

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

**of**

**on a common safety method for supervision by national safety authorities after issuing a single safety certificate or safety authorisation and repealing Regulation (EU) 1077/2012**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (recast)<sup>1</sup>, and in particular Article 6 thereof,

Whereas:

- (1) One of the purposes of Directive (EU) 2016/798 is to improve access to the market for rail transport services by defining common principles for the management, regulation and supervision of railway safety. Directive (EU) 2016/798 also provides equal treatment for all railway undertakings by applying the single safety certification requirements throughout the European Union.
- (2) Article 6(1)(c) of Directive (EU) 2016/798 provides a framework for national safety authorities to harmonise their approach to supervision across the European Union, through the application of a common safety method (CSM).
- (3) The CSMs have been gradually introduced to describe how the safety levels, the achievement of safety targets and compliance with other safety requirements are assessed.
- (4) The CSMs are to be revised at regular intervals, taking into account the experience gained from their application and the global development of railway safety and with the objective of generally maintaining and, where reasonably practicable, continuously improving safety, in accordance with Article 6(5) of Directive (EU) 2016/798.
- (5) On 1 September 2016 the Commission issued a mandate to the European Union Agency for Railways (the 'Agency') in accordance with Directive (EU) 2016/798 to revise the common safety method for assessing conformity with the requirements for obtaining railway safety certificates referred to in Commission Regulation (EU) No 1158/2010 of 9 December 2010<sup>2</sup>, the common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation referred to in Commission Regulation (EU) No 1169/2010 of 10 December 2010<sup>3</sup> and the common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation referred to in Commission Regulation (EU) No 1077/2012 of 16 November 2012<sup>4</sup>. This mandate to the Agency is aimed at further harmonising conformity assessment approaches among Member States. The Agency

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<sup>1</sup> OJ L 138, 26.05.2016, p. 102.

<sup>2</sup> OJ L 326, 10.12.2010, p. 11.

<sup>3</sup> OJ L 327, 11.12.2010, p.13.

<sup>4</sup> OJ L 320, 17.11.2012, p. 3.

submitted its recommendation on the revision of the CSMs to the Commission, supported by an impact assessment report to address the mandate of the Commission. This Regulation is based on that Agency recommendation.

- (6) After a single safety certificate or a safety authorisation is issued, the national safety authority should conduct supervision activities to check whether the management arrangements outlined in the application for a single safety certificate or a safety authorisation are being achieved during operation and that all the necessary requirements are complied with on a continuous basis, in accordance with Article 16(2)(d), Article 16(2)(j) and Article 17 of Directive (EU) 2016/798.
- (7) Essential requirements applicable to subsystems that are covered by technical specifications for interoperability are legal requirements which are to be taken into account in the safety management systems of railway undertakings and infrastructure managers. When national safety authorities supervise that interoperability constituents are operated and maintained in accordance with the essential requirements, as required by Article 16(2)(d) of Directive (EU) 2016/798, they do so with the aim of checking the correct application of the safety management systems.
- (8) In undertaking supervision, the national safety authorities should apply the fundamental principles of targeting, proportionality, consistency, transparency, accountability and cooperation. However, these principles also need a framework and process to apply them in practice in the day-to-day activities of the national safety authorities. This Regulation provides the necessary framework and process to the national safety authorities, while improving the mutual trust in their approaches to, and decision-making during supervision activities.
- (9) In accordance with Article 17(9) of Directive (EU) 2016/798, the national safety authorities should cooperate with each other and so, avoid any duplication of supervision.
- (10) Where supervision involves checking the safety requirements of products or services provided by railway undertakings, infrastructure managers or their contractors, partners or suppliers, authorisations, recognitions or certificates granted in accordance with relevant Union law to railway undertakings, infrastructure managers or their contractors, partners or suppliers should be considered as valid evidence of compliance with the relevant assessment criteria (or parts of them) defined in Commission Delegated Regulation (EU) No ... of .. on a common safety method for assessing conformity with the requirements for obtaining a railway safety certificate<sup>5</sup> and Commission Delegated Regulation (EU) No ... of .. on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation<sup>6</sup>. The monitoring of compliance ensured by competent authorities, other than national safety authorities, should therefore be taken into account to avoid any duplication of supervision (or equivalent).
- (11) In accordance with Article 17(1) and Article 17(8) of Directive (EU) 2016/798, in cases where railway undertakings and infrastructure managers are also entities in charge of maintenance that are not certified in accordance with Article 14(4) of Directive (EU) 2016/798, supervision activities carried out by national safety authorities with the aim of checking the application of the relevant CSMs referred to in Article 6 of Directive (EU) 2016/798 by entities in charge of the maintenance are justified means for

