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Document prepared by	European Railway Agency Rue Marc Lefrancq, 120 BP 20392 F-59307 Valenciennes Cedex France
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Released by	Jean-Charles Pichant	Interoperability Unit – Head of Unit
Reviewed by	Olivier Piron	Interoperability Unit – Head of Coordination Sector
Written by (author)	Félix Ardiaca C. Lorenza Lo Iacono	Interoperability Unit – Project Officers





0. DOCUMENT INFORMATION

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1. COMMUNITY LEGAL INSTRUMENTS

- 1.1. The binding legal instruments of EU legislation are regulations, directives and decisions (see for further information EUR-Lex, the free access website to European Union law):

*‘A **regulation** is a general measure that is binding in all its parts’, ‘adopted by the Council in conjunction with the European Parliament or by the Commission alone’. ‘Unlike directives (...) and decisions (...), regulations are addressed to everyone.*

A regulation is directly applicable, which means that it creates law which takes immediate effect in all the Member States in the same way as a national instrument, without any further action on the part of the national authorities’.

*‘...A **directive** is addressed to the Member States [with the] purpose to align national legislation. [It] is binding on the Member States as to the result to be achieved, but leaves them the choice of the form and method they adopt to realise the Community objectives within the framework of their internal legal order (national transposition). If a directive has not been transposed into national legislation in a Member State or if it has been transposed incompletely or if there is a delay in transposing it, citizens can directly invoke the directive in question before the national courts. [As a regulation, it can be] adopted by the Council in conjunction with the European Parliament or by the Commission alone’.*

*‘A **decision** is an individual measure, and the persons to whom it is addressed must be specified individually, which distinguishes a decision from a regulation’ (...). [It] is the instrument by which the Community institutions give a ruling on a particular matter. By means of a decision, the institutions can require a Member State or a citizen of the Union to take or refrain from taking a particular action, or confer rights or impose obligations on a Member State or a citizen. It is binding in its entirety. [It can be] adopted either by the Council, by the Council in conjunction with the European Parliament or by the Commission.’.*

- 1.2. All the TSIs in force have been adopted by Commission decisions, except the TSI on Telematic Applications for Freight, which has been adopted by a Commission regulation.

2. THE 'COMITOLOGY' PROCEDURE

- 2.1. The European Commission is among others supported by the Railway Interoperability and Safety Committee (RISC), composed of representatives of the Member States and chaired by a representative of the Commission, in accordance with Article 29 of Directive 2008/57/EC. (This Committee was established by Article 21 of Directive 96/48/EC and was formerly usually referred to as the 'Article 21 Committee'). The activities are set according to Decision 1999/468/EC and its following amendments, for implementing powers conferred on the Commission by the Council. In this context, the procedure known as 'comitology' makes provisions for the Commission to be assisted by committees and forums for discussion, aimed at establishing dialogue with national administrations before adopting implementing measures. In such a way, the Commission ensures that measures to be proposed take into account as far as possible the situation in each of the countries concerned.
- 2.2. Concerning the adoption of the TSIs, the Interoperability Directive establishes the regulatory procedure with scrutiny. As is indicated in the 'Europa Glossary':

'Regulatory committees with scrutiny (...) allow the Council and the European Parliament to carry out a check prior to the adoption of measures of general scope designed to amend non-essential elements of a basic instrument adopted by co-decision. In the event of opposition on the part of EU Parliament 'by a majority of its component members', or the Council 'by a qualified majority', the Commission may not adopt the proposed measure, although it may submit an amended proposal or a new proposal'.

3. THE RAILWAY PACKAGES

3.1. Several legal acts are to be considered under the umbrella of 'Railway Packages', grouped as follows:

- First Railway Package, adopted on 26 February 2001 and consisting of
 - Directive 2001/12/EC on the development of the Community railways (amending Directive 91/440/EEC),
 - Directive 2001/13/EC on licensing of railway undertakings (amending Directive 95/18/EC) and
 - Directive 2001/14/EC on the allocation and charging for infrastructure and safety certification (amending Directive 95/19/EC).

