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sustainable and safe railway  
system without frontiers..

# OPINION

2022-8

## OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

for

Italy

regarding

4 draft national rules of Italy on requirements on several 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 25 (3) of EU Reg. 2016/796, this opinion covers the examination of 4 draft national rules of Italy by the Agency leading to a negative assessment.

Italy submitted in the Single Rules Database (SRD) [IT system defined under EU Reg. 2016/796] 4 new draft rules all belonging to the same draft legal document named “Regolamento per la circolazione ferroviaria” on the 20<sup>th</sup> of May 2022.

The Agency submitted its assessment on the new draft rules on the 7<sup>th</sup> of June 2022, 4 new draft rules were negatively assessed.

Several bilateral meetings took place in order to exchange information with Italy. After those meetings Italy submitted its position on the Agency’s assessment in SRD: Italy rejected the Agency’s negative assessment for all involved rules on the 29<sup>th</sup> of July 2022. For each rule, Italy uploaded a justification. The Agency analysis as described in the chapter below, took in consideration also the justification presented.

This opinion is addressed to Italy with a copy to the European Commission. It is uploaded on Single Rules Database.

## 2. Legal Background

Article 25 (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 881/2004<sup>1</sup> (Agency Regulation) sets out the following:

*“2. Where, after the examination referred to in paragraph 1, the Agency considers that the draft 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 within 2 months of receipt of the draft national rule or within the extended time period agreed in accordance with paragraph 1 does not inform the Commission and the Member State concerned of its assessment, the Member State may proceed with the introduction of the rule without prejudice to Article 26.*

*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 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 a) of the Regulation (EU) 2016/796.

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<sup>1</sup> OJ L 138, 26.5.2016, p. 1.

This opinion points out the fact that the 4 draft national rules<sup>2</sup> of Italy contradict already harmonised European 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 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.
- Commission Implementing Regulation (EU) 2019/779 of 16 May 2019 laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 445/2011.

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<sup>2</sup> All rules belong to the same draft legal document named "regolamento per la circolazione ferroviaria". In the following chapter 3, links to all draft rules as presented in SRD are available.

## 3. Analysis

Rule ID	Rule Content in National Reference language	Assessment Result	MS position on ERA negative assessment	Italian justification	ERA Final Opinion in English	ERA Final Opinion in Italian
<a href="#">IT-SA-285-1-D</a>	<p>2.4.5 I veicoli eventualmente soggetti a manutenzione secondo le modalità di cui al punto 2.4.2, per poter riprendere a circolare, non devono presentare non conformità pericolose per l'esercizio ferroviario.</p>	<p>The rule repeats the exact content of rule n. IT-SA-145-1-D already subject to ERA negative assessment. As before, we reiterate that it is not possible to accept a rule that defines principles for risk management because operational risk management remains the responsibility of the operators as defined in the railway safety directive in its Article 4. Furthermore, what is specified for the IT-SA-282-1-D rule regarding the management of operational interfaces by means of safety management systems is considered valid. This interface cannot be subject to a national standard.</p>	MS Rejected ERA's Negative Assessment	<p>Si tratta di un principio generale di sicurezza che riguarda la ripresa della circolazione dei veicoli per i quali è stato necessario, per diversi motivi, svolgere in linea attività di manutenzione. Tale principio non appare ne duplicare ne contrastare le disposizioni contenute nella RSD o nel Reg. (UE) 2019/779, ma anzi integrarle relativamente ad una circostanza specifica. Il contenuto del principio andrebbe armonizzato a livello europeo.</p>	<p>The Agency maintains its negative assessment. the reasons why the national rule in question should not enter into force and/or be applied are as follows: The rule defines general principles concerning "fleet management" activities as defined by the ECM - Entity in Charge of maintenance - Regulation (Reg.EU 2019/779 as amended). The requirements for organisations carrying out activities related to vehicle maintenance are specified in Annex II of the aforementioned Regulation, with particular reference to point III. The rule under analysis also defines principles for managing the interfaces between the Railway Undertakings that use the vehicles for transport and the ECMs that are responsible for their maintenance. The CSM - Common Safety Method - on SMS - Safety Management System - Requirements (EU Reg. 2018/762) at point 5.1.3 of Annex I, defines the principles and methods for managing the interfaces with the functions of vehicle maintenance. This management is left to the SMS of railway undertakings and ECMs as it is strongly based on operational risks management. Finally, the rule defines, albeit in a general manner, principles of risk acceptance that must be managed by means of the SMSs provided for in EU Reg 2018/762 and EU Reg 2019/779 as amended. It is added that, in accordance with the Safety Directive (EU Dir. 2016/798) Art. 4, the responsibility for risk management is not a matter that can be regulated in national rules. For the reasons stated above, the national rule cannot be evaluated positively.</p>	<p>L'Agenzia mantiene la propria posizione sulla valutazione negativa espressa. Le ragioni per le quali la regola in questione non dovrebbe entrare in vigore e/o essere applicata sono espresse qui di seguito. La regola definisce principi generali che riguardano le attività di "gestione della flotta" così come definita dal ECM - Entity in Charge of maintenance - Regulation (Reg.EU 2019/779 as amended). I requisiti per le organizzazioni che svolgono attività legate alla manutenzione dei veicoli sono specificati all'Annesso II del Regolamento citato, con particolare riferimento al punto III. La regola sottoposta ad analisi inoltre, definisce principi di gestione delle interfacce tra le Imprese Ferroviarie che utilizzano i veicoli per il trasporto e gli ECM che sono invece responsabili della loro manutenzione. Il CSM - Metodo Comune di Sicurezza - on SMS - Safety Management System - Requirements (EU Reg. 2018/762) al punto 5.1.3 dell'annesso I, definisce i principi e le modalità di gestione delle interfacce con le funzioni della manutenzione veicoli. Tale gestione è demandata ai sistemi di gestione delle imprese e degli ECM in quanto fortemente basata sulla gestione dei rischi operativi. La regola infine definisce, seppur in maniera generale, principi di accettazione del rischio che devono essere gestiti per il tramite dei sistemi di gestione previsti dal Reg EU 2018/762 e dal Reg EU 2019/779 as amended. Si aggiunge che, in accordo con la Direttiva Sicurezza (EU Dir. 2016/798) Art. 4, la responsabilità della gestione del rischio non è una questione che può essere regolata da regole nazionali. Per le ragioni sopra esposte, la regola nazionale non può essere valutata positivamente.</p>

