First Agency Report

on the assessment of the implementation of the Commission Implementing Regulation (EU) 2019/779 of 16 May 2019 on Entities in Charge of Maintenance (ECM) of vehicles

addressed to the European Commission, Directorate-General for Mobility and Transport

June 2024



Disclaimer:

This report is a non-legally binding document produced by the European Union Agency for Railways and addressed to the European Commission (EC) on the implementation of Commission Implementing Regulation (EU) 2019/779 laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles. The content of this report does not represent the view of other EU institutions and bodies and notwithstanding that the decision-making processes foreseen by the applicable EU legislation may arrive at different conclusions. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

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1. Introduction

1.1. Purpose	With this evaluation, the Agency addresses for the first time a report to the European Commission (EC) on the implementation of Commission Implementing Regulation (EU) 2019/779 laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 as amended by Commission Implementing Regulation (EU) 2020/780 (hereinafter, the 'ECM Regulation'), which established a system of mandatory certification of entities in charge of maintenance (ECM) for all rail vehicles as well as set out the requirements to be met concerning the maintenance functions. The purpose of the certification system is to provide a framework for harmonising requirements and methods to assess the ability of ECM in the railway system.
	The Agency shall address reports on the implementation of this Regulation every three years following the first report with the next implementation report due by June 2027 (Article 14 of the ECM Regulation).
	The ECM Regulation, which extends the scope of maintenance certification requirements from freight wagons to all vehicles, follows the principles established under Commission Regulation (EU) No 445/2011 (repealed by the ECM Regulation). This extension is the result of an evaluation carried out by the Agency in 2015 foreseen in article 14(7) of Directive 2004/49/EC (as amended by 2008/110/EC) (summary provided in Annex 1) for which also a full impact assessment was addressed to the European Commission (EC) by the Agency in 2018 ¹ .
	The main purpose of this first evaluation of the ECM Regulation is a fitness check of the legal requirements, an evaluation of the provisions of the ECM Regulation as a whole, and an assessment on the return of experience on the interpretation and actual implementation of the legal provisions by all the stakeholders involved.
	This first report is addressed to the EC to provide the findings regarding the implementation of the legal requirements together with some high-level policy recommendations. At the same time, this first report allows the Agency to assess its own deliverables in relation to the application, awareness and interpretation of the <u>Guidance on ECM certification</u> <u>process</u> and / or Recommendation for Use (RfU) ² .

¹ The full IA is available here: <u>Recommendation on the revision of ECM Regulation - Full impact assessment .pdf</u> (europa.eu).

² According to Article 6.5 of Commission Implementing Regulation (EU) 2019/779 of 16 May 2019, "*in order to harmonise approaches to the assessment of applications, the certification bodies shall cooperate with each other both within the Member States and across the Union*". The network of Cooperation of ECM Certification Bodies

1.2. Scope	The scope of this first report includes the implementation of the whole ECM Regulation by the stakeholders concerned, the railway sector and relevant authorities and bodies at national level. The evaluation criteria applied are effectiveness, efficiency, relevance, coherence and EU added value which are the standard criteria of the <u>Better Regulation Guidelines</u> <u>and Toolbox</u> of the EC which the Agency's evaluation practice adheres to. The evaluation performed includes an assessment of the legal provisions of the ECM Regulation, a return of experience of its application and understanding by the stakeholders as well as a series of recommendations by the Agency. Those being policy recommendations are addressed to the EC while some other more practical actions with regards to understanding, dissemination and implementation of the ECM Regulation provisions are addressed to the Agency itself and/or to relevant stakeholders.
	The time period of this first report covers the first five years of application of the ECM Regulation thus from 16 June 2020 till 16 June 2024 ³ .
	The geographical scope of this report is set by Directive (EU) 2016/798 ⁴ . However, the evaluation performed is at the level of the Single European Railway Area as a whole and no national level assessment was performed.
	This evaluation does not provide an assessment of the Article 14 of Directive (EU) 2016/798, which is the policy that prescribes the provisions on the maintenance of vehicles. The ECM Regulation is in fact only an implementing act of the Directive.
1.3. Legal basis	This report has been produced pursuant to Article 14 of the ECM Regulation and it is the first report addressed to the EC five years after the entry into force of the ECM Regulation. This report contains the Agency's ex-post assessment on the basis of Article 8 (3) of Regulation (EU) 2016/796. This report was produced following the adopted ERA Procedure 'PRO_EPE_001' for Ex-Post evaluations set out in the ERA Internal Control Framework ⁵ .
	Following consultation of its Economic Steering Group, Network of Representative Bodies, Network of National Safety Authorities, Cooperation of ECM Certification Bodies, and EC, the Agency shall publish this first report on its website as required by Article 77(2) of the Regulation

⁽CCB) has agreed on the need of a framework and methodology to formalise a consensus solutions to identified issues. For this purpose, the CCB network has developed a process for structured and systematic formalisation of Recommendations for use. The Recommendations approved by the CCB network shall be applied by the Certification Bodies in order to allow a harmonised implementation of the ECM Regulation.

 $^{^{3}}$ The ECM Regulation was amended by Commission Implementing Regulation 2020/780 except article 14 of the ECM Regulation, as such it has then no impact to the first report by the Agency and deadline will be the 16/06/2024.

⁴ The legal act serving as the basis for the adoption of the ECM Regulation.

⁵ <u>DECISION n°300 adopting the ERA Internal Control Framework and repealing Decision n°191 adopting the</u> revised ERA Management Standards | European Union Agency for Railways (europa.eu).