The so-called 'Infrastructure Package' was the first set of legislation intended to increase competition in the rail sector after the first ground-breaking measures of the '90s (Directives 91/440/EEC, 95/18/EC and 95/19/EC). It is also worth remembering that the first two Directives on railway interoperability (Directives 96/48/EC for the trans-European high-speed rail system and 2001/16/EC for the trans-European conventional rail system) came out only during this period.

- Second Railway Package, adopted in April 2004 and consisting of
 - Directive 2004/51/EC (revision of Directive 91/440/EEC),
 - Directive 2004/49/EC on safety on the Community's railways (amending Directives 95/18/EC and 2001/14/EC),
 - Directive 2004/50/EC (amending Interoperability Directives 96/48/EC for the trans-European high-speed rail system and 2001/16/EC for the trans-European conventional rail system) and
 - Regulation 881/2004/EC establishing the European Railway Agency in charge of supporting the implementation of European legislation.
- Third Railway Package, adopted in 2007 and mainly consisting of
 - Directives 2007/58/EC (amending Council Directive 91/440/EEC on the development of the Community's railways and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure),
 - Directive 2007/59/EC on the certification of train drivers operating within the European Community and
 - Regulation No 1371/2007/EC on rail passengers' rights and obligations.

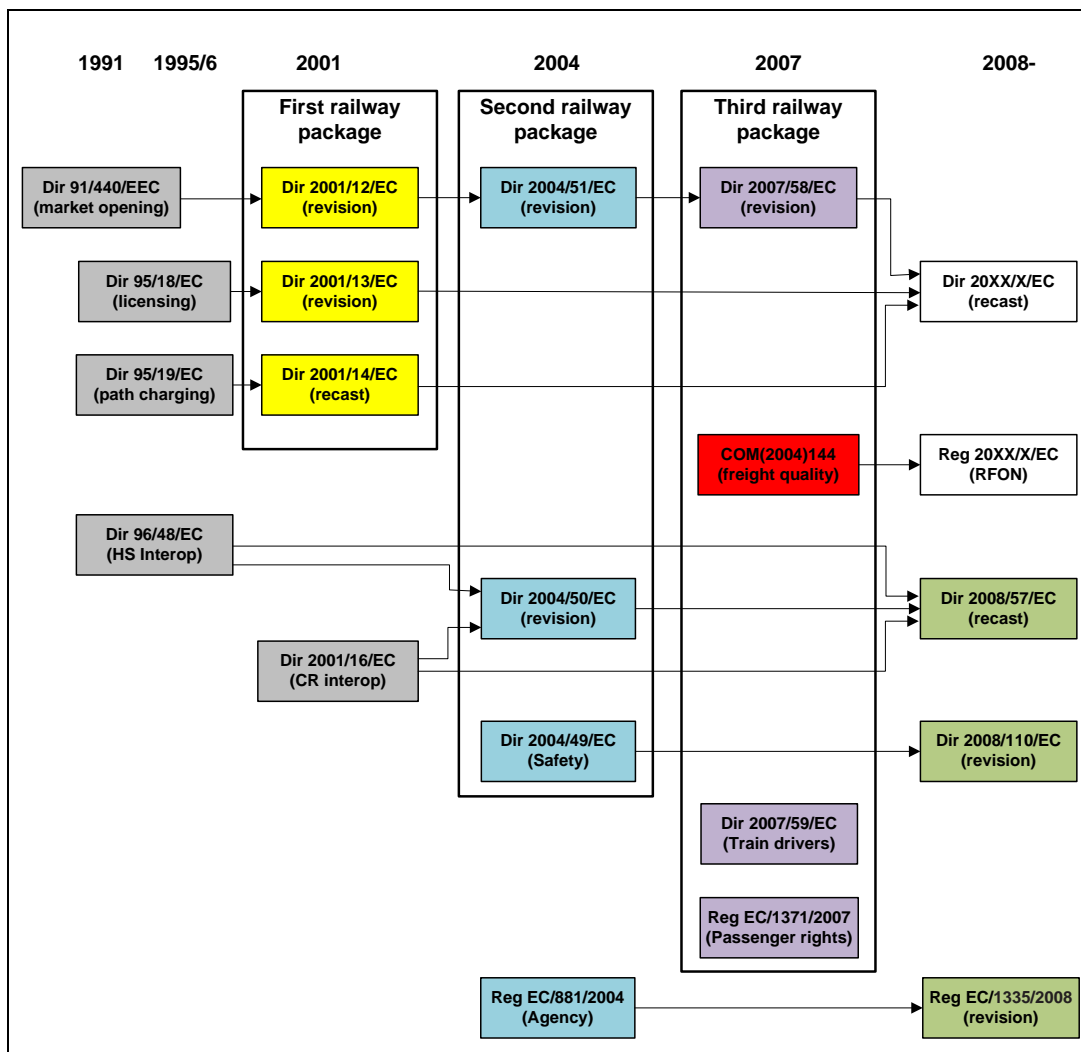
To sum up, this introduced open access rights for international rail passenger services, including cabotage by 2010 (operators may pick up and set down passengers at any station on an international route, including at stations located in the same Member State). Furthermore, rail passengers' rights (for instance non-discrimination of handicapped travellers or persons with reduced mobility, liability in case of accidents, availability of train



