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2011/217/EU:

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⁽¹⁾ Text with EEA relevance

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.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

RECOMMENDATIONS

COMMISSION RECOMMENDATION

of 29 March 2011

on the authorisation for the placing in service of structural subsystems and vehicles under Directive 2008/57/EC of the European Parliament and of the Council**(Text with EEA relevance)**

(2011/217/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the functioning of the European Union,

Having regard to 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 ⁽¹⁾, and in particular Article 30(1) thereof,

Whereas:

(1) Since 2005, the European Railway Agency (hereinafter 'the Agency') has been carrying out several activities supporting the development of an integrated, safe and interoperable EU railway system. Following the adoption of Directive 2008/57/EC, the Agency has had regular meetings with stakeholders and National Safety Authorities (NSA), particularly in the field of cross-acceptance of railway vehicles. These meetings have shown that there are different understandings of the authorisation for placing in service structural subsystems and vehicles as provided for Chapters IV and V respectively of that Directive.

(2) There is a significant risk that without a common understanding, national implementing rules may lead to diverging applications of the requirements between Member States and therefore increased difficulties for manufacturers and railway undertakings. A common understanding of these processes is also needed in order to ensure consistency between the various recommendations to be produced by the Agency in relation to several tasks mandated by 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) ⁽²⁾ and Directive 2008/57/EC.

(3) When checking the implementation of Directive 2008/57/EC by Member States the principles and interpretations set out in this Recommendation will be taken into account where appropriate.

(4) The Committee referred to in Article 29 of Directive 2008/57/EC has been consulted on this measure,

HAS ADOPTED THIS RECOMMENDATION:

1. When authorising the placing in service of structural subsystems and vehicles, Member States should ensure that the principles and directions set out in the Annex are taken into account.

In particular:

(a) one single authorisation for the placing in service of vehicles should be sufficient for the whole EU rail network when the conditions specified in Directive 2008/57/EC and in Annex are met. This is the case, for example, when a TSI conform vehicle is running only on a TSI conform network;

(b) the procedures for authorising vehicles are harmonised and include some clear steps with a fixed time limits to be taken by the competent authorities;

⁽¹⁾ OJ L 191, 18.7.2008, p. 1.

⁽²⁾ OJ L 164, 30.4.2004, p. 44.

- (c) the applicable technical rules for granting authorisations for placing in service of structural subsystems or vehicles should be stable, transparent, non-discriminatory and as far as possible harmonised; the rules should be either TSIs, or, when permitted by Directive 2008/57/EC, national rules notified to the Commission and made available through a database set up by the Commission. From the moment a TSI is adopted, Member States should not adopt any national rule related to products or subsystem parts covered by that TSI (except for those declared as 'open points' and 'specific cases' where the TSI so provides, and where applicable, derogations);
- (d) in the case of non-TSI conform vehicles, the principle of mutual recognition should be applied as far as possible in order to prevent unnecessary requirements and redundant verifications, unless these are strictly necessary for verifying the technical compatibility of the vehicle with the relevant network;
- (e) the process of authorisation for placing in service of structural subsystems or vehicles and the operation and maintenance of those subsystems or vehicles are two clearly distinct processes regulated by distinct provisions and carried out by different bodies;
- (f) technical compatibility at the interface between network and vehicles is crucial for safety. Although the safety aspect of such interface could be proven through the use of reference systems or explicit risk estimations in accordance with Commission Regulation (EC) No 352/2009 ⁽¹⁾, it is necessary, for interoperability reasons, that technical compatibility is proven on the basis of a rule-based approach (that is the use of codes of practice in accordance with Regulation (EC) No 352/2009), including harmonised Union rules such as TSIs or ENs, or, where such rules do not yet exist, on the basis of notified national rules;
- (g) for placing in service a vehicle, safe integration includes two aspects: safe integration between the vehicle's relevant subsystems (only in the case of the first authorisation) and safe integration between the vehicle and the network concerned.
- Where the interface between a vehicle and a network is covered by either a TSI requirement or a national rule, the applicant considers it as a code of practice. In that case the hazard(s) for which requirements have been identified in such TSI or national rule are considered as checked through the fulfilment of the requirements of either the TSI or the national rule. This means that if the requirements of the TSI or the national rule cover the essential requirement of safety (i.e. all relevant hazards), the safe integration is demonstrated through the implementation of the TSI or the national rule.
- If there are hazards for which requirements are not covered in the TSI or in national rules this indicates that the TSI or national rules do not fully meet the essential requirements. In that case the deficiency must be addressed in accordance with Article 7 of Directive 2008/57/EC. These missing requirements should be considered in future revisions of TSIs in order to achieve a full coverage of the interoperable interfaces by TSIs progressively. In the meantime the risks are managed by the applicant by comparison with a reference system or an explicit risk analysis in accordance with Regulation (EC) No 352/2009.
- For the sake of interoperability, it is necessary that technical compatibility and safe integration between vehicle and network are demonstrated on a rule based approach. To that end, the TSI should exhaustively cover both aspects;
- (h) if the TSI includes a specification for compatibility between vehicles, that specification is verified as part of the EC verification procedure. However there is no evidence to suggest that interoperability requires every rail vehicle to have the same coupling;
- (i) in the case of additional authorisations, Member States should not call into question the national rules covering the open points not related to technical compatibility between the vehicle and the network;
- (j) Directive 2004/49/EC makes each of the infrastructure managers and of the railway undertakings responsible for their parts of the system. The railway undertaking is solely responsible for safe operation of its trains. The infrastructure manager's role is confined to the management of the infrastructure and therefore the infrastructure manager has no responsibility for the operation of trains other than to issue movement authority. The infrastructure manager has no permissioning role;
- (k) in the case of urgent measures that Member States may consider imposing as a consequence of accidents or incidents, Member States should take care to recognise that the safety management system of the railway undertaking is the primary mechanism for management of new risks to the operation of vehicles that may have been discovered in the course of accident/incident investigations or findings in the context of supervision. Even if a Member State believes that a new rule for authorisation for placing in service is urgently required, it has to follow the procedures specified in applicable Union legislation, including notification of the draft new rule to the Commission under Directives 98/34/EC of the European Parliament and of the Council ⁽²⁾ or 2004/49/EC.

⁽¹⁾ OJ L 108, 29.4.2009, p. 4.

⁽²⁾ OJ L 204, 21.7.1998, p. 37.

2. This Recommendation is addressed to the Member States.

Done at Brussels, 29 March 2011.

For the Commission

Siim KALLAS

Vice-President

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1. Introduction

Directive 2008/57/EC sets out to establish the conditions to be met in order to achieve interoperability within the Community rail system. These conditions concern the design, construction, placing in service, upgrading, renewal, operation and maintenance of the parts of this system as well as the professional qualifications and health and safety conditions of the staff who contribute to its operation and maintenance (Article 1) ⁽¹⁾.

The main objectives of Directive 2008/57/EC are to eliminate the 'technical' barriers hindering the development of rail transport and to create an optimal level of technical harmonisation in the field of rail interoperability, thereby facilitating the opening of rail markets and the operation of international trains. In order to facilitate the movement of railway vehicles Directive 2008/57/EC establishes Technical Specifications for Interoperability (TSIs), which are essential to ensure that trains can run safely and seamlessly throughout the entire EU rail system, and the simplification of procedures for authorisation of placing in service of vehicles.

To this end, some elementary principles have been consolidated into Directive 2008/57/EC.

1. One single authorisation for the placing in service of vehicles should be sufficient for the whole EU rail network when certain conditions are met. This is the case, for example, when a TSI conform vehicle is running only on TSI conform network.
2. The procedures for authorising vehicles are harmonised and include some clear steps with a fixed time for by the competent authorities.
3. The applicable technical rules should be stable, transparent, non-discriminatory and as far as possible harmonised; the rules should be either TSIs, or, when permitted by Directive 2008/57/EC, national rules notified to the Commission and made available through a database set up by the Commission.
4. In the case of non-TSI conform vehicles, the principle of mutual recognition should be applied as far as possible in order to prevent unnecessary requirements and redundant verifications, unless these are strictly necessary for verifying the technical compatibility of the vehicle with the relevant network.

The aim of this recommendation is to clarify the procedure for authorising the placing in service of structural subsystems and vehicles as set out in Directive 2008/57/EC. Within this context, various scenarios relating to vehicles should be considered: new and upgraded/renewed vehicles, vehicle types, TSI conform vehicles, non-TSI conform vehicles, vehicles authorised to run on the Trans-European Network for Transport (TEN-T), vehicles authorised to run outside the TEN-T, vehicles authorised to run on the networks of more than one Member State and additional authorisations. In this sense, unless explicitly indicated otherwise, references in the text to 'authorisation' mean 'authorisation for the placing in service'.

All the guidelines addressed to RUs should be also valid for infrastructure managers (IMs) when they operate infrastructure inspection and maintenance trains.

2. Interoperability constituents, subsystems and vehicles

2.1. *Interoperability constituents and subsystems*

Owing to its extent and complexity the rail system has been broken down into subsystems related to either structural or functional areas (Article 2(e)).

The structural subsystems are defined in Annex II ⁽²⁾ and are the following: infrastructure, energy, trackside control-command and signalling, on-board control-command and signalling and rolling stock. The functional subsystems are defined in Annex II and are the following: operation and traffic management, maintenance, telematics applications for passengers and freight services.

Moreover, there is a need to define 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. These components are called 'interoperability constituents' (IC) (Article 2(f)). They are subject to procedures for assessing conformity and suitability for use (Article 11). ICs that comply with the directive and bear the 'EC' declaration of conformity or suitability for use can be placed on the market and subsequently be incorporated into a subsystem.

⁽¹⁾ References to Articles of Directive 2008/57/EC are mentioned in brackets in the whole text.

⁽²⁾ As set out in the amended Annex II to Directive 2008/57/EC (currently under modification).

Examples: the pantograph is an IC for the 'rolling stock' subsystem; the rail is an IC for the 'infrastructure' subsystem.

Those subsystems that are structural subsystems are subject to an authorisation for placing in service to be issued by the competent authority which, in the case of the Directive, is the National Safety Authority (NSA) to be set up by the Member States (MS) (Article 16 of Directive 2004/49/EC).

2.2. Vehicles

The rail system can also be broken down into fixed and mobile elements comprising on the one hand, the network (including lines, stations, terminals and all kinds of fixed equipment to ensure safe and continuous operation of the rail system) and, on the other hand, all vehicles travelling on this network. Therefore, a vehicle is composed of the rolling stock subsystem and, where applicable one or more parts of other subsystems (including the on-board control-command and signalling subsystem) (Articles 2(c) and 2(d)).

Since vehicles are composed of subsystems, provisions related to subsystems in Chapter IV of Directive 2008/57/EC are applicable to the vehicles' relevant subsystems, without prejudice to other provisions of Chapter V.

3. Requirements to be met when manufacturing a subsystem

3.1. Types of requirements

3.1.1. Essential requirements

When it is placed on the EU market, a product complies with the essential requirements set out in the applicable New Approach Directives⁽¹⁾ (e.g. low voltage directive, etc.) and with technical requirements laid down in other relevant directives (or legislation) (e.g. Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods⁽²⁾). The essential requirements lay down the necessary elements for protecting the public interest. They are mandatory, and only products which comply with them are allowed to be placed on the market.

Example: in the case of Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC⁽³⁾, there is a protection requirement so that the electromagnetic disturbance generated does not exceed a certain level in order to ensure that radio and telecommunications equipment or other equipment can operate as intended.