	(EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 (Agency Regulation).
1.4. Rationale and methodology applied	As background information, the Agency's past evaluation of the Commission Regulation (EU) No 445/2011 served primarily as an input into the subsequent full impact assessment of the Agency aiming at evaluating a possible extension of the ECM framework from freight wagons to all vehicles ⁶ .
	The rationale of this current evaluation for this first report is rather an implementation check of the ECM Regulation and in particular to assess the actual implementation by the stakeholders and draw some conclusions from the return of experience of applying the ECM Regulation. The subsequent aim is to provide the EC with policy recommendations for a possible revision of the ECM Regulation's provisions.
	The methodology applied for this first report included firstly a comprehensive review of the earlier evaluation done in 2015 of Commission Regulation (EU) No 445/2011, a screening of the ECM certificates stored in the <u>ERADIS</u> register of the Agency and a review of the impact assessment done in 2018 accompanying the Agency Recommendation which resulted in the present ECM Regulation.
	Secondly, an extensive targeted stakeholder consultation was organized in the form of an online survey addressed to rail sector stakeholders, ECM certification bodies, ECMs and NSAs. The remarkable number of around 400 responses was received.
	Thirdly, three hybrid workshops have been organized with ECM CBs, NSAs and with the rail sector's representative bodies. The aim of these meetings was to present the survey results and further discuss some of the many proposals received by the Agency through the online survey or direct mailing.
	Fourth, the evaluation also included two position papers prepared by the representative bodies of the rail sector in the context of the ex-post evaluation development (CER position paper and the AERRL, ALLRAIL and ERFA position paper).
	Lastly, the Agency experts from the MARS and SAFO units performing this evaluation organized four bilateral interviews to further exchange with selected stakeholders.
	The extensive consultation activities and the detailed feedback provided by the stakeholders allowed the Agency to draw conclusions and recommendations based on robust evidence on the actual implementation of the ECM Regulation, on its effectiveness, on its strengths and on its weaknesses.

⁶ The full IA report is available here: <u>Recommendation on the revision of ECM Regulation - Full impact assessment</u>.<u>pdf (europa.eu)</u>.

1.5. Statistics of	On May 2024, information on ECM in ERADIS is as follows:
ECM certificates	 45 ECM certification bodies (in EU - including Norway and Switzerland & OTIF non-EU contracting states), 940 ECM certificates (in EU - including Norway and Switzerland & OTIF non-EU contracting states), 1170 maintenance functions certificates (in EU - including Norway & Switzerland & OTIF non-EU contracting states).
1.6. Stakeholders	In addition to the Agency, the stakeholders affected by this first report are
concerned	the following:
	Component manufacturers,
	• Entities in Charge of Maintenance (ECMs),
	• ECMs certification bodies,
	• European Commission (EC),
	Infrastructure managers (IM),
	Leasing companies,
	• Manufacturers,
	Member States (MSs),
	National Investigation Bodies (NIBs),
	 National safety authorities (NSAs),
	Railway undertakings (RUs),
	Vehicle keepers.
	The specific roles in relation to the ECM certification context are detailed out in the Agency's ECM guide ⁷ . The full list of participants is provided in Annex 2.

⁷ ECM guide of the Agency: <u>Guidance on ECM certification process (europa.eu</u>).

2. Glossary of terms

Agency or ERA	The European Union Agency for Railways established by Regulation (EU) 2016/796 as a successor of the European Railway Agency established by Regulation (EC) 81/2004
BRG	Better Regulation Guidelines
ССВ	Cooperation of ECM Certification Bodies
CSM RA	Common Safety Method on Risk Evaluation and Assessment
EA	European Co-Operation for Accreditation
EC	European Commission
ECM	Entity in charge of maintenance
ECM CB	ECM Certification Body
ECM F1	Article 14 ("Maintenance of vehicles") of the DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on railway safety, letter (a):
	"a management function to supervise and coordinate the maintenance functions referred to in points (b) to (d) and to ensure the safe state of the vehicle in the railway system".
	Article 14 ("Maintenance of vehicles") of the DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on railway safety, letter (b):
ECM F2	<i>"a maintenance development function responsible to manage the maintenance documentation, including the configuration management, based on design and operational data as well as on performance and return on experience".</i>
ECM F3	Article 14 ("Maintenance of vehicles") of the DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on railway safety, letter (c):
	<i>"c) a fleet-maintenance management function to manage the vehicle's removal for maintenance and its return to operation after maintenance".</i>
ECM F4	Article 14 ("Maintenance of vehicles") of the DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on railway safety, letter (d):
	"a maintenance delivery function to deliver the required technical maintenance of a vehicle or parts of it, including the release to service documentation".
ECM guide of the Agency	Guidance on the ECM certification process developed by the Agency ⁸
ESG	Economic Steering Group
EU	European Union

⁸ It is available at: <u>Guidance on ECM certification process (europa.eu)</u> (access: 20/05/2024; version 9.0).

FFG	Freight Focus Group
GCU	General Contract of Use for wagons
Headline indicator	Headline indicators are a minimum set of high-level indicators which capture the overall implementation level of the ECM Regulation, with specific regard to the critical elements revealed in the current ex-post analysis.
IAF	International Accreditation Forum
IPA	Instrument for Pre-Accession Assistance
MS	Member State (including Norway and Switzerland)
NAB	National Accreditation Body
NIB	National Investigation Body
NRB	Network of Representative Bodies (article 38(4) of Regulation (EU) 2016/796)
NSA	National Safety Authority
NVR	National Vehicle Register
OTIF	Intergovernmental Organisation for International Carriage by Rail
RB	Representative bodies
RoE	Return of Experience
RfU	Recommendation for Use
SCC	Safety-critical component (article 4 of the ECM Regulation)
SMS	Safety management system
TF	Task force
ToR	Terms of Reference
TSI	Technical Specification for Interoperability

3. Timing and key milestones

3.1. Timing of	• Work started in June 2023 with completion in June 2024 of the final study
-	report.
study	
activities	• The planned activities were organised around the following main steps
and key	(Error! Not a valid result for table.):
milestones	1. Scoping and planning
	2. Desk research
	3. Data gathering and analysis:
	 ERA web survey: August – September 2023;
	Presentations of ERA survey results to ECM CB, NSA, NRB
	and ESG meetings (September – November 2023; March –
	April 2024);
	Dedicated workshop with the ECM CBs & NSA acting as
	CBs: 29 th November 2023,
	 Workshop with the rail sector: 31st January 2024,
	 Workshop with the NSAs: 7th February 2024;
	 Bilateral exchanges: n. 4 carried out in March-April 2024;
	4. Synthesis
	5. Drafting
	6. Consultation and finalisation:
	 Internal consultation (Agency);
	 External consultation on the draft final report involving
	the NSAs, NRBs, ESG, ECM CBs and DG MOVE and
	participants to workshops and bilateral exchanges.
	• Final submission of the report to the EC by 16 th June 2024.



