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Subject: COMMISSION REGULATION (EU) No .../.. of XXX on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance

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Delegations will find attached Commission document D020816/03.

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EUROPEAN COMMISSION

Brussels, **XXX**  
[...] (2012) **XXX** draft

**COMMISSION REGULATION (EU) No .../..**

**of **XXX****

**on a common safety method for monitoring to be applied by railway undertakings,  
infrastructure managers after receiving a safety certificate or safety authorisation and  
by entities in charge of maintenance**

(Text with EEA relevance)

**COMMISSION REGULATION (EU) No .../..**

**of XXX**

**on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance**

(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)<sup>1</sup>, and in particular Article 6 thereof,

Whereas:

- (1) The Commission should adopt the second series of common safety methods (CSM) covering at least the methods provided for in Article 6(3)(c) of Directive 2004/49/EC, on the basis of a recommendation of the European Railway Agency (the 'Agency').
- (2) On 5 October 2009 the Commission issued a mandate to the Agency in accordance with Directive 2004/49/EC to draw up a draft CSM for checking conformity of operation and maintenance of structural subsystems with relevant essential requirements. This CSM should specify the methods to be used both to check that the structural sub-systems (including traffic operation and management) are operated and maintained in accordance with all essential requirements related to safety and to monitor that the sub-systems and their integration in the systems continue to fulfil their safety requirements when operated and maintained. The Agency submitted its recommendation on the CSM to the Commission, supported by an impact assessment report to address the mandate of the Commission. This Regulation is based on the recommendation by the Agency.
- (3) To enable the safe integration, operation and maintenance of structural sub-systems within the railway system, and to ensure that essential requirements are met in operation, safety management systems of railway undertakings and infrastructure managers, and systems of maintenance of entities in charge of maintenance should include all necessary arrangements, including processes, procedures, technical, operational and organisational risk control measures. Consequently, monitoring the correct application and effectiveness

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<sup>1</sup> OJ L 164, 30.4.2004, p. 44.

of safety management systems of railway undertakings and infrastructure managers, as well as of systems of maintenance of entities in charge of maintenance, should cover the requirements for structural sub-systems within their operational context.

- (4) This Regulation should enable the effective management of safety of the railway system during its operation and maintenance activities and, where necessary and reasonably practicable, should improve the management system.
- (5) This Regulation should also enable to identify as early as possible non-compliance in applying a management system in ways that may result in accidents, incidents, near-misses or other dangerous occurrences. To manage these forms of non-compliance during operation and maintenance activities a harmonised process for monitoring activities should be used. In particular that harmonised process should be used to check the achievement of the expected outcome of the safety management systems of railway undertakings and infrastructure managers, and check the achievement of the expected outcome of the system of maintenance of the entities in charge of maintenance.
- (6) The railway undertakings and infrastructure managers should monitor the correct application and the outcomes of the arrangements they have developed through their safety management system so as to operate safely, including on specific networks.
- (7) This Regulation should facilitate access to the market for rail transport services through harmonisation of the monitoring process to ensure the continuous achievement of the safety performance of the railway system. In addition, this Regulation should help to create mutual trust and transparency between Member States, through a harmonised exchange of safety-related information between different actors involved within the railway sector in order to manage safety across the different interfaces of this sector and harmonised evidence from the application of the monitoring process.
- (8) 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 involved actors, 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 under 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<sup>2</sup>.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 27(1) of Directive 2004/49/EC,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

#### **Subject-matter and scope**

1. This Regulation establishes a common safety method (CSM) for monitoring enabling the effective management of safety in the railway system during its operation and maintenance activities and, where appropriate, improving the management system.

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<sup>2</sup> OJ L 122, 11.5.2011, p. 22.

2. This Regulation shall be used for the following:
  - (a) to check the correct application and the effectiveness of all the processes and procedures in the management system, including the technical, operational and organisational risk control measures. In case of railway undertakings and infrastructure managers checking will include the technical, operational and organisational elements that are necessary for the delivery of the certification specified on the article 10.2 (a) and 11.1 (a) and the provisions adopted to obtain the certification specified on the article 10.2 (b) and 11.1 (b) of Directive 2004/49/EC;
  - (b) to check the correct application of the management system as a whole, and if the management system achieves the expected outcomes, and;
  - (c) to identify and implement appropriate preventive, corrective or both types of measures if any relevant instance of non-compliance to points (a) and (b) is detected.
3. This Regulation shall apply to railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and entities in charge of maintenance.