3.1.2. Essential requirements of Directive 2008/57/EC

Directive 2008/57/EC sets out in Annex III a list of essential requirements which will contribute to achieve the interoperability of the rail system (Article 3(1)). These requirements are specific to the rail sector. The rail system, the subsystems, the interoperability constituents, and all interfaces meet the essential requirements. Meeting the essential requirements is a prerequisite before a structural subsystem can be placed in service (Article 4(1)). Compliance with the essential requirements of the Directive does not preclude the application of other EU provisions (Article 3(2)).

3.1.3. Technical specifications for interoperability (TSI)

The TSIs lay down the necessary specifications that subsystems apply in order to meet the essential requirements of Directive 2008/57/EC and fulfil Directive 2008/57/EC's objectives, including seeking the optimal level of technical harmonisation (Article 1(2)). The TSIs not only identify functional and technical specifications to be respected by the subsystems, but also specify the interfaces between subsystems.

TSIs identify the basic parameters that are critical to interoperability and ICs. In addition, TSIs state which procedures⁽⁴⁾ are to be used in order to assess conformity and suitability for use of ICs, on the one hand, and for the 'EC' verification procedure of the subsystem, on the other hand.

Each TSI indicates a target subsystem that may be attained gradually within a reasonable time-scale (Article 5(4)). For that purpose Chapter 4 of each TSI lays down the basic parameters and interfaces of the target subsystem and Chapter 7 lays down the implementation process to reach this target subsystem including a transition period where appropriate.

In certain cases TSIs make explicit reference to European standards or part(s) of them, or specifications where this is strictly necessary to achieve interoperability. These standards become mandatory from the moment the TSI is applicable.

⁽¹⁾ The concept of the New Approach has been revised in 2008 by a new legislative framework for conformity assessment, accreditation and market surveillance.

⁽²⁾ OJ L 260, 30.9.2008, p. 13.

⁽³⁾ OJ L 390, 31.12.2004, p. 24.

⁽⁴⁾ TSIs indicate the modules to be applied in the relevant Commission decision.

Implementation of Directive 2008/57/EC should not create barriers to the preservation and development of the existing rail network of each MS that are unjustified in cost-benefit terms, but endeavours to uphold the objective of interoperability. To that end, TSIs also take into consideration any part of the rail system that needs special provisions, and therefore define 'specific cases'.

Normally the specific case would be contained within the TSI in the form of a different value for a parameter (e.g. Iberian gauge in the Infrastructure TSI). In certain circumstances where the TSI does not contain the text of the specific case the TSI may instead make explicit reference to a national rule. Such rules are notified and the MS must designate the body to carry out the verification procedure (designated body) (Article 17).

If certain aspects corresponding to the essential requirements cannot be explicitly covered in a TSI (e.g. because of the absence of a harmonised solution, or lack of mutual recognition among the concerned parties), this TSI explicitly identifies them out as 'open points' (Article 5(6)).

3.1.4. National rules

Until such time as the target system is reached (Article 5(4)) and consequently interoperability is achieved, MS rely on national rules for implementing the essential requirements (Article 17(3)). This is because:

- for various reasons TSIs are not complete (e.g. open points, scope restricted to TEN-T for the first set of TSIs, TSIs currently under development),
- in order to ensure backward compatibility with existing installations, some subsystems in some MS may require derogations,
- most existing subsystems were placed in service before the entry into force of the Interoperability Directives or some of the TSIs and therefore do not conform to all TSIs,
- specific cases rely on national rules when the TSI does not contain the text of the specific case.

These national rules are notified to the Commission, which in turn must monitor them to prevent discriminatory national rules (Article 17(3)) imposing unnecessary requirements and redundant verifications. Only these national rules should be applied for placing vehicles in service and should be cross-referenced in the reference document (Article 27(3)).

Conclusion: According to the Directive and its principles of transparency and non-discrimination the conclusion should be drawn that only national rules that have been notified should be applied to authorise structural subsystems and vehicles.

From now on, any reference in this recommendation to national rules means 'notified national rules'.

From the moment a TSI is adopted, MS should not adopt any national rule related to products or subsystem parts covered by that TSI (except for those declared as 'open points' and 'specific cases' where the TSI so provides, and where applicable, derogations).

Indeed, any national rule over-specifying a parameter already covered by a TSI may lead to a situation of non-compatibility between two TSI conform subsystems. For instance, a national rule related to a vehicle imposing stricter requirements than the TSI PRM, may lead to a situation in which a TSI conform vehicle already authorised in another MS could not be re-authorised. Therefore, in accordance to Article 17(3) the Commission will monitor the national rules in order to avoid any arbitrary discrimination or disguised restriction (Article 17(3)).

Moreover, as regards the free movement of subsystems, Directive 2008/57/EC reflects the spirit of the new approach: when a product that complies with non-harmonised technical specifications (i.e. relevant national rules) fulfils the essential requirements, this product can be authorised to be placed in service without further checks (Article 16) ⁽¹⁾.

3.1.5. Harmonised standards (ENs)

In order to achieve the goal of a common market, technical specifications of products meeting the essential requirements may be laid down in harmonised standards (EN). In some cases, harmonised standards that cover the basic parameters of the TSIs provide presumption of conformity with the TSI. In accordance with the spirit of the new approach to technical harmonisation and standardisation, those ENs remain voluntary but their references are published on the *Official Journal of the European Union* (OJEU) and they are identified in the TSI application guide in order to facilitate their use by the industry.

⁽¹⁾ Without prejudice to the provisions of Article 15(1) and Chapter V of the Directive that are further detailed in Section 5 of this document.

3.2. *Evolution of interoperability*

Interoperability is to be achieved gradually.

Initially, in the absence of complete TSIs covering the whole railway system and pending the conformity of all subsystems to the TSIs, the essential requirements of Directive 2008/57/EC are met, for parts of the railway system or aspects not covered by the TSIs, by conformity with national rules, including rules referring to international agreements, which are notified (Article 17(3)).

In the long term, when the target system is both specified and implemented, there will no longer be a need for these national rules.

Until full interoperability is achieved, TSIs will coexist with national rules. In this transitional period, there is a need for a procedure to facilitate cross-acceptance of vehicles. To this end, all national rules that are applied by MS for placing vehicles in service will be classified and cross-referenced in the reference document (Article 27). Articles 16, 23, 25 and 27 of the Directive provide for mutual recognition (cross-acceptance) of such national rules and checks against those rules.

4. **Verifications that ICs and subsystems have been built in accordance with the applicable requirements**

4.1. *Assessment of the conformity or suitability for use of interoperability constituents (ICs)*

TSIs determine the ICs within their scope, and lay down the procedures to be applied by the manufacturer in order to assess the conformity and/or the suitability for use of the ICs. The TSI may require the assessment to be carried out by a NoBo which issues the certificate for conformity and suitability for use. The manufacturer then draws up the 'EC' declaration of conformity or 'EC' declaration of suitability for use (Article 13 and Annex IV).

In order to be placed on the market, every IC bears an 'EC' declaration of conformity and, if the conformity assessment procedure so requires, is accompanied by the corresponding 'EC' certificate. In addition, where the TSI requires type validation of in service experience, the IC is accompanied by the 'EC' declaration of suitability for use and an 'EC' certificate of suitability for use. An IC is considered as complying with the essential requirements of Directive 2008/57/EC when it bears the 'EC' declaration of conformity or 'EC' declaration of suitability for use. When ICs are subject to other EU legislation covering other aspects, the 'EC' declaration also state that the ICs likewise meet the essential requirements of that EU legislation.

4.2. *Verification procedure for subsystems ⁽¹⁾*

4.2.1. 'EC' verification procedure for subsystems

The NoBo checks the conformity of the subsystem with the applicable TSI(s) based on the information available in the relevant TSI and in the registers (Articles 5(3)(e) and 18(2)).

The task of the NoBo responsible for the 'EC' verification of a subsystem begins at the design stage and covers the entire manufacturing period through to the acceptance stage by the applicant before the subsystem is placed in service. It also covers the verification of the interfaces with the system into which it is incorporated. However, the verification task of the NoBo under Directive 2008/57/EC is limited to the requirements mentioned in the applicable TSIs. In order to perform its task, the NoBo may need to consult the registers.

For example, in the case of renewal or upgrading of a route section, the NoBo needs to be sure that the correct TSI options are chosen. In this case, the content of the TSI will not be sufficient to check the interfaces with the adjacent route sections: for example, the NoBo needs to know that the gauge and voltage are also the same on the adjacent route ⁽²⁾.

The NoBos apply the 'EC' verification procedure according to 'modules' which are specified in the TSIs and, in some cases, laid down in a specific Commission decision. They record their conclusions by drafting an 'EC' certificate of verification and compiling a technical file.

When any other EU legislation is also applicable to the subsystem or part thereof, the NoBo collate any other 'EC' certificate deriving from that legislation issued by the relevant NoBo concerned by that legislation.

⁽¹⁾ Amended Annex VI to the Directive.

⁽²⁾ See also in this document, Section 5.3 related to Safe Integration and Technical Compatibility and Section 9 related to Registers.

4.2.2. Verification procedure of subsystems in the case of national rules

The body designated by the Member States (designated body, DeBo), in the case of national rules, applies a procedure similar to the 'EC' verification procedure by drafting a certificate of verification in the case of national rules and by compiling a technical file (Article 17(3)). The applicant in turn, draws up a declaration of conformity with the national rules.

4.2.3. Declaration drawn up by the applicant⁽¹⁾

The applicant is responsible for setting up an 'EC' declaration of verification of the subsystem declaring that the subsystem is compliant with the relevant TSI(s) and compliant with the essential requirements deriving from other EU legislation, when applicable.

Likewise, if national rules apply, the applicant draws up a declaration of conformity with national rules for the parts covered by national rules. Only when all the preceding evidence and declarations have been compiled is the applicant in a position to formally apply to the competent NSA for an authorisation for placing in service of the subsystem.

'EC' certificates and 'EC' declarations are valid EU-wide. Certificates and declarations related to national rules, are valid EU-wide except for the provisions related to technical compatibility or safe integration between the vehicle and the network, because those aspects are subject to specific provisions related to placing vehicles in service (further details are given in the following Section).

The applicant annexes the technical file completed by the NoBo (mentioned in Section 4.2.1) to the 'EC' declaration of verification.

5. Authorisation for placing in service

5.1. What is authorisation for placing in service?

5.1.1. Concept

The Authorisation for placing in service procedure was first introduced in Directive 96/48/EC and was intended to complement the concept of placing on the market referred to in Section 3.1.1. Whilst a product or an Interoperability Constituent can be placed on the market without prior authorisation of a competent authority, this is not the case for a subsystem which requires an authorisation to be delivered by a competent authority before a subsystem can be placed in service (Article 15).

Each MS authorises the placing in service of those structural subsystems constituting the rail system which are located or operated in its territory (Article 15). Likewise, Chapter V of the Directive relates to the authorisation of vehicles.

Authorisation for placing in service of a subsystem is required in respect of all parts of the rail system: TEN-T lines and off-TEN-T lines, either high speed lines or conventional lines, as well as the subsystems forming the vehicles running on those lines whether or not there is a relevant TSI.

As part of the verification of the essential requirements MS check the technical compatibility of these subsystems with the system into which they are being integrated, and the safe integration of these subsystems when integrated into the rail system (Article 15).

Technical compatibility and safe integration relate to all structural subsystems, both those integrated into the vehicle and those at each side of the interface between the vehicle and the network concerned.

Authorisation is a process that has to be undertaken prior to the placing into service. In accordance with Article 15 it is envisaged that the ongoing adherence to the essential requirements is overseen as part of the supervision of the RUs or IMs SMS under Directive 2004/49/EC. A NSA intending to revoke an authorisation to place in service uses the procedures provided by Directive 2004/49/EC (Article 21(9) of Directive 2008/57/EC).

If NSAs believe that an authorised vehicle or subsystem no longer meets the essential requirements (e.g. due to poor maintenance or a design or endemic fault that has come to light since authorisation) they should take action under Directive 2004/49/EC to satisfy themselves that the risk is being adequately managed.

