

# OPINION

2022-2

## OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

for

Denmark

regarding

*a draft national rule of Denmark on requirements for functional requirements for the technical and traffic safety rules on the railway with the purpose of insuring, that infrastructure managers and railway undertakings in developing their safety rules continue to ensure a sound and uniform safety level across the corporations*

### 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

In line with Article 25 (3) of Regulation 2016/796, this opinion covers the examination of a draft national rule of Denmark by the Agency leading to a negative assessment.

This opinion is addressed to Denmark with a copy to the European Commission. It is uploaded on the Single Rules Database (SRD).

## 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.

The Danish Civil Aviation and Railway authority (hereafter known as the National Safety Authority (NSA)) has developed a draft of the executive order regarding technical and traffical safety rules on the railway. The executive order follows the danish Railway Law (lov nr. 510 af 1. maj 2019). In § 61 of the danish Railway Law there is introduced legal basis for issuing an executive order establishing rules regarding which requirements infrastructure managers (IMs) and railway undertakings (RUs) need to comply to in order to legally create and change their technical and traffical safety rules without the approval by The Danish Civil Aviation and Railway authority.

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

- Directive (EU) 2016/798 of 11 May 2016 on railway safety
- Commission delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European

---

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

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

### 3. Analysis

Denmark notified a draft safety rule in the SRD<sup>2</sup> on the 15<sup>th</sup> December 2021. According to Denmark the draft rule is needed for the following reasons:

1. *Infrastructure managers and railway undertakings are responsible for the safety on their parts of the railway and railway safety should be handled in a safety management system.*
2. *The executive order sets up functional requirements for the technical and traffic safety rules on the railway with the purpose of insuring, that infrastructure managers and railway undertakings in developing their safety rules continue to ensure a sound and uniform safety level across the corporations.*
3. *This transition towards infrastructure managers and railway undertakings developing rules without the approval of The Danish Civil Aviation and Railway authority is in this executive order called self-management.*
4. *Thus, with the introduction of self-management it is the intention, that the individual corporation by developing and subsequently changing their safety rules no longer need an approval by The Danish Civil Aviation and Railway authority. Instead, the individual corporation will need to document the necessary and sufficient resources present in the corporation and document that the safety management system contains procedures for the developing and changing of safety rules as well as documentation for the compliance of the safety rules with the requirements in this executive order.*
5. *The current form of developing technical and traffic safety rules for infrastructure managers and railway undertakings will not change with the introduction of this self-management. in the same way the requirements for the safety management system be the same as well as the safety level.*
6. *The Danish Civil Aviation and Railway authority will supervise the compliance of the developing of technical and traffic safety rules with the requirements in this executive order as well as the structural process in the corporations safety management system.*
7. *The Danish Civil Aviation and Railway authority will, in assessing the corporation's applications for surpassing to self-management, assess whether the safety management system is compliant with the relevant functional requirements in the executive order.*

---

<sup>2</sup> Rule DK-SA-205-1-D (reference in SRD)

8. *Furthermore, The Danish Civil Aviation and Railway authority will carry out ongoing supervision with the compliance of the corporation's safety rules with the requirements in this executive order as well as the corporation's compliance with the executive order.*
9. *To support the corporation's transition to self-management there will be published guidance material in 2022.*
10. *The executive order regarding technical and traffic safety rules on the railway, among other things, contains provisions regarding:*
  - *The fact that infrastructure managers and railway undertakings shall determine technical and traffical safety rules.*
  - *The process for applying to shift over to self-management.*
  - *The process after shifting over to self-management.*
  - *Which technical and traffical rules infrastructure managers and railway undertakings shall comply to when self-managing.*
  - *The role of the assessment body (safety rules) in conjunction with self-management.*
  - *The process for the corporations transition to self-management*
  - *The transition period where infrastructure managers and rail-way undertakings voluntarily can decide to shift over to self-management.*

The Agency negatively assessed the rule in the SRD on the 3<sup>rd</sup> February 2022, based on the following arguments:

1. The draft rule is not within scope of Article 8 and Annex II to the Railway Safety Directive (RSD) 2016/798. This is because it is a transposition rule of the RSD in relation to responsibilities and roles. It also introduces a new concept of self-management for a rule-making model by the sector which is inconsistent with EU legislation and indeed goes further than the roles and responsibilities established under Art 4(1)d RSD, as the IM and RU shall be responsible for safe operations and not for rule-making. It also seems to contradict Art. 9 RSD in conjunction with the CSM on SMS (EU Regulation 2018/762) which require that all risks are controlled in a safety management system and not through rule-making by a IM or RU.
2. As a consequence, such a model proposed in the draft rule would adversely affect the safety certification process for RUs either if the decision-making entity is the Agency or a NSA, given that the safety certification process is orientated to assess whether an effective SMS and associated procedures (not internal rules) are in place. In addition, as the national part of the application of a RU for a SSC is focused on the assessment of compliance of the RU with the national rules – the RU would be in a situation of rule-making and compliance with the rules the RU itself makes. There could also be duplication of the assessment if the internal rules are also implementing aspects of the SMS requirements for procedures to manage the risks.
3. The SMS in itself with all the requirements for risk management, monitoring and continuous improvement should be sufficient to ensure that safety is maintained by the sector.
4. This opinion is also supported by the ERA Legal Adviser.

For these reasons, the draft rule of Denmark cannot be accepted.

### **Bilateral between the Agency and DK**

A bilateral was held on 22<sup>nd</sup> March 2022 between the Danish NSA and Ministry and ERA. The following is a note of the discussions:

1. DK explained the background to their request for the national rule that was negatively assessed by ERA in SRD. The goal of the draft rule was to develop a framework and guidance for internal operational rules because there was a concern that not all IMs and RUs had established the necessary controls for safe operation and therefore the SMS was not covering all aspects. An example of degraded operation was given.
2. The aim of the draft rule was to establish a self-management framework for IMs and RUs when developing their internal operational rules. The compliance with the new rule (the executive order) would be assessed by the NSA. Prior to this the IMs and RUs were submitting their operational rules to the NSA for assessment. It was a transitional measure until all IMs and RUs had the necessary rules in place. Eventually the rule would be withdrawn when the IMs and RUs SMS have sufficiently evolved.
3. ERA explained that these internal operational rules should be part of the operational processes that must be established under the SMS, taking into account the operational context and risks and the necessary controls (i.e. SMS processes) that would be needed. It would be difficult for the NSA to have knowledge of all the necessary operational risks and therefore not advisable for the NSA to have an approval role for internal operational rules.
4. National rules were permitted in those areas set out in EU Regulation 2019/773, Appendix I (e.g. signalling systems/shunting/communication rules (until June 2024) etc). However, ERA could not approve any rule that did not come within the framework of Annex II of Directive (EU) 2016/798 (i.e. type 3 or 5). The draft rule was linked to the approval of an internal control under the SMS and therefore would come within the scope of type 1 or 2. It was not permitted to have these rules anymore because they were now covered by EU legislation.
5. In addition, the rule was related to elements covered by requirement 5 of EU Regulation 2018/762, which would mean that the NSA would be approving rules that would be covered by an operational process in the SMS. If the SMS was certified by ERA, it would be that the NSA would be duplicating the tasks of ERA as certifying body.
6. ERA therefore could not change their negative assessment because there was no legal provision to cover this request. The rule contains requirements that are already mandated at EU level.
7. ERA suggested that the supervision provisions should be used to check whether IMs and RUs SMS contained all the necessary elements and if not to take appropriate enforcement action. To help the IMs and RUs, workshops could be set up to manage the transition. The rule could also be available as guidance on the NSA's website. In addition, as this could also be a safety culture issue perhaps ERA could also help with the workshops.
8. ERA asked DK to also consider Appendix I of EU Regulation 2019/773, to see whether there were any permitted rules that should be notified in the SRD. DK agreed to discuss internally the issue, review the options and respond to ERA with their position.