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<sup>5</sup> OJ: Please insert the number of the revised CSM Regulation on conformity assessment.

<sup>6</sup> OJ: Please insert the number of the revised CSM Regulation on conformity assessment.

supervising the effectiveness of the safety management systems of these railway undertakings and infrastructure managers.

- (12) To be able to perform its tasks under Article 16(2)(i) of Directive (EU) 2016/798, the national safety authority also needs to form a judgement, based on the outcomes of its supervision activities, on the effectiveness of the safety regulatory framework.
- (13) In accordance with Article 17(13) of Directive (EU) 2016/798, the Agency, acting as safety certification body, and the national safety authorities should coordinate when and where appropriate to ensure the full exchange of information between assessment and supervision activities, including any notices addressed to railway undertakings. Similarly, the relevant national safety authorities should coordinate in the case of cross-border infrastructures.
- (14) The techniques for supervision commonly include interviews with people at various levels in an organisation, reviewing documents and records related to the safety management system and examining the safety outcomes of the management system revealed by inspections or related activities.
- (15) The national safety authorities should cooperate, where necessary, with other competent authorities (or bodies) that interact in the railway sector, such as the regulatory bodies and the licensing authorities within the meaning of Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area (recast)<sup>7</sup>, or the competent authorities for monitoring compliance with applicable working, driving and rest-time rules for train drivers, to deliver their respective mandates, resolve any conflicts in approach and prevent related adverse effects in the railway system.
- (16) Commission Regulation (EU) No 1077/2012 has become obsolete and should therefore be replaced by this Regulation.

HAS ADOPTED THIS REGULATION:

#### *Article 1*

##### **Subject matter**

This Regulation establishes a CSM for the supervision of the management of safety by national safety authorities of railway undertakings after they have been issued (single) safety certificates and infrastructure managers after they have been issued safety authorisations, as referred to in Article 6(1)(c) and Article 17(1) of Directive (EU) 2016/798.

#### *Article 2*

##### **Scope**

1. National safety authorities shall use this Regulation to perform their supervision activities on a continuous basis with the aim of checking:

- (a) the correct application and effectiveness of the safety management systems (or part(s) of it) of railway undertakings and infrastructure managers in controlling safety risks associated with their activities, including in particular:
  - (i) operations and maintenance;
  - (ii) the supply of material;

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<sup>7</sup> OJ L 121, 3.5.2013, p. 8.

- (iii) the management of contractors, partners and suppliers;
  - (iv) the integration and management of human factors;
  - (v) the promotion of a positive safety culture;
- (b) the application of relevant CSMs referred to in Article 6 of Directive (EU) 2016/798.
2. National safety authorities shall use this Regulation to perform their tasks under Article 16(2)(i) of Directive (EU) 2016/798 and to advise the Member States on the effectiveness of the safety regulatory framework.
3. For an infrastructure manager with cross-border infrastructure(s) or a railway undertaking operating in more than one Member State, the relevant national safety authorities shall promptly decide, after the granting of the safety authorisation or single safety certificate, which of them is to have a leading role for coordinating the supervision of the correct application and effectiveness of the safety management system, as referred to in point (a) of paragraph 1, pursuant to Article 10 of this Regulation, without prejudice to the obligations of the national safety authorities under Article 16(2)(d), Article 16(2)(j) and Article 17 of Directive (EU) 2016/798.

### *Article 3*

#### **Definitions**

For the purposes of this Regulation, the definitions of Commission Delegated Regulation (EU) No ...<sup>8</sup> and Commission Delegated Regulation (EU) No ...<sup>9</sup> shall apply.

