



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR MOBILITY AND TRANSPORT
DIRECTORATE B – EUROPEAN MOBILITY NETWORK
Single European Rail Area

Draft working document

Communication of draft technical regulations and notification of rules related to the railway system under Directives 98/34/EC, 2004/49/EC and 2008/57/EC – clarification of objectives, scope and procedures

This working document is a draft as discussed and agreed in the Task Force on National Safety Rules on 19 January 2012. This document was discussed and supported in the RISC63 session on 7 and 8 March 2012. It will be further discussed at the Committee set up under Directive 98/34/EC.

1. INTRODUCTION

EU Directives for railway safety (Directive 2004/49/EC) and interoperability (Directive 2008/57/EC) are the basis for the progressive creation of the internal market of railway equipment and services. They aim at improving rail system interoperability and maintaining a high level of safety. Harmonising railway rules at EU level is possible by introducing technical specifications for interoperability and common safety provisions.

At the same time, Directive 98/34/EC (which repealed 83/189/EEC) sets up a notification procedure for the Member States regarding draft technical regulations on products and Information Society services, with the view to avoid obstacles to intra-Union trade and to ensure the free movement of goods and Information Society services.

The final objectives of the notification process of Directive 98/34/EC and the notification processes contained within Directives 2004/49/EC and 2008/57/EC are to ensure transparency and to prevent trade barriers.

This note aims at clarifying the objectives, scope and application of the notification procedures contained within these three instruments¹, as well as avoiding redundant notifications and unnecessary administrative burden. Further work will be done to clarify National Safety Rules.

2. COMMUNICATION OF DRAFT TECHNICAL REGULATIONS UNDER DIRECTIVE 98/34/EC²

According to Article 8 of Directive 98/34/EC, the Member States of the European Union are obliged to communicate to the Commission any draft technical regulation concerning products (Art. 1 (1)) and Information Society Services (Art. 1 (2)) before they are adopted in national law³. Member States use the TRIS-Database (Technical Regulations Information System) to follow their notification obligation .

- This system is of a preventive nature: information is provided when technical regulations relating to products or rules on Information Society services are still at the draft stage, and may be amended in order to conform to the principles of the internal market and the EU law in force.

¹This document does not intend to deal with other Directives, such as the Train Drivers Directive 2007/59/EC or the Dangerous Goods Directive 2008/68/EC

² Detailed guidance is available on http://ec.europa.eu/enterprise/tris/about/index_en.htm

³ Without prejudice to exemptions in Article 10 of Directive 98/34/EC

- Once initiated by a Member State, the procedure according to Directive 98/34/EC automatically opens a standstill period⁴ of three months which cannot be closed by the Commission. The Commission and the Member States have the right to issue detailed opinions and/or comments. In case of a detailed opinion, the standstill period is automatically prolonged⁵ and according to Article 9 (2), the Member State concerned shall report to the Commission the action, it proposes to take. The Commission shall comment on this reaction.
- The Commission and Member States examine and monitor the texts within the standstill period of three months (Art. 9(1)). The comments or detailed opinions of the Commission or Member States may concern only aspects which may hinder intra-Union trade or, in respect of rules on Information Society services, the free movement of these services or the freedom of establishment of service operators. In the case of "fiscal or financial measure" these reactions cannot concern the fiscal or financial aspects of the measure.
- The system also permits the Commission to block under specific circumstances a draft legislation for 12 or 18 months⁶ in order to facilitate harmonisation work at Union level on the matter covered by the notified measure (Art. 9 (3) to (5)).

As regards the consequences of non-notification of a draft technical regulation or of adoption of the notified measure before the end of the standstill period, the European Court of Justice (Case C-194/94 CIA Security International of 30 April 1996 and Case C-226/97 Unilever of 26 September 2000) has decided that this is a breach of the notification obligation and of the obligation of postponement of adoption of Directive 98/34/EC and that it constitutes a procedural defect which renders those non-notified regulations or regulations adopted before the end of the standstill period inapplicable and unenforceable vis-à-vis third parties.

Finally, in accordance with Article 8(3) of Directive 98/34/EC the technical regulations and rules on Information Society services as adopted by the Member State has to be communicated to the Commission so that the latter can check if the comments were duly taken into account.