## *Article 2* **Definitions**

For the purposes of this Regulation the definitions of Article 3 of Directive 2004/49/EC shall apply.

In addition, the following definitions shall apply:

- (a) ‘management system’ means **either** the safety management systems of railway undertakings and infrastructure managers, as defined in Article 3(i) of Directive 2004/49/EC and complying with requirements laid down in Article 9 and Annex III of that Directive, **or** the system of maintenance of entities in charge of maintenance complying with requirements laid down in Article 14a(3) of that Directive;
- (b) ‘monitoring’ means the arrangements put in place by railway undertakings, infrastructure managers or entities in charge of maintenance to check their management system is correctly applied and effective;
- (c) ‘interfaces’ means interfaces as defined in Article 3(7) of Commission Regulation (EC) No 352/2009<sup>3</sup>.

## *Article 3* **Monitoring process**

1. Each railway undertaking, infrastructure manager and entity in charge of maintenance:
  - (a) shall be responsible for conducting the monitoring process set out in the Annex;

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<sup>3</sup> OJ L 108, 29.4.2009, p. 4.

- (b) shall ensure that risk control measures implemented by their contractors are also monitored in compliance with this Regulation. To this end, they shall apply the monitoring process set out in the Annex or require their contractors to apply this process through contractual arrangements.
2. The monitoring process shall contain the following activities:
- (a) the definition of a strategy, priorities and plan(s) for monitoring;
  - (b) the collection and analysis of information;
  - (c) the drawing up of an action plan for instances of unacceptable non-compliance with requirements laid down in the management system;
  - (d) the implementation of the action plan, if such a plan is drawn up;
  - (e) the evaluation of the effectiveness of action plan measures, if such a plan is drawn up.

#### *Article 4*

#### **Exchange of information between the involved actors**

1. Railway undertakings, infrastructure managers and entities in charge of maintenance, including their contractors, shall ensure through contractual arrangements that any relevant safety-related information resulting from applying the monitoring process set out in the Annex is exchanged between them, to enable the other party to take any necessary corrective actions to ensure continuous achievement of the safety performance of the railway system.
2. If, through the application of the monitoring process, railway undertakings, infrastructure managers and entities in charge of maintenance identify any relevant safety risk as regards defects and construction non-conformities or malfunctions of technical equipment, including those of structural sub-systems, they shall report those risks to the other parties involved to enable them to take any necessary corrective actions to ensure continuous achievement of the safety performance of the railway system.

#### *Article 5*

#### **Reporting**

1. The infrastructure managers and railway undertakings shall report to the national safety authority on the application of this Regulation through their annual safety reports in accordance with Article 9(4) of Directive 2004/49/EC.
2. The national safety authority shall report on the application of this Regulation by the railway undertakings, infrastructure managers, and as far as aware of it, by the entities in charge of maintenance in accordance with Article 18 of Directive 2004/49/EC.
3. The annual maintenance report of entities in charge of maintenance of freight wagons set out in point I.7.4(k) of Annex III to Regulation (EU) No 445/2011, shall include information about the experience of entities in charge of maintenance in applying this

Regulation. The Agency shall gather this information in coordination with the respective certification bodies.

4. The other entities in charge of maintenance that do not fall under the scope of Regulation (EU) No 445/2011 shall also share their experience with the Agency on the application of this Regulation. The Agency shall coordinate the sharing of experience with these entities in charge of maintenance.
5. The Agency shall collect all information on the experience of the application of this Regulation and, when necessary, shall make recommendations to the Commission with a view to improving this Regulation.
6. The national safety authorities shall support the Agency in collecting such information from railway undertakings and infrastructure managers.
7. The Agency shall submit to the Commission not later than three years after the entry into force of this Regulation a report analysing the effectiveness of the method and of the experience of railway undertakings, infrastructure managers and entities in charge of maintenance in applying this Regulation.

#### *Article 6*

#### **Entry into force and application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall apply from [specific date to be inserted by OPOCE- *six months after the date of entry into force*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*

**ANNEX**  
**THE MONITORING PROCESS**

**1. GENERAL**

- 1.1. The inputs to the monitoring process shall be all the processes and procedures contained in the management system, including technical, operational and organisational risk control measures.
- 1.2. The activities referred in Article 3(2) of the monitoring process are described in Sections 2 to 6.
- 1.3. This monitoring process is repetitive and iterative, as shown in the diagram below in the Appendix.

