

Moving Europe towards a
sustainable and safe railway
system without frontiers

OPINION

ERA/OPI/2023-8

OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

for

Portugal

regarding

four adopted national rules

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 four adopted national rules of Portugal by the European Union Agency for Railways (the Agency or ERA) leading to a negative assessment.

Portugal notified these adopted rules in the Single Rules Database (SRD) on 3 July 2023. The Agency assessed them and reached the conclusion (also recorded in the SRD) that the notified adopted rules contain requirements which according to the Agency's opinion do not meet the scope of 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 Portugal on 29 August 2023.

As there were questions regarding the Agency's assessment, Portugal had the 2-months timeframe for submitting its position, which was extended to 28 November 2023. On 6 November 2023, the Agency held a bilateral meeting with Portugal to provide further clarifications on the rules that it rejected. Following this meeting, on 9 November 2023, Portugal notified the Agency via SRD its rejection of the Agency's negative assessment of these four adopted national rules.

This opinion is addressed to Portugal 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 rules of Portugal do not meet the scope of the assessment 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) 2023/1693 of 10 August 2023 amending Implementing Regulation (EU) 2019/773 on the technical specification for interoperability relating to the operation and traffic management subsystem of the rail system within the European Union,*
- 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.*

3. Analysis

Rule ID	Rule content and reference in English	Assessment result	Member State's (MS) position on ERA's negative assessment	MS's justification	ERA's final opinion in English
PT SA 825 1- A	<p>The following legal document is notified by the Member State:</p> <p><i>Condições de Tração Impostas pela Infraestrutura</i></p> <p>The Member State notified Annex 2 of the adopted document as a national rule type 4 'Rules laying down requirements in respect of additional internal operating rules (company rules) that must be established by infrastructure managers and railway undertakings'.</p> <p>The rule scope is notified as: Local operational rule – Relating to specific local conditions where additional information may be needed – this is limited to requirements not covered by this Regulation.</p> <p>The content of the adopted rule: Annex 2</p> <p>Annex 2 sets conditions under which circulation is permitted on lines or sections of line where restrictions exist on maximum permissible loads, or subject to special conditions other than those imposed by categories of lines.</p>	<p>This rule contains information that should be covered by Appendices D1 and D2 of EU Regulation 2023/1693 and furthermore should be contained in the RINF database.</p> <p>Conditions on which circulation is permitted should also be part of the train path agreement between the railway undertaking and the infrastructure manager.</p>	MS rejected ERA's negative assessment	<p>The Member State (PT NSA) in their rejection state that:</p> <p><i>'We agree with the principle. However, since RINF has not been updated by our IM since 2018, we suggest to keep the information here, as the RUs will not have information available if this is not published as a National Rule'</i></p>	<p>The adopted rule is not in line with Appendices D1 (on Route compatibility and Route Book) and D2 (on the elements the infrastructure manager has to provide to the railway undertaking for the Route Book) of the Annex to Regulation 2019/773¹ (the TSI OPE) and the requirements for RINF² which have been in force since 2019 .</p> <p>There are no transition periods for the implementation of the TSI OPE, which has to be implemented in full (except Appendices A and C).</p> <p>Appendices D1 and D2 (in their current form) have been in force and are directly applicable since at least 2019. Furthermore, Member States are required to further review national rules as part of the implementation of the amended TSI (Article 5a EU Regulation 2023/1693).</p> <p>Therefore, due to the rule covering requirements set out at EU level, the Agency cannot accept the rule.</p>

¹ 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

² Commission Implementing Regulation (EU) 2019/777 of 16 May 2019 on the common specifications for the register of railway infrastructure and repealing Implementing Decision 2014/880/EU as amended