## Denmark's rejection of the Agency's negative assessment

On the 22<sup>nd</sup> April 2022, Denmark notified the Agency in SRD its rejection of the Agency's negative assessment as summarised below:

1. DK has discussed the issue internally and reviewed the options given by ERA taking the following statements into account: - Human and organisational factors play a significant role in all catastrophic railway accidents and occurrences. To secure the railway safety, which is of outmost importance, these factors need to be integrated in the safety culture and processes. Migrating towards Safety Management Systems (SMS) shows a need for strong, safety leadership and for an environment that has a positive safety culture with a systematic approach.
2. DK-SA-205-1-D is a framework for technical and traffic organisational safety that minimizes the risk of human and organisational factors leading to accidents and occurrences. It will support the companies (IM's and RU's) on the harmonization of the safety approach by contributing to a positive safety culture 1 ID of the draft rule in SRD: DK-SA-205-1-D Side 2 (3) Document no.: 738588 and integration of human and organisational factors – as stated in the ERA Work Programme 2022.
3. DK-SA-205-1-D is divided into traffic rules (operational rules) and technical rules (rules for design, construction, and maintenance of infrastructure).
4. DK agrees with ERA that the rules should already be integrated in the companies' (IM's and RU's) SMS. DK-SA-205-1-D is however needed as a transitional measure to maintain the safety level, while NSA DK will guide and help the companies to succeed in integrating the rules in their SMS.
5. Based on experiences from the existing approval process with technical and traffic rules, it is clear that many companies lack the sufficient maturity and competences to complete the transformation to self-management at the moment. For now, the companies receive a lot of support from NSA DK in the process of making and changing the rules.
6. DK-SA-205-1-D will serve as guidance while the companies learn to think risk-based instead of rule-based. DK finds DK-SA-205-1-D necessary to reach an acceptable level of implementation of the safety rules in EU Regulation 2018/762 on SMS requirements, but acknowledge ERA's assessment and will therefore suggest two major changes to the rules:
  - a. The transition period will be significantly shortened from five to only two years. The date more or less follows Article 5 in EU 2019/773, and after 1<sup>st</sup> June 2024, the DK-SA-205-1-D is phased out and will be repealed.
  - b. It will be less extensive and only the technical area and IM's will be targeted. DK believes this will make it a type 3 National safety rule according to annex II in Directive (EU) 2016/798.
7. Furthermore, DK-SA-205-1-D will neither stop, prevent, or create a barrier to interoperability, and it will not stop or prevent RU's from other countries to have access to the railway. DK-SA-205-1-D will only be directed at railway infrastructure in Denmark and at the IM's already in Denmark. DK-SA-205-1-D will reduce administrative burdens for IM's at the latest by the 1<sup>st</sup> June 2024 because they no longer need to have their technical safety rules approved by the NSA DK.
8. The time schedule for all companies to have implemented the existing legal framework in their SMS – and for DK-SA-205-1-D to be repealed: The new version of DK-SA-205-1-D will enter into force 1<sup>st</sup> July

2022. Starting from 1<sup>st</sup> June 2024 DK-SA-205-1-D is phased out and will be repealed. The companies will at that time have integrated the technical rules in their SMS, which will be in full compliance Side 3 (3) Document no.: 738588 with the Directives (EU) 2016/798 and (EU) 2016/797 and all TSIs.

9. During the transitional period from 1<sup>st</sup> July 2022 to 1<sup>st</sup> June 2024 for the technical rules, DK will through guidance, training and workshops help the companies to achieve a strong safety culture inspired by ERA and the Safety Culture Model 2.0. During this period, DK will be in close contact with, cooperate with and seek guidance from ERA on how to support the companies in the best way.

### Agency's response

DK have altered their draft rule and provided more motivation for it, which is positive. They have cited human and organisational factors (HoF) and safety culture as justification for the draft rule, and the draft rule is now restricted to IMs. They note that the draft rule will not stop, prevent, or create a barrier to interoperability, and it will not stop or prevent RUs from other countries to have access to the railway. They have also introduced a shorter transitional period (see below for more detail).

