EUROPEAN UNION AGENCY FOR RAILWAYS

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Clarification note

Changes that may adversely affect safety pursuant to Article 21(12)(b) of Directive (EU) 2016/797

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Document History

Version	*Date*	*Comments*
0.1	20/03/2020	Initial version for internal review
0.2	02/08/2024	Working document for internal review
0.3	11/10/2024	Working document for VA working party discussion
1.0	25/02/2025	Final version after VA working party
1.1	24/04/2025	Update of flowchart in figure 1 to include “critical” consequences in the first question shape in step “Effect of the change”
1.2	12/09/2025	Version after VA WP meeting no.3 - §2 changed bullet points (>) to letters and numbers - §2.b) added reference to AsBo for requirements capture and effect of risk acceptance categories negligible or tolerable - §2.c) transferred the note to regular text and rewording - §2.e) added paragraph 3 and minor wording adjustments - §2.f) minor wording adjustments - Figure 1: references to text in §2 added (green boxes) - Figure 1: rewording of text in certain shapes: - Figure 1: reference to EN 50126-1 Annex C added

The purpose of this document is to provide applicants and other external stakeholders of the vehicle authorisation business with information in regard to the specific topic referenced in the title. The clarifications contained in this document may be integrated in the next revision of the guidelines for the practical arrangements for the vehicle authorisation process, without prejudice of the formal process foreseen for updating the guideline.

The present document is a non-legally binding guidance of the European Union Agency for Railways. It 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. Description of the issue

The Article 21(12) of Directive (EU) 2016/797 describes the cases where a change to an already authorised vehicle and/or vehicle type requires a new authorisation. In particular, Article 21(12)(b) states that an authorisation is required if "*the overall safety level of the vehicle concerned may be adversely affected*".

Applicants and entities managing changes tend to evaluate Article 21(12)(b) considering all barriers and control measures in place to ensure that safety will not be impacted, that is, once the change has been implemented, verified and validated.

Because the actors in the railway sector should ensure that "*railway safety is generally maintained and, where reasonably practicable, continuously improved*" [1] a change should not be contemplated if it will adversely affect the overall level of safety of the vehicle concerned. It can thus be inferred that Article 21(12)(b) of Directive (EU) 2016/797 relates to the potential to adversely affect the overall level of safety of the vehicle concerned, and not to whether the change in its real implementation will actually have a negative impact on safety or not.

However, this would mean that almost every possible change may require an authorisation, because in the end most of the changes may negatively impact safety under some possible (but maybe infrequent) scenarios.

This lack of clear criteria to decide if a changes triggers Article 21(12)(b) or not creates difficulties in the classification of changes pursuant to Article 15(1) of Regulation (EU) 2018/545.

[1] Article 4(1)(a) of Directive (EU) 2016/798

2. Line to take

a) **The level of safety cannot be decreased, only maintained and improved where possible. For this reason, Article 21(12)(b) of Directive (EU) 2016/797 should be considered as an evaluation to be performed not yet considering any risk mitigation measure, and not as an evaluation that considers all risk mitigation measures that will be in place at a later stage.**

The actors should ensure that "*railway safety is generally maintained and, where reasonably practicable, continuously improved*" therefore, a change should not be contemplated if it will adversely affect the overall level of safety of the vehicle concerned. This means that Article 21(12)(b) relates to the potential to adversely affect the overall level of safety of the vehicle concerned, and not to whether the change, once implemented and validated, will have a real negative impact on safety or not.

An entity managing a change, when deciding if Article 21(12)(b) is triggered or not, should not take into consideration the activities either performed or to be performed to ensure that safety will not be adversely impacted (i.e. risk control measures, such as calculation notes, simulations, tests, involvement of conformity assessment bodies, redundancy of safety systems, monitoring systems, etc.). Considering such aspects in the evaluation would mean that the decision is taken after the change is implemented, verified and validated. However, such activities shall always take place, yet there is a need in many cases for an authorising entity to issue an authorisation.

The Article 21(12)(b) concerns the potential of a change to impact safety adversely before its implementation, verification and validation, and the associated need for an authorising entity to deliver an authorisation when the potential exists.