### *Article 4*

#### **Supervision process**

1. National safety authorities shall be responsible for conducting the supervision process set out in Annex I.
2. The supervision activities shall be targeted primarily at those activities which a national safety authority believes give rise to the most serious risks or where the hazards are least well-controlled. To that end, the national safety authority shall develop and implement a risk-based supervision strategy and plan(s) outlining how it targets its activities and sets its priorities for supervision.
3. National safety authorities shall apply the principle of proportionality between enforcement and risk. Action taken by a national safety authority to ensure railway undertakings and infrastructure managers achieve compliance or bring them to account for not meeting their legal obligations shall be proportionate to any risks to safety or to the potential seriousness of any non-compliance, including any actual or potential harm.
4. National safety authorities shall apply the principle of consistency of approach to ensure that a national safety authority takes a similar approach in similar circumstances to achieve similar ends
5. National safety authorities shall decide on their priorities so as to use their resources effectively but the decision on how best to do that should rest with each individual national

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<sup>8</sup> OJ: Please insert the number of the revised CSM Regulation on conformity assessment for obtaining single safety certificates.

<sup>9</sup> OJ: Please insert the number of the revised CSM Regulation on conformity assessment for obtaining safety authorisations.

safety authority. Action shall be focused on those who are responsible for the risk and who are best placed to control it.

6. National safety authorities shall apply the principle of transparency to help railway undertakings and infrastructure managers understand what is expected of them (including what they should or should not do) and what they should expect from the national safety authority.

7. National safety authorities shall be accountable for their decisions in accordance with Article 18(3) of Directive (EU) 2016/798. National safety authorities shall therefore have internal arrangements against which they can be held to account.

#### *Article 5*

### **Techniques for supervision**

The national safety authority shall adopt suitable techniques, such as audits and inspections, for the purposes set out in Article 2 and identify these techniques when planning its supervision activities.

#### *Article 6*

### **Interface with assessment**

1. The national safety authority carrying out supervision shall use and when relevant, share information gathered on the performance of the safety management system during its supervision activities for the purpose of renewing or updating single safety certificates or safety authorisations.

2. In cases where the national safety authority referred to in paragraph 1 is not responsible for issuing the single safety certificate or safety authorisation, it shall coordinate promptly with the Agency acting as safety certification body or the relevant national safety authority, in the case of cross-border infrastructure, on its request, after the receipt of an application for renewal or update.

Based on the outcome of the coordination referred to in the first subparagraph, the national safety authority shall identify and target the information which is relevant to an understanding of how well the railway undertaking's or infrastructure manager's safety management system is effectively working, including at least:

- (a) A description of major non-compliances, which may affect safety performance or create serious safety risks, and any other area of concern identified during supervision activities since the previous assessment;
- (b) The status of the action plan (or plans) established by the railway undertaking or infrastructure manager to resolve major non-compliances and any other area of concern referred to in point (a) and relevant actions that have been taken by the national safety authority to supervise resolution of these issues;
- (c) An overview of the safety performance of the railway undertaking or infrastructure manager operating in its Member State.
- (d) The status of the action plan (or plans) established by the railway undertaking or infrastructure manager to resolve residual concerns from previous assessment.

#### *Article 7*

### **Competence of the persons involved in supervision activities**

1. The national safety authority shall have a competence management system in place to ensure that supervision activities are undertaken by competent persons, which shall include:

- (a) The development of competence profiles for each job, position or role;
- (b) The selection and/or recruitment of staff, assessing them against the established competence levels;
- (c) The maintenance of competence by training, development and assessment of staff against the established competence levels.

2. The competence management system of the organisation has to ensure through its processes (e.g. training, mentoring, shadowing, on-the-job training) that staff involved in supervision demonstrate the appropriate level of competence for the performance of their tasks. The competencies listed below must be held by the individual carrying out the supervision activities or, in the case of team work, must be shared amongst the team members:

- (a) Knowledge of the relevant regulatory framework as it applies to supervision;
- (b) Knowledge of the functioning of the railway system;
- (c) Appropriate level of critical analysis to enable them to carry out supervision tasks;
- (d) Experience of the supervision of a safety or similar management system in the railway sector or a safety management system in a sector with equivalent operational and technical challenges;
- (e) Knowledge of and experience in interviewing skills;
- (f) Relevant non-technical competencies, including, but not limited to, problem solving, communication and team working that enable them to carry out their tasks.

