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Clarification note

Sharing of supervision information for the purpose of the assessment

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Document History

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1.0	21/01/2020	First version

The purpose of this document is to foster an harmonised EU approach to the safety certification process. Those concerned with this clarification note are encouraged to voluntarily apply it.

The present document is a non-legally binding guidance of the European Union Agency for Railways. It is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

1. Description of the issue

The national safety authority carrying out supervision shall use and, where 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.

However, supervision results may not be shared with a level of detail compliant with Article 5 of Regulation (EU) 2018/761.

As a consequence:

- › The safety certification body may not receive supervision information with a level of detail sufficient to understand how the railway undertaking's or infrastructure manager's safety management system is performing;
- › As a result of not receiving adequate information the safety certification body may not be in a position to consider the results of past supervision activities to prioritise or target its assessment.

2. Clarification

Although it is admissible to have different approach to sharing the outcome of supervision activities between authorities, sufficiently detailed information should be exchanged to be able form a view on how the railway undertaking's safety management system is performing. This could entail the supervision strategy and plan of the national safety authority, audit and inspection reports, description of non-conformances found by the national safety authority with related action plans set up by the railway undertakings, etc. (see section 5 of [Agency guide on supervision](#) for more details).

In the case where the national safety authority carrying out supervision identifies any major non-compliances, which may affect safety performance or create serious safety risks, the national safety authority should inform the authorities concerned. On their request, the national safety authority should share relevant information, in particular the information listed above.

3. Legal background

a) Regulation (EU) 2018/763

- Annex II. Safety assessment process

[...]

7.1. A single safety certificate may be renewed upon request of the applicant before the expiry of its validity to ensure continuity of certification.

[...]

8.1. A single safety certificate shall be updated whenever there is a substantial change proposed to the type or extent of operation in accordance with Article 10(13) of Directive (EU) 2016/798, or in case of extension of the area of operation in accordance with Article 10(14) of that Directive.

[...]"

b) Regulation (EU) 2018/761

- Article 5. Links between supervision and assessment

1. The national safety authority carrying out supervision shall use and, where 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 assessing whether 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.”

c) Directive (EU) 2016/798

- **Article 17. Supervision**

“[...]

9. The national safety authorities of Member States where a railway undertaking operates shall cooperate in coordinating their supervision activities concerning that railway undertaking to ensure that any key information on the specific railway undertaking is shared, particularly on known risks and its safety performance. The national safety authority shall also share information with other relevant national safety authorities and the Agency if it finds that the railway undertaking is not taking the necessary risk control measures.

[...]

12. For the purpose of renewing single safety certificates, the Agency, or the competent national safety authorities in the case of a safety certificate issued in accordance with Article 10(8), shall use information gathered during the supervision activities. For the purpose of renewing safety authorisations, the national safety authority shall also use information gathered during its supervision activities.

13. The Agency and the national safety authorities shall make the necessary arrangements to coordinate and ensure the full exchange of information referred to in paragraphs 10, 11 and 12.”