

OPINION

ERA/OPI/2024-07

OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

for

Denmark

regarding

health and competence requirements for certain safety-classified railway functions

Disclaimer:

The present document is a non-legally binding opinion of the European Union Agency for Railways. It does not represent the view of other EU institutions and bodies, and 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. General Context

In line with article 26 (3) of Regulation (EU) 2016/796, this opinion covers the examination of one adopted national rule of Denmark by the European Union Agency for Railways (the Agency or ERA) leading to a negative assessment.

Denmark notified the adopted rule (DK SA 1180 1 A) in the Single Rules Database (SRD) on 21 March 2024. The Agency assessed the rule and reached the conclusion (also recorded in the SRD) that the notified adopted rule contains requirements which according to the Agency's opinion do not meet the scope requirements for notification of a national rule in the field of safety, according to Article 8 of Directive (EU) 2016/798 on railway safety.

The Agency shared its negative assessment with Denmark on 21 May 2024. Denmark rejected the Agency assessment on 12 July 2024.

This opinion is addressed to Denmark with a copy to the European Commission.

It is uploaded on the Single Rules Database (SRD) and on the Agency's website.

2. Legal Background

Article 26 (3) of the Regulation (EU) 2016/796 sets out the following:

Where the examination referred to in paragraph 1 leads to a negative assessment, the Agency shall inform the Member State concerned and ask it to state its position regarding that assessment. If, following that exchange of views with the Member State concerned, the Agency maintains its negative assessment, the Agency shall within a maximum period of 1 month:

- (a) *issue an opinion addressed to the Member State concerned, stating that the national rule or rules in question has or have been the subject of a negative assessment and the reasons why the rule or rules in question should be modified or repealed; and*
- (b) *inform the Commission of its negative assessment, stating the reasons why the national rule or rules in question should be modified or repealed.*

This opinion is issued pursuant to Article 26 (3) of the Regulation (EU) 2016/796.

This opinion points out the fact that the adopted national rule of Denmark does not meet the scope requirements for an assessment.

The applicable EU legislation which is relevant for this opinion is:

- *Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety,*
- *Commission delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010,*
- *Commission Regulation (EU) No 1078/2012 of 16 November 2012 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,*
- *Commission Delegated Regulation (EU) 2018/761 of 16 February 2018 establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a*

safety authorisation pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 1077/2012,

- Commission implementation Regulation (EU) 2019/773 of 16 May 2019 on the technical specification for interoperability relating to the operation and traffic management subsystem of the rail system within the European Union and repealing Decision 2012/757/EU,

3. Analysis

The adopted rule sets out requirements on information and reporting obligations on railway companies and individuals to the National Safety Authority of Denmark when they do not meet the medical or competence requirements. It covers both railway undertakings and infrastructure managers, which are referred to as 'companies'.

The Agency in its assessment stated that the imposition of the obligation to submit information and report to a National Safety Authority on non-compliance with competence or medical fitness requirements is not permitted as a national rule. These are issues that should be picked up by the NSA during the supervision of the railway companies when checking that staff remain medically fit and competent for the task.

The Agency has, in the past, refused rules from other EU Member States on the same grounds.

Denmark (DK) stated in its response to the Agency's assessment that:

It is the opinion of The Danish NSA, that the duty to report, when a person no longer meets the health requirements, or the competence requirements outlined in § 10, cannot be replaced by a supervisory function.

Currently, The Danish NSA receives a significant number of reports in accordance with § 10 from railway companies and staff performing safety-critical tasks. These reports often lead to the suspension of the administrative decision, which documents, that the person is medical fit in accordance with the medical requirements in TSI OPE. Hence, these reports directly affect the Danish NSA's enforcement of railway staff's lacking compliance with the medical requirements.

If The Danish NSA by supervision is to discover a similar number of cases, it will pose a twofold problem:

Firstly, this solution will be very costly, as The Danish NSA would have to expand its supervisory staff with people with medical knowledge, meant for the examination of the health of individual staff members of railway companies.

Secondly, the supervisory function of The Danish NSA would lack the necessary legal authority to examine the health of staff during supervision. The disclosure of the medical information of staff performing safety-critical tasks, is currently based on consent.

Furthermore, even if the aforementioned conditions are disregarded, a model of supervision based on random samples by which The Danish NSA operates, cannot be expected to identify a similar number of cases in which staff are no longer compliant with the medical requirements.