From a strict legal point of view, however, no further justification has been provided as to why they have the legal basis to pursue the draft rule, taking into account the relevant EU legislation that is now applicable:

- There remains an overlap with a number of requirements in EU legislation (for example the HoF and safety culture are covered by EU Regulation 2018/762). In addition, the assurance of the safety level of the network in DK is not just down to the infrastructure managers, they have to work in cooperation with railway undertakings Art 4(3) Railway Safety Directive (RSD) 2016/798. The interface between the IM/RU also needs to be covered by both their SMSs. These interfaces will depend on a number of operational and local risks which cannot be mandated by national rules. The Agency remains concerned that by requiring IMs to have detailed technical safety rules, they in turn, could require railway undertakings to have additional internal rules that are not notified in SRD to meet their own IM action limits and values. (see Annex 1 for a more detailed analysis).
- A further concern is the transitional period issue and making sure that the IMs have in place all the necessary requirements to ensure the safety of their part of the system. However, under both the previous legal acts, EU Regulation 1169/2010 on granting a safety authorisation for IMs and the existing legislation EU Regulation 2018/762 on SMS requirements, the IM has to ensure continuous improvement of their SMS. This will include ensuring that any changes to the legal framework both at national and European level are regularly reviewed and necessary changes implemented into the SMS. This should then be checked by the NSA through the supervision process in Article 3 of EU Regulation 2018/761. It is important that the NSA targets its supervision activity primarily at those activities which they believe give rise to the most serious risks or where the hazards are least well-controlled. To do so, the NSA shall have methods and power to assess the day-to-day safety performance of the IM. For that purpose, the NSA should develop and implement a risk-based supervision strategy and plan(s) outlining how it targets its activities and sets its priorities for supervision.

The Agency therefore recognises the changes made to the draft rule, and sees these as important steps in the right direction. However, the Agency remains with its opinion that the requirements in the DK draft rule are covered already at EU level. Moreover, (i) the measures to limit it to IMs; and (ii) the significant reduction in the transitional period from five to two years, strictly speaking do not ensure that the draft rule is in full compliance with the EU law requirements.

#### **4. Denmark has been informed of the position of the Agency via the SRD.**

##### **The opinion**

The Agency considers that the draft national safety rule is not compliant with the relevant EU legal requirements.

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

The Annex 1 provides Denmark:

- The list of actions to be taken into account,
- An assessment table with:
  - o The national rule,
  - o The Agency assessment of the requirement and the reasons why this is not accepted,
  - o The status of the assessment indicating whether the requirement should be modified or repealed.

This opinion is addressed to Denmark, uploaded in the SRD with a copy to the European Commission.

Valenciennes, 20/05/2022

Signed

Josef DOPPELBAUER  
Executive Director



## ANNEX 1 Examination of draft national rule leading to negative assessment

The draft rule sets out a number of requirements on IMs that duplicate or further elaborate existing EU legislation. In particular the general requirement to have internal safety rules approved by the NSA which cover issues such as the management of safety risks, indicators and targets and the monitoring process which are all part of the SMS requirements cannot be permitted. In addition, the justification for the rule cites the need to improve human and organisational issues. Indeed these elements are important to ensure the safety of the railway undertakings operation within the rail system of Europe. This is why both HoF and Safety Culture are key requirements to be met in the SMS requirements of **Commission delegated Regulation (EU) 2018/762**. Infrastructure Managers have to provide evidence in their SMS processes of how they will deliver the safety of their operation by meeting the relevant requirements in the SMS. Additional rules on top of existing SMS procedures that are in place to control all technical, operational and organisation risks have no added benefits.

Denmark has been informed of the position of ERA via the Single Rules Database (SRD).

The following analyses by the Agency of some of the main requirements and scope explains why they are not permitted because they are covered by existing EU legislation and it is not possible to have a rule that duplicates, elaborates or extends the existing provisions. The analysis focuses on those aspects that duplicate or elaborate the requirements at EU level. It does not analyse the roles of the NSA.

Subsystem	Ref	National rules and acceptable means of compliance	Examination of national rules and acceptable means of compliance leading to a negative assessment	Agency assessment status
SMS	Art 4.1	<i>Functional requirements for safety rules: General requirements for technical and rail safety rules, which are part of the undertaking's safety management system and are necessary for the undertaking to achieve acceptable railway safety.</i>	<i>EU Regulation 2018/762 Article 4 and Annex II sets out all the requirements that need to be met in order to ensure the safety of their part of the system.</i>	Negative
SMS	Art 4.2	Technical safety rules: Contains requirements laid down to address railway hazards caused by errors by humans when they require, operate, operate or maintain a technical system.	<i>EU Regulation 2018/762 Annex II 4.6 Integration of human and organisational factors</i>  <i>4.6.1 The organisation shall demonstrate a systematic approach to integrating human and organisational factors within the safety management system.</i>  <i>This approach shall:</i>	Negative