Even if a change aims at improving safety (e.g. new class B signalling system in a vehicle that did not have any train protection system), if it is not executed correctly, safety may be negatively affected in the end (e.g. class B system introduced not taking into account electromagnetic compatibility and therefore not working properly when it was expected to do so).

b) **The entity managing the change, with the support of the requirements capture process (i.e. risk assessment), is the sole responsible for assessing whether the change may have a negative impact in safety or not.**

In line with the subjacent principle of the 4th Railway Package of allocating more responsibility to manufacturers, applicants and entities managing changes, and the possibility for proposers in Regulation (EU) 402/2013 to assess by themselves whether a change has an impact on safety, the **entity managing the change can take a decision**, considering the outcomes of the process for requirements capture, on **whether the change has a potential impact on safety**. It is not necessary that this decision is evaluated or endorsed by an AsBo (e.g. the AsBo in charge of the independent assessment of the requirements capture process) nor by an authorising entity (be it the Agency or the concerned NSAs for the area of use). However, the process for requirements capture for the essential requirement safety followed by the entity managing the change should be independently assessed by an AsBo.

The evaluation of the potential impact on safety should be based on the system definition and the results from the risk assessment and evaluation (requirements capture process for the essential requirement safety) but should take place before the implementation of the change; the verification and validation activities should not be considered when taking the decision (see paragraph a).

The risks associated with the execution of the change should only be considered if the manufacturing/retrofitting process impacts the design. In other words, while it is always possible that errors may occur during the execution phase (e.g. during the physical manufacturing of components, retrofitting existing systems, or modifying vehicle subassemblies), these potential errors should not influence the analysis under Article 21(12)(b). Nevertheless, certain changes are influenced by the manner in which they are executed, leading to different conclusions. For example, when increasing the length of a frame, there is a substantial difference between manufacturing the structure to the desired length from the outset than modifying an existing frame by cutting and welding additional sections.

If the **risk acceptance categories** according to EN 50126-1 Annex C are **negligible or tolerable**, the entity managing the change may conclude that the change **does not have the potential to impact safety**, and Article 21(12)(b) of Directive (EU) 2016/797 is not triggered.

Note: when the holder of a vehicle type authorisation requests the creation of a version in ERATV pursuant to Article 15(1)(c) of Regulation (EU) 2018/545, a modification of an existing ERATV entry following a change classified pursuant to Article 15(1)(b) or the entity managing a change submits a notification of a change pursuant to Article 16(4) of Regulation (EU) 2018/545, the concerned authorising entity has the duty to verify whether the process followed by the applicant to classify the change is adequate. This includes the assessment of whether the rationale for deciding if Article 21(12)(b) of Directive (EU) 2016/797 follows the principles outlined above.

c) **When as a result of a change there are new safety requirements to be applied, new hazards & risks, new risk control measures for existing risks and/or a change in the risk acceptance category, as a general rule, it should be considered that Article 21(12)(b) of Directive (EU) 2016/797 is triggered.**

When the hazards, risks, risk control measures or risk acceptance category of the unchanged vehicle are unknown, the entity managing the change may perform a risk assessment of the vehicle before the implementation, verification and validation of the change, limited to the parts impacted by the change and the identification of risks, the determination of the risk acceptance category and the identification of the control/mitigation measures (if needed), and compare it with the risk assessment of the modified system (before considering the effect of the risk control measures, see bullet point a).

If after comparing the outcomes of the two risk assessments, there are no:

1. **new hazards/risks** that did not exist in the unchanged vehicle and stem from the change and/or the implementation of the change and for which the risk acceptance category (the combination of severity and frequency of occurrence in Annex C of EN 50126-1), without considering any safety measure, is higher than negligible or tolerable;
2. **new risk control measures** for risks already existing in the unchanged vehicle (e.g. application of a different standard/code of practice , new tests following an alternative assessment methodology etc.); however, repetition of tests, calculations, simulations, etc. using the same assessment methodology does not qualify as a new risk control measure, even if the resulting documentation is new. For example, on-track tests repeated after implementing a change – using the same standard already applied in the previous authorisation – results in a new test report but are not considered a new risk control measure;
3. **changes in the risk acceptance category** (the combination of severity and frequency of occurrence in Annex C of EN 50126-1) from:
   - Tolerable to Undesirable, or
   - Undesirable to Intolerable
4. **new safety requirements** that are needed to keep the safety level (e.g. an additional on-board monitoring system, duplicated systems for redundancy in case of failure, etc.);

the entity managing the change may conclude that there is **no potential to impact safety adversely**. As a consequence, **Article 21(12)(b) is not triggered** and there is no need for a new authorisation on the grounds of adverse impact on safety.

