

Recommendation N° ERA-REC-116-2015-REC
of the European Railway Agency

on

**the amendment of the Commission implementing Regulation (EU)
No 402/2013 on the common safety method for risk evaluation
and assessment and repealing Regulation (EC) No 352/2009**

THE EXECUTIVE DIRECTOR

Having regard to Regulation (EC) No 881/2004 of the European Parliament and of the Council of 29 April 2004 establishing a European Railway Agency¹ (hereafter the Agency) and in particular Article 6 thereof,

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)², and in particular Article 6(4) thereof,

Having regard to the Commission Decision of 12 October 2010 (C(2010) 6931 final) concerning the mandate to the European Railway Agency for the revision of the Regulation (EC) No 352/2009 on a common safety method on risk evaluation and assessment (the Mandate),

Whereas:

1. Railway Safety Directive aims to improve access to the market for rail transport services by defining common principles for the management, regulation and supervision of railway safety. Directive 2004/49/EC also provides a framework to be put in place to ensure equal treatment for all actors involved in the development and operation of the railway system through the application of harmonised methods for identifying, assessing and managing risks across the EU.
2. Based on a recommendation of the European Railway Agency (the 'Agency') on the first set of common safety methods (CSMs) of 6 December 2007, the Commission adopted on 24 April 2009 Regulation (EC) No 352/2009 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 Council³.
3. To enhance the mutual recognition of the application of Regulation (EC) No 352/2009 and of the results of the risk management process specified therein, the Agency developed, under the scope of the Mandate, additional requirements for the independent assessment body, referred to in Article 6 of that Regulation, as well as further harmonised risk acceptance criteria to assess the acceptability of risks arising from failures of technical systems. Consensus with the European railway stakeholders was reached only on the first part of the development. In 2012, the Agency submitted to the Commission the Agency recommendation of 6 July 2012 on the revision of that Regulation to address the part of the Mandate related only to the developments on the independent assessment body. Based on the recommendation, the Commission adopted on 30 April 2013 the Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009⁴.
4. The impact assessment carried out in the scope of that revision highlighted nevertheless the importance of including in Regulation (EC) 402/2013 other consequence severities of risks than currently only the catastrophic severity. Additional harmonised risk acceptance criteria are necessary to support the mutual recognition between Member States of TSI compliant structural sub-systems and vehicles.

¹ OJ L 164, 30.4.2004, p. 1

² OJ L 164, 30.4.2004, p. 44

³ OJ L 108, 29.4.2009, p. 4.

⁴ OJ L 121, 3.5.2013, p. 8.

5. Under the scope of the same mandate, until 2014 the Agency continued to work with the European railway stakeholders on the development and validation of those additional risk acceptance criteria to be used during explicit risk estimation and evaluation to assess the acceptability of risks arising from failures of technical systems.
6. The Agency proposes hereby to amend the existing Regulation (EC) 402/2013 to include the requirements related to those additional risk acceptance criteria.
7. The proposed amendment of Regulation (EC) 402/2013 has been developed in accordance with the relevant requirements of Regulation (EC) No 881/2004.

HAS ADOPTED the following recommendation:

Article 1
Content and Structure

1. The Agency recommends that the Commission adopts the draft Commission Regulation included as Appendix to this Recommendation:

Appendix – Commission implementing Regulation (EU) No .../. of [...] amending Commission Implementing Regulation 402/2013 on the common safety method on risk evaluation and assessment and repealing Regulation (EC) No 352/2009.

This recommendation is addressed to the European Commission.

Valenciennes, 19/03/2015



Josef DOPPELBAUER
Executive Director

Annex: Draft of the Commission implementing Regulation (EU) No .../. of [...] amending Commission Implementing Regulation 402/2013 on the common safety method on risk evaluation and assessment and repealing Regulation (EC) No 352/2009.