

OPINION

2022-4

OF THE EUROPEAN UNION AGENCY FOR RAILWAYS regarding

the proposed interpretation of a national rule of Italy on the detailed rules for the application in the railway sector of Decree N° 388 of 15 July 2003 (Decreto del Ministero delle Infrastrutture e dei Trasporti del 24 gennaio 2011 n.19)

Disclaimer:

The present document contains an opinion of the European Union Agency for Railways pursuant to Chapter 5 of Regulation (EU) 2016/796 related to the Agency's tasks concerning national rules. 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

The Agency became aware of Infrastructure and Transport Ministry of Italy Decree 24th of January 2011 n.19 (“Regulation on the detailed rules for the application in the railway sector of Decree No 388 of 15 July 2003, pursuant to Article 45 (3) of Legislative Decree No 81 of 9 April 2008. (11G0057)”). This rule has been assessed against the relevant EU law requirements, resulting in an Agency opinion.

Pursuant to Article 26 of Regulation (EU) 2016/796, this opinion is addressed to Italy with a copy to the European Commission. Article 26 (2) and (3) of Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004¹ (Agency Regulation) sets out the following:

“ 2. Where, after the examination referred to in paragraph 1, the Agency considers that the national rules enable the essential requirements for railway interoperability to be fulfilled, the CSMS and TSIs in force to be respected and the CSTs to be achieved, and that they would not result in arbitrary discrimination or a disguised restriction on rail transport operations between Member States, the Agency shall inform the Commission and the Member State concerned of its positive assessment. In that case, the Commission may validate the rules in the IT system referred to in Article 27.

Where the Agency does not inform the Commission and the Member State concerned within 2 months of receipt of the national rules, or within the extended time period agreed in accordance with paragraph 1, the rule shall remain valid.

3. 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.”

2. Background

Within the Brennero Corridor Platform (BCP) activities (<https://www.bcplatform.eu/corridorstudies>), an *ad hoc* task force has been established in order to tackle rules applicable in Austria, Germany and Italy, dealing with the train crew composition.

While analysing the situation in the three EU Member States, it was realised that only Italy has a rule in force which *in practice would* require the adoption of a second agent trained to drive the train under certain conditions.

Considering the BCP's objective of arriving at a set of harmonised company rules in line with European legislation, the issue was analysed further in detail.

In line with this process, the interpretation supported by the Interpelli Commission of the Ministry of Labour² (Interpello n. 2/2016 Commissione per gli Interpelli del Ministero del Lavoro e delle Politiche Sociali) concerning the 'Ministerial Decree 24th January 2011 n.19 imposes operational rules on railway operators which potentially are not in line with EU railway legislation.

¹ OJ L 138, 26.5.2016, p. 1.

² It should be noted the representatives from the Italian Labour Ministry were part of the Task Force.

The Agency decided to follow Article 26 (6) of Regulation (EU) 2016/796, supported also by the European Commission with a formal request on 31/05/2022.

3. Relevant EU law

The EU legislation which is relevant for this opinion is:

- Directive (EU) 2016/798 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;
- 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) 2015/1136 of 13 July 2015 amending Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment.

The Ministerial Decree 24th January 2011 n.19 is based on Article 45, paragraph 3, of Legislative Decree No. 81 of 9 April 2008 (the latter regulating issues of occupational health and safety), with the aim of defining a regulation containing provisions on company first aid. The same decree also requires that companies or production units that carry out rail transport activities, apply the regulation with regard to work activity carried out in isolated places, i.e. any work activity in rail transport carried out in places other than the premises of the companies or production units, where there are no permanent first aid posts.

Given that Decree No. 81 of 2008 contains provisions on health and safety protection in the workplace, in principle it does not qualify as a national rule under Article 8 of the Railway Safety Directive (RSD), Directive EU 2016/798. The Agency does not have the power to accept the notification in the Single Rules Database (SRD) of any occupational health and safety legislation (covering issues such as workplace safety, work equipment, PPE, manual handling etc).

In addition, national legislation transposing EU Directives a priori and ipso facto does not qualify as notified National Rule under Article 8 of Directive (EU) 2016/796; Annex II does not identify such rules as a national safety rule type to be managed under the Directive and is therefore not within its scope.

Nevertheless, each Railway Undertaking (RU) must comply with the national law transposing EU Directives in the Member States (MS) regardless of whether it is a notified national rule under the Art. 8 of RSD or not. Moreover, the RU is responsible to make sure that when assessing risk, they consider the need to determine, provide and sustain a safe working environment which conforms to applicable legislation, in particular Directive 89/391/EEC (see Reg. 2018/762 annex 1 point 3.1.1.2).