Note that even if the criteria above are not met (i.e. new hazards/risks, new risk control measures, new safety requirements and/or worse risk acceptance categories), this does not automatically mean that Article 21(12)(b) is triggered, see paragraph e).

The entity managing the change may not perform the risk assessment of the unchanged vehicle and skip the comparative analysis. In such case, the entity managing the change should consider that comparative analysis has resulted in an unfavourable situation (new safety requirements, new hazards/risks, new safety risk control measures and/or worse risk acceptance categories) and proceed directly with analysing the impact of the change as described in bullet points d) and e). The entity managing the change would not benefit from the options outlined above or in the “safety environment” section of Figure 1, which could allow concluding that Article 21(12)(b) is not triggered in a faster and simpler way.

d) **A change triggers Article 21(12)(b) of Directive (EU) 2016/797 when it falls into the category described in Article 4(2)(a)** of Regulation (EU) 402/2013 regarding the **consequences of a failure:**

1. **Catastrophic**: "*fatalities and/or multiple severe injuries and/or major damage to the environment resulting from an accident*" pursuant to Article 3(23) of Regulation (EU) 402/2013, or
2. **Critical**: "affecting a very small number of people and resulting in at least one fatality and/or large damage to the environment" pursuant to table C.4 of EN 50126-1.

In this context, failure consequence pertains to the credible worst-case scenario in the event of failure of the system under assessment and is linked to the potential impact of the most severe but realistic worst-case scenarios that are plausible based on historical data, expert judgment, and current and foreseen operating conditions. Such scenarios should not be overly speculative, meaning that scenarios that are theoretically possible but highly improbable in real-world circumstances should not be taken into account.

e) A change that does not fulfil the criteria described in paragraph d) **does not trigger Article 21(12)(b) of the Directive if it fulfils one the following (groups of) criteria** of Article 4(2) of the Regulation (EU) 402/2013:

1. Changes which are a **novelty** (Article 4(2)(b) of the Regulation (EU) 402/2013) but are **not complex** (Article 4(2)(c) of the Regulation (EU) 402/2013) **do not trigger Article 21(12)(b)**. In this context, "novel" or "novelty" can be defined as any aspect of the vehicle that is new, innovative, or significantly different from existing practices, technologies or designs. Novelty introduces elements of uncertainty and potential unforeseen risks due to the lack of historical data and operational experience. Examples of novelties are new technologies: introduction of cutting-edge technologies such as advanced materials, state-of-the-art electronics and/or control and monitoring systems.

   Note: changes which are novel and also complex trigger Article 21(12)(b).

2. Changes that are **not a novelty** (Article 4(2)(b) of the Regulation (EU) 402/2013) but are technically **complex** (Article 4(2)(c) of the Regulation (EU) 402/2013) - whether due to their underlying principles or the challenges in the implementation in the vehicle type – yet for which there is **substantial industry experience** (e.g., the change has already been widely adopted in the railway sector and there is reliable experience, making it well-established) **do not trigger Article 21(12)(b)**; "complex" or "complexity" refers to the characteristics of the change and the interactions with the unchanged parts that increase the difficulty of understanding, predicting, and managing potential risks. Complexity in this context can arise from various factors of the change and its design and implementation, such as:
   - Use of advanced technologies (e.g. automated control systems with manual override options requiring sophisticated algorithms and robust fail-safes, sophisticated monitoring mechanisms, multiple safety systems that must work seamlessly together etc.);
   - System interdependencies: high degree of interconnectivity between different subsystems (e.g., braking, signalling, communication) where failure in one subsystem could affect others (cascading failures);
   - Intricate designs: elaborate design features that require precise engineering and extensive coordination between different engineering disciplines, or
   - Extent of the operations needed to implement the change in the vehicle (e.g. need to modify extensively the structure of the vehicle)
3. Changes that are **not a novelty** (Article 4(2)(b) of the Regulation (EU) 402/2013) **nor** are technically **complex** (Article 4(2)(c) of the Regulation (EU) 402/2013) - **do not trigger Article 21(12)(b)**.

f) All other possibilities **trigger Article 21(12)(b) of Directive (EU) 2016/797**, such as:

1. Changes that are **not a novelty but complex and are not widely implemented and/or without enough experience** in its application in the railway sector, or
2. Changes which are a **novelty and complex**

All the different possibilities covered in bullet points c, d, e and f are further described in figure 1.

g) **When as a result of the change there is a new safety assessment report by an AsBo and a new written declaration by the proposer, this does not automatically trigger Article 21(12)(b) of Directive (EU) 2016/797.**

The reference to the declaration established by the applicant is a basic design characteristic, pursuant to Article 48(1)(c)(iv) of Regulation (EU) 2018/545. This means that a change for which there is a need to establish a new declaration should not be classified pursuant to Articles 15(1)(a) or 15(1)(b) of the Regulation.

