



# ANNEX

**TO THE EXPERT GUIDANCE ON THE IMPLEMENTATION OF  
THE CYBER RESILIENCE ACT IN MAINLINE AND URBAN  
RAILWAYS**

**ON THE IMPACT OF THE CYBER  
RESILIENCE ACT (EU) 2024/2847 ON  
THE RAIL INTEROPERABILITY DIRECTIVE  
(EU) 2016/797 AND THE PRACTICAL  
ARRANGEMENTS FOR THE RAILWAY  
VEHICLE AUTHORISATION REGULATION  
(EU) 2018/545**

V 1.0.0 APRIL 2026

## EXECUTIVE SUMMARY

---

This document aims to explain the impacts and boundaries between the Cyber Resilience Act (EU) 2024/2847 (hereinafter, “the CRA”) and its compliance with the legal framework for railway vehicle authorisation (Commission implementing regulation (EU) 2018/545 (hereinafter, “the PA VA”) establishing practical arrangements for the railway vehicle authorisation process pursuant to Directive (EU) 2016/797 on the interoperability of the rail system within the European Union (hereinafter, “the IoD”).

To this end, **this annex outlines the distinct separation of cybersecurity compliance demonstration from the authorisation processes for railway vehicles. The impact of the CRA on the vehicle authorisation process is limited.** The CRA will only be reflected in the authorisation process in two instances:

1. The **CRA is one of the “other legal acts of the Union”/ “relevant union laws”** (as referred by the IoD Art. 15 para 2 and Annex IV / PA VA respectively) to which compliance is **declared at the sole responsibility of the applicant** by an EU declaration of conformity. The scope of review of railway authorities is limited to review if the EU Declaration of Verification (DOV) is part of the application documents and is covering all applicable regulations without any further review.
2. The CRA will be treated as a **part of the vehicle authorisation requirements capture process** set forth in Article 13 PA VA as the CRA is part of the applicable relevant Union law to be identified accordingly.

While the CRA leads to amendments of mandatory authorisation documents in these two instances, the change management assessment for vehicle authorisation according to Article 15 (EU) 2018/545 remains unaffected by the CRA.

**Other topics relating to the implementation of the CRA within the rail sector, including its context of application are explored in the full *Expert Guidance on the Implementation of the CRA in mainline and Urban Railways*.**

## 1. INTRODUCTION

---

Given the complexity, high economic implications, and regulatory sensitivity of the vehicle authorisation process, it is essential to clarify how cybersecurity requirements, such as those required under the CRA, should be handled for granted vehicle type authorisations and future vehicle type authorisation applications (“vehicle authorisation for placing on the market”). Clear and harmonised rules at EU level would support consistent interpretation by industry actors and EU/national authorities.



It is particularly important for the railway industry, as very complex system having own specific rules, to maintain the clear separation between the cybersecurity compliance process according to the CRA and the vehicle authorisation process according to the IoD and PA VA. Distinct boundaries between these processes are needed to maintain the integrity of the authorisation process and manage efficiently cybersecurity risk.

### 3. LEGAL BACKGROUND, APPLICATION DATE AND IMPACT OF THE CRA ON PRACTICAL ARRANGEMENTS FOR THE VEHICLE AUTHORISATION

---

The CRA entered into force on 10 December 2024 and is applicable from 11 December 2027 for Products with Digital Elements (PDE), including those in the railway sector.

The PA VA as part of the 4<sup>th</sup> Railway Package has established an EU-wide harmonized administrative procedure and formal requirements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to the IoD.

**In the context of the IoD and the PA VA, the CRA is one of the “other legal acts of the Union”/ “relevant Union laws”. Compliance is declared at the sole responsibility of the applicant as part of the EC Declaration of Verification (EC DoV) of the rail subsystem(s). Additional documentation is not legally mandated.**

### 3. CRA CONFORMITY ASSESSMENT

---

In addition to the TSIs, national rules and requirements capture process where the rail Notified Body, Designated Body and Assessment Body assess their compliance respectively, other applicable legislation of the Union may also require that certain conformity assessments are carried out. The applicant is responsible for performing the necessary conformity assessments in accordance with the provisions of the other relevant Union law.

The CRA requires an EU declaration of conformity for each ‘product with digital elements’ (PDE) confirming compliance to the essential cybersecurity requirements. Depending on the product category and class of the PDE in accordance with CRA Annex III and IV, conformity assessment of PDEs may be carried out by the manufacturer under its own responsibility or using a third-party assessor. In the case of a third-party assessment, a CRA Notified Body is required.