Rule ID	Rule Content in National Reference language	Assessment Result	MS position on ERA negative assessment	Italian justification	ERA Final Opinion in English	ERA Final Opinion in Italian
<a href="#">IT-SA-284-1-D</a>	<p>2.4.4 Sugli eventuali binari fisicamente adiacenti a quello interessato dalle attività di cui ai precedenti punti 2.4.2 e 2.4.3 si applica quanto stabilito negli stessi punti precedenti, a meno che non siano adottate idonee misure atte a evitare che gli addetti allo svolgimento delle attività e le attrezzature da essi utilizzate interferiscano con la circolazione dei convogli sui binari rimasti in esercizio.</p>	<p>The principles and operational obligations for the Infrastructure Manager expressed in this rule may be accepted as a national rule in the sole case where the purpose of the rule would be limited to operations during infrastructure works, as regulated in OPE TSI Appendix I "Operation during works". In effect, this rule follows what is already defined in the IT-SA-143-1-D rule. Please therefore make explicit the scope of the rule and use the appropriate rule type with reference to the mentioned Appendix I.</p>	MS Rejected ERA's Negative Assessment	<p>Il principio è strettamente legato ai precedenti IT-SA-282-1-D e IT-SA-283-1-D, ma in questo caso il campo di applicazione è relativo ai binari adiacenti a quello su cui si svolgono le attività. In tal caso, è lasciata libertà agli operatori di valutare, nell'ambito del proprio SMS, misure mitigative atte ad evitare le interferenze con la circolazione, altrimenti il binario va considerato interessato dalle attività svolte e applicate le misure indicate ai punti sopra richiamati. Il contenuto del principio andrebbe armonizzato a livello europeo.</p>	<p>The Agency maintains its negative assessment. the reasons why the national rule in question should not enter into force and/or be applied are as follows:</p> <p>As for rule IT-SA-283-1-D, the rule under analysis defines principles and methods for the management of situations in which operations other than train movements may interfere with normal train movements. The common safety method on SMS - Safety Management System - requirements, defines in points 3.1.1 and 5.1.3 of both Annexes, general principles and methods for risk management that railway undertakings and infrastructure managers should implement in order to perform their activities safe. Consequently, identifying hazardous situations and analysing the related risks in order to identify the necessary mitigation measures is the responsibility of operators acting through their SMSs. It is added that, according to the Safety Directive (EU Dir. 2016/798) Art. 4, the responsibility for risk management is not a matter that can be regulated by national rules. For the reasons stated above, the national rule cannot be assessed positively.</p>	<p>L'Agenzia mantiene la propria posizione sulla valutazione negativa espressa. Le ragioni per le quali la regola in questione non dovrebbe entrare in vigore e/o essere applicata sono espresse qui di seguito.</p> <p>Come per la regola IT-SA-283-1-D, La regola sottoposta ad analisi definisce principi e modalità di gestione di situazioni in cui operazioni diverse dalla circolazione dei treni possano interferire con la normale circolazione dei treni. Il metodo comune di sicurezza sui requisiti del SGS - Sistema di Gestione della Sicurezza, definisce nei punti 3.1.1 e 5.1.3 di entrambi gli Annessi, principi generali e modalità di gestione dei rischi che imprese e gestori devono attuare al fine di rendere sicure le proprie attività'. Di conseguenza, individuare le situazioni pericolose ed analizzarne i rischi collegati al fine di individuare le necessarie azioni di mitigazione e' competenza degli operatori che agiscono per il tramite dei propri SGS. Si aggiunge che, in accordo con la Direttiva Sicurezza (EU Dir. 2016/798) Art. 4, la responsabilità della gestione del rischio non e' una questione che puo' essere regolata da regole nazionali. Per le ragioni sopra esposte, la regola nazionale non puo' essere valutata positivamente.</p>
<a href="#">IT-SA-283-1-D</a>	<p>2.4.3 Qualora le attività di cui al 2.4.2 comportino una o più delle seguenti soggezioni:</p> <p>a) l'occupazione con attrezzature, mezzi o uomini, del binario o della zona ad esso adiacente fino ad una distanza di sicurezza, dalla più vicina rotaia, stabilita tenuto conto della velocità massima ammessa dal tratto di binario e del tipo di lavorazione in atto;</p> <p>b) la possibilità di interferenza con la sagoma di libero transito del binario;</p> <p>c) l'indebolimento o la discontinuità del binario, e più in generale della via;</p> <p>d) il sistema di segnalamento potrebbe concedere indebite autorizzazioni al movimento;</p>	<p>The principles and operational obligations for the Infrastructure Manager expressed in this rule may be accepted as a national rule in the sole case where the purpose of the rule would be limited to operations during infrastructure works, as regulated in OPE TSI Appendix I "Operation during works". In effect, this rule follows what is already defined in the IT-SA-143-1-D rule. Please therefore make explicit the scope of the rule and use the appropriate rule type with reference to the mentioned Appendix I.</p>	MS Rejected ERA's Negative Assessment	<p>Il principio è strettamente legato al precedente IT-SA-282-1-D e dettaglia tre criteri fondamentali di sicurezza da seguire in caso di soggezioni alla circolazione conseguenti ad attività differenti dalla circolazione che si svolgono su un binario o in prossimità di esso. Il campo di applicazione è il binario stesso su cui si svolgono le attività. Le misure individuate sembrano irrinunciabili in presenza delle soggezioni elencate alle lettere da a) a d) e si ritiene, quindi, che questa casistica non rientri nelle valutazioni del rischio degli operatori nell'ambito del proprio SMS; viene inoltre richiamata la necessità che gli operatori individuino le ulteriori misure mitigative. È auspicabile che il contenuto del principio sia armonizzato a livello europeo.</p>	<p>The Agency maintains its negative assessment. the reasons why the national rule in question should not enter into force and/or be applied are as follows:</p> <p>The rule under analysis defines principles and methods for the management of situations in which operations other than train movements may interfere with normal train movements. The common safety method on SMS - Safety Management System - requirements, defines in points 3.1.1 and 5.1.3 of both Annexes, general principles and methods for risk management that railway undertakings and infrastructure managers should implement in order to perform their activities safe. Consequently, identifying hazardous situations and analysing the related risks in order to identify the necessary mitigation measures is the responsibility of operators acting through their SMSs. It is added that, according to the Safety Directive</p>	<p>L'Agenzia mantiene la propria posizione sulla valutazione negativa espressa. Le ragioni per le quali la regola in questione non dovrebbe entrare in vigore e/o essere applicata sono espresse qui di seguito.</p> <p>La regola sottoposta ad analisi definisce principi e modalità di gestione di situazioni in cui operazioni diverse dalla circolazione dei treni possano interferire con la normale circolazione dei treni. Il metodo comune di sicurezza sui requisiti del SGS - Sistema di Gestione della Sicurezza, definisce nei punti 3.1.1 e 5.1.3 di entrambi gli Annessi, principi generali e modalità di gestione dei rischi che imprese e gestori devono attuare al fine di rendere sicure le proprie attività'. Di conseguenza, individuare le situazioni pericolose ed analizzarne i rischi collegati al fine di individuare le necessarie azioni di mitigazione e' competenza degli operatori che agiscono per il tramite dei propri SGS. Si aggiunge che, in accordo con la Direttiva Sicurezza (EU Dir. 2016/798) Art. 4, la responsabilità della gestione del rischio non e' una questione che puo' essere regolata da</p>