However, if the risk declaration is updated for editorial reasons or to cover the aspects mentioned above (i.e. absence of new hazards/risks, no new mitigation measures, etc.), it can be considered that the basic design characteristic "reference to the risk declaration" is not actually impacted, the change can be classified pursuant to Article 15(1)(b) and a new authorisation is not required from the point of view of this basic design characteristic.

Similarly, when the assessment report by an AsBo is updated to cover the criteria for not triggering Article 21(12)(b) mentioned in previous sections (i.e. absence of new hazards/risks, no new mitigation measures, etc.) and/or any other amendment of editorial nature (correction of typographic errors, wording improvement etc.), and as a result, the declaration established by the applicant needs to be updated, it should be considered that the change does not trigger the need for a new authorisation.

The process for requirements capture related to the essential requirement safety for a change must be independently assessed by an AsBo, as specified in Article 13(3) of Regulation (EU) 2018/545. However, and independent assessment by an AsBo is not required if:

1. The primary functions (what the changed system is explicitly designed to do, its core functions), and the secondary functions (any additional function that not being part of the core functions can influence safety; these include mechanisms or processes designed to support, enhance or mitigate risks in abnormal or emergency situations, such as emergency stop mechanisms) of the changed system remain unchanged, and.
2. The changed system does not perform any safety function to prevent accidents or mitigate their effects;
3. The change has no direct or indirect impact on safety, does not introduce failure modes that could result in severe consequences (e.g. injury or death), and
4. The side effects on the unchanged parts in credible worst-case scenarios do not result in severe consequences (e.g. severity categories S4 and S5 as described in EN 50126-1, Table c.5)

Note: a **direct impact on safety** occurs when a change, action, or event has an immediate and measurable effect on safety. This includes situations where safety risks are directly increased or decreased without relying on intermediate factors or conditions. For example, the failure of a critical braking system directly impacts the ability to prevent accidents. An **indirect impact on safety** arises when a change, action, or event influences safety through intermediate factors, conditions, or processes. These impacts may not be immediately apparent but can materialize over time or under specific circumstances. For example, changes to maintenance schedules might indirectly impact safety by affecting the correct functioning of equipment over an extended period.

h) **The (cumulative) additional effect of changes shall be taken into account when deciding if a change triggers Article 21(12)(b) of Directive (EU) 2016/797.**

The evaluation of the impact of a change shall consider all changes implemented since the last time that the vehicle and/or vehicle type was authorised. In other words, the starting point for the evaluation of the criteria in Article 21(12) and the applicable requirements is the last authorisation and not the status of the vehicle type and/or vehicle just before the implementation of the last change.

Notes

If a change does not impact basic design characteristics, and therefore does not require authorisation on the grounds of rules compliance pursuant to Article 21(12)(a) and/or (c) of Directive (EU) 2016/797, it may still have the potential to adversely affect the overall level of safety of the vehicle concerned and therefore trigger a new authorisation pursuant to Article 21(12)(b).

If a change does not trigger Article 21(12)(b) of Directive (EU) 2016/797, and therefore does not require a new authorisation pursuant to Article 14(1)(d) of Regulation (EU) 2018/545, it may still trigger articles 21(12)(a) and/or (c), which require a new authorisation on the grounds of rules compliance: basic design characteristics impacted beyond the acceptable thresholds or specific changes that always require a new authorisation.

Conditions for use of the vehicle and other restrictions are basic design characteristics, pursuant to Article 48(c)(iii) of Regulation (EU) 2018/545. As a result, any modification to the existing set of conditions for use (amendment of existing ones or new conditions to be introduced) as a result of a change should also be considered when performing the categorisation pursuant to Article 15(1) of the Regulation.