The Notified Body assessment of the CRA and railway authorisation requirements such as Technical Specifications for Interoperability (TSIs) (when required) are separate. However,



the applicant may choose to contract them together with the same Notified Body organisation depending on their notified competences by a Member State.

**The entities responsible for the authorisation of railway vehicles are not legally mandated to assess compliance with other applicable EU legislation, including the CRA.** Within the VA process, relevant legislation is acknowledged through its inclusion in the EC DoV, as part of the outcome of the structured requirements capture process.

**This approach ensures that the VA process remains focused, efficient, and aligned with its intended scope.** It is considered fully sufficient for demonstrating conformity within the framework of the VA process. Requiring additional evidence to prove compliance with other EU legislation would go beyond the legal remit of the authorising entities and could introduce unnecessary complexity.

## 4. INTEGRITY OF VEHICLE TYPE VALIDITY AND CYBER RISK MANAGEMENT

---

As per Article 5 of the PA VA, the holder of the vehicle type authorisation shall be responsible for the configuration management of the vehicle type and the accompanying file for the authorisation decision issued. The holder of the vehicle type authorisation, as part of the configuration management of the vehicle type, shall inform the authorising entity that issued the vehicle type authorisation about any changes in Union law that affect the validity of the vehicle type authorisation.

When there is a change in the applicable requirements of the relevant Union law and/or any relevant national rule, the holder of the vehicle type authorisation, through the configuration management of the vehicle type, should verify if:

- The vehicle type authorisation remains valid (i.e. if it is still possible to place on the market more vehicles conforming to the authorised vehicle type), e.g. when the transitional provisions of the Union law so allow; or
- There is a need to request a renewed vehicle type authorisation, or a new authorisation, and whether this should result in the authorisation of new vehicle type or vehicle type variant / version.

**The CRA does not automatically invalidate the vehicle type granted before 11 December 2027 when there is no change in authorisation type.** The applicant must assess whether changes are needed to the vehicle design in order to obtain CRA compliance at vehicle level before vehicles of the same type can be further placed on the market after 11 December 2027. If no change is needed, the type remains valid but the DoV must be updated to include CRA compliance. If a rail vehicle as a whole should be considered a PDE according to the CRA, applications for vehicle authorisation granted from 11 December 2027 shall include an



indication<sup>1</sup> of CRA compliance in the EC Declaration of Verification. The PDEs contained within the vehicle which are themselves placed on the market after 11 December 2027 shall also be CRA compliant. Vehicles authorised after 11 December 2027 may include non CRA-compliant PDE components already placed on the market before this date. An already authorised vehicle will need CRA compliance when it undergoes a “substantial modification” in the sense of the CRA (see section 6 of this Annex).

New vehicles can be built and authorised in conformity to type to all vehicle type variants and vehicle type versions that are still valid (taking into account any changes to the rules), as long as the EC certificates remain valid.

It is worth noting that, unlike the TSIs, the CRA did not provide transitional provisions which consider the status or progress of a given project at the time of its applicability. From 11 December 2027, all products with digital element (PDEs) placed on the market for the first time shall comply with the CRA.

## 5. CRA IMPACT ON THE DIFFERENT VEHICLE AUTHORISATION CASES OF THE PA VA ARTICLE 14 FROM 11 DECEMBER 2027

---

- a. First Authorisation** - From 11 December 2027, all vehicle types being authorised and/or vehicles placed on the market for the first time shall come with an indication of the CRA declaration of conformity of the vehicle in the EC Declaration of Verification. If the vehicle (type) does not contain any PDEs then it is not in scope of the CRA and no declaration of conformity is needed.
- b. Renewed vehicle type authorisation** – The CRA does not reference rail vehicle types or the need for renewal of vehicle type, so this case is not relevant. This authorisation case is only applicable pursuant to Article 24(3) of the Interoperability Directive for changes to any relevant provisions in TSIs or national rules which request a renewed authorisation and do not require a change in design of the vehicle type.
- c. Extended area of use** - For an authorisation extending the area of use of a vehicle type and/or vehicle without changes to the vehicle type (necessary condition to apply this authorisation case), the existing vehicle type authorisation and/or vehicle authorisation remains valid and the CRA does not need to be considered.
- d. New authorisation** - A new authorisation is required if there are either changes to an already authorised vehicle type and/or vehicle that meet the criteria set up in Article

---

<sup>1</sup> The indication should simply state that the latest certificate has been complied with, without including more date or individual references. The certificate should not be formally included as a document in the files at either the type authorization level or the APoM level. The certificate itself – whose achievement is covered by its own cybersecurity framework – should only be produced for VA upon request, for example during an audit.