Definition of technical regulation:

According to Article 1.11 "*technical regulation*" covers "*technical specifications and other requirements [for products] or rules on services, including the relevant administrative provisions, the observance of which is compulsory, de jure or de facto, in the case of marketing, provision of a service, establishment of a service operator or use in a Member State or a major part thereof, as well as laws, regulations or administrative*

⁴ Without prejudice to exemptions in Article 9 of Directive 98/34/EC

⁵ For four months in case of voluntary agreements and six months in case of other draft technical regulation

⁶ This period can be:

- 12 months from the date of receipt of the notification, if the Commission announces its intention of proposing or adopting a directive, regulation or decision on the matter or the Commission announces its finding that the draft technical regulation concerns a matter which is covered by a proposal for a directive, regulation or decision presented to the Council
- 18 months from the date of receipt of the notification, if the Council adopts a common position

provisions of Member States, except those provided for in Article 10, prohibiting the manufacture, importation or use of a product.”

3. NOTIFICATION OF NATIONAL TECHNICAL RULES UNDER DIRECTIVE 2008/57/EC

Section 3.1.4 of Commission Recommendation 2011/217⁷ describes NTR. According to Article 17(3) of Directive 2008/57/EC “*Member States shall draw up, for each subsystem, a list of the technical rules in use for implementing the essential requirements and notify this list to the Commission when:*

- no relevant TSI exists, or*
- a derogation has been notified under Article 9, or*
- a specific case requires the application of technical rules not included in the relevant TSI.*

This list shall be notified either:

- each time the list of technical rules that, pursuant to Article 16(3) of Directive 96/48/EC and Article 16(3) of Directive 2001/16/EC, was required to be notified by 30 April 2005 is changed, or*
- after the derogation has been notified, or*
- after publication of the TSI concerned.*

On that occasion, Member States shall also designate the bodies responsible for carrying out, in the case of these technical regulations, the verification procedure referred to in Article 18.

...

In order to prevent further barriers from being created, and with a view to taking forward the classification of national rules in accordance with Article 27, the Commission shall monitor the introduction of new rules by the Member States. If the Commission considers that the new rule constitutes a means of arbitrary discrimination or a disguised restriction on rail transport operations between Member States, a decision, addressed to the Member State concerned, shall be adopted in accordance with the regulatory procedure referred to in Article 29(3).”

⁷ Commission Recommendation 2011/217/EU 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 (OJ L 95, 8.4.2011, p. 1–29)

Only rules within the scope of national measures implementing of the Directive 2008/57/EC must be notified, taking into account the possibility for exclusions in Article 1 (3) of the same Directive.

Member States use the Notif-IT database in order to notify national technical rules.

4. NOTIFICATION⁸ OF NATIONAL SAFETY RULES UNDER DIRECTIVE 2004/49/EC

Article 8 (1) of the Railway Safety Directive requires Member States to establish national safety rules. The term ‘national safety rules’ is defined in Article 3 (h) of the same directive: *“all rules containing railway safety requirements imposed at Member State level and applicable to more than one railway undertaking, irrespective of the body issuing them”*. Article 8 (2) obliged Member States to notify all relevant national safety rules in force before 30 April 2005.

According to Article 8 (4) *“Member States shall forthwith notify the Commission of any amendment to the notified national safety rules and of any new such rule that might be adopted, unless the rule is wholly relating to the implementation of TSIs.”* National safety rules that are to be notified to the Commission according to the procedure described in Article 8 are classified in Annex II; they include:

- *“rules concerning existing national safety targets and safety methods”* (type 1);
- *“rules concerning requirements on safety management systems and safety certification of railway undertakings”* (type 2);
- *“common operating rules of the railway network that are not yet covered by TSIs, including rules relating to the signaling and traffic management system”* (type 4);
- *“rules laying down requirements on additional internal operating rules (company rules) that must be established by infrastructure managers and railway undertakings”* (type 5);
- *“rules concerning requirements on staff executing safety critical tasks, including selection criteria, medical fitness and vocational training and certification as far as they are not yet covered by a TSI”* (type 6);
- *“rules concerning the investigation of accidents and incidents”* (type 7).