			<p>(a) include the development of a strategy and the use of expertise and recognised methods from the field of human and organisational factors;</p> <p>(b) address risks associated with the design and use of equipment, tasks, working conditions and organisational arrangements, taking into account human capabilities as well as limitations, and the influences on human performance.</p> <p>7.2.3. The organisation shall provide a strategy to continually improve its safety culture, relying on the use of expertise and recognised methods to identify behavioural issues affecting the different parts of the safety management system and to put in place measures to address these.</p>	
SMS	Art 4.3	Action limits: Values set out in the company’s safety rules. The action limit shall be monitored by the establishment to determine when to take action to ensure that the immediate action limits laid down are not exceeded.	<p>EU Regulation 1078/2012</p> <p>2.4. of the Annex: The monitoring strategy and plan(s) shall define either quantitative or qualitative indicators or a mixture of both that can:</p> <p>(a) give early warnings of any deviation from the expected outcome, or assurance that the expected outcome is achieved as planned;</p> <p>(b) give information about unwanted outcomes;</p> <p>(c) support decision making.</p>	Negative
SMS	Art 4.4	Basic safety parameters: A group of parameters defining all the safety characteristics of a railway system or element.	<p>EU Regulation 2018/762 Annex II - 3.1.1 Risk assessment</p> <p>The organisation shall:</p> <p>(a) identify and analyse all operational, organisational and technical risks relevant to the character and extent of operations carried out by the organisation. Such risks shall include those arising from human and organisational factors such as workload, job design, fatigue or suitability of procedures, and the activities of other interested parties (see 1. Context of the organisation);</p>	Negative

			<i>(b) evaluate the risks referred to in point (a) by applying appropriate risk assessment methods; develop and put in place safety measures, with identification of associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities).</i>	
SMS	Art 4.5	Immediate action limits: Values for safety parameters or wear indicators set out in the company’s safety rules. Values for safety parameters or abrasion indicators set out in the company safety rules where exceeding these values would result in an unacceptable risk and therefore require immediate action to bring the system to a condition where the risk is acceptable.	<p><i>EU Regulation 1078/2012</i></p> <p><i>Annex: Drawing up of an action plan 4.1.</i></p> <p><i>For identified instances of non-compliance that are considered unacceptable, an action plan shall be drawn up.</i></p> <p><i>This shall:</i></p> <p><i>(a) lead to the enforcement of correctly implemented processes, procedures, technical, operational and organisational risk control measures as specified; or</i></p> <p><i>(b) improve existing processes, procedures, technical, operational and organisational risk control measures; or</i></p> <p><i>(c) identify and implement additional risk control measures.</i></p> <p><i>4.2. The action plan shall in particular include the following information:</i></p> <p><i>(a) objectives and results expected;</i></p> <p><i>(b) corrective, preventive or both types of measures required;</i></p> <p><i>(c) person responsible for implementing actions;</i></p> <p><i>(d) dates by which actions are to be implemented;</i></p> <p><i>(e) person responsible for evaluating the effectiveness of the action plan measures in accordance with Section 6;</i></p> <p><i>(f) a review of the impact of the action plan on the monitoring strategy, priorities and plan(s).</i></p>	Negative