Figure 1 – Overview of the planned activities and outputs

4. Data and methodology

4.1. Methodological approach	This first report is prepared in accordance with the European commissions' <u>Better Regulation Guidelines</u> (BRG) and <u>Better Regulation</u> <u>Toolbox</u> . The BRG recommend specifying a so-called 'intervention logic' of the legislation as a basis for the evaluation.
	The methodological approach embraces a mixed method approach, considering qualitative and quantitative inputs collected through the following steps:
	 Desk research: review of available reports and studies that may be of relevance for the ex-post work⁹, Data gathering and analysis via: a. Survey, b. Workshops,
	 c. Poll system to informally assess the received proposals on possible improvements of the ECM Regulation, d. Bilateral exchanges, e. Position papers from some Representative Bodies, f. Other types of exchanges / interventions (presentation of balance for disperting for disperting balance)
	 intermediary findings to stakeholders). 3. Synthesis: due to the complexity, variety of methods used and number of inputs collected, especially through the three dedicated workshops, this was a preparatory step to draft the final report. It covered the production of:
	 a. Stakeholder cards¹⁰ concerning the survey's results, b. Workshops' minutes of the main results, c. Bilateral exchanges' minutes of the main remarks, d. Other types of exchanges / interventions' minutes of the received questions.
	 Drafting: based on the inputs gathered the draft final report was prepared, Consultation and finalisation: it includes two consultations carried out with internal and external stakeholders as well as the
	assessment of the received comments and remarks,6. Submission of the final report to the EC.
4.2. Evaluation	The ECM intervention logic can be evaluated using five key criteria:
criteria	 Relevance: the extent to which the intervention's objectives are pertinent to the needs, problems and issues to be addressed; Effectiveness: the extent to which set objectives are achieved; Efficiency: the extent to which desired effects are achieved at a reasonable cost;

⁹ For example, Stakeholders' position papers; 2015 ERA Implementation report; 2018 ERA impact assessment of Commission Regulation (EU) No 445/2011 on a system of certification of ECM for freight wagons and amending Regulation n. 653/2077.

¹⁰ Stakeholder card is a summary of the ERA survey's results disaggregated by each cluster of stakeholders, used to design the ad-hoc workshops and within the process of synthesising the received inputs for drafting the report.

	 Coherence: the extent to which the ECM Regulation does not contradict other interventions with similar objectives; EU added value: the value resulting from the ECM Regulation which is additional to the value that could have been created by individual Member States or other (international) actions.
4.3. Evaluation framework	Using the criteria mentioned in the previous section, specific evaluation questions were formulated and administered with an ad-hoc survey complemented with additional inputs gathered through different methods described in section 4.4.
	In addition, the survey allowed to collect proposals from respondents on possible improvements of the ECM Regulation implementation. These were jointly discussed during dedicated workshops as follows:
	 No. 34 proposals for improvement from ECM CBs & NSA acting as CBs, No. 60 proposals for improvement, grouped in 13 clusters from the Rail Sector (ECMs, IMs, RU, vehicle keepers, manufacturers, leasing companies, etc.) from the full list of 110 proposals; No. 11 proposals for improvement from the NSAs.
	This first report further benefited from the inputs included in the two Position Papers produced during the development of the ex-post evaluation by CER ¹¹ , and AERRL / ALLRAIL / ERFA ¹² .
4.4. Data sources and	Data used were collected from the following stakeholders:
data collection	
data collection	• ECM CBs, RUs, IMs, ECMs, vehicle keepers, manufacturers, leasing companies, NSAs (including those acting as a CB), component manufacturers and others ¹³ .
data conection	• ECM CBs, RUs, IMs, ECMs, vehicle keepers, manufacturers, leasing companies, NSAs (including those acting as a CB), component
	• ECM CBs, RUs, IMs, ECMs, vehicle keepers, manufacturers, leasing companies, NSAs (including those acting as a CB), component manufacturers and others ¹³ .

¹¹ CER Position paper is available at: <u>Microsoft Word - 20231214 CER Position Paper 2019 ECM Regulation CER REX</u> (accessed: 15/04/2024).

¹² AERRL / ALLRAIL / ERFA Position paper is available at: <u>AERRL-ALLRAIL-ERFA-Comments-and-suggestions-for-</u> improvement-on-Commission-Implementing-Regulation-Website.pdf (accessed: 30/04/2024).

 $^{^{\}rm 13}$ See full list of stakeholder in section 1.6 of the report.

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	The ERADIS database was also consulted to share the main statistics concerning the number of ECMs, ECM certificates and ECM CBs.
	The Agency received several proposals for the ECM Regulation improvement within the survey ¹⁴ in the original language (i.e. German, French), which needed translation.
4.5. Report limitations	For the organisation of the dedicated workshop with the rail sector the Agency was asked for the possibility of German translation.
	These aspects could have led to translation issues and / or have reduced the response rate pf the survey in some parts of Europe.