Occupational health and safety legislation EU requirements are defined in Directive 89/391/EEC.

Considering the impact on railway operations, the Agency is of the opinion that the Italian Ministerial Decree 24th January 2011 n.19 does not impose specific operational rules but it rather:

- requires infrastructure managers and railway undertakings to coordinate with each other and with public emergency services;
- Imposes the presence of certain equipment both on board trains and along the infrastructure;
- Imposes compulsory first aid training.

By virtue of the discussion in the dedicated task force within the BCP (Brenner Corridor Platform) the Agency became aware that:

Article 4 (1) of Ministerial Decree 24th January 2011 n.19 establishes the following obligations:

*“The infrastructure managers and railway companies, coordinating with each other and with the public emergency services, prepare operating procedures to implement a specific intervention plan that provides for **each point** of the railway network the most effective ways in order to guarantee qualified assistance **as quickly as possible** also for the transport of the injured.”*

As possible interpretation of the aforementioned terms “each point” together with “as quickly as possible” made by “Commissione per gli Interpelli del Ministero del Lavoro e delle Politiche Sociali”, , creates a situation whereby train personnel must be rescued with a stricter standard than the Essential Health Care Levels that the Health Service is obliged to guarantee to all citizens.

As a consequence, when implementing such a rule in their organization, the RUs come to a conclusion that any modality adopted to guarantee medical assistance for each point of the line, can never take place more quickly than the presence on board of a second person able to drive the train in the event of sudden illness preventing the driver from driving the train (Discussion at Brennero Corridor Platform meetings – task force on second person in the Cab).

Hence, the interpretation supported could lead to the situation that, at the operational level, the use of two people in the train driver's cab, both of whom are capable of driving the train even in an emergency situation, is required.

4. The opinion

The interpretation of the Italian Ministerial Decree 24th January 2011 n.19 constitutes an operational rule requiring railway undertakings to make specific arrangements regarding train crew composition.

The Agency's opinion is that the aforementioned interpretation, which could result in the mandatory use of two people in the train driver's cab, contradicts with the following EU legislation:

- Regulation (EU)2019/773; more precisely against Appendix J, which defines the Train crew as members of the on-board staff of a train, who are certified as competent and appointed by a railway undertaking to carry out specific, designated safety related tasks on the train, for example the driver or the guard.
- Regulation (EU) 2018/762; more precisely against points 2.3.1, 3.1.1 and 5.1 of its Annex, defining that the RU must assign roles and responsibilities to its personnel carrying out safety critical tasks on the basis of its own specific risk analysis that also takes into account the operational profile of the RU.
- EU Regulation 2018/762; more precisely against points 5.5 of its Annex, defining that it is up to the RU to define its emergency management procedures in cooperation with all parties involved.
- Directive (EU) 2016/798; more precisely against Article 4 reserving the roles and responsibilities of railway actors while managing risk is a responsibility of the RU, not to be decided at the level of a MS.

The Agency's opinion is also that it is at the level of the RU to define its train crew organisation and composition in accordance with its risk and specificities in its Safety Management System (SMS).

For the aforementioned reasons, in accordance with Article 26 (3) of Regulation 2016/796, this opinion covering the examination of Ministerial Decree 24th January 2011 n.19 of Italy by the Agency leads to a negative assessment.

Following this opinion, Italy is requested to state its position regarding the Agency's assessment.

This opinion is transmitted to the European Commission (DG MOVE).

Valenciennes, 13/06/2022

Signed
Josef DOPPELBAUER
Executive Director

Annex

Impact Assessment

Light Impact Assessment

on the proposed interpretation of a national rule of Italy on the detailed rules for the application in the railway sector of Decree N° 388 of 15 July 2003 (Decreto del Ministero delle Infrastrutture e dei Trasporti del 24 gennaio 2011 n.19)

Annexed to the Agency Opinion 2022-4

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1. Context and problem definition

1.1. Problem and problem drivers

Whitin the Brennero Corridor Platform (BCP) activities (<https://www.bcplatform.eu/corridorstudies>), an ad hoc task force has been established in order to tackle rules applicable in Austria, Germany and Italy, dealing with the train crew composition.

While analysing the situation in the three EU Member States, it was realised that only Italy has a rule in force, the 'Ministerial Decree 24th January 2011 n.19, which, due to the interpretation issued by the "Commissione Interpelli" of the Ministry of Labour (Interpello n. 2/2016 Commissione per gli Interpelli del Ministero del Lavoro e delle Politiche Sociali), requires under certain conditions the presence on-board of a second person trained to drive the train, imposing thus operational rules (mainly on railway undertakings) not in line with EU railway legislation.