#### *Article 8*

##### **Decision-making criteria**

1. The national safety authority shall establish and publish decision-making criteria on how it evaluates the correct application of a safety management system by a railway undertaking or infrastructure manager and the effectiveness of the safety management system in controlling safety risks associated with the activities of the railway undertaking or infrastructure manager. These criteria shall also include information on how the national safety authority manages and deals with non-compliances identified in the safety management system of the railway undertaking and infrastructure manager.

2. The national safety authority shall adopt and publish a procedure to enable railway undertakings, infrastructure managers and any other interested party to submit a complaint on decisions taken during supervision activities, without prejudice to the requirement for a judicial review of those decisions.

#### *Article 9*

##### **Coordination and cooperation between national safety authorities**

1. National safety authorities involved in the supervision of an infrastructure manager with cross-border infrastructure(s) or of a railway undertaking operating in more than one Member State shall coordinate their approach to supervision, as referred to in Article 17(7) and Article 17(9) of Directive (EU) 2016/798 respectively, to ensure that any key information on the specific infrastructure manager or railway undertaking (particularly on known risks and its safety performance) is shared and used to target supervision activities on the areas of greatest

risk for the whole operation. To that end, the national safety authorities shall develop arrangements based on the framework for coordinated and joint supervision set out in Annex II to this Regulation.

2. National safety authorities shall develop cooperation arrangements with the Agency, national investigation bodies, certification bodies for entities in charge of maintenance and other competent authorities in order to share information and to coordinate their response to any failure to comply with the safety regulatory framework.

#### *Article 10*

##### **Repeal**

Commission Regulation (EU) No 1077/2012 is hereby repealed.

References to the repealed Regulation shall be construed as references to this Regulation.

#### *Article 11*

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

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

It shall apply from 16 June 2019 in the Member States that have not notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798. It shall apply from 16 June 2020 in all Member States.

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

Done at Brussels,

*For the Commission*

*The President*

**PROCESS FOR OVERSEEING CONTINUED COMPLIANCE WITH THE LEGAL OBLIGATION INCUMBENT ON RAILWAY UNDERTAKINGS AND INFRASTRUCTURE MANAGERS TO USE A SAFETY MANAGEMENT SYSTEM AS REFERRED TO IN ARTICLE 9 OF DIRECTIVE (EU) 2016/798**

**1. General**

The national safety authority shall develop a structured and auditable process for the complete activity which takes into account the elements below. This ensures that the supervision process is iterative and takes into account the need to continually improve, as shown in the diagram below in the Appendix.

**2. Setting up the supervision strategy and plan(s)**

The national safety authority shall:

- (a) collect and analyse data/information from a variety of sources as an input to the strategy and the plan or plans. Sources could include information gathered during the assessment of safety management systems, outcomes of previous supervision activities, information from authorisations of subsystems or vehicles, national investigation bodies accident reports/recommendations, other accident/incident reports or data, railway undertakings' or infrastructure managers' annual safety reports to the national safety authority, annual maintenance reports from entities in charge of maintenance, complaints from members of the public and other relevant sources.
- (b) identify in the supervision strategy risk areas for targeted supervision activities, including those emerging in the human factors analysis and strategy, where relevant;
- (c) develop a supervision plan or plans showing how it will give effect to the supervision strategy during the lifecycle of valid (single) safety certificates and safety authorisations;
- (d) produce an initial estimate of resources required to give effect to the plan or plans, based on the target areas identified;
- (e) allocate resources to give effect to the plan or plans;
- (f) address in the supervision strategy and plan(s) any matters relating to cross-border operations or infrastructure(s) through coordination with other national safety authority (or authorities).

**3. Communicating the supervision strategy and plan(s)**

The national safety authority shall:

- (a) communicate the overall objectives of the supervision strategy and overall explanation of the plan or plans to relevant railway undertakings or infrastructure managers and, where appropriate, more widely to other stakeholders;
- (b) provide relevant railway undertakings or infrastructure managers with an overall explanation on how the supervision plan or plans will be undertaken.