Article 8 (5) to (7) specifies the following procedure for introducing new national rules:

- *“In order to keep the introduction of new specific national rules to a minimum and thus prevent further barriers from being created, and with a view to the gradual*

⁸ Submission of draft NSR and notification of adopted NSR

harmonisation of safety rules, the Commission shall monitor the introduction of new national rules by Member States” (Article 8 (5)).

- *“If, after the adoption of CSTs, a Member State intends to introduce a new national safety rule which requires a higher safety level than the CSTs, or if a Member State intends to introduce a new national safety rule which may affect operations of railway undertakings from other Member States on the territory of the Member State concerned, the Member State shall consult all interested parties in due time ...” and the following procedure shall apply (Article 8(6)): “[t]he Member State shall submit the draft safety rule to the Commission for examination, stating the reasons for introducing it” (Article 8 (7)).*
- *“If the Commission finds that the draft safety rule is incompatible with the CSMs or with achieving at least the CSTs, or that it constitutes a means of arbitrary discrimination or a disguised restriction on rail transport operations between Member States, a Decision, addressed to the Member State concerned, shall be adopted in accordance with the procedure referred to in Article 27(2)” (Article 8 (7)).*
- *“If the Commission has serious doubts as to the compatibility of the draft safety rule with the CSMs or with achieving at least the CSTs, or considers that it constitutes a means of arbitrary discrimination or a disguised restriction on rail transport operations between Member States, the Commission shall immediately inform the Member State concerned, which shall suspend the adoption, entry into force or implementation of the rule until a Decision is adopted, within a period of six months, in accordance with the procedure referred to in Article 27(2)” (examination procedure) (Article 8 (7)).*

Only rules within the scope of national measures implementing of the Directive 2004/49/EC must be notified, taking into account the possibility for exclusions in Article 2 (2) of the same Directive.

Member States use the Notif-IT database in order to notify according to Directive 2004/49/EC.

5. OVERLAPS

Draft technical regulations which should be communicated under Directive 98/34/EC relate to products and rules on Information Society services. National Safety Rules according to Annex II of Directive 2004/49/EC do neither relate to products, nor Information Society services. Therefore, we consider that there is no overlap between these two sets of rules.

Only type 4 and type 6 NSR according to Annex II of Directive 2004/49/EC may relate to TSIs and may be covered by NTR. We consider that the only relevant TSI for these rules is the TSI Operation and Traffic Management.

Draft National Technical Rules that set out requirements for products must be notified under Directive 98/34/EC and after their adoption they must also be notified under Directive 2008/57/EC.

6. IT TOOL TO BE USED FOR NOTIFICATION, SUBMISSION AND COMMUNICATION

6.1. Notif-IT

The Commission decided – with involvement of the Committee on the interoperability and safety of the European rail system (RISC) – that NSR and NTR are only to be notified through Notif-IT. There are two different modules for NSR and NTR. With the view of reducing workload, many entered items can be retrieved and re-used for new notifications or when a rule has to be notified as both NSR and NTR.

The national safety rules and the national technical rules in use have to be notified via Notif-IT application, which is described in the [Notif-IT User Guide](#) (direct link to Notif-IT: <https://webgate.ec.europa.eu/risdb/home.do>).

6.2. TRIS-Databse

The communication of draft national technical rules which have to be notified at draft stage in the framework of Directive 98/34/EC is made **via TRIS**.

TRIS (Technical Regulations Information System) is a database developed by the Commission in order to facilitate the access for Member States and economic operators to the national technical regulations. It contains the notified texts and their translations in all EU languages and is accessible on the Europa website <http://ec.europa.eu/enterprise/tris>.

7. EXAMPLES

- **Notification 2010/502/D**: draft Technical Regulations for Tramways Electrical Systems (TRStrab EA): Taking into account the possibility of Article 1(3) of Directive 2008/57/EC to exclude local systems (such as, for example, metros, trams and light rail systems), technical regulations regarding products in this area in case of exclusion need to be notified in the framework of Directive 98/34/EC at a draft stage. Therefore, only the notification through TRIS is needed.