tickets and personal security of passengers in stations) will have to be guaranteed to all passengers on all lines. In addition, it opens the railway labour market by enabling 'certified' train drivers to move through RUs of different countries. Lastly, difficulties to apply such passenger legislation are duly taken into account, allowing MSs to exempt RUs from complying with it for domestic traffic (both long-distance and local traffic) for a maximum period of 10 years. Subsequently '(...) for simplifying legislation, the Commission proposed consolidating and merging the Railway Interoperability Directives (...) [and then] the new Railway Interoperability Directive entered into force on 18 July 2008 (...)'¹.

- 3.2. In the following years new measures were adopted, particularly the recast of the high-speed and conventional rail system interoperability directives (Directive 2008/57/EC) and amendment of the Safety Directive (Directive 2008/110/EC). Other measures are under preparation.
- 3.3. The following picture summarises the evolution of rail legislation ('Dir' means Directive, 'Reg' means Regulation and 'COM' is a Commission proposal for a regulation or a decision).

Figure 1: Railway packages



¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52009DC0464:EN:NOT>

4. DEVELOPMENT AND REVISION OF THE TSIs

- 4.1. Since 2006, the Agency has been responsible for drafting and updating the TSIs according to Articles 6(1) and 6(2) of the Interoperability Directive.
- 4.2. The drafting procedure is broken down into two stages:
- identification of the basic parameters, interfaces and specific cases, where necessary, in collaboration with the bodies representative of the railway sector;
 - drawing up of the TSI on the basis of the identified basic parameters and also taking *'into account of technical progress, standardisation work already carried out, working parties already in place, and acknowledged research work'*. This draft shall be provided with *'an overall assessment of the estimated costs and benefits of the implementation of TSIs'*, in order to evaluate *'the likely impact for all the operators and economic agents involved'*.
- 4.3. For drawing up recommendations related to adoption of new or revision of existing TSIs, the Agency establishes working parties. These working parties consist of representatives of the bodies representing the railway sector (ALE, CER, EIM, EPTTOLA, ETF, ERFA, UIP, UIRR, UITP, UNIFE) and national safety authorities.
- 4.4. Then a preliminary draft is submitted *'in order to minimise as far as possible rejection risk at the time of the procedure'* concerning TSI adoption and publication.
- 4.5. Furthermore, *'the Agency [consults] associations and bodies representing users during the drafting and review phases of the TSIs'* and *'[takes] account of the opinion of the social partners'*. A report with the outcomes of this consultation is submitted by the Agency with the final draft of each TSI.
- 4.6. The TSI revision process follows the following general principles:
- *'to take account of developments in technology or social requirements'*;
 - to ensure full compliance with the essential requirements of the subsystems concerned;
 - to ensure consistency between the development of TSIs and European standards *'which prove necessary for interoperability'*.
- 4.7. The TSIs are revised in a transparent manner with involvement of the sector and regular reporting to the MSs via the Railway Interoperability and Safety Committee (RISC).
- 4.8. A request for revision of a TSI may be made by a MS (via the RISC), by an NSA (via the NSA Network), by any representative body referred to in Article 3(2) of the Agency Regulation or a NoBo. In the case of a NoBo, this is entitled to issue a Question/Clarification document through the NB Rail Group.
- 4.9. These requests are taken into account by the Agency when revising the TSIs.
- 4.10. The revision request should include:
- a clear identification of the author (group/name);
 - a reference number;
 - the subject, including, where applicable, the name of the document and the clause referred to;