⁽¹⁾ Amended Annex V to the Directive.

5.1.2. Authorisation for the placing in service of subsystems

Authorisation for placing in service applies to structural subsystems as defined by Annex II⁽¹⁾ to Directive 2008/57/EC (energy, infrastructure, rolling stock, trackside control-command and signalling, on board control-command and signalling) and further defined in the relevant TSIs (Article 15).

5.1.3. Authorisation for placing in service of vehicles

Directive 2008/57/EC sets out the provisions in order to grant authorisation for placing in service of vehicles (Chapter V). As a vehicle is composed of one or more structural subsystems, the provisions of Directive 2008/57/EC related to the authorisation for placing in service of subsystems apply (Article 15), without prejudice to other provisions related to the placing in service of vehicles (Chapter V).

An authorisation granted for a vehicle by one MS is valid in all MS without prejudice to the decision of the second MS to require an additional authorisation (Article 23). In the case of vehicles which do not conform to TSI, the authorisation is limited to the network of the MS that grants it (Articles 24 and 25). However, there is limited scope for verification of additional authorisations.

The authorisation of a vehicle is the recognition by the MS that the vehicle design operating state meets the essential requirements of the Directive and other EU legislation when the vehicle is intended to be used on the network of that MS.

The authorisation granted to a vehicle may stipulate conditions of use and other restrictions (Article 21(6)). For example, an authorisation should specify the voltage of the lines on which the vehicle is allowed to run in the case of electric traction vehicles. However, issues of route⁽²⁾ specific compatibility between the design characteristics of the vehicle and specific characteristics of particular routes (e.g. weight restrictions, electrification systems, train protection systems) should be dealt with under the Safety Management System (SMS) of the RU, applying the conditions of use and restrictions laid down in the authorisation and the technical file and the information on the nature of the infrastructure supplied by the IM in the Register of Infrastructures (RINF) (see Section 6 of this document).

To avoid geographical specificity and the need to re-authorise a vehicle if the characteristics of a route change (e.g. new electrification or change of voltage), any conditions of use attached to a vehicle authorisation for placing in service (over and above those already covered by the boundaries of the scope of use for which the vehicle was designed) should be specified in terms of the parameters of the technical design characteristics of the infrastructure (e.g. to operate only on track circuits of xxHz frequency) and not in terms of geography.

Remark: the authorisation for placing in service is a very different concept to 'homologation' which was carried out in the past by national railway companies. Homologation was in essence a product acceptance carried out by the national railway company when purchasing a product, whilst authorisation is a legal requirement to gain permission to place a subsystem or vehicle in service based on a defined set of verifications carried out by bodies nominated by the government and by the NSA.

5.2. The border between the authorisation for placing in service and the operation and maintenance of subsystems and vehicles

5.2.1. General principles

In order to 'facilitate the progressive creation of the internal market in equipment and services for the construction, renewal, upgrading and operation of the rail system within the Community' (Article 1), it is appropriate to separate the authorisation for placing in service of the structural subsystems/vehicles from the regulation of their operation.

This separation enables vehicles belonging to a given vehicle type to be placed in service by different manufacturers or contracting entities, to be operated by different railway undertakings, and to be maintained by different Entities in Charge of Maintenance (ECM) according to different maintenance regimes depending on the operational context.

For example a manufacturer may apply for authorisation for a locomotive or locomotive type for a network in a MS in order to sell it to a number of different RUs or leasing companies, etc., for operation by different RUs, each of whom will have different arrangements in their respective SMS for managing and maintaining locomotives.

Alternatively an RU may operate an authorised locomotive previously operated by another RU on the same network without the need for a new authorisation.

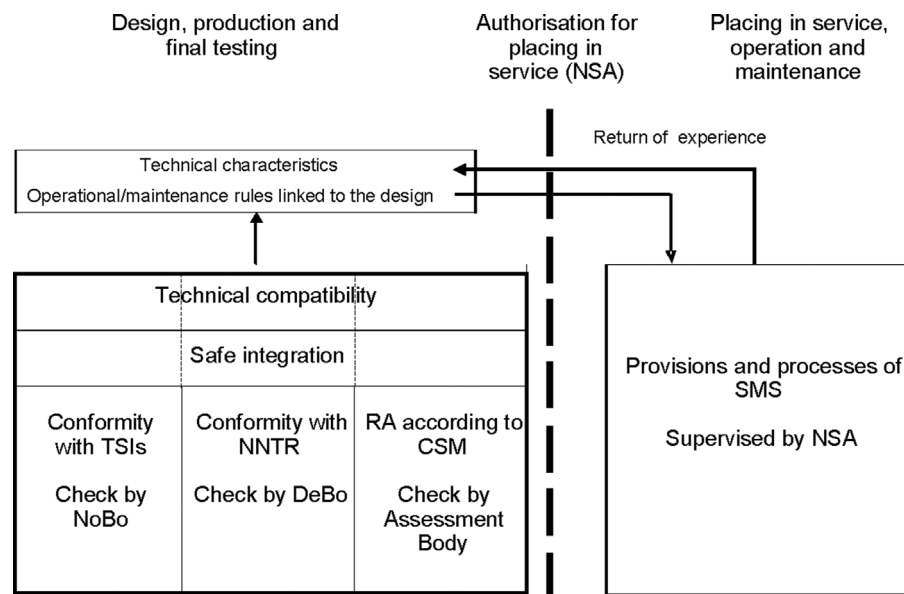
⁽¹⁾ Annex II to Directive 2008/57/EC is currently under modification by the Commission.

⁽²⁾ The itinerary intended to be operated by a train.

In order to clarify the boundary, Directive 2008/57/EC has established the rules and the authorisation process to achieve the design operating state of a vehicle. Once a subsystem is placed in service, care should be taken to ensure that it is operated and maintained in accordance with the essential requirements that relate to it. Under Directive 2004/49/EC the responsibility for meeting these requirements lies with the IM or the RU for their respective subsystems, without prejudice to the responsibilities of other actors (Article 4.4 of Directive 2004/49/EC). NSAs can check compliance with these requirements when granting safety certificates and safety authorisations to RUs and IMs (Articles 10, 11 and 16 of Directive 2004/49/EC).

An exception to that dividing line applies in relation to operation and maintenance rules, see Section 5.2.2.

From a general point of view Directive 2008/57/EC regulates the technical characteristics (mainly design, production and final testing) of the subsystems and vehicles and the process of their authorisation for placing in service and Directive 2004/49/EC regulates the entities that use, operate and maintain them, as shown in the following diagram.



In the diagram hereinabove:

- 'NNTR' means 'national technical rules notified in accordance with Article 17', but includes as well rules for open points, derogations and where required specific cases,
- 'RA according to CSM' means 'risk assessment following the CSM' and is related to the aspects of technical compatibility and safe integration which are relevant to the essential requirements but are not covered by TSIs or NNTR,
- technical characteristics and operational/maintenance rules linked to the design can be extracted from the process of authorisation and are part of the technical file,
- the return of experience is the process by which technical characteristics need to be modified as a result of real operation and maintenance of subsystems/vehicles. The management of change is part of the SMS of IMs and RUs, as explained in the next two Sections.

5.2.2. Operational and maintenance requirements to be verified before the authorisation for placing in service

In accordance with Article 15(2) of Directive 2008/57/EC, MS check that the subsystems comply with the provisions on operation and maintenance that relate to the design operation state before they are placed in service. This means that there is a need to check, before issuing an authorisation for placing in service, that the subsystems will be able to be operated and maintained according to the operating and maintenance rules specified in the relevant TSI.

TSIs on operation and traffic management are also developed and adopted under Directive 2008/57/EC but, as they cover a non-structural subsystem there is no need for authorisation of that subsystem. All specifications relating to operational requirements that should be defined at the design operating state (e.g. braking characteristics, horns on driving vehicles) are covered by the structural TSIs.

The Operations and Traffic Management TSI (OPE TSI) describes the requirements for 'the procedures and related equipment enabling a coherent operation of the different structural subsystems' (Annex II). It does not relate to the obligations in respect of the authorisation of the design operating state which is obtained by an applicant (e.g. a manufacturer) but to the harmonised procedures that are necessary to ensure the consistent operation of the respective parts of the railway system which is carried out by the IMs and RUs under their SMSs.

One of the primary purposes of the OPE TSI is to harmonise the division of operational responsibilities between IMs and RUs which would otherwise need to be covered by a highly complex set of multilateral cooperation agreements.

All the requirements that are relevant to maintenance and necessary for implementing the essential requirements in order to achieve interoperability are included in the structural TSIs, based on the technical characteristics of the subsystem. On that basis the applicant delivers preliminary maintenance and operation documentation that has to be included in the technical file of the relevant subsystem. The technical file is an essential starting reference for the ongoing management of maintenance and includes the initial operation and maintenance manuals. After the placing in service it is the responsibility of the RU or IM in conjunction with an ECM, to continuously review maintenance interventions and amend this information to ensure that it reflects the duty cycle and return of experience (Article 4 and Article 9 of Directive 2004/49/EC). It should also be noted that the management of change is part of the SMS of IMs and RUs.

5.2.3. Safety Management Systems (SMSs)

Pursuant to Directive 2004/49/EC, when carrying out their duties and fulfilling their responsibilities, IMs and RUs implement a SMS, that fulfils the EU and national requirements and contains common elements. The processes for ensuring the safe operation (including use and maintenance) of vehicles/subsystems are covered by the SMS of the RU (for vehicles) and IM (for networks).

One of the purposes of the safety certificate and the safety authorisation respectively is to provide evidence that the RU and IM has established its SMS and can meet the essential requirements laid down in TSIs during the operation of the relevant subsystems. The safety certificates and the safety authorisations are revised at regular intervals, which is not the case of the authorisation for placing in service. However, the authorisation for placing in service always remains valid, except in the event of any substantial change affecting the design operating state (technical characteristics) that could occur, for example in the case of renewal or upgrade, depending on the extent of the works. Thus, changes to an RU operation are regulated by the Directive 2004/49/EC, and changes to the design operating state of a vehicle or subsystem are regulated by the authorisation process in accordance with Directive 2008/57/EC.

5.3. *Technical compatibility, safe integration and compatibility between vehicles*

5.3.1. Technical compatibility

Technical compatibility is one of the 'essential requirements' which must be met by 'the rail system, subsystems and interoperability constituents including interfaces' (Article 4).

Technical compatibility is defined in Annex III to Directive 2008/57/EC: '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'. It is also specified for different structural subsystems (Annex III points 2.2.3, 2.3.2 and 2.4.3).

In addition, Annex I Section 3 identifies technical compatibility as a cornerstone for quality of services, performance, safety and costs of the rail system.

A RU operating a train will need to know whether the particular route is capable of supporting the operation of its train, i.e. whether it is technically compatible.

As a consequence, TSIs contain the specifications necessary for the subsystem and its interfaces to be interoperable and meet the essential requirements (including that of technical compatibility). Thus, where relevant TSIs exist and apply, verification of technical compatibility is to be carried out by reference to TSIs (Article 17(2)).

Where there is no relevant TSI covering the essential requirement of technical compatibility (e.g. the interface to legacy signalling/train protection systems, non-TSI conform infrastructure, energy, and CCS subsystems) national rules apply.

This means that until the interfaces to all parts of the network are all covered by the TSIs, MS should put in place rules that specify any requirements in addition to those in TSIs that are necessary for technical compatibility between vehicles and non-TSI conform parts of the network for which they are responsible. This will include, for example, the legacy requirements for on-board train protection systems so that vehicle on-board CCS systems may be designed, installed and verified as being able to read and react to signals from the line-side transponders of the legacy system.

