Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 402/2013

of 30 April 2013

on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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)[(1)], and in particular Article 6(4) thereof,

Whereas:

(1) In accordance with Directive 2004/49/EC, common safety methods (CSMs) should be gradually introduced to ensure that a high level of safety is maintained and, when and where necessary and reasonably practicable, improved.

(2) On 12 October 2010 the Commission issued a mandate to the European Railway Agency (the 'Agency') in accordance with Directive 2004/49/EC to revise Commission Regulation (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council[(2)]. The revision should cover the results of the analysis by the Agency under Article 9(4) of the Regulation of the overall effectiveness of the CSM for risk evaluation and assessment and experience with its application as well as further developments in the roles and the responsibilities of the assessment body referred to in Article 6 of that Regulation. The revision should also include the qualification requirements (by developing a recognition/accreditation scheme) for the assessment body according to its role in the CSM, with a view to improving clarity in order to avoid differences in application across the Member States, taking into account the interfaces with existing Union authorisation/certification procedures in the railway sector. If feasible, the revision of Regulation (EC) No 352/2009 should also cover further developments in risk acceptance criteria that could be used to assess the acceptability of a risk during explicit risk estimation and evaluation. The Agency submitted its recommendation on the revision of the CSM to the Commission, supported by an impact assessment report to address the mandate of the Commission. This Regulation is based on that Agency recommendation.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 402/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(3) In accordance with Directive 2004/49/EC the basic elements for the safety management system should include procedures and methods for carrying out risk evaluation and implementing risk control measures whenever a change in operating conditions or new material imposes new risks on the infrastructure or on operations. That basic element of the safety management system is covered by this Regulation.

(4) Article 14a(3) of Directive 2004/49/EC requires entities in charge of maintenance to establish a system of maintenance in order to ensure that the vehicles for which they are in charge of maintenance are in a safe state of running. To manage changes in equipment, procedures, organisation, staffing or interfaces, the entities in charge of maintenance should have in place risk assessment procedures. That requirement for the system of maintenance is also covered by this Regulation.

(5) As a consequence of the application of Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways[(3)] and of Article 9(2) of Directive 2004/49/EC, particular attention should be paid to risk management at the interfaces between the actors which are involved in the application of this Regulation.

(6) Article 15 of 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[(4)] requires Member States to take all appropriate steps to ensure that the structural subsystems constituting the rail system may be placed in service only if they are designed, constructed and installed in such a way as to meet the essential requirements concerning them when integrated into the rail system. In particular, the Member States must check the technical compatibility of these subsystems with the railway system into which they are being integrated and the safe integration of these subsystems in accordance with the scope of this Regulation.

(7) The absence of a common approach for specifying and demonstrating compliance with safety levels and requirements of the railway system among the Member States has proved to be one of the obstacles to liberalisation of the railway market. Such a common approach should be established through this Regulation.

(8) To facilitate mutual recognition between Member States, the methods used for identifying and managing risks and the methods for demonstrating that the railway system in the territory of the Union conforms to safety requirements should be harmonised among the actors involved in the development and operation of the railway system. As a first step, it is necessary to harmonise the procedures and methods for carrying out risk evaluation and implementing control measures whenever a change in operating conditions or new material imposes new risks on the infrastructure or on operations, as referred to in point (2)(d) of Annex III to Directive 2004/49/EC.

(9) If there is no existing notified national rule for defining whether or not a change is significant for the safety in a Member State, the company or organisation in charge of implementing the change (the 'proposer') should initially consider the potential impact of the change in question on the safety of the railway system. If the proposed change has an impact on safety, the proposer should assess, by expert judgement, the significance of the change based on a set of criteria that should be set out in this Regulation. This

assessment should lead to one of three conclusions. In the first situation the change is not considered to be significant and the proposer should implement the change by applying its own safety method. In the second situation the change is considered to be significant and the proposer should implement the change by applying this Regulation, without the need for a specific intervention of the national safety authority. In the third situation the change is considered to be significant but there are provisions at the level of the European Union which require a specific intervention of the relevant national safety authority, such as a new authorisation for placing in service of a vehicle or a revision/update of the safety certificate of a railway undertaking or a revision/update of the safety authorisation of an infrastructure manager.

(10) Whenever the railway system already in use is subject to a change, the significance of the change should also be assessed taking into account all safety-related changes affecting the same part of the system since the entry into force of this Regulation or since the last application of the risk management process set out in this Regulation, whichever is the latest. The purpose is to assess whether or not the totality of such changes amounts to a significant change requiring the full application of the CSM for risk evaluation and assessment.

(11) The risk acceptability of a significant change should be evaluated by using one or more of the following risk acceptance principles: the application of codes of practice, a comparison with similar parts of the railway system, or an explicit risk estimation. All principles have been used successfully in a number of railway applications, as well as in other transport modes and other industries. The ‘explicit risk estimation’ principle is frequently used for complex or innovative changes. The proposer should be responsible for the choice of the principle to apply.