It is the experience of The Danish NSA, that an explicit legal authority is to be desired, determining the duty of staff and railway operators to report a lack of compliance, since The Danish NSA has in its dialogue with Danish railway operators learned that many rely on the wording in the executive order, to understand the extent of the duty to report a lack of compliance. This explicit legal authority is also useful, since the administrative decisions of The Danish NSA documenting staff's compliance with the medical requirements, are a matter between the individual member of staff and The Danish NSA, which the railway operators are not privy to the details of. If railway operators are to report on the medical conditions of their staff to the Danish NSA, a clear legal authority is needed.

Based on the arguments stated above, it is the assessment of The Danish NSA, that the revoking of § 10, would lead to a deterioration of railway safety in Denmark.

Finally, it is noted that article 18 of The Train Driver's Directive (TDD) contains a rule like the one in § 10, determining the duty to report on a lack of compliance with the directive's medical requirements. The Danish NSA finds this discrepancy between the TDD and TSI OPE unfortunate.

The Agency maintains its original opinion despite the arguments from DK because of the following reasons:

- a) The argument made by DK is noted. However, national rules are in principle permitted for the railway companies, in this instance railway undertakings, to comply with what is necessary in relation to meeting the safety management system requirements for the Single Safety Certificate and not to replace supervision activities that the NSA should undertake in their role under Articles 16 and 17 of Directive (EU) 2016/798. This includes monitoring the effectiveness of the safety management systems that railway companies should set up in order to manage all the risks from their operation.
- b) National legislation such as the law transposing the Train Drivers Directive (TDD) or parts of it is not to be notified as a national rule in the SRD. This is because a notification to the SRD would result in a duplication of the notification processes; the European Commission would have to verify the completeness and correctness of transposition of EU law into national law. This information is then made publically available.
- c) The notification of national rules is now dependent on whether they are permitted by Commission Implementing Regulation (EU) 2019/773, *Appendix I* (as amended in 2023 and was subject to consultation with Member States). In this particular instance, there is no provision in either Annex I (1) Areas for national rules or (2) List of open points. The only relevant permitted areas are 'alcohol, drugs and psychotropic limits', which is not relevant to this requirement.
- d) If the national legislation contains rules transposing the TDD, then this can remain in national legislation and the reporting can continue. However, there is no provision for it to be notified as a national rule in the SRD.
- e) In relation to the issue of management of competence including health, under both Directive (EU) 2016/798 and Commission Delegated Regulation (EU) 2018/762, it is the responsibility of railway companies to have an effective safety management system to control the risks arising from their operations. This also includes ensuring that they take a systematic approach to supporting human performance, in this case the competence of their employees and their suitability to undertake activities that can affect the safety of that operation.

4. The opinion

The Agency considers that the provisions in the adopted national safety rule of Denmark do not fall within the scope of notification of a national rule in the field of safety in SRD, according to Article 8 of Directive (EU) 2016/798 on railway safety. For this reason, in accordance with Article 26 (3) of Regulation (EU) 2016/796, the Agency with this opinion confirms its negative assessment.

This opinion is addressed to the Kingdom of Denmark, with a copy to the European Commission (DG Move).

Valenciennes, 26/07/2024

Josef DOPPELBAUER
Executive Director

Annex 1

Impact Note

regarding one adopted national rule by Denmark on health and competence requirements for certain safety-classified railway functions

Issued as per Art. 8(1) of Regulation (EU) 2016/796 and the Impact Assessment procedure adopted by the ERA Management Board (Decision n.290, 16/03/2022)

1. Context and assessment of impacts

1.1. The national rule in object

As part of the assessment of the national safety rules under Article 8 of Directive (EU) 2016/798 in conjunction with article 26 of Regulation (EU) 2016/796, the Agency received from Denmark the notification of one adopted national rule (DK SA 1180 1 A) in the Single Rules Database (SRD) on 21 March 2024. The rule sets out requirements on information and reporting obligations on railway companies and individuals to the Danish National Safety Authority when they do not meet the medical or competence requirements.

1.2. Analysis performed

In its first assessment, the Agency indicated that the imposition of the obligation to submit information and reports to the National Safety Authority on non-compliance with competence or medical fitness requirements is not permitted as a national rule. These are issues that should be picked up by the NSA during the supervision of the railway companies when checking that staff remain medically fit and competent for the task. The Agency has, in the past, refused rules from other EU Member States on the same grounds.