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	<p>e) il sistema di protezione della marcia dei treni potrebbe non fornire informazioni coerenti con l'indicazione del sistema di segnalamento,</p> <p>esse devono comunque essere svolte nel rispetto dei seguenti principi:</p> <ul style="list-style-type: none"> <li>- sul tratto di binario interessato deve essere inibito, tramite i sistemi di segnalamento e protezione, l'inoltro dei treni e delle manovre;</li> <li>- devono essere messe in atto misure mitigative di sicurezza idonee ad evitare che gli eventuali veicoli in movimento oltrepassino indebitamente i punti che delimitano il tratto di binario interessato;</li> <li>- l'eventuale circolazione dei veicoli e la loro sosta sul tratto di binario interessato deve essere disciplinata, oltre che nel rispetto di quanto stabilito nella presente parte 2, anche di quanto disposto negli ulteriori punti del presente regolamento, se applicabili in funzione delle caratteristiche dei veicoli e della attività da svolgere. Qualora in tali circostanze il regolatore della circolazione dell'area soggetta alle attività di cui al presente punto sia diverso da quello che regola la circolazione nel normale esercizio, deve essere disciplinato, ai sensi del capitolo 2.2, lo scambio di informazioni necessarie a garantire la sicurezza della circolazione nello svolgimento dell'attività di competenza.</li> </ul>				<p>(EU Dir. 2016/798) Art. 4, the responsibility for risk management is not a matter that can be regulated by national rules. For the reasons stated above, the national rule cannot be assessed positively.</p>	<p>regole nazionali. Per le ragioni sopra esposte, la regola nazionale non puo' essere valutata positivamente.</p>