Rule ID	Rule content and reference in English	Assessment result	Member State's (MS) position on ERA's negative assessment	MS's justification	ERA's final opinion in English
PT SA 827 1 - A	<p>The following legal document is notified by the Member State: <i>Plano de Emergência Geral</i></p> <p>The Member State notifies the whole rule in the adopted document as a national rule type 4 'Rules laying down requirements in respect of additional internal operating rules (company rules) that must be established by infrastructure managers and railway undertakings'.</p> <p>The rule scope is notified as: Managing an emergency situation and emergency responses (see point 4.2.3.7) - Role of local/national authorities and emergency services.</p> <p>The adopted rule contains, amongst other things, requirements on tasks and emergency procedures.</p>	<p>This rule sets out a general emergency plan for the railway system in PT. The majority of the information contained is the responsibility of the railway undertakings and the infrastructure manager in co-operation with each other taking into account the outcomes from their risk assessment.</p> <p>This is clearly set out in detail in Sections 5.5 of both Annex I and II to Regulation 2018/762³. The Agency explained that it could accept Annexes 1 and 2 of the PT legal document as an area for national rules as permitted under Appendix I (1) to the Annex of the TSI OPE as amended/replaced by Commission Implementing Regulation (EU) 2023/1693 on managing an emergency situation and emergency responses</p> <p>In addition, the Agency may accept specific requirements for emergency management on aspects in relation to operation on specified bridges and tunnels as a local operational rule.</p>	MS rejected ERA's negative assessment	<p>The Member State (PT NSA) in their rejection state that:</p> <p><i>'We believe that, in addition to Annexes 1 and 2, some chapters of IET 96 are still needed in order for the RUs to consider in their SMSs. We see that this information is not contradictory with the CSM on SMS. In case of emergency all RUs (and IM) should follow the same general principles set out in this rule and further detail them in their SMSs - as foreseen in CSM on SMS. The chapters we believe are still needed are: 1.5; 2.2; 2.2.8; 3; 9; 11; 14; 19.</i></p> <p><i>We also underline that all RUs in PT already follow the proposed approach in their SMSs - follow the terminology and procedures in IET 96'</i></p>	<p>The adopted rule duplicates the requirements for railway undertakings and infrastructure managers to set out detailed procedures for managing an emergency in their safety management systems.</p> <p>Furthermore Regulation 2018/762 Annex II requirement 5.5.7 requires infrastructure managers 'to co-ordinate emergency plans with all railway undertakings that operate on the organisations infrastructure, with the emergency services, so as to facilitate their rapid intervention, and with any other party that could be involved in an emergency situation'.</p> <p>The Agency has explained during a bilateral meeting that it may accept specific requirements for emergency management (Annexes 1 and 2) on aspects in relation to operation on specified bridges and tunnels as a local operational rule, providing that in the interests of interoperability, railway undertakings have access to other infrastructure if they do not wish to apply the adopted rule. The Agency may also accept requirements in relation to notification to authorities. However, the whole adopted rule (and other related rules) needs to be reviewed and updated to take these aspects into account before it can be accepted.</p> <p>Therefore, the current rule as notified cannot be accepted due to it covering requirements at EU level.</p>

³ 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

Rule ID	Rule content and reference in English	Assessment result	Member State's (MS) position on ERA's negative assessment	MS's justification	ERA's final opinion in English
PT SA 832 1 - A	<p>The following legal document is notified by the Member State:</p> <p style="text-align: center;"><i>Procedimentos de Emergência Específicos</i></p> <p>The Member State notifies the whole rule in the adopted document as a national rule type 4 'Rules laying down requirements in respect of additional internal operating rules (company rules) that must be established by infrastructure managers and railway undertakings'.</p> <p>The rule scope is notified as: Local operational rule - Relating to specific local conditions where additional information may be needed – this is limited to requirements not covered by this Regulation.</p> <p>The adopted rule contains, amongst other things, requirements on roles and responsibilities, emergency vehicles, fire on board trains, evacuation of trains, stations etc, dangerous goods, detection of explosive devices, adverse weather conditions.</p>	<p>This rule sets out specific emergency plans for a number of scenarios.</p> <p>Many of the scenarios are risks that the railway undertaking and infrastructure manager should identify and manage through their risk assessment procedures, which should then be part of the control measures of which emergency plans should be included.</p> <p>This is clearly set out in detail in requirements 3.1 and 5.5 of the Annexes I and II to Regulation 2018/762..</p> <p>The Agency may accept specific requirements for emergency management on aspects in relation to operation on specified bridges and tunnels as a local operational rule.</p>	MS rejected ERA's negative assessment	<p>The Member State (PT NSA) in their rejection state that:</p> <p><i>'Rule ICET296 annex 1 point 6.1 includes the information that need to be transmitted to the IM in case of emergency. Annexes 4, 5, 6, 7 and 8 are also needed to be taken into account by the RUs in their SMS.</i></p> <p><i>We believe that publishing this information in a national rule (from the IM) brings transparency to all RU'.</i></p>	<p>The adopted rule duplicates the requirements at EU level for railway undertakings and infrastructure managers to set out detailed procedures for managing an emergency as per EU Regulation 2018/762.</p> <p>In addition, there is a concern that by specifying the scenarios and identifying risk areas, railway undertakings and infrastructure managers may believe this to be the complete requirements that they need to follow and not take into account additional operational risks that may come from their own risk assessment. This is why the responsibility for the identification of emergency situations (taking into account information from the risk assessment and knowledge of degraded operation and emergency situations) is the responsibility of the railway undertaking and infrastructure manager.</p> <p>The Agency has explained during a bilateral meeting that we may accept specific requirements for emergency management (Annex III) on aspects in relation to operation on specified bridges and tunnels as a local operational rule, providing that in the interests of interoperability, railway undertakings have access to other infrastructure if they do not wish to apply the adopted rule. However, the whole adopted rule (and other related rules) needs to be reviewed and updated to take these aspects into account before it can be accepted.</p> <p>Therefore, the current rule as notified cannot be accepted due to it covering requirements at EU level.</p>

