requirements, other than those laid down by European Union or international rules which are applicable within the State to railway undertakings, infrastructure managers or third parties;

“network” means the lines, stations, terminals, and all kinds of fixed equipment needed to ensure safe and continuous operation of the railway system;

“notifying authority” means the Minister;

“operative date” means the date published by the Minister in *Iris Oifigiúil* upon which the European Vehicle Register becomes operational as respects the State;

“placing in service” means all the operations by which a subsystem is put into its operational service;

“placing on the market” means the first making available on the European Union's market of an interoperability constituent, subsystem or vehicle ready to function in its design operating state;

“product” means a product obtained through a manufacturing process, including interoperability constituents and subsystems;

“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;

“Railway Safety Regulations” means European Union (Railway Safety) Regulations 2020 (S. I. No.476 of 2020);

“railway system” means the elements listed in Annex I;

“railway undertaking” has the meaning assigned to it in the Regulations of 2015 and any other public or private undertaking, the activity of which is to provide transport of goods or passengers by rail on the basis that the undertaking is to ensure traction, including undertakings which provide traction only;

“register of infrastructure” means the register of infrastructure maintained under Regulation 46;

“Regulation (EU) 2016/796” means Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016⁷;

“Regulations of 2015” means the European Union (Regulation of Railways) Regulations 2015 (S.I. No. 249 of 2015) (as amended by the European Union (Regulation of Railways) (Amendment) Regulations 2020 (S.I. No. 398 of 2020));

⁷ OJ No. L138, 26.05.2016, p.1

“renewal” means any major substitution work on a subsystem or part of it which does not change the overall performance of the subsystem;

“safety authority” means Commission for Railway Regulation;

“series” means a number of identical vehicles of a design type;

“subsystems” means the structural or functional parts of the railway system, as set out in Annex II;

“technical specification” means a document that prescribes technical requirements to be fulfilled by a product, subsystem, process or service;

“technical specification for interoperability” means a specification adopted by the European Commission in accordance with the 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 railway system;

“TSI” means technical specification for interoperability;

“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;

“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;

“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;

“vehicle register” means the national vehicle register established under Regulation 43 and from the operative date the European Vehicle Register.

(2) A word or expression which is used in these Regulations and which is also used in the Directive has, unless the context requires otherwise, the same meaning in these Regulations as it has in that Directive.

(3) In these Regulations, save as otherwise indicated—

- (a) a reference to an Article is a reference to an Article of the Directive, and
- (b) a reference to an Annex is a reference to an Annex to the Directive.

Scope

3. These Regulations do 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 railway system and intended only for the operation of local, urban or suburban passenger services, as well as undertakings operating solely on those networks,
- (d) 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,
- (e) infrastructure or vehicles reserved for a strictly local, historical or touristic use,
- (f) 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,
- (g) 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, and
- (h) the electric traction energy supply system of the Dublin suburban passenger service.

Safety authority

4. (1) The Commission for Railway Regulation is the national safety authority competent for the railway system in the State for the purposes of the Directive and these Regulations.

(2) The safety authority shall comply with the requirements of a national safety authority under the Directive.

Revocations

5. (1) The following are revoked:

- (a) the European Communities (Interoperability of the Rail System) Regulations 2011 (S.I. No. 419 of 2011);
- (b) the European Communities (Interoperability of the Rail System) (Amendment) Regulations 2013 (S.I. No. 186 of 2013);
- (c) the European Communities (Interoperability of the Rail System) (Amendment) Regulations 2014 (S.I. No. 523 of 2014);
- (d) the European Communities (Interoperability of the Rail System) (Amendment) Regulations 2015 (S.I. No. 551 of 2015).

(2) An approval, authorisation or renewal issued under the Regulations revoked under paragraph (1), which is in force immediately before the making of these Regulations, continues as if made under these Regulations.

Part 2
TSIs

Content of TSIs

6. (1) 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 these Regulations and without prejudice to Article 4(3)(f).

(2) 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 these Regulations and without prejudice to Article 4(3)(f).

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

Non-application of TSIs

7. (1) The safety authority may allow an applicant not to apply one or more TSIs or parts of them in the cases referred to in Article 7(1).

(2) In the case referred to in Article 7(1)(a), the safety authority shall communicate to the European Commission, within one year of entry into force of each TSI, a list of projects that are taking place within the State and which, in the view of the safety authority, are at an advanced stage of development. Applicants shall inform the safety authority of projects that are at an advanced stage of development in accordance with the safety authority's published guidance.