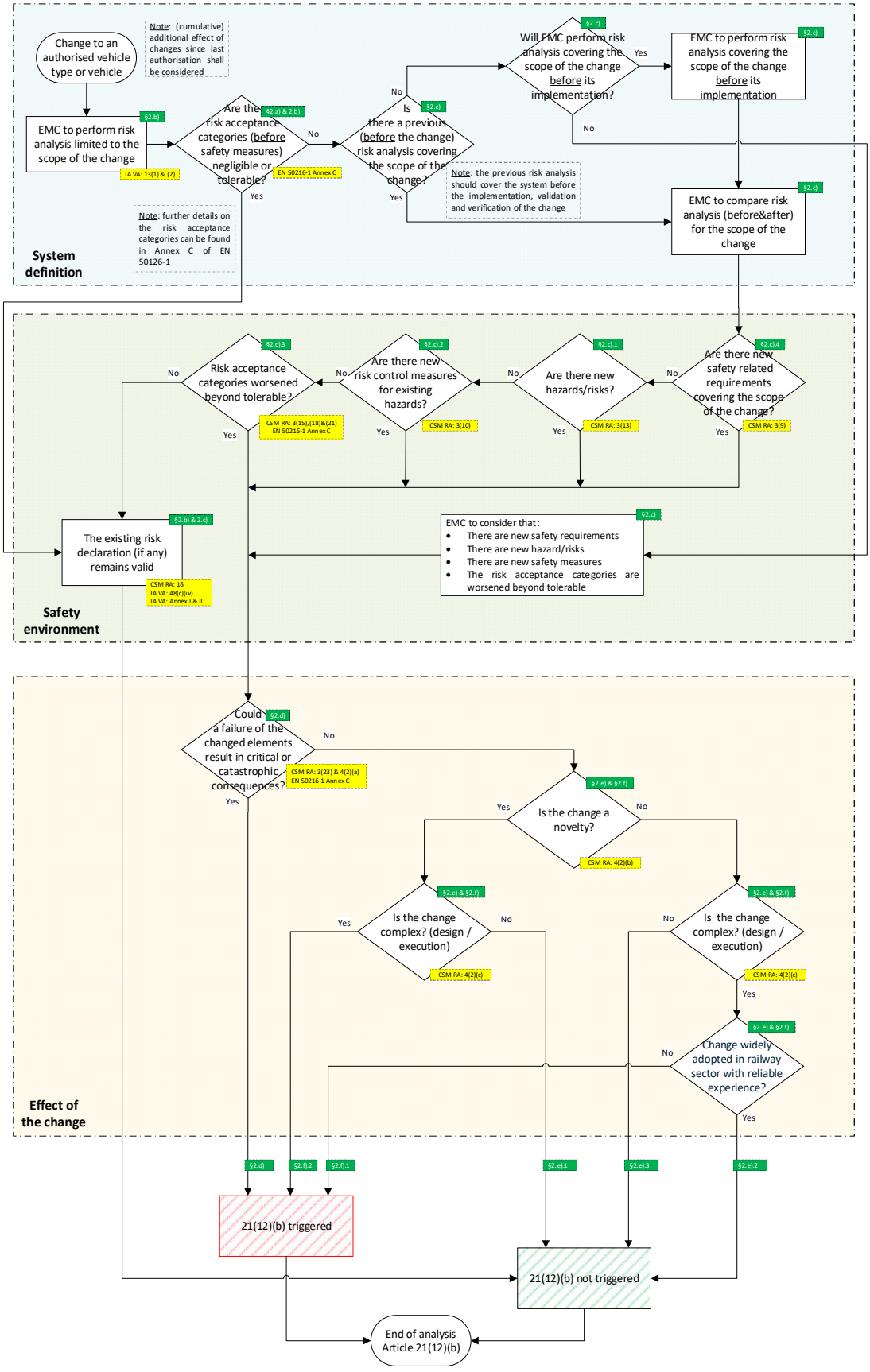

Figure 1:Flowchart for deciding if Article 21(12)(b) of Directive (EU) 2016/797 is triggered

3. Background

a) Directive (EU) 2016/797

› Recital (4)

"In order to contribute to the completion of the single European railway area, reduce the costs and duration of authorisation procedures and improve railway safety it is appropriate to streamline and harmonise authorisation procedures at Union level."