- a description of the problem; and
- possibly, a proposed solution.

4.11. In case of an error being detected in a TSI, the procedure laid down in Article 7 of the Interoperability Directive shall apply.

5. 'NEW APPROACH' AND THE INTEROPERABILITY DIRECTIVE

5.1. Principles of the 'new approach' and 'global approach' directives

5.1.1. The framework of rules designed to achieve interoperability is based on the principles of the 'new approach' and 'global approach' to EU regulations. The new approach principles relating to technical harmonisation and standardisation were laid down by a Council resolution of 1985. This resolution established the following principles:

- legislative harmonisation is limited to essential requirements that products placed on the EU market must meet if they are to benefit from free movement within the Union;
- technical specifications that would enable products to meet the essential requirements set out in new approach directives are laid down in 'harmonised' standards, the reference numbers of which are published in the Official Journal of the European Union (C series);
- compliance with 'harmonised' standards remains voluntary and manufacturers may always apply other technical specifications to meet the essential requirements;
- products manufactured in compliance with 'harmonised' standards benefit from a presumption of conformity with the corresponding essential requirements.

5.1.2. In addition to the new approach principles, it was necessary to establish uniform conditions for product conformity assessment. The 1989 Council resolution on the 'global approach' to certification and testing set out guiding principles for EU policy on conformity assessment. To this end, EU legislation describes modules for the different phases of the conformity assessment procedures and lays down criteria for the use of these procedures and for the designation of bodies carrying out these procedures.

5.1.3. Finally, on 23 June 2008 the EU Parliament and Council adopted the New Legislative Framework (published in the OJ on 13 August 2008) as a modernisation of the New Approach for marketing of products. This package of measures is made up of:

- Regulation (EC) No 764/2008 relating to the application of certain national technical rules to products lawfully marketed in another Member State, repealing Decision No 3052/95/;
- Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, repealing Regulation (EEC) No 339/93, and
- Decision 768/2008/EC on a common framework for the marketing of products, repealing Council Decision 93/465/EEC.

5.1.4. All of these are aimed at providing greater clarification, particularly for the following purposes:

- better rules on market surveillance to protect both consumers and professionals from unsafe products, including imports from third countries. (This applies to procedures for products which can be a hazard for health or the environment, which in such a case will be withdrawn from the market).
- enhancing the confidence in and quality of conformity assessments of products through reinforced and clearer rules on the requirements for notification of conformity assessment bodies (testing, certification and inspection laboratories), including the increased use of accreditation.

- enhancing the credibility of CE marking that will be protected as a Community collective trade mark, giving additional means for taking legal action against manufacturers who abuse it.
 - establishing a common legal framework for industrial products in the form of provisions to support market surveillance and application of CE marking, amongst other things.
- 5.1.5. The Guide to the implementation of directives based on the new approach and the global approach (ISBN92-828-7500-8, Office for Official Publications of the European Communities, 2000), not yet updated according to the New Legislative Framework, is still a useful reference for the overall approach.