It is possible in the transition phase that some MS may not yet have met the requirement to have put in place a full set of transparent national rules (Article 17) to cover the vehicle-network interface when there is no relevant TSI, to the same level of detail as the TSIs. This may be because the specification of these interfaces, which is so necessary in order to preserve existing levels of national interoperability, have in the past been covered by the internal rules of the national railway companies. In such case, the use of risk assessment methods to demonstrate technical compatibility based on the second and third principles of the CSM on RA is not recommended because this may lead to incompatibility of interface specifications between projects and loss of interoperability.

Conclusion: Technical compatibility at the interface between network and vehicles is crucial for safety. Although the safety aspect of such interface could be proven through the 2° and 3° principle of the CSM on risk assessment, it is necessary, for interoperability reasons, that technical compatibility is proven on the basis of a rule-based approach (1° principle of the CSM on RA), including EU harmonised rules such as TSIs or ENs, or, where such rules does not yet exist, on the basis of notified national rules.

5.3.2. Safe integration

When authorising the placing in service of structural subsystems, MS check that these subsystems are designed, constructed and installed in such a way as to meet the essential requirements, and, in particular, they check that they are safely integrated into the system into which they are placed (Article 15(1)). In order to ensure the safe operation of the railway system and the management of risks associated therewith.

To this end and as a general rule, the following needs to be demonstrated:

- for the placing in service of an individual subsystem, the safe integration between this subsystem and all other subsystems in which it is integrated,
- for the placing in service of a vehicle, the safe integration between the vehicle's relevant subsystems (only in the case of the first authorisation) and the safe integration between the vehicle and the network concerned.

However the safe integration checks are not required in all circumstances; for example, in the case of vehicles and under specific conditions, Chapter V of the Directive 2008/57/EC has removed such obligations in the case of vehicles already authorised in one MS and operated in another MS.

Safe integration is part of the essential requirements (Article 15(1)). Therefore it is covered, as a general rule, by TSIs or national rules (Article 17).

When demonstrating safe integration by applying the CSM on RA, the applicant will have:

- to refer to either the TSIs requirements or the national rules, by application of the first risk acceptance principle 'use of codes of practices', or
- if the subject is not covered by the TSI and national rules, to perform an explicit risk estimation or a similarity study to identify the missing requirements (third and second risk acceptance principles of the CSM on RA) which should be made public, so that what the NSA accepts is made transparent.

As stated in the CSM on RA, the application of the CSM on RA for safe integration must not lead to requirements that are contradictory to those laid down in the TSIs. By analogy, this also applies to national rules. This means that, where there are TSI requirements or national rules, they remain mandatory. If this were not the case, interoperability would never be achieved.

Conclusions:

- *in the case that the interface between a vehicle and a network is covered by either a TSI requirement or a national rule, the applicant considers it as a code of practice and the hazard(s) for which requirements have been identified in such TSI or national rule, are considered as checked through the fulfilment of the requirements of either the TSI or the national rule. This means that if the requirements of the TSI or the national rule cover the essential requirement of safety (i.e. all relevant hazards), the safe integration is demonstrated through the implementation of the TSI or the national rule,*

- if there are hazards for which requirements are not covered in TSI or national rules this indicates that the TSI or national rules do not fully meet the essential requirements and the deficiency must be addressed according to Art 7. These 'missing requirements' should be considered in future revisions of TSIs in order to progressively arrive at a full coverage of the interoperable interfaces by TSIs. In the meantime the risks are managed by the applicant by comparison with a reference system or an explicit risk analysis according to the CSM on RA regulation,
- for the sake of interoperability, it is necessary that technical compatibility and safe integration between vehicle and network are demonstrated on a rule based approach. To that end, TSI should cover exhaustively both aspects.

It should be noted that all the requirements for authorisation to place into service are included in Directive 2008/57/EC and that both 2008/57/EC and 2004/49/EC Directives are complied with simultaneously. This means that:

- if requirements are necessary to maintain the existing level of safety under Directive 2004/49/EC over and above those foreseen in the TSIs then so as not to restrict movement of TSI conform trains, they should:
 - take the form of requirements on infrastructure or operations (to be included in the relevant TSIs as a duly justified specific case), or
 - if a vehicle related measure is unavoidable it should be included in the TSI as a duly justified specific case,
- MS should not invoke Directive 2004/49/EC to impose additional requirements for authorisation for placing in service.

5.3.3. Compatibility between vehicles

When preparing trains, RUs will have to use vehicles which are technically compatible with the network but also that can be coupled among themselves. As the coupling system can be left to the choice of an RU for the management of its own fleet or to an agreement of several RUs for the management of a shared fleet, there is no evidence to suggest that interoperability or the optimal level of harmonisation requires every rail vehicle to have the same coupling.

However, as the vehicles after coupling have to remain safe, the TSI should include at least the functional requirements related to the coupling that need to be verified in the context of the EC verification procedure.

A specific situation concerns wagons used in the context of single wagon load in the standard gauge network. Taking into account the size of this fleet one could envisage the inclusion of a standard coupling specification into the TSI; however because it is not necessary for interoperability the specification of the coupling should not be mandatory for all wagons, but only applicable to wagons using that standard coupling. ERA is currently studying the optimisation of the right place for such specifications: if RUs share vehicles under a commercial agreement (e.g. GCU), is the best place to manage these specifications in the agreement itself, in voluntary standards, in harmonised standards or in TSIs?

Conclusion: if the TSI includes a specification for compatibility between vehicles, that specification is verified as part of the EC verification procedure. However there is no evidence to suggest that interoperability requires every rail vehicle to have the same coupling.

5.4. Authorisations in the case of TSI conform and non-TSI conform vehicles

5.4.1. Authorisation of TSI conform vehicles

Provisions related to the first authorisation are set out in Article 22 of Directive 2008/57/EC.

If all subsystems integrating the vehicle have been authorised according to Chapter IV of Directive 2008/57/EC, the MS directly authorise a vehicle without further checks because these have already been covered by checks under the procedure for placing in service of subsystems, including technical compatibility and safe integration (Articles 15 and 22 (2)(a)). In cases where the subsystems integrating the vehicle have not been authorised according to Chapter IV of Directive 2008/57/EC, the following paragraphs are relevant.

In the case of vehicles whose subsystems bear all necessary 'EC' declarations of verification, there are two types of technical compatibility: one between subsystems within the vehicle and the other between the vehicle and the network (Article 22(2)(b)).

Likewise, there is provision for a separate check of safe integration both between the subsystems integrating the vehicle and between the vehicle and the network.

The DeBo checks the conformity with the national rules relating to open points and specific cases.

As regards additional authorisation, Article 23 of Directive 2008/57/EC applies.

Directive 2008/57/EC ensures that there is mutual recognition of the different ways of meeting the essential requirements in order to avoid new checks as part of an additional authorisation.

In this case, NSA may only mandate further requirements or additional risk analyses (on the basis of the CSM on RA) related to:

- the technical compatibility between the vehicle and the network concerned, including the national rules applicable to the open points needed to ensure such compatibility, and
- the national rules applicable to specific cases duly identified in the TSIs.

Conclusion: MS should not call into question the national rules covering the open points not related to technical compatibility between the vehicle and the network.

However, this should not mean that the national rules which are not related to technical compatibility between the vehicle and the network are automatically considered equivalent and thus classified A in the reference document. It means that the reference document, in the context of TSI conform vehicles, is only used in the case of open points related to the technical compatibility between the vehicle and the network, or in specific cases. It is only in the latter two cases (technical compatibility between the vehicle and the network and specific cases), after the adoption of the reference document referred to in Article 27 of the Directive, that the NSA is not allowed to call into question requirements that are mutually recognised and as such, are classified in the Group A pursuant to Annex VII to Directive 2008/57/EC.

Example: No further checks for an additional authorisation of a CCS TSI conform vehicles running on CCS TSI conform lines (provided that they both have been certified as fully compliant with the specifications referred to in the Commission Decision 2010/79/EC ⁽¹⁾).

and

Where a CCS TSI conform vehicle is to be given an additional authorisation for a non-CCS TSI conform network then CCS related checks may only cover the technical compatibility between the vehicle on-board and network CCS systems.

5.4.2. Authorisation of non-TSI conform vehicles

Non-TSI conform vehicles are those that are not in conformity with all TSIs in force, including those that are subject to derogations, or where a significant part of the essential requirements is not laid down in one or more TSI. In the latter case, although a vehicle might be in conformity with all relevant TSIs, the term non-TSI conform is used for the sake of simplicity only.

For the first authorisation Article 24 of Directive 2008/57/EC applies. This is a very similar process to that used for TSI conform vehicles. The main difference is that the scope of the checks to be carried out against national rules is defined by the list of parameters in the reference document — whereas, for TSI conform vehicles, the scope of the checks against national rules is determined by the rules necessary for ensuring technical compatibility with the network, the list of open points and specific cases in each TSI.

However, for the parts covered by TSIs, the 'EC' verification procedure applies; this includes technical compatibility and safe integration, as described in earlier Sections.

Concerning the additional authorisation, Article 25 of Directive 2008/57/EC applies.

In this case, the scope of checks is broader and is not so constrained as in the case of TSI conform vehicles. MS may invoke any rules necessary to meet the essential requirements provided they relate to parameters covered by the reference document. However:

- they may not call into question any of the non-network parts of the first authorisation unless they can demonstrate a substantial safety risk to the applicant. This option is not open to the NSA for TSI conform vehicles nor it is open for non-TSI conform vehicles in the case where the rules covering the relevant parameter belong to group 'A',

as the calling into question is without prejudice to the free movement of subsystems (Article 16), the first verification of the essential requirements for the subsystems by the MS takes precedence and the second NSA can only invoke the checks if the first checks were not covered by an 'EC' verification declaration,

⁽¹⁾ OJ L 37, 10.2.2010, p. 74.

- they can ask for a risk assessment or tests to verify conformity with national rules in respect of any of the records of operation and demonstrations of network compatibility. But after the reference document is in force only for group B and C rules.

Many MS differentiate between requirements that apply to existing authorised vehicles and those applied for authorisation of new and upgraded/renewed vehicles. If an application for an additional authorisation is made for an existing non-TSI conform vehicle in a second MS, Article 25 would allow the second MS to check only the compatibility with the network of the latter MS. The second MS respects the first authorisation, even though it may have been done under an older regime, except in case of a significant safety risk. This is consistent with the need to avoid discrimination between vehicles that were first authorised in one MS and vehicles that were first authorised in another MS.

Therefore, for the purpose of clarity MS should make clear in their national rules which of the provisions apply to all subsystems in service and which rules are to be complied with only by new and upgraded/renewed subsystems to be authorised for placing into service.

5.5. *Vehicle type authorisation*

Directive 2008/57/EC lays down two procedures for type authorisation:

- a vehicle type may be first authorised (Article 26.1) on the basis of type examination without any vehicle of this type being authorised to be placed in service (the term 'type examination' is not confined to an at desk examination of drawings, it includes all necessary tests of a prototype). If a type is authorised then any vehicle authorisations should be based on a declaration of conformity to type without further checks (Article 26.3),

or

- an individual vehicle may be first authorised, in which case the type must be simultaneously authorised (Article 26.2).

Furthermore, if a vehicle obtains an additional authorisation for placing in service in a second MS, then the vehicle type must be authorised in the second MS and subsequent vehicle authorisations in this second MS shall be based upon a declaration of conformity to this type without further checks.

5.6. *Authorisations for vehicles running on TEN and off TEN*

The geographical scope of TSIs adopted so far is the rail part of the TEN-T network (Annex I). On 29 April 2010, the Commission granted a mandate to the Agency for the extension of the scope of the TSIs.