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<a href="#">IT-SA-282-1-D</a>	<p>2.4.2 Lo svolgimento su un tratto di binario di attività differenti dalla circolazione dei treni e delle manovre, inclusa la manutenzione all'infrastruttura ferroviaria e ai veicoli, deve avvenire senza pregiudicare la sicurezza dell'esercizio ferroviario, secondo modalità a tal fine stabilite in relazione alla natura del lavoro, alle attrezzature utilizzate e alle caratteristiche del tratto di binario interessato.</p>	<p>The part of this rule relating to infrastructure works can be accepted as the OPE TSI in its Appendix I leaves room for national rules with specific reference to operations in the case of infrastructure works Interference between activities other than train operations remains a matter of interface risk management systems of the operators involved. With specific reference to vehicle maintenance activities and with generic reference to interface management, the principle is expressed in Reg 762/2018 Annex II point 3.1.1 and Reg 2019/779 point 2.1. The management of this type of interface is not permitted at national level.</p>	MS Rejected ERA's Negative Assessment	<p>Prendiamo atto che la parte relativa alla manutenzione dell'infrastruttura è accettata. Si ritiene però necessario stabilire un principio generale di sicurezza applicabile anche alle attività manutentive ai veicoli che si svolgono in linea e che quindi possono pregiudicare la sicurezza della circolazione. Non vengono imposte soluzioni tecniche od organizzative, la cui valutazione è lasciata alla responsabilità degli operatori. Il contenuto del principio andrebbe armonizzato a livello europeo</p>	<p>The Agency maintains its negative assessment. the reasons why the national rule in question should not enter into force and/or be applied are as follows: As already expressed in the first ERA analysis, the part of this rule related to infrastructure works can be accepted as the OPE TSI (EU Reg. 2019/773 as amended), in Appendix I, leaves room for national rules with specific reference to operation in case of works. Interference between activities other than railway operation remains a risk management issue at the interface of the operators involved. With specific reference to vehicle maintenance activities and with generic reference to interface management, the principle is expressed in Reg. EU 762/2018 Annex II point 3.1.1 and in Reg. EU 2019/779 as amended in Annex II point 2.1. It is added that, according to the Safety Directive (EU Dir. 2016/798) Art. 4, the responsibility for risk management is not a matter that can be regulated by national rules. For the reasons stated above, the national rule cannot be assessed positively.</p>	<p>L'Agenzia mantiene la propria posizione sulla valutazione negativa espressa. Le ragioni per le quali la regola in questione non dovrebbe entrare in vigore e/o essere applicata sono espresse qui di seguito.  Come già espresso in sede di prima analisi di ERA, la parte di questa regola relativa ai lavori all'infrastruttura può essere accettata in quanto la STI OPE (EU Reg. 2019/773 as amended), nell'appendice I, lascia spazio alle norme nazionali con riferimento specifico all'esercizio in caso di lavori di infrastruttura. L'interferenza tra attività diverse dall'esercizio ferroviario rimane una questione di gestione del rischio di interfaccia degli operatori coinvolti. Con riferimento specifico alle attività di manutenzione dei veicoli e con riferimento generico alla gestione delle interfacce, il principio è espresso nel Reg. EU 762/2018 Allegato II punto 3.1.1 e nel Reg. EU 2019/779 as amended all'Annesso II punto 2.1. Si aggiunge che, in accordo con la Direttiva Sicurezza (EU Dir. 2016/798) Art. 4, la responsabilità della gestione del rischio non è una questione che può essere regolata da regole nazionali. Per le ragioni sopra esposte, la regola nazionale non può essere valutata positivamente.</p>

#### 4. The opinion

In accordance with article 25 (3) of Regulation 2016/796, the opinion covers the examination of draft national rules of Italy by the Agency leading to a negative assessment.

