

Moving Europe towards a sustainable and  
safe railway system without frontiers.

# OPINION

*ERA/OPI/2026-9*

## OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

for

BELGIUM

regarding

two (2) notified draft national rules setting out requirements on  
operational aspects

### 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 8 Directive (EU) 2016/798 (“Railway Safety Directive” or “RSD”) and Article 25 Regulation (EU) 2016/796 (“the Agency Regulation”), this opinion covers the examination by the European Union Agency for Railways (hereinafter “the Agency” or “ERA”) of two (2) Belgian draft national rules setting requirements on several operational aspects.

Belgium notified these rules in the Single Rules Database (“the SRD”) on 11 August 2025<sup>1</sup>. The Agency assessed them and reached the conclusion (also recorded in the SRD) that the notified draft rules contain requirements which, according to the Agency’s opinion, are not in line with the EU legal framework, mainly Commission Implementing Regulation (EU) 2019/773 (“TSI OPE”) and Commission Delegated Regulation (EU) 2018/762 establishing common safety methods on safety management system requirements (“CSM-SMS”)<sup>2</sup>.

The Agency shared with Belgium its negative assessment on 08 October 2025 through SRD.

Considering the complexity of the notified rules and to facilitate several further exchanges, Belgium had the 2-months’ timeframe for submitting their position extended to 18 May 2026. On 18 May 2026, Belgium notified the Agency via SRD its rejection of the Agency’s negative assessment of two (2) adopted national rules.

This opinion is addressed to Belgium with a copy to the European Commission (“EC”).

It is uploaded on the SRD and on the Agency’s website.

## 2. Legal Background

Article 25 (3) Agency Regulation 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 the reasons why the national rule or rules in question should not enter into force and/or be applied; and*
- (b) inform the Commission of its negative assessment, stating the reasons why the national rule or rules in question should not enter into force and/or be applied.*

This opinion is issued pursuant to Article 25 (3) Agency Regulation.

This opinion points out that the draft national rules by Belgium are not within the scope of the assessment and/or conflict with already harmonised EU legislation, according to the analysis and the Annex to this opinion. 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 Implementing 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, as amended by:
  - o Commission Implementing Regulation (EU) 2020/778 of 12 June 2020
  - o Commission Implementing Regulation (EU) 2021/2238 of 15 December 2021

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<sup>1</sup> This date applies for both rules [BE-SA-1655-1-D](#) and [BE-SA-325-2-D](#).

<sup>2</sup> Detailed information as also the reference to the legal acts is included in the table in part 3 of this opinion.

- Commission Implementing Regulation (EU) 2023/1693 of 10 August 2023
  - Commission Implementing Regulation (EU) 2025/458 of 10 March 2025,
- 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 Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009,
- Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work.

### 3. Analysis

Two (2) notified draft rules that received negative assessments are included in the same legal document, i.e. Arrêté royal du 9 août 2020 déterminant les exigences applicables au personnel de sécurité et au personnel des entités en charge de l'entretien'.

The rules were notified as type 5 rules with the following scope defined: 'medical fitness'.

In the table below the Agency details the content of the negatively assessed rules as notified, Belgium's position and the Agency's analysis:

No	Rule ID	Rule content	Notified as	ERA's assessment result	Member State's (MS) position on ERA's negative assessment	MS position (translated in English by the Agency)	ERA's final opinion
1	<a href="#">BE-SA-1655-1-D</a>	<b>Arrêté royal du 9 août 2020 déterminant les exigences applicables au personnel de sécurité et au personnel des entités en charge de l'entretien – New Article 7/1:</b> Pursuant to Section 4.7 of the OPE TSI, safety personnel performing safety-critical tasks related to the operation of a passenger train shall demonstrate their psychological fitness by undergoing an examination conducted by or under the supervision of a psychologist qualified to perform such examinations.	5. Rules concerning requirements in respect of staff executing safety-critical tasks, including selection criteria, medical fitness and vocational training and certification, in so far as they are not yet covered by a TSI – applicable for Train crews	The TSI OPE, as amended in 2023, does not admit any national rule under appendix I on health and safety conditions (4.7) other than alcohol, drugs and psychotropic medication limits. During exchanges with the sector we became aware of possible misunderstandings under point 4.7.2 of TSI OPE on the possibility to have additional national rules. During the last Working Parties this problem is resolved and there is no longer any flexibility for MS to notify additional rules on this aspect. The TSI OPE text will be amended in short term. The TSI OPE is directly applicable no duplications nor extensions are allowed under the current circumstances. As a consequence, also Rule ID BE-SA-468-1-D cannot longer be accepted.	MS rejected ERA's negative assessment	This rule is applicable to staff performing safety-critical tasks falling outside the scope of TSI OPE. EC is currently working on a mandate for ERA to adopt new provisions covering the risks related to competence and medical/psychological fitness of all staff performing safety-critical tasks (through a possible new CSM on competence management - which would be BE's preferred choice, or an amendment of TSI OPE, or of CSM on SMS). Therefore, we consider these provisions to fall within not covered rules", as EU is intending the regulate them in the future, while they are not listed in open points of the TSI. In order not to reduce the level of safety on the BE network (and then later possibly increase it again on the basis of the future EU regulation), we therefore request the possibility to keep our national rule until the moment where EU law has covered this subject. Once the EU law will have covered that aspect, we will of course remove our national rule."	The Agency upholds its first assessment. The additional argumentation does not provide elements to review the Agency's position. This is because there is EU law in place which is already applicable – there is no legal gap. The rule is notified as a type 5 rule with scope 'medical fitness'. The TSI OPE, as amended in 2023, does not allow any national rule under appendix I on health and safety conditions (4.7) other than alcohol, drugs and psychotropic medication limits.  Consequently, there is no legal basis and margin for the adoption of such a national rule as Belgium did. ERA insists on its opinion that there is no risk for a reduced level of safety as the Regulation 2018/762 states 'staff having a role that affects safety are competent in the safety-related tasks for which they are responsible'; this should be managed by the RU's and IM's safety management system accordingly. National rules are only permitted under appendix I of the TSI OPE.  The rule cannot be accepted and therefore also rule ID BE-SA-468-1-D cannot longer be accepted.
2	<a href="#">BE-SA-325-2-D</a>	<b>Arrêté royal du 9 août 2020 déterminant les exigences applicables au personnel de sécurité et au personnel des entités en charge de l'entretien – Art.12:</b> Art. 12. § 1. Pursuant to section 4.7 of the OPE TSI, the safety personnel referred to in this chapter shall demonstrate their psychological fitness by undergoing an examination conducted by or under the supervision of a psychologist	5. Rules concerning requirements in respect of staff executing safety-critical tasks, including selection criteria, medical fitness and vocational training and certification, in so far as they are not yet covered by a TSI – applicable for shunter, staff moving in the	The TSI OPE, as amended in 2023, does not admit any national rule under appendix I on health and safety conditions (4.7) other than alcohol, drugs and psychotropic medication limits. During exchanges with the sector we became aware of possible misunderstandings under point 4.7.2 of TSI OPE on the possibility to have additional national rules. During the last Working Parties this problem is resolved and there is no longer any flexibility for MS to notify additional rules on this aspect. The TSI OPE text will be amended in short term. The TSI OPE is directly applicable no duplications or extensions are allowed under the current	MS rejected ERA's negative assessment	Article 7/1 aims to implement the flexibility granted to Member States under point 4.7 of the Annex to Commission Regulation (EU) 2019/773 of May 16, 2019, concerning the technical specification for interoperability relating to the "Traffic Operation and Management" subsystem of the rail system in the European Union and repealing Decision 2012/757/EU, with regard to the performance of psychological assessments prior to the assignment of train attendants. Point 4.7 of the Annex to Regulation (EU) 2019/773 allows Member States to determine whether a psychologist or a doctor may carry out or supervise examinations to demonstrate psychological fitness before assigning train attendants. The Belgian State has opted for these examinations to be carried out or supervised by a psychologist qualified to carry out this examination, as provided for in Article 7/1.	The Agency upholds its first assessment. The additional argumentation does not provide elements to review the Agency's position. This is because there is EU law in place which is already applicable – there is no legal gap.  More precisely:  The rule is notified as a type 5 rule with scope 'medical fitness'. The TSI OPE, as amended in 2023, does not allow the adoption of any national rule under appendix I on health and safety conditions (4.7) other than alcohol, drugs and psychotropic medication limits.