As provided for in Article 8(3) of Directive 2008/57/EC, until such time as the extension of the scope of the TSIs to cover the whole of the rail network takes effect:

(a) authorisations for the placing in service

- of vehicles and on-board control-command and signalling subsystems to be used at least partially on the part of the network that does not yet fall within the scope of the TSIs, in respect of that part of the network,
- of infrastructure, energy and trackside control-command and signalling subsystems on the parts of the network that do not yet fall within the scope of the TSIs,

are granted in accordance with the national rules referred to in Article 17(3) of Directive 2008/57/EC ⁽¹⁾;

- ##### (b) authorisations for the placing in service of vehicles to be used occasionally on the part of the network that does not yet fall within the scope of the TSIs, in respect of that part of the network, are granted in accordance with Articles 21 to 27 and the national rules referred to in Article 17(3) of Directive 2008/57/EC.

This means that, in order to be authorised for a complete network of a MS, a vehicle should be checked against two sets of rules in the first case (one for the TEN-T network and one for off-TEN), unless MS decided otherwise in their national legislation transposing Directive 2008/57/EC, but only one set of rules if the vehicle occasionally operates on off-TEN.

⁽¹⁾ Directive 2008/110/EC of the European Parliament and of the Council (OJ L 345, 23.12.2008, p. 62) amended Directive 2004/49/EC amending the content of Annex III in such a way that the reference to Article 8 is not any more necessary.

5.7. Authorisations for vehicles coming from third countries

The general principle is that before being used on a network, a vehicle coming from a third country for the first time needs to be authorised to be placed in service by the national safety authority which is competent for this network (Article 21(1)).

In the case of vehicles running between a Member State and a third country, on a network whose track gauge is different from that of the main rail network within the Community and subject to specific cases or derogations, international agreements may be applicable (Article 21(11)). This is typically the case of vehicles running between the Baltic States and third countries using the Russian gauge.

As an exception to the general rules authorisations for placing in service which have been granted before 19 July 2008 including those delivered under international agreements, such as RIC and RIV, remain valid in accordance with the conditions under which authorisations have been granted (Article 21(12)).

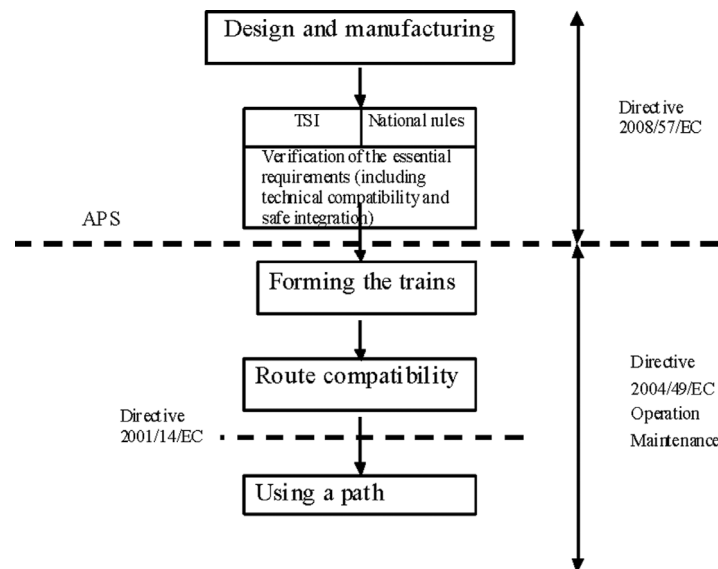
Finally, as far as international agreements are concerned, it is reminded that when the EU is a member of such agreements, the rules of such agreements are binding to the EU and its Member States. For example, when the EU will be a full member of COTIF 99 and applies the revised Appendix ATMF, vehicles authorised in a third country applying COTIF will be able to enter the EU network if they were authorised by a competent authority on the basis of requirements identical or equivalent to those in force in the EU and following a similar conformity assessment procedure. The revised ATMF Appendix specifies the conditions which would lead to a mutual recognition of authorisations issued inside and outside the EU, thus the possibility of entering in the EU without an additional authorisation, which should be the case for freight wagons similar to the old RIV regime.

6. Process to be followed after authorisation

6.1. Forming a train

Once vehicles have been authorised the RU may use them to form a train.

OPE TSI (Section 4.2.2.5 Train composition) establishes that the RU defines the rules and procedures for train formation and constraints upon this process (e.g. loading gauge of open freight wagons, placing of dangerous goods in a certain position, ensuring enough traction and braking power). Processes to conform to these rules are covered by the SMS of the RU.



6.2. Ascertaining route compatibility

The SMS of the RU covers the procedures to ensure the compatibility of the train with the route (e.g. maximum length, type of electrification, minimum radius curves). The SMS of the RU will need to take account of the provisions/conditions relating to train operation covered in the OPE TSI ⁽¹⁾ and national rules.

⁽¹⁾ Commission Decision 2006/920/EC of 11 August 2006 concerning the technical specification of interoperability relating to the subsystem Traffic Operation and Management of the trans-European conventional rail system (OJ L 359, 18.12.2006, p. 1) and Commission Decision 2008/231/EC of 1 February 2008 concerning the technical specification of interoperability relating to the operation subsystem of the trans-European high-speed rail system adopted referred to in Article 6(1) of Council Directive 96/48/EC and repealing Commission Decision 2002/734/EC of 30 May 2002 (OJ L 84, 26.3.2008, p. 1).

Before the RU procures access to the network for the train from the IM, they should first know the nature of the access that the IM has offered for sale. The RU needs to be sure that the route to which they intend to purchase access is capable of supporting the vehicles and the trains they intend to run.

Within the register of infrastructure the RUs should find the information on the nature of the infrastructure that they need in order to establish whether the train they intend to run are compatible with the specific route. For each parameter the IM should describe in the register the limit values of the interface parameters to which the route section is maintained. The register should also cover the case of conformity when the TSI presents a number of choices or leaves the IM free to use national rules.

The RUs rely upon the integrity of this information to ensure the safe operation of their trains.

The obligation of IM to make public the nature of infrastructure already exists today (Directive 2001/14/EC of the European Parliament and of the Council⁽¹⁾ as far as network access is concerned; Directive 2004/49/EC, 2008/57/EC and OPE TSI as far as operation is concerned). Until the register of infrastructure is in force, exhaustive and operational, the IM should publish this information in another form. This does not empower the IM to impose a sort of second authorisation to the vehicles/trains of the RU. Once an RU has established, by using the register of infrastructure and the technical file of vehicles, and considering the restrictions on the authorisation for placing in service of the vehicle, that the route is compatible with the vehicles it intends to use in the train, it should then refer to the provisions of the OPE TSI (particularly its Sections 4.2.2.5 'Train composition', 4.2.2.6 'Train braking' and 4.2.2.7 'Ensuring that the train is in running order') to ascertain whether there are any train related restrictions inhibiting operation on the route (e.g. speed limits, length limits, power supply limits).

Once the RU has established route-train compatibility it is in a position to operate the train.

It is important to note that Directive 2004/49/EC makes each of the IM and the RU responsible for their parts of the system. The RU is solely responsible for safe operation of its trains. The IM role is confined to the management of the infrastructure and therefore the IM has no responsibility for the operation of trains other than to issue movement authority.

6.3. *Obtaining the path (allocating capacity)*

Article 5.1 of Directive 2001/14/EC states that, 'Railway undertakings shall, on a non-discriminatory basis, be entitled to the minimum access package and track access to service facilities that are described in Annex II. The supply of services referred to in Annex II, point 2 shall be provided in a non-discriminatory manner and requests by railway undertakings may only be rejected if viable alternatives under market conditions exist'.

Therefore RUs have a right of access; RUs do not have to ask the IM for permission/authorisation/acceptance for access and IMs should not impose a 'vehicle or train authorisation' or 'acceptance' process (e.g. some form of 'route acceptance') as part of the access regime. All matters relating to safety and technical compatibility are covered by the interoperability and safety directives, only the NSA has the authority to authorise and it is the responsibility of the RU to make sure that it is using vehicles and trains which are compatible with the infrastructure.

If, during the process of authorisation an IM or RU has concerns relating to the authorisation for placing in service of a vehicle or fixed equipment of other party, it should bring this to the attention of the other party and if they are still not satisfied, raise the issue with the NSA, which should take account of these comments in the decision to authorise.

If an IM or RU has concerns relating to the use of a specific vehicle or piece of fixed equipment on a specific line, it should bring this to the attention of the other party in order to find a commonly agreed solution. If they cannot find such a solution they should raise the issue with the NSA, which takes decisions in accordance with its powers.

However whilst the IM has no permissioning role in vehicle authorisation, under Directive 2001/14/EC they are responsible for capacity allocation. The allocation of a train path is in fact the act of allocating rail infrastructure capacity to trains. In some cases there may not be enough capacity to accommodate all the applications of all the RUs applying for capacity. In this case the rules of Directive 2001/14/EC apply.

7. **Modifications in a subsystem or vehicle that is already authorised**

7.1. *Procedure to be followed*

Subsystems shall comply with the TSIs in force at the time of their placing in service, upgrading or renewal (Article 5(2)). However, the fact of being upgraded or renewed does not lead automatically to a new authorisation for placing in service of that subsystem.

⁽¹⁾ OJ L 75, 15.3.2001, p. 29.

In accordance with Article 20 of Directive 2008/57/EC, the MS taking into account the file submitted by the contracting entity or manufacturer and the implementation strategy of the TSIs, will decide whether the extent of the works means a new authorisation for placing in service. In the case of a new authorisation, the MS decide to what extent the TSIs need to be applied to the project. A new authorisation for placing in service is required whenever the overall safety level of the subsystem concerned may be adversely affected by the works envisaged (where the works bring about a significant change to the design operating state of the subsystem — technical characteristics covered by TSIs or national technical rules). If the design operating state is not changed then no new authorisation is required.

As far as the EC verification procedure of subsystems is concerned, since the upgrade or renewal may not concern the whole subsystem, the applicant may apply for an 'intermediate statement verification' for the part upgraded/renewed and the related certificate issued by the NoBo and declaration issued by the applicant (Annex VI⁽¹⁾). However, where a new authorisation for placing in service is required, an 'EC' certificate and declaration of verification procedure is also required for granting authorisation. In this case the relevant certificates and declaration indicate the precise reference to TSIs or the parts thereof, which were not examined in terms of their conformity during the 'EC' verification procedure.

7.2. *Link between specific cases, derogations and partial application of TSIs in the case of renewal/upgrading*

Directive 2008/57/EC does not provide for a hierarchy between Derogations (Article 9), Specific cases (Article 5(5)) and partial application of TSIs in the case of renewal/upgrading (Article 20).

As regards the choice between future derogations to be requested and specific cases to be written in the TSI, the following principles are recommended to be considered by the relevant parties in order to reduce bureaucracy:

- identified permanent non-compliance with the target system specified in Chapter 4 of TSIs should be dealt with through specific cases: this would avoid numerous unnecessary derogation requests (the need for the specific case must be declared by the MS during the TSI drafting, so that these specific cases may be included in the TSI),
- identified temporary or local/one off cases of non-compliance with a TSI should be dealt with through future derogation requests: this would avoid numerous unnecessary specific cases in the TSI.

When implementing a project, the following questions should be asked in the following order:

- (a) is it possible to implement the target system?
- (b) if not, is there a specific case specified in the TSI?
- (c) if not, is this a case for a derogation request?
- (d) if not and if it is an upgrading/renewal project, what part of the target system can be applied? (In some cases, the implementation strategy of a TSI may have provisions related to this subject.)

In cases (a) and (b) the MS will be able to take decisions without intervention from the Commission or other MS. In cases (c) and (d) the Commission and the other MS will have access to the information and, in some cases, will be able to intervene:

- either through a Comitology procedure (Commission and all MS),
- or through a bilateral discussion (Commission and relevant MS).