(3) In the cases referred to in Article 7(1)(a) and (b), the safety authority shall communicate to the European Commission its decision not to apply one or more TSIs or parts of them.

(4) In the cases referred to in Article 7(1)(a), (c), (d) and (e), the safety authority shall submit to the European 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 will be applied instead of the TSIs.

(5) In the cases referred to in the third subparagraph of Article 21(6), the applicant shall submit the file to the Agency.

(6) Pending the decision of the European Commission, the alternative provisions referred to in paragraph (4) may be applied without delay.

Part 3 Interoperability Constituents

Assessment of interoperability constituents

8. (1) A person shall not place an interoperability constituent on the market in the State unless it—

- (a) has been subjected to the procedure for assessing conformity and suitability for use indicated in the relevant TSI or the corresponding European specifications, and
- (b) is accompanied by an ‘EC’ declaration of conformity or suitability for use which covers the interoperability constituent and, if the TSI so requires, by the certificates referred to in Regulation 10(2).

(2) In this Regulation “relevant TSI” means—

- (a) the TSI applicable to the interoperability constituent which is in force at the time it is placed on the market, or
- (b) the TSI identified by the safety authority as resulting from the application of a derogation under Regulation 7.

(3) A person who contravenes this Regulation commits an offence and is liable—

- (a) on summary conviction, to a class A fine, or
- (b) on conviction on indictment, to a fine not exceeding €250,000.

(4) In a prosecution under this Regulation it shall be a defence to show that—

- (a) the interoperability constituents placed on the market consist of spare parts for subsystems that were already placed in service when the corresponding TSI entered into force, or
- (b) the relevant TSI provided for a period of transition for the interoperability constituents placed on the market and the conditions of that TSI have been complied with.

Placing on market of interoperability constituents

9. (1) An entity shall take all necessary steps to ensure that an interoperability constituent—

- (a) is placed on the market only if it enables interoperability to be achieved within the railway system while at the same time meeting the essential requirements,
- (b) is used in its area of use as intended and is suitably installed and maintained.

(2) Paragraph (1) does not—

- (a) prevent the placing on the market of those constituents for other applications, or
- (b) prohibit, restrict or hinder the placing on the market of interoperability constituents for use on the railway system where the constituents comply with these Regulations. In particular checks are not required which have already been carried out as part of the procedure for ‘EC’ declaration of conformity or suitability for use as provided for in Regulation 11.

(3) Where the safety authority considers that an entity is not complying with paragraph (1), it may by notice issue a direction to the entity to take the necessary steps to comply with that paragraph in the manner and within the time specified in the direction. The entity may, within 14 days of the issue of notice of the direction, make representations to the safety authority, which having considered them, may confirm, amend or withdraw the direction.

(4) Where a direction is confirmed (with or without modification) under paragraph (3) the entity may, within 14 days of the confirmation of the decision, appeal against the decision to the Circuit Court. The court may affirm or modify the direction or allow the appeal. The decision of the Circuit Court is final other than on a point of law, which lies to the High Court.

(5) A direction of the safety authority under paragraph (3) takes effect—

- (a) upon the expiration of the period allowed to make representations, if none are made within that period, or
- (b) if made within that period and the direction is confirmed (with or without modification) upon the expiration of the time allowed to make an appeal, if no appeal is made, or if an appeal is made, upon the determination of the appeal or its withdrawal.

(6) In this Regulation “entity” means the manufacturer of the constituent or his or her authorised representative or other person referred to in Regulation 11(5).

Conformity or suitability for use of interoperability constituents

10. (1) The safety authority 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, 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, 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 his or her authorised representative.

(4) 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).

‘EC’ declaration of conformity or suitability for use

11. (1) The ‘EC’ declaration of conformity or suitability for use of an interoperability constituent shall be established according to the procedure outlined in this Regulation.

(2) In order to establish the ‘EC’ declaration of conformity or suitability for use of an interoperability constituent, the manufacturer or his or her authorised representative shall apply the provisions laid down by the relevant TSIs.

(3) 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 or her authorised representative has lodged the application.

(4) Where interoperability constituents are the subject of other legal acts of the European 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.

(5) Where neither the manufacturer nor his or her authorised representative has met the obligations laid down in paragraphs (2) and (4), those obligations shall be incumbent on any person who places interoperability constituents on the market. For the purposes of these Regulations, 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 or her own use.