The Agency considers that the draft national safety rules are not compliant with the relevant EU legal requirements as described in the analysis.

This opinion is addressed to Italy, uploaded in the SRD with a copy to the European Commission (DG MOVE).

Valenciennes, 29/08/2022

Signed

Josef DOPPELBAUER  
Executive Director



# Annex 1 : Light Impact Assessment

## Light Impact Assessment

*regarding 4 draft national rules of Italy on requirements on several operational aspects.*

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<b>1. Context and problem definition</b>																											
<b>1.1. Problem and problem drivers</b>																											
<p>In May 2022 Italy submitted in the Single Rules Database (SRD) four new draft rules all belonging to the same draft legal document named “Regolamento per la circolazione ferroviaria”.</p> <p>The rules under analysis defines principles and methods for the management of situations in which operations other than train movements (including maintenance of railway infrastructure and vehicles) may interfere with normal train movements.</p> <p>The Agency considers that risk management should be addressed within the companies’ safety management systems in order to identify hazardous situations, analyse the related risks and take the necessary mitigation measures, rather than being regulated by national rules. Moreover, the draft national rules under analysis contradict already harmonised European legislation.</p> <p>In line with article 25 (3) of EU Reg. 2016/796, the Agency Opinion covers the examination of these four draft national rules of Italy by the Agency leading to a negative assessment. According to Art. 8(1) of the same Regulation, an impact assessment shall accompany the Agency Opinion.</p>																											
<b>1.2. Evidence of the problem</b>																											
<p>On the 7<sup>th</sup> of June 2022 the Agency submitted its negative assessment on the four new draft rules. Several bilateral meetings took place to exchange information with the Italian NSA. After those meetings Italy submitted its position on the Agency’s assessment in SRD, rejecting the negative assessment for all involved rules on the 29<sup>th</sup> of July 2022. For each rule, Italy uploaded a justification.</p> <p>The set of Italian draft rules in scope, with concise information on the Agency analysis and the possible impacts, is provided in Appendix 1.</p>																											
<b>1.3. Baseline scenario</b>																											
<p>The baseline scenario (Option 0) is that the current EU and national legal framework in Italy will be maintained without the four national rules under analysis being adopted.</p>																											
<b>1.4. Main assumptions</b>																											
<p>This LIA focuses on the full set of draft rules under analysis, providing a high-level overview on the expected impacts for different types of stakeholders. As on this level of aggregation the impacts per stakeholder group can be hard to discern, additional details of the rules with a qualitative assessment of the main costs and benefits are presented in Appendix 1.</p>																											
<b>1.5. Stakeholders affected</b>																											
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Keepers	<input type="checkbox"/>	European Commission (EC)	<input checked="" type="checkbox"/>																								
Entity Managing the Change (EMC)	<input checked="" type="checkbox"/>	European Union Agency for Railways (ERA)	<input checked="" type="checkbox"/>																								
Training centres	<input checked="" type="checkbox"/>	Other (Please specify) ...	<input type="checkbox"/>																								
<p>Beside institutions and authorities, the stakeholders impacted are mostly those active in the Italian market, including international entities providing cross-border rail services into Italy. Of all stakeholder groups, IMs and RUs are expected to be most impacted.</p>																											