In cases (c) and (d), the partial application of the TSI is not recommended in the case of infrastructure and track-side equipment, because this may hamper the free movement of trains for a long period. Partial application of TSI in the case of rolling stock is less onerous as it affects only to the keeper of the vehicle and the RUs using it. Finally, the provision of information requested under Article 20(2) is valuable in determining both the future developments/revisions of the TSIs and the progress of interoperability. It also allows the Commission to verify the correct application of Directive 2008/57/EC.

As a reminder, specific cases and derogations may also exist in the case of new projects.

⁽¹⁾ Annex VI is currently under modification by the Commission.

8. Roles and responsibilities

Directive 2008/57/EC defines a series of roles and responsibilities for a set of entities. In some cases an entity may fulfil more than one of these responsibilities. In some cases these entities may sub-contract particular tasks, but they may not create new requirements, roles or responsibilities. A subcontractor is bound by the same constraints as the responsible entities and must act as the entities. The subcontracting entities remain fully responsible.

8.1. Applicant for the authorisation for placing in service

The 'applicant' is not a single entity; it is the party making the relevant application. Directive 2008/57/EC provides for the possibility of applicants submitting applications for the following:

- Intermediate Statement Verifications,
- EC verification,
- verification according to national rules,
- CSM assessment (Regulation (EC) No 352/2009),
- subsystem authorisation for placing in service,
- vehicle first authorisation for placing in service,
- vehicle additional authorisation for placing in service,
- authorisation of a vehicle type.

The applicant for the authorisation for placing in service of a subsystem:

- makes the application for authorisation for placing in service of a subsystem,
- ensures that the subsystem has undergone the verification procedure and provides the NSA with the necessary evidence,
- could be responsible for the following under Article 20
 - 'In the event of renewal or upgrading, the contracting entity or the manufacturer shall send the MS concerned a file describing the project',
- where appropriate, invites the CSM or RA assessment body to produce the safety assessment report.

In the same way, the applicant for vehicle authorisation:

- makes the application,
- submits a 'file' (Article 23 — TSI conform vehicles) or a 'technical file' (Article 25 — non-TSI conform vehicles) in the case of additional authorisations.

Note 1: If an RU or an IM happens to be an applicant for authorisation for placing in service they bear all the responsibilities allocated to the applicant for authorisation for placing in service, but this is independent from their activity as RU or IM. The fact that it is an RU and IM (or even another company) has no impact on its roles and responsibilities as applicant for an authorisation for placing in service.

Note 2: the applicant for the authorisation for placing in service is not necessarily the one who arranges for the 'EC' verification procedure and the national verification procedure. E.g. for a vehicle the manufacturer may arrange for a complete verification procedure (select and invite a NoBo(s), establish the 'EC' declaration, arrange for the verification of conformity with national rules by the DeBo(s) and arrange for the risk assessment) and then the vehicle owner or keeper may apply for the authorisation for placing in service.

8.2. *Railway Undertaking (RU)*

RUs are one of the entities (along with manufacturers, keepers, etc.) that may act as applicants.

Article 15(3) of Directive 2008/57/EC makes reference to the obligation placed by Directive 2004/49/EC on SMSs of RUs to ensure that subsystem and vehicles meet the essential requirements. It therefore includes the obligation to maintain technical compatibility. For technical compatibility to be maintained the SMS of the RU ensures that vehicles it operates are maintained in conformity with the TSIs and national rules defining the requirements for technical compatibility between vehicles and infrastructure.

8.3. *Infrastructure Manager (IM)*

This Section only applies to the IM in its capacity as an infrastructure manager only, not as an operator of inspection/maintenance/works trains.

The IM has a direct responsibility in the context of facilitating the authorisation process. In the case of additional tests required by the NSA Article 23(6) requires that 'the infrastructure manager, in consultation with the applicant, shall make every effort to ensure that any tests take place within 3 months of the applicant's request.'

Moreover, Article 15(3) makes reference to the obligation in Directive 2004/49/EC for IM's SMS to ensure that their subsystems meet the essential requirements. This leads to the obligation of maintaining technical compatibility.

For an IM to meet its obligation to maintain technical compatibility (along with the other essential requirements) whilst vehicles are being used on the network, the IM as part of its SMS should maintain his subsystems in conformity with the TSIs and national rules that define the requirements for technical compatibility between vehicles and infrastructure. Where the network does not conform to TSIs or national rules, the IM should maintain it to a declared set of limits published in the RINF.

In order to maintain technical compatibility the IM — as part of its SMS — should inform RUs of the nature of the infrastructure of its various route sections by describing the parameters referring to the specifications of the register of infrastructure. To ensure that compatibility of the route section with trains is maintained over time the IM should manage and maintain the infrastructure to the limits declared and advise the RUs of any changes to the nature of the infrastructure.

IMs are also one of the entities (along with manufacturers, keepers, etc.) that may act as applicants.

8.4. *Entity in Charge of Maintenance (ECM)*

Article 14(a) of Directive 2004/49/EC amended by Directive 2008/110/EC states that, before it is placed in service, each vehicle must have an ECM assigned to it.

Bearing in mind that authorisation to place in service is independent of the operation of a vehicle by an RU or the maintenance of the vehicle by an ECM, and that Directive 2004/49/EC relates to the operation (use) and maintenance of vehicles, the ECM may be assigned either before or after a vehicle has been authorised to be placed in service, but always before it is registered in the national vehicle register (ECM is a mandatory field in the NVR) and before it is actually placed in service or used on the network.

It also follows that the ECM has no role in, nor any relevance to, the authorisation process.

8.5. *Notified Body (NoBo)*

Notified Bodies verify conformity with TSIs and draw up the 'EC' certificate of verification intended for the applicant.

Article 18(2) of Directive 2008/57/EC states that NoBo verification 'shall also cover verification of the interfaces of the subsystem in question with the system into which it is incorporated, based on the information available in the relevant TSI and in the registers provided for in Articles 34 and 35.'

This implies that the NoBo has a role in checking technical compatibility with other subsystems, which is consistent with the fact that technical compatibility is covered by TSIs. The scope of these checks is limited to the relevant TSIs.

Each NoBo compiles a technical file in respect of the verifications they have carried out.

8.6. *Designated Body (DeBo)*

Article 17 of Directive 2008/57/EC says 'On that occasion, (when national rules apply) MS shall also designate the bodies responsible for carrying out, in the case of these technical regulations, the verification procedure referred to in Article 18' (the Procedure for establishing the 'EC' declaration of verification).

This indicates that where national rules apply, the DeBo carries out the same procedure as the NoBo and compiles a technical file covering the scope of their verification.

8.7. *National Safety Authority (NSA)*

NSAs act on behalf of the MS to grant authorisation for placing in service.

The tasks of the NSA are described in Article 16 of Directive 2004/49/EC. Regarding the decision making procedure, the NSA decides within 4 months after all requested information has been provided, without prejudice to specific time limits set out in Article 21 of Directive 2008/57/EC. This means that the time limit of 4 months is applicable, for example, to the case of a request of first authorisation for placing a vehicle in service.

Due to the fact that the procedures can take several months, it is recommended that the rules to be applied by the NSA for a specific authorisation process are those that were in force at the date of the application and that no new rule is imposed during the subsequent process.

In the case of urgent measures that MS may consider imposing as a consequence of accidents or incidents, MS should take care to recognise that the SMS of the RU is the primary mechanism for management of new risks to the operation of vehicles that may have been discovered in the course of accident/incident investigations or findings in the context of supervision.

Even if an MS believes that a new rule for authorisation for placing in service is urgently required it has to follow the procedures specified in applicable European legislation, including notification of a draft to the Commission under Directives 98/34/EC or 2004/49/EC. Such rules are laid down, applied and enforced in an open and non-discriminatory manner, and they should not create unnecessary additional barriers to the European rail transport system.

In addition, the experience of the follow-up given to the dramatic accident of Viareggio in June 2009 has shown that competent authorities should exchange information through the network/working group established by ERA before taking urgent national measures; this coordination mechanism improves the quality and the neutrality of the analysis and a better informed choice of the adequate measures, be it mandatory or voluntary, be it at European or national level.

8.8. *Member State (MS)*

MS are responsible for transposing Directives into national law and enforcing compliance.

In respect of authorisations for placing in service the MS has — according to Article 17 of Directive 2008/57/EC — the responsibility to draw up and notify the list of national rules to cover the essential requirements in case of derogation, specific case (if the specific case so requires), open points or non-existence of the relevant TSI. The MS also designate the bodies responsible for the verification of conformity with national rules. MS also make them available to IMs, RUs and applicants for authorisation for placing in service.

The MS should in the absence of relevant TSIs rely on, make public, and enforce rules covering the Essential Requirements including that of technical compatibility between vehicles and their network. In order to preserve national interoperability and avoid discrimination between applicants these rules should be at the same level of detail as TSIs and unambiguous in their requirements (i.e. they should specify values for the relevant parameters and conformity assessment methods).

MS are also responsible for notifying the NoBos and DeBos.

8.9. *Assessment body in the context of the CSM on RA (CSM assessment body)*

A CSM assessment body is involved in the verification of safe integration when required by Article 15(1) of Directive 2008/57/EC as described in the CSM on RA.

The NSA may act as the CSM assessment body in the context of granting authorisation for placing in service:

- in the context of the 'EC' verification procedure of the subsystem, where the TSI requires the intervention of a CSM assessment body (Article 7.3 of CSM on RA),
- as prescribed in the CSM on RA (Articles 2(2)(b), 5(1)(a) and 7(2) of CSM on RA).

However, whenever a NSA acts as a CSM assessment body, this task should be functionally separated and carried out by persons that are not in charge of the application of authorisation for placing in service and the related decision granting authorisation.

9. Registers

9.1. Network statement

The network statement is a requirement set out in Article 3 of Directive 2001/14/EC as a tool to grant access rights, so that the IM can provide the necessary information on, amongst other things, the 'nature of the infrastructure' available, which will allow the RU to request capacity on a route. The RU should know the nature of infrastructure on the route so that he can establish that the route is compatible with his train.

Further to an analysis of IMs existing network statements, it appears that the information provided is not harmonised and insufficient for the purpose of checking the technical compatibility between the train and the network. In the context of the recast of Directive 2001/14/EC, in order to prevent any burdensome tasks and overlaps, the network statement and the register of infrastructure must be consistent, as far as the information related to 'the nature of the infrastructure' is concerned.

9.2. Register of infrastructure (RINF)

The register of infrastructure was introduced as a tool to ensure compatibility between trains and routes and to describe the conformity of new, renewed and upgraded infrastructure placed into service under Directive 2001/16/EC. Its scope was limited to the TEN-T. The content of the register of infrastructure had to be described in the relevant TSIs.

Article 35 of Directive 2008/57/EC confirmed that approach and extended the scope of the register of infrastructure to the whole of the network.

As a consequence the extended register of infrastructure should provide the information needed in order to establish the compatibility in a harmonised manner and to ensure application of Directive 2008/57/EC as far as the nature of the infrastructure is concerned in consistency with Directive 2001/14/EC.

Thus, when the 'nature of infrastructure' changes in a way that affects compatibility of trains the description of the network should be updated according to the specifications to be adopted (Article 35).

To make the compatibility check efficient the parameters of the register of infrastructure and the European register of authorised vehicle type should be aligned.