(6) If the safety authority finds that the ‘EC’ declaration has been drawn up improperly, it shall ensure that the interoperability constituent is not placed on the market by serving on the manufacturer or his or her authorised

representative or other person referred to in paragraph (5) a notice requiring in such a case, the manufacturer or his or her authorised representative or the other person to restore the interoperability constituent to a state of conformity under the conditions laid down by the safety authority in the notice. The notice shall be withdrawn by the safety authority if the conditions are met.

(7) A person upon whom a notice under paragraph (6) has been served who places an interoperability constituent on the market in contravention of the notice or while the notice is in force commits an offence and is liable –

- (a) on summary conviction, to a class A fine, or
- (b) on conviction on indictment, to a fine not exceeding €250,000.

Non-compliance of interoperability constituents with essential requirements

12. (1) Where the safety authority finds that an interoperability constituent covered by an ‘EC’ declaration of conformity or suitability for use and placed on the market is, when used as intended, unlikely to meet the essential requirements, or fails to comply with those requirements, the safety authority shall by notice served on the entity concerned restrict its field of application, prohibit its use, withdraw it from the market or recall it. The notice takes effect upon its service or upon such date specified in it.

(2) The safety authority shall give reasons in the notice 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, or
- (c) inadequacy of European specifications.

(3) Where the decision referred to in paragraph (1) results from inadequacy of European specifications the safety authority shall, as appropriate, in accordance with Article 11(3) apply one or more of the measures referred to in that paragraph.

(4) Without prejudice to Article 4(3), where an entity feels that a measure taken under paragraph (1) in respect of it is unjustified, it may within 7 days of service of a notice on it under that paragraph make representations to the safety authority in respect of the measure taken. The safety authority shall consider the representation and inform the entity of its decision.

(5) An entity who, without reasonable excuse, fails to comply with a notice served under paragraph (1) on it commits an offence and is liable —

- (a) on summary conviction, to a class A fine, or
- (b) on conviction on indictment, to a fine not exceeding €250,000.

(6) Where an interoperability constituent covered by an ‘EC’ declaration of conformity fails to comply with the essential requirements, the entity which drew up the declaration commits an offence and is liable on summary conviction, to a class A fine.

(7) The safety authority shall inform –

- (a) the European Commission, the Agency and the other Member States of measures taken and reasons for its decisions under paragraph (1), and
- (b) the European Commission and the other Member States of any prosecution taken under paragraph (5) or (6).

(8) In this Regulation “entity” means the manufacturer who drew up the ‘EC’ declaration of conformity or suitability of use or his or her authorised representative or other person referred to in Regulation 11(5).

Conformity with TSIs and national rules

13. (1) The safety authority shall consider as meeting the essential requirements, those structural subsystems constituting the railway system which are covered, as appropriate –

- (a) by the ‘EC’ declaration of verification established by reference to TSIs, in accordance with Regulation 16, or
- (b) the declaration of verification established by reference to national rules in accordance with Regulation 16(3),

or by both.

(2) National rules for implementing the essential requirements and, where relevant, acceptable national means of compliance, shall apply in the cases referred to in Article 13(2).

Part 4
Subsystems

Free movement of subsystems

14. Without prejudice to the provisions of Chapter V of the Directive, the safety authority shall not, in the State and on grounds relating to these Regulations, prohibit, restrict or hinder the construction, placing in service and operation of structural subsystems constituting the railway system which meet the essential requirements. In particular, the safety authority 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 the Directive, with a view to verifying compliance with identical requirements under identical operational conditions.

Notification of national rules

15. (1) The safety authority shall –

- (a) make notifications of national rules for the purposes of Article 14 to the European Commission and the Agency,

- (b) ensure that national rules referred to in Article 14(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,
 - (c) upon request under Article 14(3) provide additional information on those national rules, and
 - (d) publish guidance on the process for drafting and publishing national rules.
- (2) The safety authority 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.
- (3) The safety authority may decide not to notify rules and restrictions of a strictly local nature. In such cases, the safety authority shall mention those rules and restrictions in the registers of infrastructure referred to in the register of infrastructure.
- (4) National rules not notified in accordance with Article 14 shall not apply for the purposes of these Regulations.

'EC' declaration of verification

16. (1) The 'EC' declaration of verification shall be established in accordance with the following:
- (a) the applicant shall request the conformity assessment body or bodies that is selected to establish the 'EC' declaration of verification to apply the procedure set out in Annex IV;
 - (b) the applicant shall establish the 'EC' declaration of verification of a subsystem. The applicant shall declare on his or her sole responsibility that the subsystem concerned has been subject to the relevant verification procedures and that it satisfies the requirements of relevant European Union law and any relevant national rule. The 'EC' declaration of verification and the accompanying documents shall be dated and signed by the applicant;
 - (c) 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 the new 'EC' declaration of verification;
 - (d) if the relevant TSIs allow, the notified body may issue certificates of verification for one or more subsystems or certain parts of those subsystems.
- (2) The notified body may issue intermediate statement verifications to cover certain stages of the verification procedure or certain parts of the subsystem.