<p><b>1.6. Subsidiarity and proportionality</b></p> <p>In order to preserve interoperability and ensure a harmonised legal framework for the rail sector, according to Art. 8 of Directive (EU) 2016/798 Member States are not anymore allowed to freely adopt national safety rules except in restricted cases provided by EU legislation.</p> <p>The examination of draft national rules falls under the Agency’s competence as per Art. 25 of Regulation (EU) 2016/796</p>
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<p><b>2. Objectives</b></p> <p><b>2.1. Specific objectives</b></p> <p>The specific objective of this initiative is to provide Italy with an assessment of the problem defined above with regards to the national rules being assessed by the Agency (see also Appendix 1). These rules impact interoperability across Europe and coherence of the EU legal framework.</p>
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<p><b>3. Options</b></p> <p><b>3.1. List of options</b></p> <p>Option 0 is the baseline scenario as described above, representing the current situation of the EU and national legal framework in Italy, where the set of national rules under analysis is not adopted/applicable. Option 1 is the option where the Agency reconsiders its negative assessment of Italy’s draft national rules delivered as per Art. 25(3) of Regulation (EU) 2016/796 and the rules will be adopted.</p>
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<p><b>4. Impacts of the options</b></p> <p><b>4.1. Qualitative analysis</b></p> <p><b>Stakeholder assessment</b></p> <p>This section focuses on the full set of four Italian rules being assessed by ERA in this TO. As mentioned above, on this level of aggregation the impacts per stakeholder group can be hard to discern, which is why the impacts are aggregated on the level of sector organisations, NSA/MS and EC/ERA. Below a general qualitative non-exhaustive description/overview of impacts for different types of stakeholders is provided for the whole group of assessed rules. Additional details on each national rule and on the related costs and benefits estimated are presented in Appendix 1.</p>														
<table border="1"> <thead> <tr> <th colspan="4"><i>Option 0 (Baseline)</i></th> </tr> <tr> <th><i>Category of stakeholder</i></th> <th><i>Impact type</i></th> <th><i>Description</i></th> <th><i>Overall Impact</i></th> </tr> </thead> <tbody> <tr> <td rowspan="2">IMs/RUs/ ECMs/...</td> <td>Positive</td> <td>The current legal framework is preserved; the management of situations in which operations other than train movements may interfere with normal train movements, is set according to each company’s Safety Management System as per EU law (identifying hazardous situations and analysing the related risks in order to identify the necessary mitigation measures) and not regulated by national rules.  No additional national rules (contradicting harmonised EU legislation) have to be followed by the relevant companies.</td> <td rowspan="2">Rather positive</td> </tr> <tr> <td>Negative</td> <td>N/A</td> </tr> </tbody> </table>	<i>Option 0 (Baseline)</i>				<i>Category of stakeholder</i>	<i>Impact type</i>	<i>Description</i>	<i>Overall Impact</i>	IMs/RUs/ ECMs/...	Positive	The current legal framework is preserved; the management of situations in which operations other than train movements may interfere with normal train movements, is set according to each company’s Safety Management System as per EU law (identifying hazardous situations and analysing the related risks in order to identify the necessary mitigation measures) and not regulated by national rules.  No additional national rules (contradicting harmonised EU legislation) have to be followed by the relevant companies.	Rather positive	Negative	N/A
<i>Option 0 (Baseline)</i>														
<i>Category of stakeholder</i>	<i>Impact type</i>	<i>Description</i>	<i>Overall Impact</i>											
IMs/RUs/ ECMs/...	Positive	The current legal framework is preserved; the management of situations in which operations other than train movements may interfere with normal train movements, is set according to each company’s Safety Management System as per EU law (identifying hazardous situations and analysing the related risks in order to identify the necessary mitigation measures) and not regulated by national rules.  No additional national rules (contradicting harmonised EU legislation) have to be followed by the relevant companies.	Rather positive											
	Negative	N/A												

NSA/MS	Positive	No additional effort to ensure the enforcement of the national rules on top of other existing oversight requirements pertaining to EU law.	Neutral
	Negative	Some effort to amend the “Regolamento per la circolazione ferroviaria”.	
EC/ERA	Positive	The current legal framework with tendency to reduce national rules is preserved, at benefit of interoperability across Europe and coherence of the EU legal framework.	Rather positive
	Negative	N/A	

<i>Option 1</i>			
<i>Category of stakeholder</i>	<i>Impact type</i>	<i>Description</i>	<i>Overall Impact</i>
IM/RU/ECMs/...	Positive	N/A	Rather negative
	Negative	The legal framework to operate in Italy is modified and some requirements for the management of situations in which operations other than train movements may interfere with normal train movements, are regulated by the new draft rules which have to be followed by the relevant companies.	
NSA/MS	Positive	No additional effort to amend the “Regolamento per la circolazione ferroviaria”	Neutral
	Negative	Additional effort to ensure the enforcement of the national rules on top of other existing oversight requirements pertaining to EU law.	
EC/ERA	Positive	N/A	Rather negative
	Negative	The current legal framework is not preserved, going opposite of the policy goal to reduce national rules and with an impact on interoperability across Europe and coherence of the EU legal framework.	

**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.

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

**Coherency assessment**

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

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

**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 chapter 4 above, is provided.

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

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 0 is the preferred option and it is recommended to issue a negative Agency opinion with regards to the national rules by Italy under assessment. Interoperability and coherence of the EU legal framework across the Union risk to be weakened by national rules dealing with the management of situations in which operations other than train movements may interfere with normal train movements, while identifying hazardous situations and analysing the related risks (in order to identify the necessary mitigation measures) should be the responsibility of companies (notably RUs/IMs) through their safety management systems.

The goal of preserving safety is already regulated by the current EU legal framework and by the companies' Safety Management Systems. The draft national rules under analysis contradict already harmonised EU legislation, creating unnecessary burden on stakeholders with doubtful benefit.

**5.3. Risk assessment**

This light impact assessment is not based on primary or secondary data but on desk research, expert judgement and justifications/information submitted by the Italian authorities. This LIA/analysis has focused on the full set of (four) draft rules, providing a high-level and qualitative overview on the expected impacts for different types of stakeholders. The risks associated with this assessment are deemed to be low.

5.