As part of the task force's work, it was therefore decided to seek a technical opinion from ERA; the representatives from the Italian Labour Ministry were part of this task force. ERA received a formal request for a Technical Opinion on the concerned Italian Decree from the Commission on 31/05/2022.

In line with Article 26 (6) of Regulation 2016/796, this opinion covers the examination of a national rule of Italy by the Agency leading to a negative assessment. According to Art. 8(1) of Regulation (EU) 2016/796, this impact assessment is accompanying the Agency Opinion.

1.2. Evidence of the problem

The Ministerial Decree 24th January 2011 n.19 is based on Article 45, paragraph 3, of Legislative Decree No. 81 of 9 April 2008 (the latter regulating issues of occupational health and safety), with the aim of defining a regulation containing provisions on company first aid.

The same decree also requires that companies or production units that carry out rail transport activities, apply the regulation with regard to work activity carried out in isolated places, i.e. any work activity in rail transport carried out in places other than the premises of the companies or production units, where there are no permanent first aid posts (this includes ordinary and extraordinary maintenance activities carried out in the areas of the railway network in operation).

Given that Decree No. 81 of 2008 contains provisions on health and safety protection in the workplace, in principle it does not qualify as a national rule under Article 8 of the Railway Safety Directive (RSD), Directive EU 2016/798; thus the Agency does not have the power to accept its notification in the Single Rules Database (SRD) of any occupational health and safety legislation (covering issues such as workplace safety, work equipment, PPE, manual handling etc.).

Occupational health and safety legislation EU requirements are defined in Directive 89/391/EEC.

Considering the impact on railway operations, the Agency is of the opinion that the Italian Ministerial Decree 24th January 2011 n.19 does not impose specific operational rules

However, the interpretation of the "Commissione per gli Interpelli del Ministero del Lavoro e delle Politiche Sociali" of Article 4 (1) of the Decree requires under certain conditions the presence on-board of a second person trained to drive the train, thus imposing operational rules not in line with EU railway legislation for which RUs (and IMs for maintenance operations using yellow fleet trains) shall define train crew organisation and composition in accordance with their risk and specificities in their Safety Management Systems. Moreover, this leads to a situation whereby train personnel must be covered with a stricter standard than the Essential Health Care Levels that the Health Service is obliged to guarantee to all citizens, although it is not clear what are the problem drivers or root causes for such specificity (e.g. safety concerns, follow-up of specific incidents occurred, etc.).

1.3. Baseline scenario

The baseline scenario (Option 0) is the current situation of the EU and national legal framework in Italy, where the interpretation of the Italian Ministerial Decree 24th January 2011 n.19 imposes an operational rule requiring to make specific arrangements for train crew composition. If no action is taken the problem will persist, negatively affecting interoperability and generating extra costs due to a lack of harmonised requirements for rail operations across the Union.

1.4. Main assumptions

The main assumptions related to the estimation of the possible annual saving for crossing border trains if the issue is solved are reported and explained in the Issue Logbook commissioned by DG MOVE to the Panteia consortium.

On certain lines or line sections in Italy a second person should assist the driver in his tasks and must be able to intervene in case of unexpected events, including health issues of the driver. This is understood as a burden imposed on RUs but where the impact is difficult to be measured. With the current elements it is not possible to anticipate how the second driver would be (re)assigned to other activities nor, for the same driver, the number of trains he/she operates per year. For the Italian borders no specific values/figures were possible to be collected during the course of the project. For this reason, the average values from Romania, Bulgaria and Portugal were used as reference and adjusted to the country Purchasing Power Parity.

1.5. Stakeholders affected

Railway undertakings (RU)	☒	Member States (MS)	☒
Infrastructure managers (IM)	☒	Third Countries	☐
Manufacturers	☐	National safety authorities (NSA)	☐
Keepers	☐	European Commission (EC)	☒
Entity Managing the Change (EMC)	☐	European Union Agency for Railways (ERA)	☒
Notified Bodies (NoBo)	☐	Citizens living nearby railway tracks	☐
Associations	☐	Persons with reduced mobility (PRM)	☐
Shippers	☐	Passengers	☐
Ticket vendors	☐	Other (Please specify) ...	☐

Beside institutions and authorities, the stakeholders impacted are mostly those active in the Italian market as local entities/individuals or as entities providing cross-border rail services into Italy. Infrastructure Managers are impacted mainly in relation to the ordinary and extraordinary maintenance activities carried out in the areas of the railway network in operation (and falling under the scope of the Italian Ministerial Decree 24th January 2011 n.19).