› Article 21(12)(b)

"12. In the event of renewal or upgrading of existing vehicles which already have a vehicle authorisation for placing on the market, a new vehicle authorisation for placing on the market shall be required if:

[…]

(b) the overall safety level of the vehicle concerned may be adversely affected by the works envisaged

[…]"

b) Directive (EU) 2016/798

› Recital (11)

"Common safety targets ('CSTs') and CSMs have been gradually introduced to ensure that safety is maintained at a high level and, when necessary and where reasonably practicable, improved. They should provide tools for the assessment of the safety and performance of operators at Union level as well as in the Member States. Common safety indicators ('CSIs') have been established in order to assess whether systems comply with the CSTs and to facilitate the monitoring of railway safety performance."

› Article 4. Roles of actors in the Union rail system in developing and improving railway safety

"1. With the aim of developing and improving railway safety, Member States, within the limits of their competences, shall:

(a) ensure that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Union law and international rules and of technical and scientific progress, and giving priority to the prevention of accidents;

(b) ensure that all applicable legislation is enforced in an open and non-discriminatory manner, fostering the development of a single European rail transport system;

[…]

2. The Agency shall ensure, within the limits of its competences, that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Union law and of technical and scientific progress and giving priority to the prevention of serious accidents.

[…]"

c) Directive 2008/57/EC

› Article 20(1)

"In the event of renewal or upgrading, the contracting entity or the manufacturer shall send the Member State concerned a file describing the project. The Member State shall examine this file and, taking account of the implementation strategy indicated in the applicable TSI, shall decide whether the extent of the works means that a new authorisation for placing in service within the meaning of this Directive is needed.

Such new authorisation for placing in service shall be required whenever the overall safety level of the subsystem concerned may be adversely affected by the works envisaged. If a new authorisation is needed, the Member State shall decide to what extent the TSIs need to be applied to the project. […]"

d) Regulation (EU) 402/2013

› Recital (9)

"*If there is no existing notified national rule for defining whether or not a change is significant for the safety in a Member State, the company or organisation in charge of implementing the change (the 'proposer') should initially consider the potential impact of the change in question on the safety of the railway system. If the* ***proposed change has an impact on safety****, the proposer should assess, by expert judgement, the significance of the change based on a set of criteria that should be set out in this Regulation. This assessment should lead to one of three conclusions.*

In the first situation the ***change*** *is* ***not*** *considered to be* ***significant*** *and the proposer should implement the change by applying its* ***own safety method****.*

In the second situation the ***change*** *is considered to be* ***significant*** *and the proposer should implement the change by applying this Regulation,* ***without the need for a specific intervention of the national safety authority****.*

In the third situation the ***change*** *is considered to be* ***significant*** *but there are* ***provisions at the level of the European Union which require*** *a specific intervention of the relevant national safety authority, such as a* ***new authorisation*** *for placing in service of a vehicle or a revision/update of the safety certificate of a railway undertaking or a revision/update of the safety authorisation of an infrastructure manager."*

› Article 2(2). Scope

"When, on the basis of an assessment under the criteria set out in Article 4(2)(a) to (f):

(a) the change is considered significant, the risk management process set out in Article 5 shall be applied;

(b) the change is considered not significant, keeping adequate documentation to justify the decision shall be sufficient."

› Article 3(23). Definitions: " *'catastrophic consequence' means fatalities and/or multiple severe injuries and/or major damage to the environment resulting from an accident;*"

› Article 4. Significant changes

"1. If there is no notified national rule for defining whether a change is significant or not in a Member State, the proposer shall consider the potential impact of the change in question on the safety of the railway system.
If the proposed change has no impact on safety, the risk management process described in Article 5 need not be applied.

2. If the proposed change has an impact on safety, the proposer shall decide, by expert judgement, on the significance of the change based on the following criteria:

(a) failure consequence: credible worst-case scenario in the event of failure of the system under assessment, taking into account the existence of safety barriers outside the system under assessment;

(b) novelty […];

(c) complexity of the change;

(d) monitoring […];

(e) reversibility […];

(f) additionality […]

3. The proposed shall keep adequate documentation to justify its decision."

› Article 46(6). Decision for the authorisation or the refusal of the authorisation

"The authorisation decision shall not contain any time limited conditions for use of the vehicle and other restrictions, unless the following conditions are fulfilled:

(a) it is required because the conformity to the TSIs and/or national rules cannot be completely proven before the issuing of the authorisation; and/or

(b) the TSIs and/or national rules require that the applicant produces a plausible estimate of compliance.

The authorisation may then include a condition that real use demonstrates performance in line with the estimate within a specified period of time."