(3) The safety authority shall designate the bodies responsible for carrying out the verification procedure in respect of national rules and the designated bodies shall be responsible for the tasks involved.

(4) The safety authority shall inform the European Commission and the other Member States of the designated bodies referred to in paragraph (3).

(5) 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.

(6) 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.

Non-compliance of subsystems with essential requirements

17. (1) Where the safety authority finds that a structural subsystem covered by the ‘EC’ declaration of verification accompanied by a technical file does not fully comply with these Regulations and, in particular, does not meet the essential requirements, it may request by way of notice served on the entity concerned that additional checks be carried out in accordance with the notice stating whether the failure to fully comply with these Regulations is due to –

- (a) non-compliance with the essential requirements or with a TSI, or incorrect application of a TSI, or
- (b) inadequacy of a TSI.

(2) The safety authority shall forthwith inform the European Commission of any additional checks requested under paragraph (1) and set out the reasons therefor.

(3) An entity who fails to comply with a request under paragraph (1) commits an offence and is liable –

- (a) on summary conviction, to a class A fine, or
- (b) on conviction on indictment, to a fine not exceeding €250,000.

(4) In this Regulation “entity” means the manufacturer who drew up declaration of verification concerned or his or her authorised representative or other person referred to in Regulation 11(5).

Part 5

Placing on the market and placing in service

Authorisation for placing in service fixed installations

18. (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 (5).

(2) The safety authority shall authorise the placing in service of the energy, infrastructure and trackside control-command and signalling subsystems which are located and operated in the State.

(3) The safety authority shall provide detailed guidance in accordance with Article 18(3), free of charge, on how to obtain the authorisation referred to in paragraph (2).

(4) A person who places in service or operates a trackside control-command or signalling, energy or infrastructure subsystem, without authorisation under paragraph (2) commits an offence and is liable –

- (a) on summary conviction, to a class A fine, or
- (b) on conviction on indictment, to a fine not exceeding €250,000.

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

- (a) the declarations of verification referred to in Regulation 16;
- (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) or Global System for Mobile Communications — Railway (GSM-R) equipment, the positive decision of the Agency issued in accordance with Article 19; 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.

(6) An applicant's request shall be dealt with by the safety authority in accordance with Article 18(5).

(7) In the event of renewal or upgrading of existing subsystems, the applicant shall send a file describing the project to the safety authority. Within one month of receipt of the applicant's request, the 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 safety

authority shall examine the file and make a decision in accordance with Article 18(6).

(8) A decision refusing a request for an authorisation for the placing in service of fixed installations shall be duly substantiated by the safety authority. The applicant may, within one month of receipt of the negative decision, submit a request that the safety authority review its decision. The request shall be accompanied by a justification. The request shall be dealt with by the safety authority in accordance with Article 18(7). If a negative decision of a safety authority is confirmed, the applicant may bring an appeal before the High Court. The court may confirm or reverse the decision (with or without modification). The decision of the High Court is final, other than on a point of law, which lies to the Court of Appeal.

(9) The safety authority may attach such conditions as it considers appropriate to an authorisation granted under this Regulation. Where the safety authority has authorised the placing in service of energy, infrastructure or trackside control-command and signalling subsystems in accordance with this Regulation, section 42 of the Act of 2005 need not apply.

Harmonised implementation of ERTMS in European Union

19. 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 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 safety authority 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.

Placing on market of mobile subsystems

20. (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.

Vehicle authorisation for placing on market

21. (1) An applicant shall only place a vehicle on the market in the State after receiving the vehicle authorisation to do so issued by the Agency in accordance with Article 21(5) to (7) or by the safety authority in accordance with paragraph (9).

(2) An applicant who places a vehicle on the market in contravention of paragraph (1) commits an offence and is liable –

- (a) on summary conviction to a class A fine,
- (b) on conviction on indictment to a fine not exceeding €250,000.

(3) In its application for 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.

(4) An application for vehicle authorisation for placing on the market shall be accompanied by a file concerning the vehicle or vehicle type and include documentary evidence of:

- (a) the placing on the market of the mobile subsystems of which the vehicle is composed in accordance with Regulation 20, on the basis of the 'EC' declaration of verification;
- (b) the technical compatibility of the subsystems referred to in subparagraph (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 subparagraph (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 (3), 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 the Article 6 of Directive (EU) 2016/798.