**4. Delivering the supervision activities**

The national safety authority shall:

- (a) give effect to the plan or plans ;



- (b) take proportionate action(s) to deal with failure of a railway undertaking or an infrastructure manager to comply with its legal obligations, including issuing any urgent safety alerts and applying temporary safety measures when necessary;
- (c) evaluate how adequately a railway undertaking or an infrastructure manager has developed and implemented an action plan or plans to remedy any non-compliance or residual concern within a specified time period;
- (d) document the results of its supervision activities.

#### **5. Outcomes of supervision activities**

The national safety authority shall:

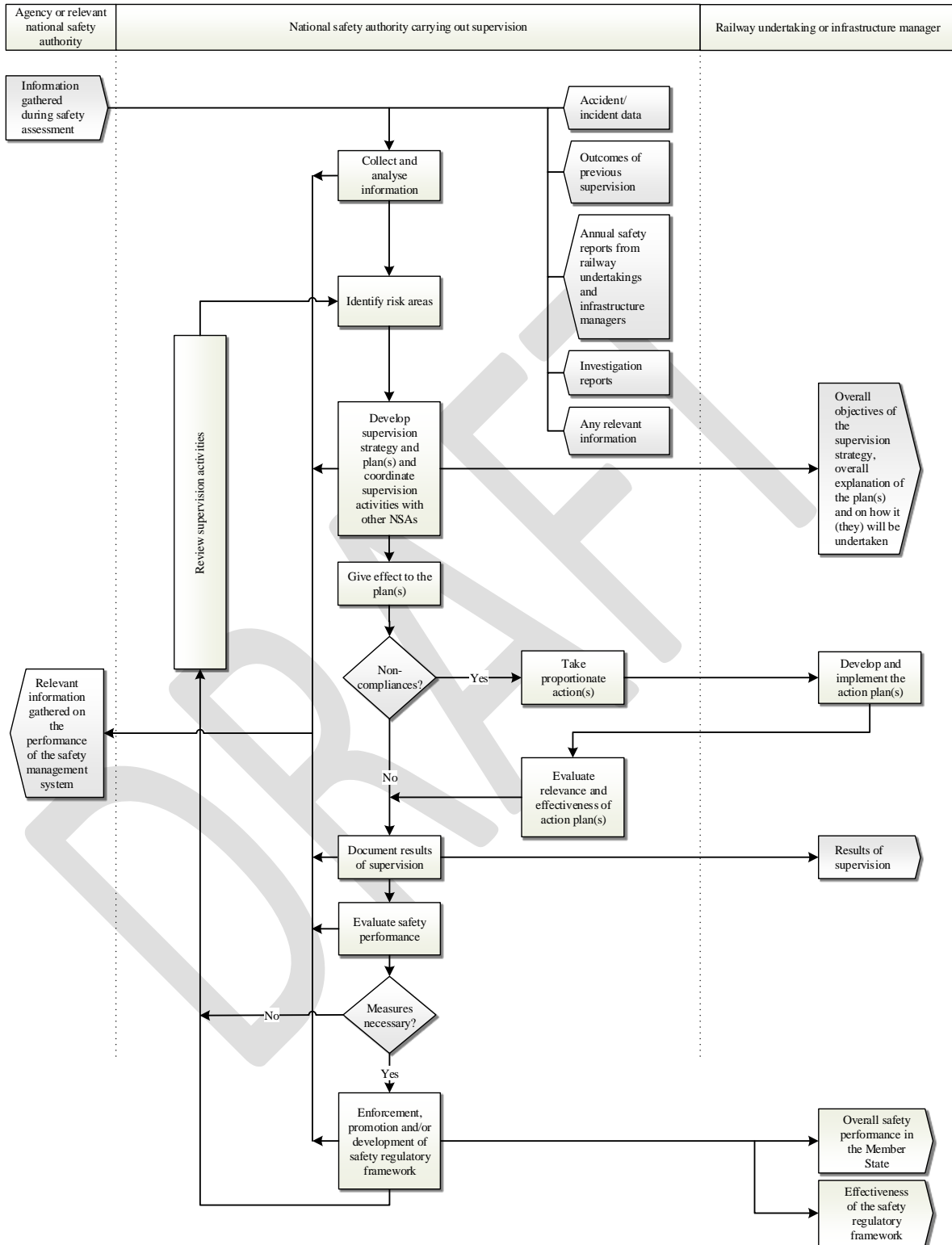
- (a) share results of its supervision activities with the relevant railway undertaking or infrastructure manager, including identifying areas of non-compliance on the part of the railway undertaking or infrastructure manager and any areas of good practice to support safety improvement;
- (b) have an overview of the safety performance of the individual railway undertakings or infrastructure managers operating in its Member State;
- (c) publish and communicate to relevant stakeholders its views on the overall safety performance in the Member State;
- (d) publish and communicate to relevant stakeholders its views on the effectiveness of the safety regulatory framework;
- (e) use and when relevant, share information on the performance of the safety management system gathered during the supervision of railway undertakings or infrastructure managers, prior to reassessing the application for a renewal or an update of the single safety certificate or the safety authorisation, with the Agency acting as safety certification body or the relevant national safety authority, in the case of cross-border infrastructure.