<b>6. Monitoring and evaluation</b>
<b>6.1. Monitoring indicators</b>
N/A
<b>6.2. Future evaluations</b>
N/A

**7. Sources and methodology**

**7.1. Sources**

Desk research	<input checked="" type="checkbox"/>	Interviews	<input type="checkbox"/>
ERA database	<input checked="" type="checkbox"/>	Meetings	<input checked="" type="checkbox"/>
External database	<input type="checkbox"/>	Survey	<input type="checkbox"/>

The main sources for this impact assessment have been the Single Rule Database (SRD) (where Italy notified its draft national rules and related justifications), desk research of EU legislation relevant in the fields and meetings with (and experts knowledge of) in-house ERA staff.

**Appendix 1. Summary of assessed Italian rules and costs/benefits**

Rule ID	Description of the rules and final ERA opinions	Main SHs impacted	Costs	Benefits
<a href="#">IT-SA-282-1-D</a>	<p>The part of this rule related to infrastructure works can be accepted as the OPE TSI (EU Reg. 2019/773 as amended), in Appendix I, leaves room for national rules with specific reference to operation in case of infrastructure works.</p> <p>Interference between activities other than railway operation remains a risk management issue at the interface of the operators involved. With specific reference to vehicle maintenance activities and with generic reference to interface management, the principle is expressed in Reg. EU 762/2018 Annex II point 3.1.1 and in Reg. EU 2019/779 as amended in Annex II point 2.1.</p> <p>It is added that, according to the Safety Directive (EU Dir. 2016/798) Art. 4, the responsibility for risk management is not a matter that can be regulated by national rules.</p> <p>The text of this draft national rule (as provided in the SRD in Italian) is reported below:</p> <p><b>IT-SA-282-1-D:</b> <i>“2.4.2 Lo svolgimento su un tratto di binario di attività differenti dalla circolazione dei treni e delle manovre, inclusa la manutenzione all’infrastruttura ferroviaria e ai veicoli, deve avvenire senza pregiudicare la sicurezza dell’esercizio ferroviario, secondo modalità a tal fine stabilite in relazione alla natura del lavoro, alle attrezzature utilizzate e alle caratteristiche del tratto di binario interessato”.</i></p>	RUs, IMs, ECMS	<p>The draft national rule is, for some parts/aspects, contradicting existing EU legislation, being in contrast with the policy goal of reducing unnecessary burden on stakeholders with doubtful benefit. Interoperability for operations within and to/from Italy and coherence of the EU legal framework across the Union risk to be weakened/affected.</p> <p>Unnecessary efforts to ensure the enforcement of the additional national rule on top of all other existing oversight requirements pertaining to EU law.</p>	<p>The Agency's view is that the part of this rule related to infrastructure works can be accepted as the OPE TSI (EU Reg. 2019/773 as amended), in Appendix I, leaves room for national rules with specific reference to operation in case of infrastructure works.</p> <p>With reference to vehicle maintenance activities and to interface management, instead, the Agency assesses that the possible benefits could be achieved also through alternative means, harmonised at EU level.</p> <p>The goal of preserving safety is already regulated by the current EU legal framework and by the companies' Safety Management Systems.</p>
<a href="#">IT-SA-283-1-D</a> <a href="#">IT-SA-284-1-D</a>	<p>The rules under analysis defines principles and methods for the management of situations in which operations other than train movements may interfere with normal train movements.</p> <p>The common safety method on SMS - Safety Management System - requirements, defines in points 3.1.1 and 5.1.3 of both Annexes, general principles and methods for risk management that railway undertakings and infrastructure managers should implement in order to perform their activities safe. Consequently, identifying hazardous situations and analysing the related risks in order to identify the necessary mitigation measures is the responsibility of operators acting through their SMSs.</p> <p>It is added that, according to the Safety Directive (EU Dir. 2016/798) Art. 4, the responsibility for risk management is not a matter that can be regulated by national rules.</p> <p>The text of these draft national rules (as provided in SRD in Italian) is reported below:</p> <p><b>IT-SA-283-1-D:</b> <i>“2.4.3 Qualora le attività di cui al 2.4.2 comportino una o più delle seguenti soggezioni:</i></p>	RUs, IMs, ECMS	<p>The draft national rules are overlapping with and contradicting existing EU legislation by defining principles and methods for the management of situations in which operations other than train movements may interfere with normal train movements, instead of leaving the responsibility for risk management to the companies through their SMSs.</p> <p>This is in contrast with the policy goal of reducing national rules and creating unnecessary burden on stakeholders with doubtful benefit. Interoperability for operations within and to/from Italy and coherence of the EU legal framework across the Union risk to be weakened/affected.</p> <p>Unnecessary efforts to ensure the enforcement of the additional national rule on top</p>	<p>The Agency assesses that the possible benefits could be achieved also through alternative means, harmonised at EU level.</p> <p>The goal of preserving safety is already regulated by the current EU legal framework and by the companies' Safety Management Systems.</p>