¹⁴ It refers to section 4.1 – 'Methodological approach', point 2, letter a).
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5. Analysis and findings

5.1. Framework	Based on the rationale and methodology applied (section 1.4), further detailed in section 1, the results are provided on the basis of the criteria that characterise the BRGs of the EC.
	Considering the inputs collected, for each criteria is provided below:
	(1) the summary of the evaluation at the beginning of each sub-section, and(2) the main findings in each of the following sections, while full and more detailed findings of the ERA survey are included in Annex 3.
	The objectives and main results of the 2015 implementation report and the 2018 impact assessment of Commission Regulation (EU) No 445/2011 are also referred to as part of the analysis.
5.2. Assessment	Summary of the evaluation for 'Relevance'
5.2.1. Relevance	The ECM Regulation was aimed to establish a harmonised system of certification of ECM for all railway vehicles, methods to assess the ability for ECMs in the railway system. Overall, our findings show considerable relevance alignment of the ECM Regulation interventions with the needs and priorities of the stakeholders directly involved within the broader system. However, room for improvement was identified and described as follow.
	Findings & improvements
	On the basis of the survey inputs, it seems that the vast majority of survey responses (78%) agreed that the ECM Regulation has facilitated the harmonisation of requirements and methods to assess the ability of ECMs for vehicles . The agreement increases for recognised ECM CBs (100%), manufacturer (97%), accredited ECM CBs (94%), component manufacturers (88%), NSAs acting as CBs (88%) and ECMs (80%), while the disagreement came mainly from leasing companies (13%), RUs (11%), IMs (10%) and vehicle keepers (8%) (Figure 15).
	On the harmonisation of requirements and methods, it is worth to mention that within the <u>2015 implementation study</u> of the Commission Regulation (EU) No 445/2011 the key objectives for the ECM certification framework were to reduce the diversity of requirements assessment for ECMs.
	The relevance of this topic for stakeholders was confirmed also, on the basis of the <u>CER Position paper</u> regarding the RoE of the ECM Regulation, where it was claimed that this Regulation has proven to be relevant to the actual needs of stakeholders, generating positive impacts on the railway system:
	 enhancing railway safety, and fostering a more harmonised approach in the assessment of the ability of ECMs.
	On the basis of the workshops, bilateral exchanges and two position papers, it seems that there are issues with regards to:

 The definition of role, responsibility and process between: ECM F1, F2, F3 and F4: more detailed description of the maintenance functions for the integrated companies (especially with a RU), maintenance of components for maintenance level 4 and level 5 (requested to be included in the ECM Regulation¹⁵), especially in case it is outsourced to suppliers;
On these points, a new "TSI Maintenance" and the possible integration of the SMS with the maintenance management system were put forward,
• ECMs, the vehicle keepers and manufacturers,
Also the <u>CER Position paper</u> mentioned the difficulties: (1) in the application of the ECM role when the company is also a RU, due to the overlapping of the SMS with the maintenance management system which also impact on the documentation to be provided during the ECM certification process; and (2) in understanding the respective responsibilities on the exchange of information between ECM F3 and F2 when the last one needs operational data to upgrade maintenance files (i.e. maintenance plan) and RoE on operation. ECM F3 activities are often carried out by the same staff of the ECM F4.
As pointed out in the <u>AERRL</u> , <u>ALLRAIL and ERFA position paper</u> , when the manufacturers act also as maintenance providers it might lead to distortions of market competition, giving them a clear competitive advantage due to the availability of information and materials, with specific regard to: A) the documentation and software for preventive and, in particular, corrective maintenance; B) information required to carry out modifications to vehicles independently of the manufacturer; C) materials, tools and spare parts, etc Therefore, it was highlighted that there is the need to have a framework to: 1) harmonise the requirements for ECMs (including the management of the SCCs and to carry out appropriate maintenance measures); and 2) regulate the legal position of ECMs vis-à-vis vehicle manufacturers and other players, with the intention of creating a non-discriminatory market.
Enhancing clarity in the definition and allocation of responsibilities among keepers, ECMs and RUs operating vehicles was a specific objective mentioned in the <u>2018 impact assessment</u> of Commission Regulation (EU) No 445/2011, considering that the Do-Nothing situation was characterised by a lack of clarity in the definition and allocation of responsibilities among concerned stakeholders.
 The creation of a binding framework for all stakeholders (e.g. suppliers and service providers) in case of subcontracting aimed to set clear guidelines and expectations to ensure that all parties fulfil their responsibilities and obligations, The increased responsibility of the ECMs for specifications at component level: increasing disagreement between the ECMs and

¹⁵ This request was proposed by only a stakeholder.
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	companies that offer component overhaul as to who is responsible for
	 companies that offer component overhaul as to who is responsible for drawing up the specifications for the overhaul, The more detailed definition and description of the requirements and SCCs (providing examples) at least for a minimum set of them, The requirements for "return to operation" and "release to service" should be detailed in terms of the form and necessary scope of the related documents, The consideration of cybersecurity as an additional requirement for ECM, better integration of interfaces between ECM and energy supply companies, The content of maintenance documentation and the requirements when there is a change of ECM, especially regarding the issue of "intellectual property", The harmonisation, standardisation and simplification of documents, forms and procedures, The harmonisation across CBs in delivering a certification and doing supervision of ECMs: wide variety of both certification cost/quality and production process was stressed. This leads to a need to strengthen the harmonised monitoring of CBs in terms of both items verified and frequency of checks.
5.2.2. Effectiveness	Summary of the evaluation for 'Effectiveness'
	Based on the inputs collected with the ex-post report development, it seems that the ECM Regulation is resulting in a high level of achievement of objectives with relevant and sustainable impacts in an efficient and consistent manner. However, areas for improvement were identified and described as follows.
	Findings & improvements
	The aspects of effectiveness of the ECM Regulation are covered by the following evaluation questions collected through the <u>survey</u> :
	 Overall advantages of the ECM Regulation outweigh any disadvantages, The scope extension of the ECM scheme to other types of vehicles than freight wagons has been an advantage, The introduction of ECM certification has reduced the problems associated with maintenance tasks for vehicles, The introduction of ECM certification has facilitated maintenance control/supervision, The ECM certification has positively influenced railway safety.
	Concerning the first evaluation question (Figure 14), the vast majority of respondents (69%) agreed that overall advantages of the ECM Regulation outweigh disadvantages . The agreement increases for ECM CBs (100% for recognised CBs and 88% for accredited ECM CBs) and NSAs (100% for NSAs acting as CBs and 90% for NSAs not acting as CBs), while the disagreement came mainly from RUs, vehicle keepers and IMs but with marginal shares of