(12) When a widely recognised code of practice is applied, it should therefore be possible to reduce the impact of applying the CSM, in accordance with the principle of proportionality. In the same way, where there are provisions at the level of the Union which require specific intervention by the national safety authority, that authority should be allowed to act as the independent assessment body in order to reduce double checking, undue costs to the industry and time to market.

(13) To report to the Commission on the effectiveness and application of this Regulation, and where applicable to make recommendations to improve it, the Agency should be able to gather relevant information from the various actors involved, including from the national safety authorities, from the certification bodies of entities in charge of maintenance of freight wagons and from other entities in charge of maintenance that do not fall within the scope of Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons[(5)].

(14) Accreditation of an assessment body should normally be granted by the national accreditation body which has exclusive competence to assess if the assessment body meets the requirements set by harmonised standards. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products[(6)] contains detailed provisions on the competence of such national accreditation bodies.

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(15) Where harmonised Union legislation provides for the selection of conformity assessment bodies for its implementation, transparent accreditation, as provided for in Regulation (EC) No 765/2008, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of those bodies. However, national authorities may consider that they possess the appropriate means to carry out this evaluation themselves. In such cases, the Member State should provide the Commission and the other Member States with all the documentary evidence necessary for verification of the competence of the recognition body it selects for implementation of the Union legislation. In order to achieve a similar level of quality and trust as expected through accreditation, the requirements and rules for the evaluation and surveillance of assessment bodies in the case of recognition should be equivalent to those used for accreditation.

(16) An independent and competent external or internal individual, organisation or entity, a national safety authority, a notified body or a body designated according to Article 17 of Directive 2008/57/EC could act as an assessment body provided it fulfils the criteria required in Annex II.

(17) Recognition of internal assessment bodies in compliance with this Regulation does not require an immediate revision of already delivered safety certificates to railway undertakings, safety authorisations to infrastructure managers and certificates to entities in charge of maintenance. Their revision can be made at the next application for renewal or update of the safety certificate, safety authorisation or certificate of the entity in charge of maintenance.

(18) In existing legislation there are no limits in the number of assessment bodies accredited or recognised in each Member State and there are no obligations to have at least one. Where the assessment body is not already designated by existing Union or national legislation, the proposer may appoint any assessment body in the Union or in a third country accredited under equivalent criteria and meeting equivalent requirements to those contained in this regulation. The Member State should be able to use accreditation or recognition or any combination of these two options.

(19) Regulation (EC) No 352/2009 has become obsolete and should therefore be replaced by this Regulation.

(20) In view of the new requirements introduced by the present Regulation in terms of accreditation and recognition of the assessment body, the implementation of this Regulation should be deferred in order to give sufficient time to the actors concerned to put in place and implement this new common approach.

(21) The measures provided for in this Regulation are in accordance with the opinion of the Committee established in accordance with Article 27(1) of Directive 2004/49/EC,

HAS ADOPTED THIS REGULATION:

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Article 1

Subject matter

1 This Regulation establishes a revised common safety method (CSM) for risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC.

2 This Regulation shall facilitate the access to the market for rail transport services through harmonisation of:

a the risk management processes used to assess the impact of changes on safety levels and compliance with safety requirements;

b the exchange of safety-relevant information between different actors within the rail sector in order to manage safety across the different interfaces which may exist within this sector;

c the evidence resulting from the application of a risk management process.

Article 2

Scope

1 This Regulation shall apply to the proposer as defined in Article 3(11) when making any change to the railway system in a Member State.

Such changes may be of a technical, operational or organisational nature. As regards organisational changes, only those changes which could impact the operational or maintenance processes shall be subjected to consideration under the rules of Article 4.

2 When, on the basis of an assessment under the criteria set out in Article 4(2)(a) to (f):

a the change is considered significant, the risk management process set out in Article 5 shall be applied;

b the change is considered not significant, keeping adequate documentation to justify the decision shall be sufficient.

3 This Regulation shall apply also to structural sub-systems to which Directive 2008/57/EC applies:

a if a risk assessment is required by the relevant technical specification for interoperability (TSI); in this case the TSI shall, where appropriate, specify which parts of this Regulation apply;

b if the change is significant as set out in Article 4(2), the risk management process set out in Article 5 shall be applied within the placing in service of structural sub-systems to ensure their safe integration into an existing system, by virtue of Article 15(1) of Directive 2008/57/EC.

4 The application of this Regulation in the case referred to in paragraph 3(b) of this Article shall not lead to requirements contradictory to those laid down in the relevant TSIs. If such contradictions occur, the proposer shall inform the Member State concerned which may then decide to ask for a revision of the TSI in accordance with Article 6(2) or Article 7 of Directive 2008/57/EC or a derogation in accordance with Article 9(2) of that Directive.

5 The railway systems excluded from the scope of Directive 2004/49/EC according to its Article 2(2) are excluded from the scope of this Regulation.