Rule ID	Rule content and reference in English	Assessment result	Member State's (MS) position on ERA's negative assessment	MS's justification	ERA's final opinion in English
PT SA 796	<p>The following legal document is notified by the Member State:</p> <p><i>Disposição de um registo nacional de todos os trabalhadores que desempenham funções críticas para a segurança do sistema ferroviário</i></p> <p>The Member State notifies the whole rule in the adopted document as a type 5 rule 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</p> <p>The rule scope is notified as requirements for staff: shunters and train crew.</p> <p>The adopted rule This rule establishes the need to send data of the staff performing safety critical task for register to the Ministry which is then used for supervision.</p>	<p>The main body of the rule sets out requirements on competence, knowledge and skills, medical and psychological assessments, identification of safety critical workers which is a copy and paste of Regulation 208/762. In addition, it requires railway undertakings and infrastructure managers to notify the Member State the list of employees performing functions critical to the safety of the rail system, specifying the functions, checks, training and their expiry date. In addition, this information must be updated on a monthly basis if there are any changes to the list.</p> <p>The Member State has identified the following staff as performing functions critical to the safety of the rail system</p> <ul style="list-style-type: none"> a) Accompanying trains on board, in composition or from the driver's cab; b) Train preparation, in particular for checking the condition and safety of rolling stock; c) Traffic management, including manoeuvring control activities. <p>The Agency maintained that legislation on the maintenance of a</p>	MS rejected ERA's negative assessment	<p>The Member State (PT NSA) in their rejection state that:</p> <p><i>'The internal regulation, including data information, established in Deliberação N.º 34-A, aims to execute our supervision role regarding the railway staff with safety critical tasks.</i></p> <p><i>We looked into the requirements established in the COMMISSION IMPLEMENTING REGULATION (EU) 2019/773 of 16 May 2019 and defined a common understanding and categorization of the tasks done by personnel with safety critical tasks, including a job description, regardless the name given by each RU and IM. This procedure allows us to monitor the fulfilment and maintenance of each requirement set out in the implementing act mentioned'.</i></p>	<p>The adopted rule duplicates the requirements at EU level for railway undertakings and infrastructure managers to set out detailed procedures for competence as per EU Regulation 2018/762.</p> <p>Portugal maintains its position that this information is needed for supervision so that it can identify who has the required competence and whether this is up to date.</p> <p>The Agency is of the opinion that it is not for the Member State to identify safety critical tasks, this remains the responsibility of the railway undertaking and infrastructure manager. In addition it is not the list of functions which is important but the actual process within the safety management and competence management system (CMS) which is key to ensuring safety.</p> <p>The NSA during their supervision tasks should be auditing the CMS to confirm whether the railway undertaking or infrastructure manager has:</p> <ul style="list-style-type: none"> (1) included all the necessary safety critical tasks and safety related functions (and not just those identified in the rule), (2) ensured that the training is adequate for the operational context and risks identified by the railway undertaking and infrastructure manager (including non technical skills); and (3) that this is up to date and relevant to the current tasks. <p>Such a list for the Member State would not provide confirmation that this information is up to date and relevant to the risks.</p>

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		database of safety critical workers is not permitted as a national rule under the TSI OPE.			

4. The opinion

The Agency considers that the provisions in the four adopted national safety rules of Portugal do not meet the scope of notification of a national rule in the field of safety, 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 Portugal, with a copy to the European Commission (DG Move).