1.6. Subsidiarity

The problem is to be addressed at EU level since, as per the baseline scenario, the current situation generates a suboptimal situation for rail interoperability. In order to preserve interoperability and ensure a harmonised legal framework for the rail sector, according to Art. 8(6) of Directive (EU) 2016/798 and Art. 26(6) of Regulation (EU) 2016/796, if the Agency becomes aware of any national rule, whether notified or not, which has become redundant or is in conflict with the CSMs or any other Union law in the railway field or creates an unjustified barrier to the single railway market, the procedure provided for in Article 26 of Regulation (EU) 2016/796 (i.e. examination of the existing national rules) shall apply.

2. Objectives

2.1. Specific objectives

The specific objective of this initiative is to provide Italy with an assessment of the problem defined above with regards to Ministerial Decree 24th January 2011 n.19 and its interpretation, which is having an impact on interoperability and market access.

3. Options

3.1. List of options

Option 0 is the baseline scenario as described above, representing the current situation of the EU and national legal framework in Italy, where the interpretation of the Italian Ministerial Decree 24th January 2011 n.19 imposes an operational rule requiring to make specific arrangements for train crew composition.

Option 1 is the sole alternative option and consists in the scenario where the Italian Ministerial Decree 24th January 2011 n.19 is revised within the framework of the Railway Safety Directive by removing the possibility of interpretations that have an impact on rail operations against the enforce European regulatory framework.

4. Impacts of the options

4.1. Qualitative analysis

Stakeholder assessment

Option 0 (Baseline)			
Category of stakeholder	Impact type	Description	Overall Impact
RU	Positive	N/A	Very negative
	Negative	The current legal framework is maintained and the interpretation of the Italian Ministerial Decree 19/24th January 2011 n.19 issued by the "Commissione Interpelli" of the Ministry of Labour imposes to RUs specific arrangements for train crew organisation and composition, requiring under certain conditions (i.e. isolated places) the presence on-board of a second person trained to drive the train. RUs will continue sustaining additional costs, partially quantified in the Issue Logbook commissioned by DG MOVE to the Panteia consortium ('Methodology for cost benefit analysis of the solutions and pilot projects and impacts estimation', 2022), which focuses on the impact of this requirement only for cross border trains. The Issue Logbook study highlights/specifies that two people on one locomotive are only required on certain lines or line sections and that the reason is not related to the railway regulations but rather to the health & safety regulations. The second person should assist the driver in his tasks and must be able to intervene in case of unexpected events, including health issues of the driver. Overall, for the around 150000 trains crossing the Italian borders in 2019, the Issue Logbook estimates an annual saving (related to planning efforts and unnecessary human resources) of around 125 million € if the issue is solved.	
IM	Positive	N/A	Rather negative
	Negative	The current legal framework is maintained and the interpretation of the Italian Ministerial Decree 19/24th January 2011 n.19 issued by the "Commissione Interpelli" of the Ministry of Labour requires under certain conditions (i.e. isolated places) the presence on-board of a second person trained to drive the train, with additional costs still sustained by IMs,	

		mainly within the context of the ordinary and extraordinary maintenance activities carried out in the areas of the railway network in operation (and falling under the scope of the Italian Ministerial Decree 19/24th January 2011 n.19).	
MS	Positive	The current legal framework is maintained and no additional efforts are needed to revise/amend the Italian Ministerial Decree 19/24th January 2011 n.19 within the framework of the Railway Safety Directive by removing the possibility of interpretations that have an impact on rail operations against the inforce European regulatory framework	Neutral
	Negative	Possible further/new requests of interpretation/clarification for Art. 4(1) of the Italian Ministerial Decree 19/24th January 2011 n.19 could be expected. Additional effort to ensure the enforcement of the national rule on top of all other existing oversight requirements pertaining to EU law.	
ERA	Positive	N/A	Very negative
	Negative	The current legal framework is maintained, going opposite to the policy goal of reducing national rules (direct or indirect) and with a negative impact on interoperability and market access.	
EC	Positive	N/A	Very negative
	Negative	The current legal framework is maintained, going opposite to the policy goal of reducing national rules (direct or indirect) and with a negative impact on interoperability and market access.	