12%, 11% and 10%, respectively (although even the majority of these stakeholders still have a positive perception of advantages over disadvantages).
This was also confirmed in the <u>CER Position paper</u> where it is recognised that to a larger extent the benefits of this Regulation outweigh the disadvantages.
As emerged from the <u>workshops and the two position papers</u> , there could still be the following issues related to:
 Administrative burden (increase of documentation, in particular regarding the identification of maintenance F1, F3 - within a RU - and F4 and for ECMs), The maintenance of historical vehicles to preserve them in the long term and their exclusion from the ECM Regulation.
The vast majority of respondents (67%) agreed that the scope extension of the ECM scheme to other types of vehicles than freight wagons has been an advantage. The agreement increases for NSAs (88% for NSAs acting as CBs and 90% NSAs not acting as CBs), accredited ECM CBs (89%) and manufacturers (87%), while the disagreement came mainly from leasing companies (14%), IMs (14%), vehicle keepers (10%) and ECMs (10%) (Figure 18). The scope extension was also identified as a key area in need of adjustment in the context of the Commission Regulation (EU) No 445/2011 by the <u>2018 impact assessment</u> carried out by the Agency.
Just over half of the survey responses (56%) agreed that the introduction of the ECM certification has reduced the problems associated with maintenance tasks for vehicles , although there is a 23% of respondents who neither agree nor disagree. The agreement increases for manufacturers (83%) and ECM CBs (75% and 67% for recognised and accredited, respectively), while the disagreement came mainly from leasing companies (31%), IMs (22%), vehicle keepers (22%) and RUs (22%) (Figure 7).
A vast majority of survey responses (78%) agreed that the introduction of ECM certification has facilitated maintenance control/supervision . The agreement increases for ECM CBs (100% and 95% for recognised and accredited, respectively), manufacturer (93%), component manufacturer (89%) and NSAs acting as CBs (88%), while the disagreement came mainly from leasing companies (13%), vehicle keepers (11%), RU (11s), and IMs (8%) (Figure 8).
Based on the results from the workshop with the rail sector, there could be still the following issues related to:
• The process of the ECM to carry out its surveillance/monitoring activity of outsourcing activities, especially those related to the execution of the maintenance, in partial outsourcing carried out by the maintenance F4 itself, when these activities may be applied to vehicles or component repair activities,

 The 12 months visit cycle, regarding the CB's surveillance activities of the ECM compliance to the requirements, creates an issue concerning the needed resources for the ECM (extra costs), due to the "high frequency" that required manpower preparation/follow-up efforts – that was seen as a cost driver. On this issue, from the workshop with NSAs, it was mentioned the preference to use a risk-based approach to supervision and monitoring of the ECMs (instead of having a 1-year site visit). However, some NSAs were against both a risk-based approach and the extension of the 12-month visit cycle. The possibility to change the Regulation was also discussed in the workshop with CBs and with rail sector, although without resulting in a generalised agreement. The opportunity for heritage vehicles to have a lighter certification (Annex 3 of the Railway Safety Directive) with a more general requirement looking at competency and flexibility of maintenance and repairs for vehicles.
Based on the results from the <u>workshop with the CBs</u> , there could still be the following issue related to:
• The need for a clear description of what the ECM certificates contain in their individual parts (including the templates contained in the Annexes of the ECM Regulation).
Continuing on the issue of supervision and surveillance, as emerged from the <u>workshops and bilateral interviews</u> , there could be still the following issues related to:
 The surveillance system of the ECMs could be based on a risk-based approach (instead of the 12-month cycle), The supervision of ECMs by CBs revealed that when comparing ECMs certified by different CBs, the CBs' assessment focus on different requirements, while it should be standard across CBs (this affects not only safety but also the market of ECM certification; in turn, it can impact also on the quality of the ECM activities), The supervision of subcontracting ECM activities, especially when there are many levels of subcontracting, The role of NSAs as foreseen in Article 11 of the ECM Regulation is mainly focused on RUs and IMs, resulting in a lack of common practices.
A vast majority of survey responses (77%) agreed that the ECM certification has positively influenced railway safety . The agreement increases for manufacturer (97%), accredited ECM CBs (89%), component manufactures (83%), ECMs (79%), while the disagreement came mainly from IMs (12%), vehicle keepers (11%) and RUs (11%) ¹⁶ (Figure 9). This result is in line with the

¹⁶ However, also for IMs, vehicle keepers and RUs the percentage of agreement is important, 66%, 73% and 75%, respectively.

	evidence included in the <u>2015 implementation study</u> of Commission Regulation (EU) No 445/2011 where most survey responses agreed with the positive impact of the ECM certification on railway safety.
	As identified in the <u>workshops and bilateral interviews</u> , there could be still the following issues related to:
	• The requirements for small / medium companies depending also on the types of vehicle certified,
	On this, additional administrative burden for this type of enterprises was also recalled in the <u>2018 impact assessment</u> of the Commission Regulation (EU) No 445/2011.
	 The opportunity of a common interpretation of individual certificates, Detail in which cases it is necessary to change the ECM certificate and the certificate in the maintenance function (except for administrative changes), The audit time for the services to be delivered by the ECM CB.
5.2.3. Efficiency	Summary of the evaluation for 'Efficiency'
	Based on the inputs collected with the ex-post report development, it seems that the ECM Regulation is resulting in a high level of achievement of results in an economic and timely way . However, room for improvement was identified and described as follow.
	Findings & improvements
	The aspects of efficiency of the ECM Regulation are covered by the following evaluation questions collected through the <u>survey</u> :
	 Overall advantages of the ECM Regulation outweigh any disadvantages, Certification costs have decreased since the introduction of the ECM framework, The ECM certification has reduced the time and resources required for customers to search and select a suitable ECM, Costs and resources for maintenance management have decreased by the ECM Regulation.
	As mentioned in the previous section, regarding the first evaluation question (Figure 14), the vast majority of respondents (69%) agreed that overall advantages of the ECM Regulation outweigh disadvantages . The agreement increases for ECM CBs (100% for recognised CBs and 88% for accredited ECM CBs) and NSAs (100% for NSAs acting as CBs and 90% for NSAs not acting as CBs), while the disagreement came mainly from RUs, vehicle keepers and IMs but with marginal shares of 12%, 11% and 10%, respectively.
	Regarding the disadvantages related to increased costs, it was claimed in the <u>CER position paper</u> the increase in costs especially for ECM F1, F3 (within a RU) and F4 due to an increase of requested documentation due to new functions mainly due at the SCCs' requirements and the use of SAIT.