#### **6. Reviewing supervision activities**

On the basis of information gathered and experience gained during supervision activities and the safety performance both at individual level and at Member State level, the national safety authority shall at regular intervals:

- (a) conduct a review of the supervision strategy and plan(s) to check that the original targeted activity, use of data/information from a variety of sources, supervision outcomes and resource allocation are appropriate, changing priorities as necessary;
- (b) revise the plan or plans if needed and consider the impact of the changes on the supervision strategy;
- (c) contribute when necessary with its views and any proposals to its Member State to overcome any deficiencies in the safety regulatory framework.

# Appendix



## ANNEX II

### FRAMEWORK FOR COORDINATED AND JOINT SUPERVISION

The relevant national safety authorities shall develop arrangements based on the following principles and specific elements:

1. Agree which railway undertakings and infrastructure managers are operating in such a manner as to require coordinated or joint supervision.
2. Agree on common language(s) and the level of confidentiality of the information to be used for the purposes of their coordination arrangements.
3. Agree what information to exchange and a timetable for the exchange:
  - (a) exchange relevant information on railway undertakings and infrastructure managers identified under point 1 and share results from their assessment activities;
  - (b) provide copies of safety authorisations where appropriate;
  - (c) share results from related supervision activities, including enforcement decisions and actions, where relevant;
  - (d) share information on the safety performance of railway undertakings and infrastructure managers identified under point 1 in each Member State.
4. Share decision-making criteria:
  - (a) share information on how each national safety authority targets its activities for each railway undertaking and infrastructure manager concerned as part of the supervision plan;
  - (b) establish a dialog between relevant national safety authorities on the proposed response to dealing with major compliance gaps.
5. Manage coordination:
  - (a) share existing supervision strategies and plans;
  - (b) establish common points of interest and/or common issues;
  - (c) plan efficiently individual, coordinated or joint initiatives without causing unnecessary inconvenience to the railway undertakings and infrastructure managers and by avoiding overlaps in the scope of these initiatives.
6. Agree on which national safety authority (or authorities) should follow up actions for which completion is deferred for supervision where appropriate.
7. Agree what areas to target in a coordinated or joint manner:
  - (a) identify key risks for the relevant railway undertakings and infrastructure managers to be addressed in a coordinated or joint manner by national safety authorities;
  - (b) agree which national safety authority will lead activities on what issues, where relevant, on the basis of well-established criteria;
  - (c) agree what types of joint supervision activities to undertake, where relevant;
  - (d) agree how railway undertakings and infrastructure managers should be made aware of the arrangements and agreements national safety authorities are reaching.
8. Share good practice:

- (a) develop arrangements to review and coordinate on a regular basis the supervision activities for the relevant railway undertakings and infrastructure managers;
- (b) develop arrangements to evaluate the effectiveness of the coordination and cooperation between national safety authorities, including the Agency as appropriate.

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