SMS	Art 4.6	Function relevant to railway safety: A function carried out by means of a railway technical system which helps to reduce the risk of rail accidents.	The appropriate 'railway technical system' will be considered to be the appropriate ' <b>safety measures</b> ' put into place under EU Regulation 2018/762 Annex II 3.1.1 (b).	Negative
SMS	Art 4.7	Safety-related conditions of use: Conditions which minimise hazards associated with technical systems by imposing restrictions on the user of the systems or requiring the user to carry out specific activities in order to limit the risk of hazards resulting in accidents.	Conditions which minimise hazards will be linked to the results of the risk assessment under EU Regulation 2018/762 Annex II <b>on risk assessment (3.1.1), operational planning and control (5.1), management of change (5.4), monitoring (6.1) and continual improvement (7.2)</b> and the results of monitoring under EU Regulation 1078/2012.  In addition EU Regulation 2018/762 Annex II 7.2.3. states: <i>The organisation shall provide a strategy to continually improve its safety culture, relying on the use of expertise and recognised methods to identify behavioural issues affecting the different parts of the safety management system and to put in place measures to address these.</i>	Negative
SMS	Art 4.10	Regelassessor: The independent and competent person, external or internal person, organisation or entity conducting investigations to determine whether a safety rule, an amendment thereto or an exemption from the technical safety rules ensures that the undertaking maintains or improves the level of safety in a documented and system-borne manner so that all reasonably foreseeable hazards associated with the techniques used are controlled	EU Regulation 2018/762 Annex II 2.3 requires:  2.3.1 The responsibilities, accountabilities and authorities of staff having a role that affects safety (including management and other staff involved in safety-related tasks) shall be defined at all levels within the organisation, documented, assigned and communicated to them.  2.3.2. The organisation shall ensure that staff with delegated responsibilities for safety-related tasks shall have the authority, competence and appropriate resources to perform their tasks without being adversely affected by the activities of other business functions.  2.3.3. Delegation of responsibility for safety-related tasks shall be documented and communicated to the relevant staff, accepted and understood.	Negative
SMS	Art 4.13	Monitoring system: Monitoring activities carried out according to a written process.	The need for specific proactive monitoring by the infrastructure managers is also explicitly dealt with in <i>Commission Regulation (EU) No 1078/2012</i> .	Negative

SMS	Art 5	<p>The undertaking shall ensure that relevant technical safety rules have been drawn up in accordance with procedures laid down in the undertaking's safety management system. The security rules shall meet the functional requirements set out for the relevant areas in Chapters 7 and 8. The undertaking must comply with these safety rules at all times, but see Section 36.</p> <p><i>Paragraph 2.</i> The procedures laid down in the undertaking's safety management system, cf. paragraph 1, shall comply with Section 6.</p> <p><i>Paragraph 3.</i> Companies are fully responsible for ensuring that the safety rules fulfil their purpose</p>	<p>For both Article 5 and 6, these national requirements duplicate and extend the requirements in EU Regulation 2018/762.</p> <p>In addition the proposal for self management is already a key part of the SMS, including the need to manage and control operational, organisational and technical risks.</p>	Negative
SMS	Art 6	<p>Undertakings may apply to the Transport Authority to move to self-management of technical safety rules. The application shall contain evidence of compliance with the relevant requirements of Section 6 (1) and Chapters 6-10 of this Order. The application shall contain the following supporting documents:</p> <ol style="list-style-type: none"> <li>1) Cross-references between the undertaking's safety management system and the requirements of the Order.</li> <li>2) Description of the responsibilities, powers, tasks and competences of staff responsible for or contributing to processes or parts thereof.</li> <li>3) Indication of the company's applicable technical and road safety rules.</li> </ol> <p><i>Paragraph 2.</i> The Transport Authority may at any time request additional documentation in connection with the processing of the application.</p> <p><i>Paragraph 3.</i> The Transport Authority shall approve the undertaking's transition to self-management of technical safety rules. When examining the application, the Transport Authority shall assess whether the</p>		Negative

		undertaking’s safety management system ensures compliance with the relevant requirements in Section 6 (1) and Chapters 6 to 9 of this Order.		
SMS	Art 7	<p>In the case of technical safety rules, amendments to technical safety rules or exemptions from technical safety rules, the undertaking shall carry out an assessment of materiality on the basis of the following criteria:</p> <ol style="list-style-type: none"> <li>1) Worst consequence if a rule fails to achieve its purpose or there is no risk mitigation action in case of deviation.</li> <li>2) Novelty of the safety rule or deviation.</li> <li>3) The complexity and extent of the security rule, modification or deviation.</li> <li>4) Accumulation.</li> </ol> <p><i>Paragraph 2.</i> In assessing the novelty of the safety rule or deviation, the following factors shall be taken into account:</p> <ol style="list-style-type: none"> <li>1) New users of the rule or new users involved as a result of the deviation and new professional areas covered.</li> <li>2) New ways for the user to act or communicate.</li> <li>3) New ways for the user to interact with technical systems.</li> </ol> <p><i>Paragraph 3.</i> The assessment of complexity and scope shall take into account the following factors:</p> <ol style="list-style-type: none"> <li>1) Number of of and where: complicated the physical interfaces are against other technical interfaces; systems.</li> <li>2) Number of of and where: complicated the interfaces are with other disciplines.</li> </ol>	<p>There are duplication and elaboration with EU Regulation 2015/1136 of 13 July 2015 amending Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment.</p> <p>This Regulation should be used by IMs as part of their SMS to manage change.</p>	Negative