**2. DEFINITION OF A STRATEGY, PRIORITIES AND PLAN(S) FOR MONITORING**

- 2.1. Based on their management system, each railway undertaking, infrastructure manager and entity in charge of maintenance shall be responsible for defining its strategy, priorities and plan(s) for monitoring.
- 2.2. The decision on what to prioritise shall take into account information from areas that give rise to the greatest risks and, if not monitored effectively, could lead to adverse consequences for safety. An order of priority for monitoring activities shall be set, and the time, effort and resources required shall be indicated. Prioritisation shall also take into account results from previous applications of the monitoring process.
- 2.3. The monitoring process shall identify as early as possible instances of non-compliance in the application of the management system that might result in accidents, incidents, near-misses or other dangerous occurrences. It shall lead to the implementation of measures to remedy such instances of non-compliance.
- 2.4. The monitoring strategy and plan(s) shall define either quantitative or qualitative indicators or a mixture of both that can:
  - (a) give early warnings of any deviation from the expected outcome, or assurance that the expected outcome is achieved as planned;
  - (b) give information about unwanted outcomes;
  - (c) support decision making.

**3. COLLECTION AND ANALYSIS OF INFORMATION**

- 3.1. The collection and analysis of information shall be carried out according to the strategy, priorities and plan(s) defined for the monitoring.
- 3.2. For each defined indicator referred to in point 2.4, the following shall be carried out:
  - (a) a collection of necessary information;



- (b) an evaluation as to whether the processes, procedures, technical, operational and organisational risk control measures are correctly implemented;
- (c) a check on whether the processes, procedures, technical, operational and organisational risk control measures are effective and whether they achieve the expected outcomes;
- (d) an evaluation of whether the management system as a whole is correctly applied and whether it achieves the expected outcomes;
- (e) an analysis and evaluation of instances of identified non-compliance with points (b), (c) and (d), as well as identification of their causes.

#### **4. DRAWING UP OF AN ACTION PLAN**

4.1. For identified instances of non-compliance that are considered unacceptable, an action plan shall be drawn up. This shall:

- (a) lead to the enforcement of correctly implemented processes, procedures, technical, operational and organisational risk control measures as specified, or;
- (b) improve existing processes, procedures, technical, operational and organisational risk control measures, or;
- (c) identify and implement additional risk control measures.

4.2. The action plan shall in particular include the following information:

- (a) objectives and results expected;
- (b) corrective, preventive or both type of measures required;
- (c) person responsible for implementing actions;
- (d) dates by which actions are to be implemented;
- (e) person responsible for evaluating the effectiveness of the action plan measures in accordance with Section 6;
- (f) a review of the impact of the action plan on the monitoring strategy, priorities and plan(s).

4.3. For managing safety at interfaces the railway undertaking, infrastructure manager or entity in charge of maintenance shall decide, with agreement of the other actors involved, who shall be in charge of implementing the required action plan or parts of it.

#### **5. IMPLEMENTATION OF THE ACTION PLAN**

5.1. The action plan defined in Section 4 shall be implemented so as to correct identified instances of non-compliance.

## **6. EVALUATION OF THE EFFECTIVENESS OF THE ACTION PLAN MEASURES**

- 6.1. Correct implementation, appropriateness and effectiveness of measures identified in the action plan shall be checked using the same monitoring process as described in this Annex.
- 6.2. Evaluation of the action plan's effectiveness shall in particular include the following actions:
- (a) verification of whether the action plan is correctly implemented and completed according to schedule;
  - (b) verification of whether the expected outcome is achieved;
  - (c) verification of whether in the meantime the initial conditions have changed and the risk control measures defined in the action plan are still appropriate for the given circumstances;
  - (d) verification of whether other risk control measures are necessary.

## **7. EVIDENCE FROM THE APPLICATION OF THE MONITORING PROCESS**

- 7.1. The monitoring process shall be documented to prove it has been applied correctly. This documentation shall be made available primarily for internal assessment purposes. Upon request:
- (a) railway undertakings and infrastructure managers shall make this documentation available to the national safety authority;
  - (b) entities in charge of maintenance shall make this documentation available to the certification body. If interfaces are managed through contracts, the entities in charge of maintenance shall make this documentation available to the respective railway undertakings and infrastructure managers.
- 7.2. The documentation produced under point 7.1. shall include in particular:
- (a) a description of the organisation and staff appointed to carry out the monitoring process;
  - (b) the results of the different activities of the monitoring process listed in article 3(2) and in particular the decisions made;
  - (c) regarding instances of identified non-compliance that are considered unacceptable, a list of all necessary measures to be implemented to achieve the required outcome.

**Appendix**  
**Framework for the monitoring process**