The 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.

(5) Whenever tests are necessary in order to obtain documentary evidence of the technical compatibility referred to in subparagraphs (b) and (d) of paragraph (4), the safety authority 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 safety authority shall take measures to ensure that the tests take place.

(6) In the case of paragraph (9), the 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 applied in accordance with Article 21(4).

(7) As part of the assessment pursuant to Article 21(5)(a) and (b) and in the case of justified doubts, the safety authority may request that tests be conducted on the network. In order to facilitate those tests, the safety authority 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 safety authority.

(8) The safety authority shall cooperate with the Agency with a view to reaching a mutually acceptable assessment under Article 21(5) and (7).

(9) Where the area of use is limited to a network or networks within the State, the safety authority 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 safety authority shall assess the file in relation to the elements specified in paragraph (4) and in accordance with the procedures to be established in the implementing act adopted pursuant to Article 21(9). Within one month of receipt of the request of the applicant, the 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 the State and in the event of non-application of one or more TSIs or parts of them as referred to in Regulation 7, the safety authority shall issue the vehicle authorisation only after application of the procedure laid down in that Regulation. The safety authority shall take full responsibility for the authorisations it issues.

(10) Vehicle authorisations for placing on the market shall state:

- (a) the area of use;
- (b) the values of the parameters set out in the TSIs and, where applicable, in the national rules, for checking the technical compatibility between the vehicle and the area of use;
- (c) the vehicle's compliance with the relevant TSIs and sets of national rules, relating to the parameters referred to in subparagraph (b);
- (d) the conditions for use of the vehicle and other restrictions.

(11) Any decision refusing the vehicle authorisation for placing on the market or excluding part of the network in accordance with a negative assessment as referred to in Article 21(7) shall be duly substantiated. The applicant may, within a period of one month from receipt of the negative decision, request that the safety authority review the decision. The 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 safety authority is confirmed, the applicant may bring an appeal before an appeal panel set up by the safety authority and independent of the safety authority. The appeal panel shall determine its own procedure and may confirm, reverse or vary the decision. The decision of the appeal panel is final, save on a specified point of law an appeal lies to the Circuit Court in whose circuit the applicant carries on business.

(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 subparagraph (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 (4) concerning the additional area of use. The applicant shall submit the file to the Agency. If the applicant has received a vehicle authorisation in accordance with paragraph (9) and wishes to extend the area of use within the State, it shall supplement the file with the relevant documents referred to in paragraph (4) concerning the additional area of use. It shall submit the file to the safety authority which shall, after following the procedures laid down in paragraph (9) issue an updated authorisation covering the extended area of use.

(14) This Regulation 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 European 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 European Commission. The conformity of those vehicles with the essential requirements of these Regulations shall be ensured by the railway undertaking concerned in the context of its safety management system. If such rules are not compliant, the safety authority shall cooperate with the European Commission in order to lay down appropriate actions to be taken, involving relevant international bodies, if necessary.

(15) This Regulation does not apply 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 the 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.

(16) Where the Agency or the safety authority has authorised the placing on the market of a vehicle in accordance with Article 21, section 43 of the Act of 2005 shall not apply.

Checks before the use of authorised vehicles

22. (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 Regulation 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;
- (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 the Railway Safety Regulations 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.

(3) A railway undertaking who fails to comply with this Regulation commits an offence and is liable on summary conviction to a class A fine.

Type authorisation of vehicles

23. (1) The safety authority may, where appropriate, in accordance with the procedure laid down in Regulation 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 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 safety authority may only concern the changed rules.

(4) 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 of 9 July 2008⁸.

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

Conformity of vehicles with an authorised vehicle type

24. (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 Regulation 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 Regulation 23(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.

Transitional regime for using vehicles

25. (1) Authorisations for the placing in service of vehicles which have been granted pursuant to the provisions set out in Chapter V of Directive 2008/57/EC⁹ 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.

(2) Vehicles authorised for placing in service pursuant to Article 54(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 Regulation 21.

Non-compliance of vehicles or vehicle types with essential requirements

26. (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, the safety authority and any other national safety authority 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, the safety authority and any other national safety authority concerned.

⁸ OJ No. L218, 13.08.2008, p.82

⁹ OJ No. L191, 18.07.2008, p.1

(2) When the safety authority becomes aware, for instance within the process of supervision provided for in the Railway Safety Regulations, 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 Regulation 23 or by the safety authority, in accordance with Regulation 21(9) or 23, 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 into conformity. The 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 on-going.