9.3. European register of authorised type of vehicles (ERATV)

The European Register of Authorised Types of Vehicles should identify in a one-to-one manner all types of vehicles authorised for placing in service on the Community rail network in order to serve the following purposes:

- to allow the NSAs to simplify the authorisation for placing in service of vehicles which conform to an authorised type,
- to facilitate the cross-acceptance process by providing additional information on the authorised types of vehicle,
- to allow any organisation interested in running a railway related business (railway undertaking, vehicle owner or keeper, leasing company, etc.) to know which are the vehicle types that are authorised to be placed in service in each MS and to give the applicants a reasonable certitude of the outcome of an application for authorisation of placing in service of a vehicle,
- to allow the NSAs, investigation bodies, etc. to retrieve the main technical characteristics of any vehicle authorised to be placed in service,

- to allow the Agency to retrieve information on the types authorised in different MS distinguishing between TSI conform vehicles and non-TSI conform vehicles, and
- to allow any organisation interested in running a railway related business to gain a general idea of which vehicle types might be compatible with a particular network. This register should not serve as the final check of technical compatibility of a train with a network or route section of a network. This is because a train may not be compatible with a route, even when all the vehicles of which it consists are compatible with the same route. Train-route compatibility is covered by the provisions of the OPE TSI (see Section 5 of this document),
- to know the restrictions attached to a vehicle type.

9.4. National vehicle register (NVR)

NVR is to be used to identify any authorised vehicle and to serve the following purposes:

- record of authorisation and the identification number allocated to vehicles,
- looking for European-wide, brief information related to a particular vehicle,
- enable contact with the owner and keeper, and
- identify the ECM of any vehicle in service.

9.5. Reference Document

Article 27 of Directive 2008/57/EC requires the adoption of the reference document related to national rules applied by MS when placing vehicles in service. It is used:

- to define the parameters to be checked for vehicle authorisation — which should be the same parameters as the ones required to be defined in the TSI; and
- to record the equivalence and classification of national vehicle authorisation rules to facilitate mutual recognition.

The reference document will be used for all authorisations for placing vehicles in service which are subject to Directive 2008/57/EC and where conformity with national rules is required. TEN and off-TEN lines are concerned. As regards to TSI conform vehicles, it will enable to verification of the technical compatibility with the network, and of the compliance with the national rules related to specific cases and closure of open points related to the technical compatibility between the vehicle and the network. As regards to non-TSI conform vehicles the reference document will allow comparison of national rules related to the list of parameters to be checked by NSAs when granting authorisation, except for the aspects covered by a TSI, if any.

9.6. Vehicle keeper marking list (VKM)

The updated register is regularly published on the Agency's website (currently it is published every first Wednesday of the month).

A Vehicle Keeper Marking (VKM) is a code, consisting of 2 to 5 letters that is inscribed on each vehicle.

The VKM is representation of the full name or abbreviation of the vehicle keeper, if possible in a recognisable manner.

A VKM is unique in all countries covered by OPE TSI and all countries that enter into an agreement that involves the application of the system of vehicle numbering and vehicle keeper marking as described in OPE TSI.

A VKM can be used in the network only after publication by the central body (ERA or OTIF).

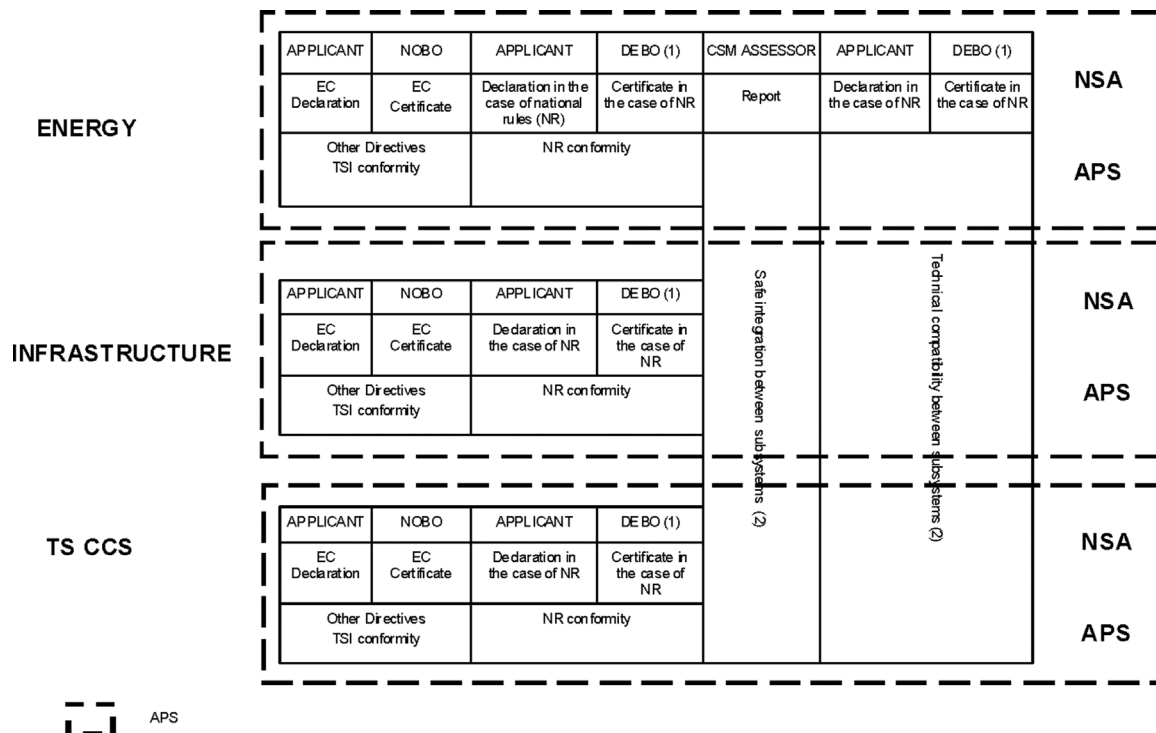
10. Graphics related to the authorisation procedures of Directive 2008/57/EC

The procedures to be followed for the authorisation for placing in service of subsystems and vehicles are illustrated in the attached figures.

Remark: Despite of the apparent complexity of the procedures, it has to be noted that several actions can be carried out by the same actor at the same time. In addition, several additional authorisation procedures for the same vehicle can be carried out at the same time as the first authorisation.

Figure 1

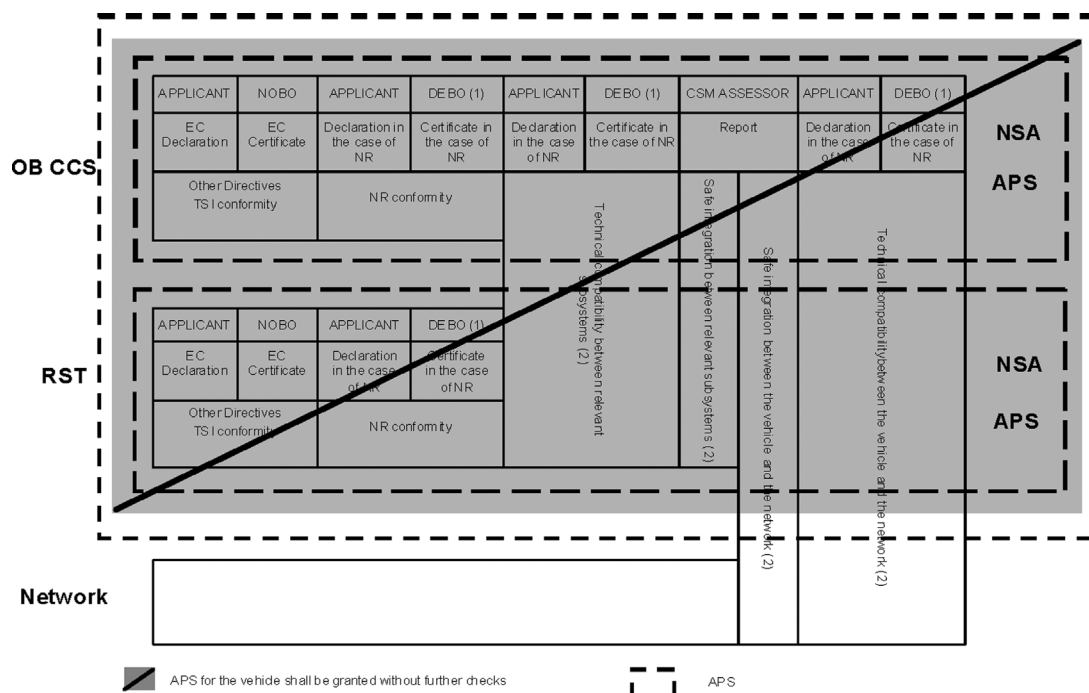
Art. 15 APS of APS of fixed fixed subsystems



- (1) For the sake of the graphic the DeBo tasks have been split but it could be carried out by the same DeBo. In any case there must be only one certificate in the case of NR for each subsystem.
- (2) These verifications could have been already done in the context of the 'EC' verification procedure if the TSI provides for it. In addition, all these verifications can be combined in one step.

Figure 2

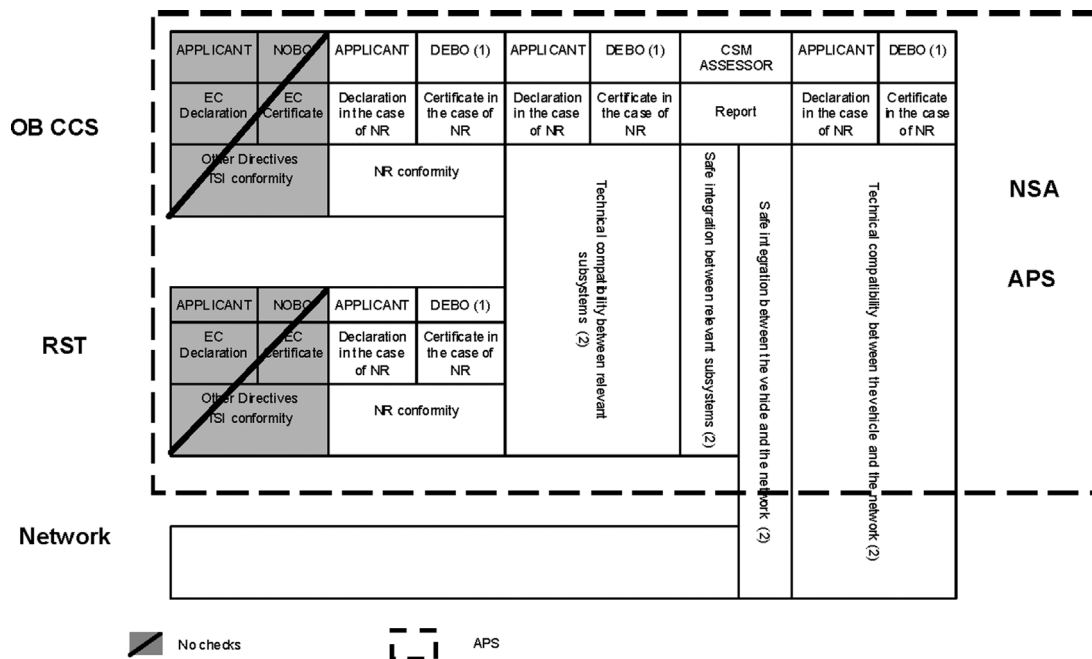
Art. 22 (2)(a) 1st APS TSI-conform conform vehicles



- (1) For the sake of the graphic the DeBo tasks have been split but it could be carried out by the same DeBo during the APS of each subsystem. In any case there must be only one certificate in the case of NR for each subsystem.
- (2) During the APS of each subsystem, these verifications could have been done in the context of the 'EC' verification procedure if the TSI provides for it. In addition, all these verifications can be combined in one step.