21(12) of the interoperability directive, or a new vehicle type is created based on an already authorised vehicle type, pursuant to Article 15(4) of the PA VA.

**For a new authorisation in the case of changes to an already authorised vehicle with changes to PDEs, then it will need to be compliant with the CRA if it underwent a “substantial modification” in the sense of the CRA.** The unchanged parts remain unaffected, in accordance with PA VA.

- e. Authorisation in conformity to type** - An authorisation in conformity to type can only be issued as long as the vehicle type authorisation and the EC certificates for subsystems and Interoperability Constituents (including quality management system (QMS) approval) are valid. **Conformity to type for vehicles according to vehicle types authorised before 11 December 2027 is only possible if the type remains valid without change in design.** In this case the CRA EU declaration of conformity for the vehicle is added to the EC DoV of type authorisation after 11 December 2027. If changes are needed to the existing type then it is assessed according article 15 of (EU) 2018/545. If changes that trigger a new authorisation are needed to the existing type then the new authorisation should be processed first to obtain a valid type, before a conformity to type is submitted.

It is noted that vehicles fleets delivered over a period spanning the 11 December 2027 date may consist of a mix of vehicles, both non-CRA and CRA compliant, depending on the date of placing on the market of the individual vehicles.

## 6. IMPACT OF MODIFICATIONS TO THE PRODUCT WITH DIGITAL ELEMENTS

---

Under the CRA, a “substantial modification” means a change to the product with digital elements following its placing on the market, which affects the compliance to the essential cybersecurity requirements set out in Part I of Annex I of the CRA or which results in a modification to the intended purpose for which the product with digital elements has been assessed.

It is therefore expected that security updates (software or hardware modification) intended to address identified vulnerabilities will not be considered as a substantial modification and consequently will not require an amendment to the CRA conformity assessment.

Where a CRA substantial modification has taken place, it is appropriate that the compliance of the PDE is verified and that, where applicable, it undergoes a new conformity assessment procedure according to the CRA. Where applicable, if the manufacturer has previously undertaken a conformity assessment involving a third party, a change that leads to a substantial modification should be notified to the third party.



Where a substantial modification under the CRA has occurred and the CRA EU declaration of conformity updated accordingly, this does not automatically imply an impact on the EC declarations for verification for the subsystems and vehicle authorisation.

Nonetheless, all changes to a rail vehicle and vehicle type – regardless of their being substantial modifications or not in the context of the CRA – shall also be analysed and categorised independently in accordance with Article 15 of the PA VA. This assessment is necessary to determine the impact of the change on the authorised vehicle or vehicle type.

**Therefore, the analysis of modifications under the CRA and the analysis of modifications under the PA VA Regulation are distinct and must be conducted separately or sequentially.**

## 7. SPECIAL VEHICLES

---

Special vehicles, as the fourth category of the rolling stock in the TSIs, represent a special case, as these vehicles are used in three modes, i.e. running, travelling and working. Therefore, they are to be considered as vehicles and machine at the same time. As vehicles, they are regulated under IoD and associated legal acts including TSIs. As machines, they are regulated by the Machinery Directive 2006/42/EC, respective Machinery Regulation 2023/1230/EC from 20<sup>th</sup> January 2024. All regulations which shall apply for the vehicle shall apply in the same way for the machine. Special vehicles are characterised by a high number of customized solutions in combination of low series volume of the manufactured product, which results in no economy of scale. Therefore, conformity to type has a limited application for special vehicles, and an extensive authorisation process as foreseen for series production brings incommensurable efforts for a manufacturer of special vehicles. To avoid further complexities, special vehicles shall adopt an identical approach to the CRA for both regulatory frameworks, which shall apply a pre-condition for placing on the market.



## ANNEX - LIST OF ABBREVIATIONS

---

<b>CRA</b>	Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act)
<b>DeBo</b>	Designated Body
<b>EC DoV</b>	EC Declaration of Verification
<b>IC</b>	Interoperability Constituents
<b>IoD</b>	Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union
<b>NoBo</b>	Notified Body
<b>PA VA</b>	Commission Implementing Regulation (EU) 2018/545 of 4 April 2018 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council
<b>PDE</b>	Products with Digital Elements
<b>TSIs</b>	Technical Specifications for Interoperability
<b>QMS</b>	Quality Management System