(3) When, in the cases set out in paragraph (1) or (2), 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 safety authority may apply temporary safety measures under its supervision tasks, in accordance with the Railway Safety Regulations. Temporary safety measures in the form of a suspension of type authorisation of a vehicle may be applied by the safety authority.

(4) Where the safety authority suspends type authorisation under paragraph (3), the railway undertaking concerned may make representations, within 14 days of notice of the suspension, to the safety authority, who shall consider them. If the safety authority confirms its decision, the undertaking may, with 7 days of notice of the decision, appeal to the judge of the Circuit Court in whose circuit it carries on business against the suspension. The judge may confirm the decision or direct the safety authority to restore the type authorisation. The decision of the judge is final, other than on a point of law, which lies to the High Court.

(5) In the cases referred to in paragraph (3), where appropriate, the safety authority, 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, it shall notify its decision to the holder of the authorisation for placing on the market or of the vehicle type authorisation, giving the reasons for its decisions. The holder may, within a period of one month from receipt of the decision of the safety authority, request it to review the decision. In that case, the decision to revoke shall be temporarily suspended. The safety authority shall have one month from the date of receipt of the request for review in which to confirm or reverse its decision.

Where relevant, in the event of disagreement between the Agency and the 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) shall be suspended.

(6) 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.

(7) If the decision of the safety authority is confirmed, the holder of the vehicle authorisation may bring an appeal, within two months of the notification of that decision, to the High Court. The court may confirm or reverse the decision (with or without modification). The decision of the High Court is final, other than on a point of law, which lies to the Court of Appeal.

(8) When the 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.

(9) The decision of the safety authority to revoke the authorisation shall be reflected in the vehicle register, 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 safety authority 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 Regulation shall apply.

(10) 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 Regulation 21 in the case of individual vehicles or Regulation 23 in the case of a vehicle type.

(11) When, in the cases provided for in paragraph (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.

Part 6

Conformity Assessment Bodies

Notifying authority

27. (1) The Minister is appointed as the notifying authority in the State and shall be responsible for the establishment and the carrying out of the necessary procedures for the assessment, notification and monitoring of conformity assessment bodies, including compliance with Regulation 33.

(2) The notifying authority shall comply with the requirements and obligations made of a notifying authority under Chapter VI of the Directive.

Accreditation body

28. (1) The accreditation body shall carry out the assessment and monitoring referred to in Regulation 27(1) of conformity assessment bodies in accordance with Regulation (EC) No 765/2008¹⁰.

(2) The notifying authority shall have full responsibility for the tasks performed by the accreditation body under these Regulations.

Conformity assessment bodies

29. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in Article 30(2) to (7) and in Articles 31 and 32.

Impartiality of conformity assessment bodies

30. A conformity assessment body shall be a third-party body independent of the organisation or manufacturer of the product it assesses and in relation to the impartiality of the body shall comply with the requirements of Article 31.

Personnel of conformity assessment bodies

31. (1) The personnel responsible for carrying out conformity assessment activities shall have the skills referred to in Article 32.

(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.

Presumption of conformity of a conformity assessment body

32. Where a conformity assessment body demonstrates its conformity with the criteria laid down in the harmonised standards referred to in Article 33, it shall be presumed to comply with the requirements of Articles 30 to 32, in so far as the applicable harmonised standards comply with those requirements.

Subsidiaries of, and subcontracting by, notified bodies

33. (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.

¹⁰ OJ No. L218, 13.08.2008, p.30

(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.

Accredited in-house bodies

34. (1) An applicant may use an accredited in-house body to carry out conformity assessment for the purpose of implementing the procedures referred to in Article 35(1). 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 and shall meet the requirements of Article 35(2).

(2) Information concerning the accreditation of an in-house body shall be given to the notifying authority, at its request, by the undertaking of which it forms a part or by the accreditation body.

Application for notification

35. (1) A conformity assessment body shall submit an application for notification to the notifying authority in accordance with Article 36.

(2) An 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 the 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.

Notification procedure

36. The notifying authority shall follow the notification procedure set out in Article 37.

Changes to notifications

37. (1) Where the 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 European 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 authority 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.

Operational obligations of notified bodies

38. (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the relevant TSI in accordance with Article 41(2).

(2) 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.

(3) 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.

(4) A requirement under this Regulation may be by way of a notice.

(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.

Appeals against decisions of notified bodies

39. (1) The notifying authority shall establish an appeal panel for the purposes of considering appeals against restrictions, suspensions or withdrawals rendered by notified bodies under Regulation 38.