In its reply, Denmark remained of the opinion that the duty to report, when a person no longer meets the health or competence requirements, cannot be replaced by a supervisory function. For them this solution will be costly, since in their opinion the Danish NSA would have to expand its supervisory staff with people with medical knowledge, meant for the examination of the health of individual staff members of railway companies. Secondly, they indicated that the supervisory function of the Danish NSA would lack the necessary legal authority to examine the health of staff during supervision. Finally, in their opinion, a model of supervision based on random samples, cannot be expected to identify the same number of cases in which staff are no longer compliant with the medical requirements. Denmark also noted that article 18 of the Train Driver's Directive (TDD) contains a rule like the one in § 10, determining the duty to report on a lack of compliance with the directive's medical requirements.

In the final opinion the Agency confirmed its initial assessment that the current rule as notified cannot be accepted, since its provisions do not fall within the scope of notification of a national rule in the field of safety in SRD, according to Article 8 of Directive (EU) 2016/798 on railway safety. It is the responsibility of railway companies to have an effective safety management system to control the risks arising from their operations; this also includes ensuring that they take a systematic approach to supporting human performance, in this case the competence of their employees and their suitability to undertake activities that can affect the safety of that operation.

1.3. Assessment of impacts

The national rule in object adopted by Denmark falls within the scope of the Light Impact Assessment 'Revision of the Common Safety Methods on Conformity Assessment and of the Common Safety Methods on Supervision' performed by the Agency in February 2017 and of the Full Impact Assessment on the TSI OPE Revision carried out in 2018.

The impacts were therefore already adequately assessed and it is confirmed that the adopted rule compromises uniformity of application of well-established EU requirements, increases the risk of low transparency of the national rules framework that stakeholders have to comply within Denmark as well as interoperability of RUs.

In particular, the obligation to submit information and reports to the Danish National Safety Authority on non-compliance with competence or medical fitness requirements is not permitted as a national rule, since it is not in the scope of either 1) Annex I (Areas for national rules) or 2) list of open points of EU Regulation 2019/773. If the national legislation contains a rule transposing the Train Driver Directive, then this can remain in the national legislation but there is no provision for it to be notified as a national rule. In SRD

Regarding the points raised by Denmark in its reply, the Danish NSA would not need to expand its supervisory staff with people with medical knowledge, meant for the examination of the health of staff members during supervision (and for which it lacks also the necessary legal authority). The NSA will need to check that the railway company has a system in place to ensure that staff performing specific tasks have the necessary competence and health requirements; the NSA will need to check the evidence (e.g. documents) and the procedures used by the company for that purpose (with no need to directly examine the health of the staff during supervision).

Similarly, to the NSA it is not required to know all the cases in which staff is no longer compliant with the competence and medical requirements; the focus should be on checking that there are procedures ensuring that those employees do not perform the tasks for which (and as long as) they are not medically fit and/or competent.

It is the responsibility of railway companies to have an effective safety management system to control the risks arising from their operations; this also includes ensuring that they take a systematic approach to supporting human performance, in this case the competence of their employees and their suitability to undertake activities that can affect the safety of that operation.

The adopted national rule is not compliant with already harmonised EU legislation, risking to weaken/affect interoperability and coherence of the EU legal framework across the Union, being in contrast with the policy goal of reducing national rules and creating unnecessary burden on stakeholders (including additional reporting burden on railway companies and unnecessary efforts to ensure the enforcement of the additional national rules on top of all other existing requirements pertaining to EU law).

1.4. Stakeholders affected

Railway undertakings (RU)	<input checked="" type="checkbox"/>	Member States (MS)	<input type="checkbox"/>
Infrastructure managers (IM)	<input checked="" type="checkbox"/>	Third Countries	<input type="checkbox"/>
Manufacturers	<input type="checkbox"/>	National safety authorities (NSA)	<input checked="" type="checkbox"/>
Keepers	<input type="checkbox"/>	European Commission (EC)	<input checked="" type="checkbox"/>
Entity Managing the Change (EMC)	<input type="checkbox"/>	European Union Agency for Railways (ERA)	<input checked="" type="checkbox"/>
Notified Bodies (NoBo)	<input type="checkbox"/>	Shippers	<input type="checkbox"/>
Associations	<input type="checkbox"/>	Other (Please specify) ...	<input type="checkbox"/>

2. Preferred option

2.1. Recommendation

No alternative options are to be assessed and it is confirmed a negative assessment of the national rule in object adopted by Denmark.