		<p>3) Number of of and where: complicated the activities are, as the rule or deviation, impose: the users, there shall be: use the rule or are involved in the deviation.</p> <p>4) The number of external parties covered and to be consulted.</p> <p>5) The number of staff groups to apply the rule or to be involved in the deviation.</p> <p>6) The number of rules to which the rule or deviation refers or affects.</p>		
--	--	--	--	--

## **ANNEX 2 The original request uploaded in SRD**

Rule ID DK-SA-205-1-D can be consulted on following link:

[SRD - Single Rules Database \(europa.eu\)](https://europa.eu/srd)



## **ANNEX 3 Light impact assessment**

# Light Impact Assessment

## Annex 3

### Impact Assessment Note

*a draft national rule of Denmark on requirements for functional requirements for the technical and traffic safety rules on the railway with the purpose of insuring, that infrastructure managers and railway undertakings in developing their safety rules continue to ensure a sound and uniform safety level across the corporations*

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)

<b>1. Context and assessment of impacts</b>
<b>1.1. The national rule in object</b>
Denmark notified a draft national rule via SRD as per Art. 25 of Regulation (EU) 2016/796 technical and traffic safety rules on the railway with the purpose of insuring, that infrastructure managers and railway undertakings in developing their safety rules continue to ensure a sound and uniform safety level across the corporations.
<b>4.2. 1.2. Analysis performed</b>
In its first assessment the Agency provided substantial evidence that the draft national rule in object is overlapping with a number of EU legal requirements. Denmark claims the draft rule as a transitional measure in order to allow additional time for RUs/IMs to adapt their processes in order to address risks by self management in their Safety Management Systems (SMS) and following up on the Agency initial analysis decided to shorten the duration of the rule from 5 to 2 years and to limit the scope to IMs thus not impacting interoperability of RUs. The Agency however remained of its negative opinion given that SMS of RUs and IMs are interfacing and, beside the overlap of the draft rule with EU requirements for IMs, RUs would also be impacted by possible new rules developed by IMs which are not notified and for which relevant safety hazards are not addressed in the SMS.
<b>4.3. 1.3. Assessment of impacts</b>
The draft rule by Denmark falls within the scope of the Light Impact Assessment 'Revision of the Common Safety Methods on Conformity Assessment and the Common Safety Methods on Supervision' performed by the Agency in February 2017. The impacts were therefore already adequately assessed and it is confirmed that the adoption of the draft rule would compromise uniformity of application of well-established EU requirements on SMS, increase the risk of low transparency of the national rules framework that stakeholders have to comply within Denmark as well as interoperability of RUs. The alleged low engagement and understanding of RUs/IMs of their obligation with regards to SMS and self-management would be better addressed by guidelines, training and information campaign rather than by a national rule.

<b>4.4. 1.4. Stakeholders affected</b>			
Railway undertakings (RU)	<input checked="" type="checkbox"/>	Member States (MS)	<input type="checkbox"/>
Infrastructure managers (IM)	<input checked="" type="checkbox"/>	Third Countries	<input type="checkbox"/>
Manufacturers	<input type="checkbox"/>	National safety authorities (NSA)	<input checked="" type="checkbox"/>
Keepers	<input type="checkbox"/>	European Commission (EC)	<input type="checkbox"/>
Entity Managing the Change (EMC)	<input type="checkbox"/>	European Union Agency for Railways (ERA)	<input type="checkbox"/>
Notified Bodies (NoBo)	<input type="checkbox"/>	Shippers	<input type="checkbox"/>
Associations	<input type="checkbox"/>	Other (Please specify) ...	<input type="checkbox"/>

<b>2. Preferred option</b>	
<b>4.5. 2.1. Recommendation</b>	
No alternative options are to be assessed and it is confirmed a negative assessment of the draft rule by Denmark.	