(2) An appeal panel shall consist of at least 3 but not more than 5 persons appointed by the notifying authority, one of whom shall be designated by the notifying authority to be chairperson of the panel. An appeal panel shall not consist of any person who decided or was involved in the decision to restrict, suspend or withdraw the relevant certificate or approval decision. An appeal panel shall establish its own procedure. An appeal shall be heard in a fair and impartial manner.

(3) Where a notified body decides to restrict, suspend or withdraw a certificate held by a manufacturer, the manufacturer may, within 14 days of the notification of a decision under Regulation 38, appeal to an appeal panel against the restriction, suspension or withdrawal, as the case may be. The certificate stands restricted, suspended or withdrawn, as the case may be, from the date of notification of the decision under Regulation 37, unless the appeal panel, upon an application to it, decides otherwise, pending the outcome of the appeal. On hearing the appeal the appeal panel may confirm the decision, vary it or allow the appeal and shall notify the appellant of its decision. The decision of the appeal panel is final except that an appeal lies to the High Court on application to it on a specified point of law. Such an application does not affect the decision of the appeal panel and its operation.

Obligation of notified bodies to provide information

40. (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 safety authority and other competent national safety authorities shall also be informed of any refusal, restriction, suspension or withdrawal of a certificate under subparagraph (a).

(2) Notified bodies shall provide the other bodies notified under these Regulations 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.

Coordination of notified bodies

41. Notified bodies shall participate in the work of the sectoral group of notified bodies as referred to in Article 44, directly or by means of designated representatives.

Designated bodies

42. (1) The requirements relating to conformity assessment bodies set out in Articles 30 to 34 shall also apply to bodies designated under Regulation 16(3), except:

- (a) in the case of skills required by its personnel under Regulation 31(1), where the designated body shall have appropriate knowledge and understanding of the law relating to railway safety;
- (b) in the case of documents to be kept at the disposal of the notifying authority under Regulation 33(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 Regulation 38 shall also apply to bodies designated under Regulation 16(3), except that those obligations refer to national rules instead of TSIs.

(3) The information obligation laid down in Regulation 40(1) shall also apply to designated bodies, which shall inform the safety authority accordingly.

Part 7

Vehicle Registers

Vehicle register

43. (1) Until the European Vehicle Register as referred to in Article 47(5) is operational, the safety authority shall keep a vehicle register.

(2) The vehicle register shall:

- (a) comply with the common specifications as adopted by the European Commission under Article 47(2);
- (b) be kept updated by the safety authority;
- (c) be accessible to the other national safety authorities and investigating bodies designated in Articles 16 and 22 of Directive (EU) 2016/798 and in response to any legitimate request, to the safety authority 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.

(3) The 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 as 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 the vehicle register is not linked with the national vehicle registers of other Member States in accordance with the specification adopted by the European Commission as referred to in Article 47(2), the safety authority shall update the vehicle register, as regards the data with which it is concerned, with the modifications made by another Member State in its own register.

Registration of vehicles authorised to be placed on market

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

(2) When the area of use of the vehicle –

- (a) is restricted to the territory of the State, it shall be registered in the State, or
- (b) covers the territory of the State and another Member State or other Member States, it shall be registered in the State or one of the other Member States concerned.

(3) 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 safety authority.

(4) In the case of vehicles authorised for the first time in a third country and subsequently used in the State, the safety authority 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.

(5) A keeper of a vehicle who fails to comply with paragraph (1) or (3) commits an offence and is liable on summary conviction to a class A fine.

Vehicle numbering

45. (1) Upon registration of a vehicle in the vehicle register, each vehicle shall be assigned, and marked with, an European vehicle number (EVN) by the safety authority.

(2) 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.

(3) A person shall not place a vehicle on the market in the State unless the vehicle carries an EVN assigned by the national safety authority in the Member State of registration.

(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 European Union, the safety authority may accept vehicles clearly identified in accordance with a different coding system.

(5) A person who fails to comply with paragraph (3) commits an offence and is liable on summary conviction to a class A fine.

Register of infrastructure

46. (1) An infrastructure manager who is responsible for a part of the railway system in the State shall maintain a register of infrastructure (“register of infrastructure”) stating the values of the network parameters of each subsystem or part of subsystem concerned, as set out in the relevant TSI. The manager shall publish on a website details of these values and shall notify to the safety authority the address of the website where the details have been published.

(2) The infrastructure manager shall update the register of infrastructure in accordance with the common specifications for the register of infrastructure as adopted by the European Commission.