Figure 3

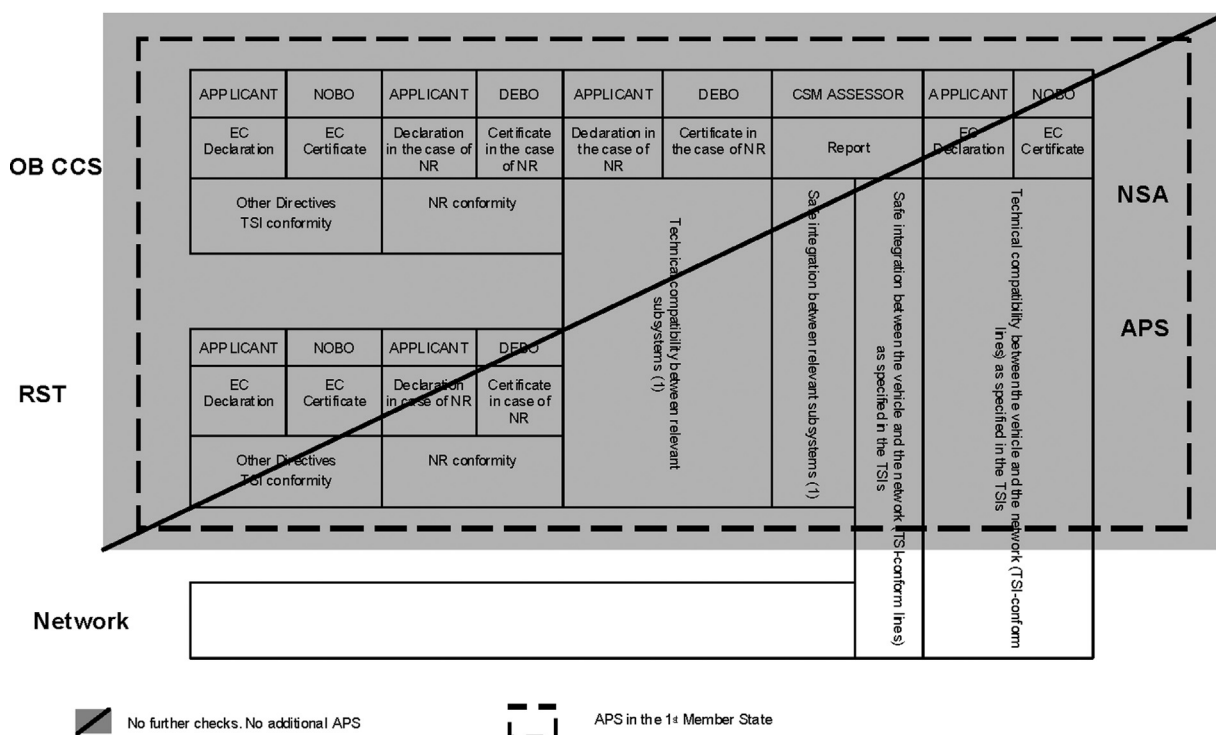
Art. 22(2)(b) 1st APS TSI-conform conform vehicles



- (1) For the sake of the graphic the DeBo tasks have been split but it could be carried out by the same DeBo. In any case there must be only one certificate in the case of NR for vehicle.
- (2) These verifications could have been already done in the context of the 'EC' verification procedure if the TSI provides for it. In addition, all these verifications can be combined in one step

Figure 4

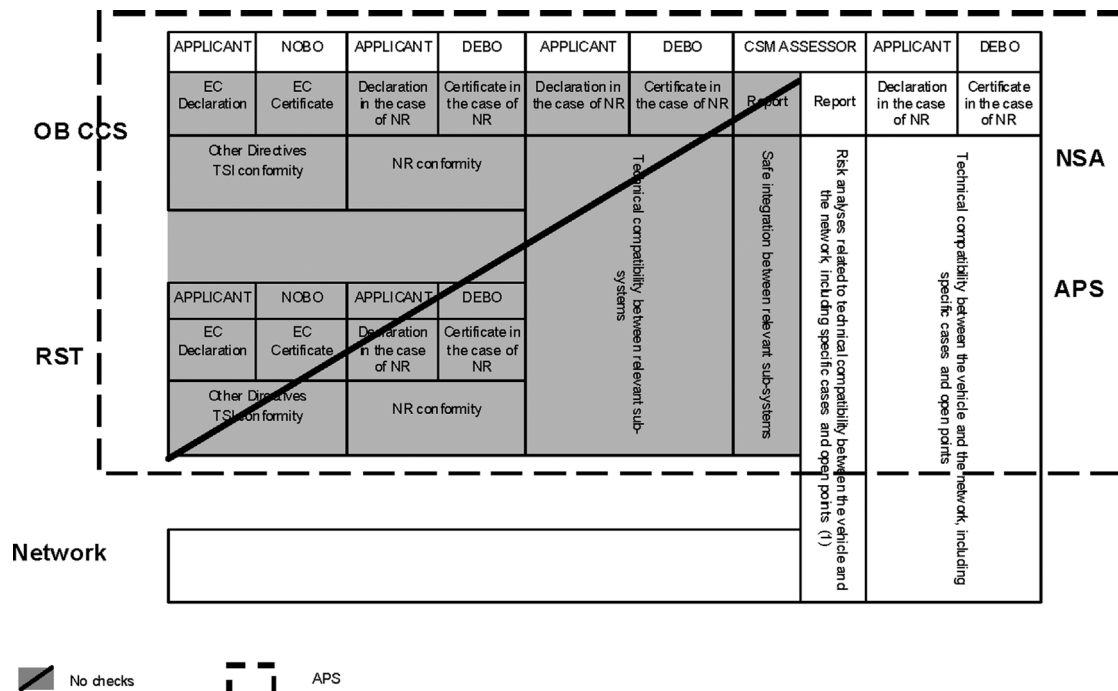
Art 23 (1) Additional APS TSI-conform «going everywhere» vehicles



- (1) During the 1st APS, these verifications could have been done in the context of the 'EC' verification procedure if the TSI provides for it.

Figure 5

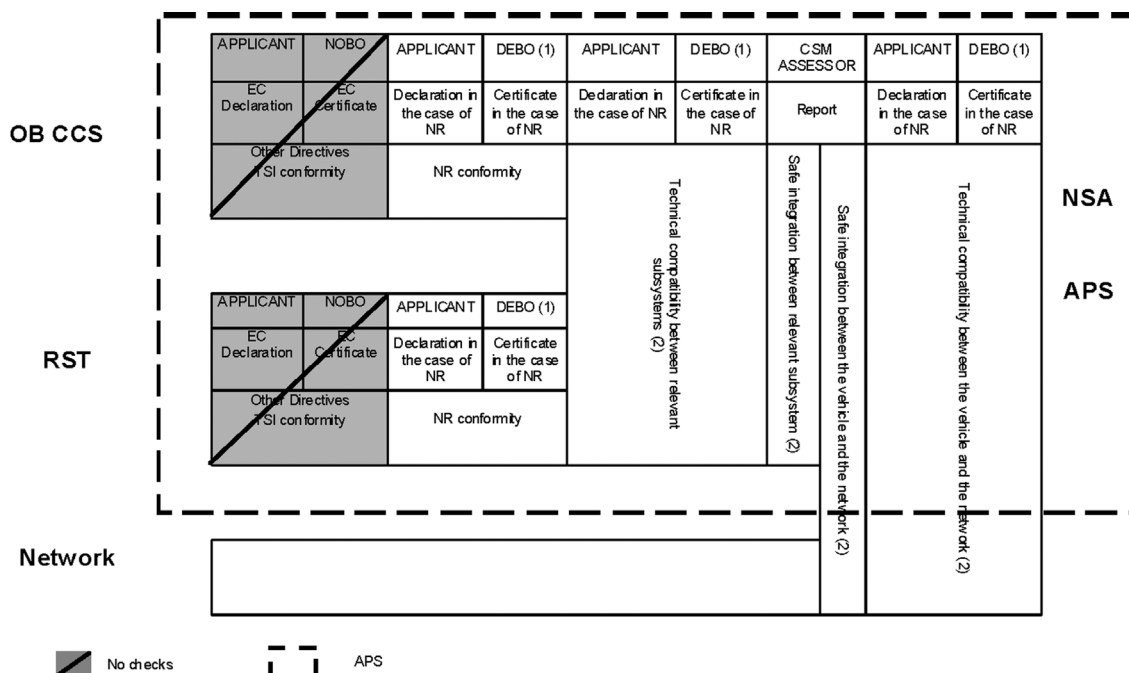
Art 23 Additional APS TSI-conform vehicles



(1) Only if the 2nd NSA requests it. Only B and C rules can be invoked.

Figure 6

Art 24 1st APS non-TSI conform vehicles

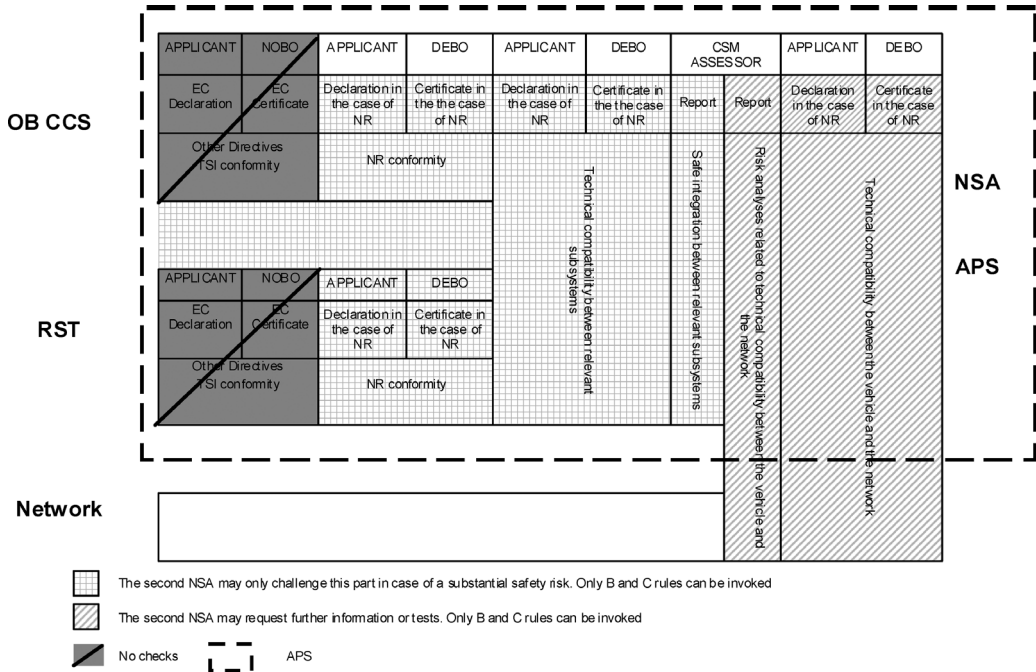


(1) For the sake of the graphic the DeBo tasks have been split but it could be carried out by the same DeBo. In any case there must be only one certificate in the case of national rules for each vehicle

(2) These verifications could have been already done in the context of the 'EC' verification procedure if the TSI provides for it. In addition all these verifications can be combined in one step

Figure 7

Art 25 Additional APS non-TSI conform vehicles



LIST OF ABBREVIATIONS

Abbreviation	Definition
CCS	Control-Command and Signalling
CSM on RA	Common Safety Methods on Risk Assessment
DeBo	Designated Body
ECM	Entities in Charge of Maintenance
ERATV	European Register of Authorised Type of Vehicles
IC	Interoperability Constituents
IM	Infrastructure Manager
MS	Member State(s)
NNTR	Notified National Technical Rules
NoBo	Notified Body
NSA	National Safety Authorities
NVR	National Vehicle Register
OJEU	Official Journal of the European Union
OPE TSI	Traffic Operation and Management TSI
RINF	Register of Infrastructure
RU	Railway Undertaking
SMS	Safety Management System
TEN-T	Trans-European Network for Transport
TSI	Technical Specifications for Interoperability
VKM	Vehicle Keeper Marking List

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