Unfortunately, this qualitative statement was not supported by quantitative evidence.
Half of the survey responses (51%) disagreed that certification costs have decreased since the introduction of the ECM framework , with a 22% of respondents who neither agree nor disagree, a 16% of responses who do not know or not applicable and a low 11% of overall agreement. The disagreement increases for NSAs acting as CBs (75%) and leasing companies (62%), while the agreement came mainly from manufacturer and component manufacturers (both 30%) and recognised ECM CBs (25%) (Figure 12).
The increase of certification costs emerged also in the 2015 implementation study of the Commission Regulation (EU) No 445/2011where half of the survey respondents experienced an increase.
Regarding the average cost for a certificate ¹⁷ , based on the inputs gathered from the <u>workshop with the CBs</u> (where only a third of participants replied to the question), it emerged as follows:
 The cost for an ECM certificate varies from 2.000€ to 20.000€; it increases for a new certificate while for a change of the certificate the cost is around one third and for renewal the cost is only a sixth, The cost for an ECM F4 certificate varies from 4.500€ to 7.000€.
On this regard, one stakeholder from the workshop with the rail sector highlighted their particular experience re. the possible trade-off between the cost of the certificate and its quality/reliability ¹⁸ :
 A certificate of few thousands' euro with 1-day visit, provided at the end of the day, and A certificate of 10.000 euro – 15.000 euro with 7 – 8-day visit (separated between ECM F1 / F2, and F4), and provided after a few months.
Certificate costs collected for the <u>2018 impact assessment</u> of Commission Regulation (EU) No 445/2011 ¹⁹ are within the range provided above.
Half of the survey responses (50%) agreed that the ECM certification has reduced the time and resources required for customers to search and select a suitable ECM, although there is a 18% of respondents who neither agree nor disagree, and a 15% of responses who do not know or not applicable. The

¹⁷ The mentioned average costs refer to the external costs paid by ECMs, and they do not include the internal costs incurred by ECMs for preparing for the ECM certification.

¹⁸ It is worth to highlight again that the cost figures provided represent the view of one specific actor of the rail sector so more in-depth investigations are needed to further gather more precise and disaggregated data and from a plurality of actors (differentiating between initial costs to annual costs for both ECM and workshop, link between cost and quality, etc.). On this issue, this implementation evaluation proposes, among its recommendations, a dedicated one on this issue (section 6).

¹⁹ Recommendation on the revision of ECM Regulation - Full impact assessment .pdf (europa.eu). 120 Rue Marc Lefrancq | BP 20392 | FR-59307 Valenciennes Cedex Tel. +33 (0)327 09 65 00 | era.europa.eu

agreement increases for ECM CBs (75% and 61% recognised and accredited ones, respectively) and manufacturers (65%), while the disagreement came mainly from IMs (26%), recognised ECM CBs (25%) and RUs (23%) (Figure 10).
Just over half of survey responses (57%) agreed that the costs and resources for maintenance management have decreased by the ECM Regulation , with a 24% of respondents who neither agree nor disagree and, and a 9% of responses who do not know or not applicable. The disagreement increases for leasing companies (94%), RUs (68%) and IMs (66%), while the agreement came mainly from recognised ECM CBs (50%), manufacturers (20%) and accredited ECM CBs (17%). It is worth to mention that the NSAs (both acting / not acting as CBs) declared that they did not know or that it was not applicable to them (88% and 100%, respectively) (Figure 11).
Based on the findings of the <u>bilateral exchanges</u> , there could be room for improvement with regard at the following issues which impact on cost and resources:
• Responsibility of integrated management system in companies (ex. IM/RU & ECM): understanding responsibilities of different actors in the railway sector. The responsibilities of the keeper and the IM/RU vary across EU countries; there is a need for a contract between the keeper and IM/RU regarding locomotives.
Based on the findings of <u>workshops</u> , there could be room for improvement with regard at the following issues which impact on cost and resources and received an important level of agreement across stakeholders:
• Article 3 of ECM Regulation need to be aligned with Article 14 (4) of Directive 2016/798: "Each entity in charge of maintenance shall be certified and be awarded an entity in charge of maintenance certificate (ECM certificate)".
Based on the findings of workshops and bilateral exchanges, there could be room for improvement with regard to the following issues:
 The need to improve the exchange of information between stakeholders: ECMs claimed the need to access necessary information from manufacturers to carry out maintenance on vehicles and subsystems (including documentation on material, spare parts, tools, and software configuration) foresee a dedicated
 obligation into the legislation, ECMs claimed the need for clarification in the exchange with the manufacturers concerning the SCCs, Between i) RUs and IMs, ii) from ECM to NIB, and iii) from CBs to NIB,
The relevance of a comprehensive exchange of information between manufacturers, keepers and the ECMs was mentioned also in the <u>AERRL, ALLRAIL and ERFA position paper</u> aimed to ensure an effective, non-discriminatory market of maintenance of railway vehicles. This includes not only detailed technical documentation, but also