	<p>qualified to perform such an examination.</p> <p>§ 2. Unless the infrastructure user decides otherwise within the framework of its safety management system, safety personnel who were in service and performing safety-critical tasks prior to December 13, 2020, are deemed to meet the “pre-employment” requirements referred to in Section 4.7.2.1.2 of the OPE TSI.</p> <p>When a member of the safety staff changes positions and was already in service before December 13, 2020, or has already undergone a psychological examination in accordance with section 4.7.2.1. 2 of the OPE TSI, the Infrastructure user may, after consulting a physician qualified to conduct such an examination, take into account the health or safety requirements that applied to the previous assignment when deciding whether a new “pre-employment” examination is necessary. The same applies if a member of the safety staff changes from infrastructure user.</p>	<p>track areas and other staff</p>	<p>circumstances. As a consequence, also Rule ID BE-SA-325-1-A as also other drafts cannot longer be accepted.</p>	<p><b>Additional justification:</b> The European Commission has informed Belgium, following a question from us, that the OPE TSI will be amended in the future so that the choice of whether psychological assessments are carried out and/or supervised by a psychologist will be transferred to railway undertakings and infrastructure managers and will no longer be the responsibility of Member States.</p> <p>Until the OPE TSI is amended, however, a Member State may, in accordance with point 4.7.2.1.2, determine, for the staff referred to in point 4.7.1, whether a psychological examination must be carried out by or under the supervision of a psychologist.</p> <p>This concerns the following staff:</p> <ul style="list-style-type: none"> <li>• Train crew other than train drivers,</li> <li>• Staff performing tasks related to the preparation of trains, and</li> <li>• Staff performing tasks related to the departure and authorisation of train movements.</li> </ul> <p>The Belgian State is therefore of the opinion that a national rule may be retained in relation to these members of staff and to shunting staff (Appendix I, point 1, a) of the OPE TSI) and local operations (Appendix I, point 1, e) of the OPE TSI), as these are areas in which Member States are authorised to adopt national rules.</p> <p>In order to restrict the scope of Article 12 of the Royal Decree on ‘Security Personnel’ to the security personnel referred to above, the Belgian State proposes to amend the scope provided for in Article 2, § 3 as follows:</p> <p><i>“§ 3. The requirements set out in Chapter 3 apply to all security personnel of the UIs referred to in Article 3, 84°, a) and b) of the Railway Code, with the exception of personnel performing critical safety tasks relating to the driving or accompanying of a passenger train.</i></p> <p><i>By way of derogation from paragraph 1, Article 12, § 1 shall apply only to staff performing critical safety tasks relating to the preparation of trains, those relating to the departure and authorisation of train movements, and those performed in the context of shunting or local operations.”</i></p> <p>Once the OPE TSI has been adapted, the Belgian State will repeal the national rule as amended above.</p> <p>The only question that remains unanswered is whether administrative staff are considered to be personnel involved in train preparation. On this point, we would like to obtain the ERA’s interpretation and, if possible, have a clarification included in the TSI OPE application guide.</p> <p>In this way, and according to the Belgian State, administrative staff should be considered covered, without it being necessary to amend the provisions of the TSI or to provide for a national rule on this subject.</p>	<p>Consequently, there is no legal basis for a national rule. National rules are only permitted under appendix I of the TSI OPE.</p> <p>The Belgian rule appears to be an example of arbitrary provisions that can lead to discrimination and constraints for interoperability.</p> <p>On the question whether administrative staff are to be considered personnel involved in train preparation; this is not covered by the TSI OPE but for the railway undertaking to decide on in its safety management system risk assessment outputs as laid down by the Regulation 2018/762. The TSI OPE as amended in 2023 made it very clear that only train preparers and train accompanying staff are covered by appendices F and G. Train drivers are covered by the Directive 2007/59/EC and all other staff is covered by the Regulation 2018/762 more specific within the safety management system of the RU and the IM. Therefore, it is not applicable for the TSI OPE and its application guide but more a matter of the SMS implementation. The proposal Belgium made for amending the rule can also not accepted, the argumentation provided here above applies.</p> <p>Both rules BE-SA-325-2-D and BE-SA-325-1-A cannot be accepted.</p>
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#### **4. The opinion**

The Agency is of the opinion that the provisions in the two (2) draft national safety rules of Belgium are not compliant with relevant EU legal requirements as described in part 3 Analysis of this opinion. For this reason, in accordance with Article 25 (3) of Regulation (EU) 2016/796, the Agency with this opinion confirms its negative assessment.