Rule ID	Description of the rules and final ERA opinions	Main SHs impacted	Costs	Benefits
	<p>a) l'occupazione con attrezzature, mezzi o uomini, del binario o della zona ad esso adiacente fino ad una distanza di sicurezza, dalla più vicina rotaia, stabilita tenuto conto della velocità massima ammessa dal tratto di binario e del tipo di lavorazione in atto;</p> <p>b) la possibilità di interferenza con la sagoma di libero transito del binario;</p> <p>c) l'indebolimento o la discontinuità del binario, e più in generale della via;</p> <p>d) il sistema di segnalamento potrebbe concedere indebite autorizzazioni al movimento;</p> <p>e) il sistema di protezione della marcia dei treni potrebbe non fornire informazioni coerenti con l'indicazione del sistema di segnalamento,</p> <p>esse devono comunque essere svolte nel rispetto dei seguenti principi:</p> <ul style="list-style-type: none"> <li>- sul tratto di binario interessato deve essere inibito, tramite i sistemi di segnalamento e protezione, l'inoltro dei treni e delle manovre;</li> <li>- devono essere messe in atto misure mitigative di sicurezza idonee ad evitare che gli eventuali veicoli in movimento oltrepassino indebitamente i punti che delimitano il tratto di binario interessato;</li> <li>- l'eventuale circolazione dei veicoli e la loro sosta sul tratto di binario interessato deve essere disciplinata, oltre che nel rispetto di quanto stabilito nella presente parte 2, anche di quanto disposto negli ulteriori punti del presente regolamento, se applicabili in funzione delle caratteristiche dei veicoli e della attività da svolgere. Qualora in tali circostanze il regolatore della circolazione dell'area soggetta alle attività di cui al presente punto sia diverso da quello che regola la circolazione nel normale esercizio, deve essere disciplinato, ai sensi del capitolo 2.2, lo scambio di informazioni necessarie a garantire la sicurezza della circolazione nello svolgimento dell'attività di competenza".</li> </ul> <p><b>IT-SA-284-1-D:</b> "2.4.4 Sugli eventuali binari fisicamente adiacenti a quello interessato dalle attività di cui ai precedenti punti 2.4.2 e 2.4.3 si applica quanto stabilito negli stessi punti precedenti, a meno che non siano adottate idonee misure atte a evitare che gli addetti allo svolgimento delle attività e le attrezzature da essi utilizzate interferiscano con la circolazione dei convogli sui binari rimasti in esercizio".</p>		<p>of all other existing oversight requirements pertaining to EU law.</p>	
<p><a href="#">IT-SA-285-1-D</a></p>	<p>The rule defines general principles concerning "fleet management" activities as defined by the ECM - Entity in Charge of maintenance - Regulation (Reg.EU 2019/779 as amended). The requirements for organisations carrying out activities related to vehicle maintenance are specified in Annex II of the aforementioned Regulation, with particular reference to point III.</p> <p>The rule under analysis also defines principles for managing the interfaces between the Railway</p>	<p>RUs, IMs, ECMS</p>	<p>The draft national rule is overlapping with and contradicting existing EU legislation, being in contrast with the policy goal of reducing unnecessary burden on stakeholders with doubtful benefit. Interoperability for operations within and to/from Italy and coherence of the EU</p>	<p>The Agency assesses that the possible benefits could be achieved also through alternative means, harmonised at EU level.</p> <p>The goal of preserving safety is already regulated by the current EU legal framework and by the</p>

Rule ID	Description of the rules and final ERA opinions	Main SHs impacted	Costs	Benefits
	<p>Undertakings that use the vehicles for transport and the ECMS that are responsible for their maintenance. The CSM - Common Safety Method - on SMS - Safety Management System - Requirements (EU Reg. 2018/762) at point 5.1.3 of Annex I, defines the principles and methods for managing the interfaces with the functions of vehicle maintenance. This management is left to the SMS of railway undertakings and ECMS as it is strongly based on operational risks management.</p> <p>Finally, the rule defines, albeit in a general manner, principles of risk acceptance that must be managed by means of the SMSs provided for in EU Reg 2018/762 and EU Reg 2019/779 as amended.</p> <p>It is added that, in accordance with the Safety Directive (EU Dir. 2016/798) Art. 4, the responsibility for risk management is not a matter that can be regulated in national rules.</p> <p>The text of this draft national rule (as provided in SRD in Italian) is reported below:</p> <p><b>IT-SA-285-1-D:</b> <i>“2.4.5 I veicoli eventualmente soggetti a manutenzione secondo le modalità di cui al punto 2.4.2, per poter riprendere a circolare, non devono presentare non conformità pericolose per l’esercizio ferroviario”.</i></p>		<p>legal framework across the Union risk to be weakened/affected.</p> <p>Unnecessary efforts to ensure the enforcement of the additional national rule on top of all other existing oversight requirements pertaining to EU law</p>	<p>companies’ Safety Management Systems.</p>