Option 1			
Category of stakeholder	Impact type	Description	Overall Impact
RU	Positive	The Italian Ministerial Decree 19/24th January 2011 n.19 is revised within the framework of the Railway Safety Directive by removing the possibility of interpretations that have an impact on rail operations against the European regulatory framework. RUs define train crew organisation and composition in accordance with their risks and specificities in their SMSs. As reported above, the Issue Logbook estimates an annual saving of around 125 million € only for the cross border trains (not counting the local/national traffic).	Very positive
	Negative	N/A	
IM	Positive	The Italian Ministerial Decree 19/24th January 2011 n.19 is revised within the framework of the Railway Safety Directive by removing the possibility of interpretations that have an impact on rail operations against the European regulatory framework. This will lead to savings for IMs, mainly within the context of the ordinary and extraordinary maintenance activities carried out in the areas of the railway network in operation (and falling under the scope of the Italian Ministerial Decree 19/24th January 2011 n.19).	Rather positive
	Negative	N/A	
MS	Positive	The Italian legal framework becomes more clear and aligned with the EU legislation. No additional effort is needed to ensure the enforcement of the national rule on top of all other existing oversight requirements pertaining to EU law.	Neutral
	Negative	Some efforts are needed to revise/amend the Italian Ministerial Decree 19/24th January 2011 n.19 within the framework of the Railway Safety Directive by removing the possibility of interpretations that have an impact on rail operations against the European regulatory framework.	
ERA	Positive	The Italian Ministerial Decree 19/24th January 2011 n.19 is revised within the framework of the Railway Safety Directive by removing the possibility of interpretations that have an impact on rail operations against the	Very positive

		European regulatory framework. The policy goal of reducing national rules is preserved, with a positive impact on interoperability and market access.	
	Negative	N/A	
EC	Positive	The Italian Ministerial Decree 19/24th January 2011 n.19 is revised within the framework of the Railway Safety Directive by removing the possibility of interpretations that have an impact on rail operations against the European regulatory framework. The policy goal of reducing national rules is preserved, with a positive impact on interoperability and market access.	Very positive
	Negative	N/A	

Railway system assessment

The following table provides a quick overview of the impact of the options in key aspects for rail safety and interoperability assessment.

	Option 0 (baseline)	Option 1
<i>Safety</i>	Very high	Very high
<i>Interoperability</i>	Very low	Very high
<i>Market access</i>	Rather low	Rather high
<i>Competitiveness</i>	Very low	Very high
<i>Effectiveness</i>	Very low	Very high

Coherency assessment

The EU legal framework is impacted by the national rule under assessment

	Option 0 (baseline)	Option 1
<i>Coherence</i>	Very low	Very high

5. Comparison of options and preferred option

5.1. Comparison of options

Below a quick comparison of the options with impact on the key stakeholders as noted in 4. above is provided.

	Option 0 (baseline)					Option 1				
<i>Stakeholder impact</i>	RU	IM	MS	ERA	EC	RU	IM	MS	ERA	EC
<i>Effectiveness</i>	Very low					Very high				
<i>Coherence</i>	Very low					Very high				

Colour legend

Very low/neg.	Rather low/neg.	Neutral	Rather high/pos.	Very high/pos.
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5.2. Preferred option(s)

Option 1 is the preferred option and it is recommended to revise/amend the Italian Ministerial Decree 19/24th January 2011 n.19 within the framework of the Railway Safety Directive by removing the possibility of interpretations that have an impact on rail operations against the European regulatory framework.

The interpretation of Art. 4(1) of the Italian Ministerial Decree 19/24th January 2011 n.19 issued by the "Commissione Interpelli" of the Ministry of Labour imposes specific arrangements for train crew organisation and composition, requiring under certain conditions (i.e. isolated places) the presence on-board of a second person trained to drive the train; this creates unnecessary burden

on stakeholders with no clear benefit. Interoperability for operations within and to/from Italy, market access and coherence of the EU legal framework across the Union are negatively affected.

5.3. Risk assessment

This light impact assessment is not based on primary or secondary data but on desk research and expert opinion. The risk variables are therefore low risk for all options.

Risk variables	Option 0	Option 1
IA Inputs	Low risk	Low risk
IA Outcomes	Low risk	Low risk

6. Monitoring and evaluation

6.1. Monitoring indicators

N/A

6.2. Future evaluations

N/A

7. Sources and methodology

7.1. Sources

Desk research	☒	Interviews	☐
ERA database	☐	Meetings	☒
External database	☐	Survey	☐

The main sources for this impact assessment have been desk research of EU legislation relevant in the fields, the Issue logbook (commissioned by DG MOVE to the Panteia consortium), meetings with (and experts knowledge of) in-house ERA staff.