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

Valenciennes,

Oana GHERGHINESCU  
Executive Director

Enclosure: Annex 1

# Annex 1

## Impact Note

*Regarding two (2) notified draft national rules by Belgium setting out requirements on operational aspects*

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)

<p><b>1. Context and assessment of impacts</b></p>
<p><b>1.1. The national rule in object</b></p> <p>In line with article 25 (3) of Regulation (EU) 2016/796, this opinion covers the examination of two (2) notified draft national rules notified by Belgium in the Single Rules Database (SRD) 11<sup>th</sup> August 2025.</p> <p>The Agency assessed them and reached the conclusion (also recorded in the SRD) that the notified rules contain requirements which according to the Agency's opinion are not in line with the EU legal framework, mainly Regulation (EU) 2019/773 (TSI OPE). In particular, this opinion points out that the national rules proposed by Belgium are not within the scope of the assessment and/or conflict with already harmonised EU legislation.</p>
<p><b>1.2. Analysis performed</b></p> <p>The Agency shared with the Belgium its negative assessment on the 08 October 2025 through SRD.</p> <p>Considering the complexity of the notified rules and to facilitate several further exchanges, Belgium had the 2-months' timeframe for submitting their position extended to 18 May 2026.</p> <p>On 18 May 2026, Belgium notified the Agency via SRD its rejection of the Agency's negative assessment of the two (2) notified draft national rules</p> <p>In chapter 3 of this opinion the Agency provides an overview of the assessment of the 2 draft rules. In particular, the 2 rules proposed were found to be not within the scope of the assessment and/or conflict with already harmonised EU legislation. Indeed, the opinion concluded that for all the rules these could be covered by already existing European Instructions. The opinion of the Agency is that the 2 notified draft rules subject to this opinion contain requirements which according to the Agency's opinion are not in line with the EU legal framework, mainly Regulation (EU) 2019/773 (TSI OPE) and Regulation (EU) 2018/762 establishing common safety methods on safety management system requirements (CSM-SMS).</p>
<p><b>1.3. Assessment of impacts</b></p> <p>The two (2) notified draft national rules of Belgium fall within the scope of the Light Impact Assessment 'Revision of the Common Safety Methods on Conformity Assessment and 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 these rules would compromise uniformity of application of well-established EU requirements and increase the risk of low transparency of the national rules framework that stakeholders have to comply within Belgium.</p> <p>In particular the rules negatively assessed duplicate or are not in line with requirements and/or procedures to be addressed in the companies' Safety Management System. It is for the SMS of RU/IM to develop their processes and procedures on the basis of the requirements specified in EU law, including TSI OPE Regulation (EU) 2019/773.</p> <p>As such, there is EU law in place which is already applicable and there is, therefore, no legal gap. The rule is notified as a type 5 rule with scope 'medical fitness'. The TSI OPE, as amended in 2023, does not admit any national rule under appendix I on health and safety conditions (4.7) other than alcohol, drugs and psychotropic medication limits.</p> <p>Interoperability and coherence of the EU legal framework across the Union risk to be weakened by duplicating or further supplementing, in the national law, requirements already covered (in a harmonised way) at European level, going against the policy goal of reducing national rules and creating unnecessary burden on stakeholders (including unnecessary efforts to ensure the enforcement of the additional national rules on top of all other existing oversight requirements pertaining to EU law), with no (or doubtful) benefit.</p>

<b>1.4. Stakeholders affected</b>			
Railway undertakings (RU)	<input checked="" type="checkbox"/>	Member States (MS)	<input checked="" 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"/>

<b>2. Preferred option</b>
<b>2.1. Recommendation</b>
No alternative options are to be assessed and it is confirmed a negative assessment of the two (2) notified draft national national rules notified by Belgium.