5.2. Principles of the ‘new approach’ as applied to Directive 2008/57/EC and the related TSIs

- 5.2.1. Compared to strictly ‘new approach’ Directives, the TSIs represent an additional level between the Directive’s ‘essential requirements’ and any corresponding standards, reflecting the complexity of the rail system and the need to integrate its various subsystems while meeting the essential requirements.
- 5.2.2. Regarding the standardisation documents, the applicable legal definitions are the following:

- in the context of the ‘New approach’:
A *‘harmonised standard’* is a standard which has been:
 - mandated by the Commission under a ‘new approach’ (or ‘new approach’-type) directive, and
 - developed by the European standardisation organisations (CEN, CENELEC, ETSI) in accordance with the general internal rules of these organisations.

Such standards can be considered to carry a broad consensus.

The reference numbers of ‘harmonised’ standards are published in the Official Journal of the European Union (C series). ‘Harmonised’ standards are then transposed by standardisation organisation of the MSs at national level.

- in the context of Directive 2008/57/EC (Article 2(h)):
‘European specification’ means a common technical specification, a European technical approval or a national standard transposing a European standard, as defined in Annex XXI to Directive 2004/17/EC;
- in the context of Directive 2004/17/EC of the European Parliament and of the Council (Annex XXI):

‘Standard’ means a technical specification approved by a recognised standardising body for repeated or continuous application, compliance with which is in principle not compulsory’;

‘European standard’ means a standard approved by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (CENELEC) as a European standard (EN) or harmonization document (HD), according to the common rules of those organisations, or by the European Telecommunications Standards Institute (ETSI) according to its own rules as a European telecommunications standard (ETS);

‘Common technical specification’ means a technical specification drawn up in accordance with a procedure recognised by the Member States with a view to uniform



application in all Member States and published in the Official Journal of the European Communities.'

- 5.2.3. In addition to the standards referred to above, other documents relevant to the TSIs cover issues such as performance criteria, testing methods or product specifications.



6. THE EUROPEAN STANDARDISATION CONTEXT

- 6.1. There are three European standardisation organisations (ESOs) working in partnership:
- CEN (European Committee for Standardisation);
 - Cenelec (European Committee for Electrotechnical Standardization);
 - ETSI (European Telecommunications Standards Institute).
- The CEN covers all the subjects outside the scope of Cenelec and ETSI.
- 6.2. The mission of the ESOs is to promote voluntary technical harmonisation in Europe, in conjunction with worldwide organisations.
- 6.3. With regard to the elements of the railway system, those are mainly treated:
- for the CEN, under the Technical Committee TC 256 'Railway applications'. This rule is not absolute however, certain elements falling within the competence of general technical committees, such as for example the Technical Committee TC 250 'Structural Eurocodes' for the structures or the Technical Committee TC 154 'Aggregates' for ballast;
 - for Cenelec, under the Technical Committee TC 9X 'Railway applications';
 - for ETSI, under the Technical Committee Railway Telecommunications (TCRT)
- and their respective subcommittees.
- 6.4. The ESOs' process for developing standards respects the following principles:
- Openness and transparency: all interested parties can take part in the preparation of standards. This is usually achieved through the national standardisation bodies.
 - Consensus: whenever possible, European standards are developed and adopted with the agreement of all the interested parties. When necessary, adoption of the final text is obtained by weighted majority voting.
 - National commitment: national members are normally obliged to eliminate any previous national standard which may conflict with a European standard.
 - Technical coherence.
 - Global coherence: the ESOs take into account the activities of the European sectoral bodies (such as aerospace, iron and steel, etc.) and the work of international standardisation bodies, especially the ISO.
- 6.5. The ESOs do not themselves publish the European standards. The ratified texts are sent to the national members, which publish them as national measures, keeping the EN catalogue entry (e.g. BS EN71, DIN EN71, etc.).
- 6.6. In addition, national members may adopt international standards, from ISO (or IEC), for example. In this case, the national reference numbers also maintain the original ISO (or IEC) reference (e.g. BS ISO 13296).
- 6.7. Also, the CEN or Cenelec may adopt international standards from ISO (or IEC). In this case, the standards published by the national members have triple prefixes (e.g. DIN EN ISO 9000).