- **Notification 2010/365/NL:** draft decree laying down rules for the accessibility of public transport and the adaptations to be made to ensure it (Public Transport (Accessibility) Decree): The draft decree provides for generic measures to improve the accessibility of vehicles, stops, stations and travel information (both in vehicles and in stations) so as to ensure non-discrimination against disabled persons. It is in the scope of Directive 2008/57 because Annex II of that Directive also includes the needs for persons with reduced mobility and also because of the interaction with the TSI PRM adopted by the Commission on 21.12.2007⁹. With regard to Directive 98/34/EC, inter alia Article 4 contains technical requirements on products; moreover, the draft concerns rules on a travel information system (Information Society Service). In this case, the rule shall be notified through TRIS already at the draft stage, and also through Notif-IT when the rule enters into force.

⁹ 2008/164/EC: Commission Decision of 21 December 2007 concerning the technical specification of interoperability relating to persons with reduced mobility in the trans-European conventional and high-speed rail system

Annex: Comparison of objectives and different aspects of the communication, submission or notification procedure of national rules under Directives 98/34/EC, 2004/49/EC and 2008/57/EC

Directive(s)	2008/57/EC, Interoperability	2004/49/EC, Safety		98/34/EC, Technical Regulations
Scope	NTR in Use	Draft NSR	Adopted NSR	Draft technical regulation
Article	17(3)	8 (6) and (7)	8 (2) and (4)	8 (1)
Aim	<p>Transparency</p> <p>Prevent the creation of further technical barriers</p> <p>Avoid arbitrary discrimination</p>	<p>Transparency</p> <p>Prevent the creation of further barriers</p> <p>Avoid arbitrary discrimination</p>	<p>Transparency</p> <p>Prevent the creation of further barriers</p>	<p>Transparency</p> <p>Avoid the creation of obstacles to trade within the Internal Market</p>
Standstill period	No	Suspension, if EC has serious doubts	No	Yes (Article 9)
Notification: in which cases	<p>Each time there is</p> <ul style="list-style-type: none"> - a change in the list of notified rules, - a derogation is notified (see Annex IX, point b), third indent or - a TSI concerned is published¹⁰ 	<p>Each time when</p> <ul style="list-style-type: none"> - draft NSR requires higher safety level than CST, or - may affect operations of other MS' RUs. 	<p>Any amendment to already notified NSR or any new NSR, unless the rule is wholly relating to the implementation of TSIs.</p>	<p>Any draft technical regulation except those listed under Article 10.1</p>

¹⁰ Concerning the link between TSIs and remaining NTR, please refer to point 3.1.4 of the Commission Recommendation 2011/217/EU

Directive(s)	2008/57/EC, Interoperability	2004/49/EC, Safety		98/34/EC, Technical Regulations
Scope	NTR in Use	Draft NSR	Adopted NSR	Draft technical regulation
IT tools	- NOTIF-IT (<i>Remark: this includes adopted technical regulations notified via TRIS</i>)	- NOTIF-IT (<i>Remark: relevant module is not yet developed</i>)	NOTIF-IT	TRIS
Languages	No explicit provision	No explicit provision	No explicit provision	Each notification is translated in all EU languages
Possibility to introduce amendment to the notified rules during the notification process	No	Yes	No	Yes
Examination by the Commission Services and/or ERA	Yes	Yes	Yes	Yes
Commission can block a draft	Not applicable	Yes	Not applicable	Yes
Possibility of comments by other MS	No	Yes, in case when EC has serious doubts about draft NSR and initiates procedure according to Article 27(2)	No	Yes

Directive(s)	2008/57/EC, Interoperability	2004/49/EC, Safety		98/34/EC, Technical Regulations
Scope	NTR in Use	Draft NSR	Adopted NSR	Draft technical regulation
Possible forms of reaction	EC: informs MS on the acceptance or refusal of the notification EC: Commission Decision	EC: Commission Decision MS: Suspension of the adoption, entry into force or implementation of the rule concerned	EC: informs MS on the acceptance or refusal of the notification	EC and MS: Detailed opinion, comments
Consequences of the breach of the notification obligation	No explicit provision Infringement procedure	No explicit provision Infringement procedure	No explicit provision Infringement procedure	A non-notified technical regulation can be declared not enforceable by national courts.