Valenciennes, 7/12/2023

Signed

Josef DOPPELBAUER
Executive Director

5. Annex

Impact Assessment Note
regarding four adopted national rules by Portugal

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 Portugal the notification of four adopted national rules in the Single Rules Database (SRD) on 3 July 2023:

- For PT SA 825 1- A, Annex 2 of the adopted document 'Condições de Tração Impostas pela Infraestrutura' is notified as a national rule type 4. It sets conditions under which circulation is permitted on lines or sections of line where restrictions exist on maximum permissible loads, or subject to special conditions other than those imposed by categories of lines.
- For PT SA 827 1 - A, the whole adopted document 'Plano de Emergência Geral' is notified as a national rule type 4. It contains, amongst other things, requirements on tasks and emergency procedures.
- For PT SA 832 1 - A, the whole adopted document 'Procedimentos de Emergência Específicos' is notified as a national rule type 4. It contains, amongst other things, requirements on roles and responsibilities, emergency vehicles, fire on board trains, evacuation of trains, stations etc, dangerous goods, detection of explosive devices, adverse weather conditions.
- For PT SA 796, the whole adopted document 'Disposição de um registo nacional de todos os trabalhadores que desempenham funções críticas para a segurança do sistema ferroviário' is notified as a national rule type 5. It establishes the need to send data of the staff performing safety critical task for register to the Ministry.

1.2. Analysis performed

In its first assessment, the Agency expressed the opinion that the notified adopted rules contain requirements which do not meet the scope of 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 Portugal on 29 August 2023 and on 9 November 2023 the Agency was notified via SRD that the MS rejected ERA's negative assessment.

The final opinion by the Agency confirmed its initial assessment that the current rules as notified cannot be accepted. The four rules do not meet the scope of notification of a national rule in the field of safety, according to Article 8 of Directive (EU) 2016/798 on railway safety. They cover and duplicate requirements at EU level for railway undertakings and infrastructure managers.

In particular, as better/deeper detailed above in the TO:

- Rule PT SA 825 1- A contains information that should be covered by Appendices D1 and D2 of EU Regulation 2023/1693 and furthermore should be contained in the RINF database.
- Rule PT SA 827 1 - A sets out a general emergency plan for the railway system in PT; the majority of the information contained is the responsibility of the railway undertaking and infrastructure manager in co-operation with each other taking into account the outcomes from their risk assessment. This is clearly set out in detail in EU Regulation 2018/762 Annexes I and II requirement 5.5.

The Agency has explained during a bilateral meeting that specific requirements may be accepted for emergency management (Annexes 1 and 2) on aspects in relation to operation on specified bridges and tunnels as a local operational rule, providing that in the interests of interoperability, railway undertakings have access to other infrastructure if they do not wish to apply the adopted rule. The Agency may also accept requirements in relation to notification to authorities. However, the whole adopted rule (and other related rules) needs to be reviewed and updated to take these aspects into account before it can be accepted.

- Rule PT SA 832 1 – A sets out specific emergency plans for a number of scenarios. Many of the scenarios are risks that the railway undertaking and infrastructure manager should identify and manage through their risk assessment procedures, which should then be part of the control measures of which emergency plans should be included. This is clearly set out in detail in EU Regulation 2018/762 Annexes I and II requirements 3.1 and 5.5.

The Agency has explained during a bilateral meeting that specific requirements may be accepted for emergency management (Annexes III) on aspects in relation to operation on specified bridges and tunnels as a local operational rule, providing that in the interests of interoperability, railway undertakings have access to other infrastructure if they do not wish to apply the adopted rule. The Agency may also accept requirements in relation to notification to authorities. However, the whole adopted rule (and other related rules) needs to be reviewed and updated to take these aspects into account before it can be accepted.

- Rule PT SA 796 establishes the need to send data of the staff performing safety critical task for register to the Ministry which is then used for supervision; Portugal considers that this information is needed for supervision so that they can identify who has the required competence and whether this is up to date.

The Agency is of the opinion that it is not for the Member State to identify safety critical tasks, this remains the responsibility of the railway undertaking and infrastructure manager. In addition it is not the list of functions which is important but the actual process within the safety management and competence management system (CMS) which is key to ensuring safety. The NSA during their supervision tasks should be auditing the CMS to confirm whether it has included all the necessary safety critical tasks and safety related, the training is adequate for the operational context and risks identified by the railway undertaking and infrastructure manager and that this is up to date and relevant to the current tasks. Such a list would not provide this information.

1.3. Assessment of impacts

The national rules in object adopted by Portugal fall 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 rules compromise uniformity of application of well-established EU requirements, increase the risk of low transparency of the national rules framework that stakeholders have to comply within Portugal as well as interoperability of RUs.

In particular, the adopted rules cover and duplicate requirements at EU level for railway undertakings and infrastructure managers. The Agency may accept requirements in relation to notification to authorities and specific requirements for emergency management on aspects in relation to operation on specified bridges and tunnels as a local operational rule; however, the related adopted rules needs to be reviewed and updated.

These Portuguese national rules, as notified, are 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 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			
The most affected stakeholder are the railway undertakings.			
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"/>

2. Preferred option
2.1. Recommendation
No alternative options are to be assessed and it is confirmed a negative assessment of the national rules in object adopted by Portugal.