› Article 48. The information in the issued vehicle type authorisation

"The vehicle type authorisation issued by the authorising entity shall contain the following information:

[…]

(c) an identification of the basic design characteristics of the vehicle type:

(i) stated in the type and/or design examination certificates;

(ii) the area of use of the vehicle;

(iii) the conditions for use of the vehicle and other restrictions;

(iv) the reference, pursuant to the provisions of Article 16 of Regulation (EU) No 402/2013, including the document identification and the version, to the written declaration by the proposer referred to in Article 3(11) of Regulation (EU) No 402/2013, covering the vehicle type;

[…]"

e) Guidelines for the practical arrangements for the vehicle authorisation process ERA1209/222

› 3.3.2.4. New authorisation case – 14(1)(d)

"[…]

Decision criteria if a new authorisation is required according to the criteria of Article 21(12) of Directive (EU) 2016/797:

[…]

b) "The overall safety level of the vehicle concerned may be adversely affected by the works envisaged"

*The actors should ensure that "railway safety is generally maintained and, where reasonably practicable, continuously improved" therefore, a change should not be contemplated if it **will** adversely affect the overall level of safety of the vehicle concerned.*

*It can thus be inferred that this clause relates to the **potential** to adversely affect the overall level of safety of the vehicle concerned, and not to whether the change in its real implementation will actually have a negative impact on safety or not.*

An entity managing a change, when deciding if Article 21(12)(b) is triggered or not, should not take into consideration the activities undertaken to ensure that safety will not be adversely impacted (calculation notes, simulations, tests, involvement of conformity assessment bodies etc.). Considering such activities would mean that the decision is taken after the change is implemented, verified and validated (an "ex-post" evaluation). However, such activities always take place regardless of the authorisation case, yet there is a need for an authorising entity to

issue an authorisation. The Article 21(12)(b) concerns the potential of a change to impact safety adversely before its implementation, verification and validation ("ex-ante" evaluation), and the associated need for an authorising entity to deliver an authorisation when the potential exists. The Article 21(12)(b) does not relate to whether a change actually impacts or not safety in the end, because the level of safety shall be maintained and improved where possible, which means that a change that decreases the level of safety shall not be implemented.

To evaluate whether the overall level of safety of the vehicle concerned may be affected, the entity managing the change should use its requirements capture process for the essential requirement safety and compare the risk assessment before and after the implementation of the change (considering all the activities that are required for the implementation of the change, not only the final solution). When there are no new safety requirements and the (new) risk assessment:

- *Does not contain new hazards/risks;*
- *Does not require changes in the existing control or mitigation measures;*
- *Does not require new control or mitigation measures for the existing hazards/risks, and*
- *The risk acceptance category for each risk remains unchanged*

it could be considered that Article 21(12)(b) is not triggered. This assessment should be independently assessed by an AsBo in the framework of the requirements capture process related to essential requirement safety. When it is clear that the change does not have the potential to impact safety without the need to perform any risk assessment, the independent assessment by an AsBo would not be needed.

When there is no existing risk assessment (e.g., vehicles placed on the market under Directive 2008/57/EC or before), the entity managing the change should:

- *Perform the risk assessment of the situation before the change under consideration (limited to the changed parts and the interfaces with the unchanged parts);*
- *Perform the risk assessment of the changed vehicle (also limited to the changes and the operations needed to implement the change)*
- *Analyse the differences between both risk assessments (for the impacted parts) as mentioned above, concerning new hazards/risks, mitigation measures, etc.*

It should be noted that if a change does not affect basic design characteristics, and therefore does not require authorisation on the grounds of rules compliance pursuant to Article 21(12)(a) and/ or (c) of Directive (EU) 2016/797, it may still have the potential to adversely affect the overall level of safety of the vehicle concerned and therefore trigger a new authorisation.

[…]

From the point of view of the evaluation of Article 21(12) of Directive (EU) 2016/797 and the requirements capture process, all changes implemented in the vehicle and/or vehicle type since the last time it was authorised should be considered. In other words, the starting point for the evaluation of the criteria in Article 21(12) and the applicable requirements is the last authorisation and not the status of the vehicle type and/or vehicle just before the implementation of the last change. It is not mandatory that such (past) changes comply with the rules in force at the moment the application for authorisation is submitted; they should comply with the applicable rules at the moment they were implemented. In any case, all changes performed should be documented and traced to the applicable requirements, and the related evidence should be part of the file accompanying the application."