	 transparent system documentation that provides all parties with a clear overview of maintenance requirements and processes. This topic was also identified as an area in need of adjustment in the 2018 impact assessment of the Commission Regulation (EU) No 445/2011. The need to integrate in the ECM Regulation the description of the content of the maintenance file/documentation as included in the ECM Guide of the Agency, The opportunity to define the content and scope of the Outsourced Maintenance Functions Entity report (Article 10 of the ECM Regulation) with a separated document from the ECMs, The need to have a better dissemination strategy of the ERADIS functionalities related to the lack of knowledge (e.g. for suggesting/consulting RfUs), The request of reformulation of the accredited CBs so that it can also verify this requirement.
s r a c v a (Regarding the exchange of information between stakeholders, the use of the SAIT tool was discussed. On this topic, half of the survey responses (52%) mentioned that they regularly check the Safety Alert IT Tool (SAIT) to input and access information . The agreement increases for manufacturers (64%), component manufacturer (63%), leasing companies (60%) and ECMs (59%), while the disagreement came mainly from NSA acting as CBs (25%), accredited ECM CBs (17%) (Figure 23). It is worth to mention that for NSAs including those acting as CBs) majority of responses resulted to be "do not know / not applicable" ²⁰ .
	This topic was also discussed in the <u>workshops</u> with the rail sector and <u>NSAs</u> , resulting in:
	 Recognition by the rail sector of the importance to have implemented the SAIT tool to exchange between the actors safety related information in the railway system; nonetheless, room for its improvement and its usage were shared especially with regard to requests from ECMs for additional information or documents, Although it is not a position shared by all NSAs, it was highlighted the need of having access to rail incidents' data regarding rolling stock and ECMs²¹.
C	n the <u>CER position paper</u> , it was mentioned that the increase of documentation (in particular regarding the identification of maintenance F1, F3 - within a RU - and F4), and the unclear proposal and definition on SCCs

 $^{^{\}rm 20}$ Currently, NSAs do not have access to the SAIT tool.

²¹ On this topic, it should be pointed out that further discussions and exchanges between NSAs, other stakeholders and the Agency are needed to explore more the possibility to grant access to the SAIT tool to NSAs. 120 Rue Marc Lefrancq | BP 20392 | FR-59307 Valenciennes Cedex Tel. +33 (0)327 09 65 00 | era.europa.eu 23 / 52

	created unnecessary cost and legal uncertainty. This statement was not supported with quantitative evidence.
5.2.4. Coherence	Summary of the evaluation for 'Coherence'
	Based on the inputs collected with the ex-post report development, it seems that the ECM Regulation is resulting in a satisfactory level of compatibility of its interventions with other interventions with similar objectives. However, room for improvement was identified and described as follows.
	Findings & improvements
	The aspects of coherence of the ECM Regulation are covered by the following evaluation questions collected through the <u>survey</u> :
	 We make use of Art. 3(4) allowing compliance with the ECM Regulation through the Safety Management System instead of through an ECM certification, The ECM certification bodies have implemented and applied consistently the different provisions of the ECM Regulation.
	Concerning the use of article 3(4) allowing compliance with the ECM Regulation through the Safety Management System (SMS) instead of through an ECM certification, survey responses are polarised between disagreement (40%) and do not know / not applicable (29%). The agreement increases for NSA acting as CBs (63%), recognised ECM CBs (50%) and NSAs not acting as CBs (30%), while disagreement came mainly from RUs (55%), vehicle keepers (50%) and IMs (38%) (Figure 20). For all stakeholders the responses marked as "do not know / not applicable" are substantial, except for the NSA acting as CBs.
	Based on the findings of workshops and bilateral exchanges, there could be room for improvement with regard at the following issues:
	 Integration of the safety management system and the maintenance management system: the structure of the ECM Regulation is different to the Commission Delegated Regulation (EU) 2018/762 that entities which are both (RU/IM and ECM) have to work with two different structures (Annex I and II - Safety management system requirements); on this, the need for a new "TSI on maintenance" to explain the responsibilities of each actor was put forward as possibility, Alignment of article 3 of the ECM Regulation with article 14(4) of the Directive (EU) 2016/798, In the ECM Regulation a "positive safety culture", "human and organisational factors" and "awareness" are not required like in the Commission Delegated Regulation (EU) 2018/762 (Annex I – Safety management system requirements related to railway undertakings), Coordination between the GCU contract and the ECM Regulation regarding certification for outsourced maintenance functions.
	A vast majority of survey responses (68%) agreed that the ECM certification bodies have implemented and applied consistently the different provisions of the ECM Regulation. The agreement increases for manufacturer (87%),

	accredited ECM CBs (83%), NSAs (76% and 80% for acting and not acting as CBs, respectively), while the disagreement came mainly from recognised ECM CBs (25%) and leasing companies (19%) (Figure 13). It should be specified that the recognised ECM CBs still agreed for 75% of responses. Based on the findings of <u>workshops</u> , there was agreement with the proposal aimed to:
	 Request that all ECMs shall be certified by an ECM CB without the opportunity of the assessment during the SSC phase (via the SMS) (article 3(4) of the ECM Regulation)²², Adjust the requirements to assimilate them to the structure of ISO 9001, and to facilitate the integration of the maintenance management system, Verify potential synergies between the existing certification scheme of ISO 22163 and the ECM certification / have official compliance confirmation between the ECM Regulation and ISO 22163 (or ISO 9001) and ISO 45001 standards.
5.2.5. Added value	Summary of the evaluation for 'Added value'
	Based on the inputs collected with the ex-post report development, it seems that the value resulting from the ECM Regulation implementation is clearly additional to the value that could have been created by individual MSs. However, room for improvement was identified and described as follow.
	Findings & improvements
	The aspects of added value of the ECM Regulation are covered by the following evaluation question collected through the <u>survey</u> :
	 Since the ECM Regulation a higher number of maintenance providers have started operations compared to the number of maintenance providers that have closed, The ECM Regulation has influenced the business setup of maintenance providers (merging with other companies, selling divisions, etc.), We make use of an ECM certification body outside our main country of operations, Overall advantages of the ECM Regulation outweigh any disadvantages.
	Regarding the first evaluation question, almost half of the respondents (40%) did not know whether, since the ECM Regulation, there has been an increase in the number of maintenance providers that have started operations compared to the number of maintenance providers that have closed . While the NSAs acting as CBs most agreed with this statement (51%) compared with the other stakeholders, leasing companies disagreed the most (42%).
	Although responses are evenly distributed among the response categories, 31% of respondents agreed that the ECM Regulation has influenced the business setup of maintenance providers (merging with other companies,