(3) 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.

(4) The register of infrastructure may stipulate conditions for the use of fixed installations and other restrictions.

(5) Where the safety authority considers an infrastructure manager is not complying with this Regulation, it may by notice direct compliance. The manager may within 7 days of service of the notice make representations to the safety authority, who shall consider them and inform the infrastructure manager of its decision.

(6) An infrastructure manager who fails, without reasonable excuse, to comply with a notice under paragraph (6) commits an offence and is liable on summary conviction to a class A fine.

(7) The register of infrastructure maintained under Regulation 31 of the European Communities (Interoperability of the Rail System) Regulations 2011 (S.I. No. 419 of 2011) continues in being.

Part 8

Enforcement

Inspectors

47. Inspectors appointed by the Commission for Railway Regulation under the Act of 2005—

- (a) are deemed to be inspectors to carry out any inspections, audits and investigations that are needed for the accomplishment of the tasks of the safety authority under these Regulations and to enforce these Regulations,
- (b) have the right of access to all relevant documents and to premises, installations and equipment of infrastructure managers and railway undertakings, and
- (c) have the powers of inspectors under Part 7 (other than sections 76 to 79) of the Act of 2005 to perform those functions and,

accordingly, a reference in that Part to the Act of 2005 includes a reference to these Regulations.

Compliance orders

48. (1) Where a notice has been served by the safety authority under Regulation 12(1) or 17(1) and activities are carried on in contravention of the notice or there is non-compliance with the notice, the High Court may, on the application of an inspector, by order prohibit the continuance of the activities or direct compliance with the requirements of the notice, as the case may be.

(2) An application to the High Court for an order under paragraph (1) shall be by motion and the Court, when considering the matter, may make such interim or interlocutory order (if any) as it considers appropriate and the order by which an application under paragraph (1) is determined may contain such terms and conditions (if any) as to the payment of costs as the Court considers appropriate.

Proceedings – summary offences

49. Proceedings for an offence under these Regulations may be brought summarily by the safety authority.

Offences by bodies corporate

50. (1) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent, connivance or approval of, or to have been attributable to the neglect on the part of, any person being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person, as well as the body corporate, commits an offence and is liable to be proceeded against and punished as if he or she committed the first-mentioned offence.

(2) Where the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and defaults of a member in connection with his or her functions of management as if he or she were a director or manager of a body corporate.

Service of notices, etc.

51. (1) A notice, notification or other document that is required to be given to a person under these Regulations shall be in writing and addressed to the person concerned and given to the person in any of the following ways:

- (a) by delivering it to the person;

- (b) by leaving it at the address at which the person carries on business or ordinarily resides or, in case an address has for service been given, at that address;
- (c) by sending it by pre-paid post to the address at which the person carries on business or ordinarily resides or, in case an address has for service been given, to that address;
- (d) where there is a facility for receiving the notice, notification or other document by electronic means at the address at which the person carries on business or ordinarily resides or, in case an address has for service been given, at that address; by transmitting it by such means to that address, provided the notice, notification or other document is also delivered in any of the other ways referred to in this paragraph.

(2) For the purposes of paragraph (1), a company formed and registered under the Companies Act 2014 (No. 38 of 2014) or an existing company within the meaning of that Act is deemed to be ordinarily resident as its registered office and every other body corporate and every unincorporated body of persons is deemed to be ordinarily resident at its principle office or place of business.



GIVEN under my Official Seal,
29 October, 2020.

EAMON RYAN,
Minister for Transport.

EXPLANATORY NOTE

(This note is not part of the Instrument and does purport to be a legal interpretation.)

The purpose of these Regulations is to give effect to 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. The Directive is part of the Technical Pillar of the EU Fourth Railway Package and sets out the conditions to be met to achieve technical interoperability and overall compatibility of the rail system throughout the European Union. In Ireland, these transposition Regulations apply to the Iarnród Éireann rail network.

These Regulations replace and revoke the European Communities (Interoperability of the Rail System) Regulations 2011 (S.I. No. 419 of 2011).

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2,
D02 DR67.

Tel: 076 110 6834
E-mail: publications@opw.ie

DUBLIN
PUBLISHED BY THE STATIONERY OFFICE
To be purchased from
GOVERNMENT PUBLICATIONS,
52 ST. STEPHEN'S GREEN, DUBLIN 2,
D02 DR67.

Tel: 076 110 6834
E-mail: publications@opw.ie

ISBN 978-1-4468-8341-9



9 781446 883419

€ 8.00