 ²² On this issue, ERA need more qualitative and quantitative evidence from stakeholders in order to determine the satisfactory way forward, and there was no general agreement among all NSAs.
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selling divisions, etc.) . The agreement increases for recognised ECM CBs (50%) and manufacturers (44%), while disagreement came mainly from the leasing companies (25%) and RUs (14%). It is worth to mention that NSAs (not acting as CBs) claimed not to know / not applicable (80%).
Half of the survey responses (49%) disagreed with the use of an ECM certification body outside our main country of operations . The disagreement increases for manufacturers (66%), IMs (62%) and RUs (60%). When comparing with the overall agreement to this statement (25% of responses), the leasing companies (47%) and ECMs (27%) are the ones with the highest shared of agreement. It should be specified that the NSAs (both acting and not acting as CBs) claimed not to know / not applicable (88 and 90%, respectively).
As mentioned in the previous section, regarding the first evaluation question (Figure 14), the vast majority of respondents (69%) agreed that overall advantages of the ECM Regulation outweigh disadvantages.
Based on the findings of <u>workshops and bilateral exchanges</u> , there could be room for improvement with regard at the following issues:
• The national implementation of the EU Regulation on ECM might complicate the activities of ECM when operating in different MSs,
On this topic, the findings confirmed what the 2015 implementation study of Commission Regulation (EU) No 445/2011 pointed out concerning to the persistence of divergent interpretations of the ECM legal framework between MSs. It was further confirmed in the 2018 impact assessment of the then existing Regulation with the presence of 'unwritten and local' knowledge on how vehicles are maintained to be compatible with specific infrastructures, as well as diversity arrangements put in place by actors in different MSs.
• Although Directive (EU) 2016/798 permits exemptions, it could be clearer what the possibilities are for heritage vehicles to grant these exemptions to the national level,
 In case of integrated management companies, the responsibilities of the keeper and the RU varies in base of the EU country, Harmonisation across CBs in delivering a certification and doing supervision (see dedicated point in previous sections).
In addition, in the <u>CER position paper</u> , it was mentioned that in the Spanish translation of the ECM Regulation uses different words to refer to the SCCs.

6. Conclusions and Recommendations

6.1. Summary

The 2024 ECM Implementation Report offers the following conclusions:

- The implementation of the Commission Implementing Regulation (EU) 779/2019 as amended is a *success* as the ECM certification has been *widely adopted* for all types of vehicles by the railway sector and stakeholders and the vast majority of stakeholders involved in this first report agreed that *overall advantages of this Regulation outweigh disadvantages*.
- Nevertheless, there are matters for reflection and improvements related to the definition and allocation of responsibilities among actors, the exchange of information (including their communication) and maintenance documentation between actors, the harmonisation of the requirements / content of the ECM certificate / supervision of ECMs by CBs, the integration of the safety management system (SMS) and the maintenance management system and the exchange of common practices within the NSAs concerning the activities carried out based on the Article 11 of the ECM Regulation.

These elements will be considered further in the coming period with a view to determine proportionate and relevant follow-up actions. Below, a set of recommendations and actions are put forward.

6.2. Recommendations

This chapter contains a total of **14 short and mid-long-term recommendations**, which are either:

- encouraging an amendment of the ECM Regulation, or
- suggesting new RfUs to be adopted by the cooperation of ECM Certification bodies, or
- proposing amendments of the Agency's ECM guide, or
- proposing a more balanced application of the ECM Regulation across MSs, or
- promoting the organisation of professional trainings by the Agency for all stakeholders, or
- promote the consolidation of existing data collection and analysis and the design and implementation of additional ones for monitoring and supervision purposes of the ECM Regulation implementation by the Agency, or
- proposing a new TSI Maintenance to address the main needs of actors in a systemic way.

6.2.1 Short term actions

The Agency recommends the following change in the **ECM Regulation**:

1. Changing the frequency of the ex-post evaluation carried out by the Agency: The Agency considers appropriate to amend Article 14 of the ECM Regulation obliging the Agency to prepare and submit to the EC subsequent reports on the implementation of this Regulation every five years following the first report instead of every three. This change would allow alignment with the orientation proposed in the BRGs of the EC suggesting an indicative 5-year rolling evaluation plan and the need to have at least 3 years' of reasonably full data on the implementation of the intervention. Nevertheless, this change should be complemented by a proper monitoring system as recommended in the next section.

The Agency recommends the following changes in **its ECM guide**²³ and proposals of new **RfUs. They** are summarised in **11 clusters**:

- 2. Enhancing clarity in the **definition and responsibilities' allocation** among the concerned actors (ECM functions also at component level -, RUs, IMs, manufacturers, keepers and integrated companies), and in the ECM certification process,
- 3. Providing clarity in the domain of exchange of data (and their communication) and maintenance documentation between the concerned actors to guarantee a clear overview of maintenance requirements and processes; it is important also to enhance and put emphasis on the NSAs' and the Agency's discretion under Article 6(8) ECM Regulation to request information from any certification body on the situation concerning an individual ECM certification and the subsequent obligation of the certification body to reply within maximum 2 weeks,
- Expanding the description of the terms "return to operation" and "release to service", defined in Article 2 and Annex II of ECM Regulation, with specific reference to the documentation to be exchanged between stakeholders (e.g. template, scope),
- 5. Fostering clarity of Article 4 and Annex II of ECM Regulation²⁴ regarding the **definition** and **harmonisation of the requirements for ECMs** concerning the **SCCs**,
- 6. Improving harmonisation across CBs when delivering a certificate and carrying out supervision of *ECMs* (especially for the subcontracting activities),
- Promoting the exchange of common practices among the NSAs in the NSA network concerning the ECM supervision of requirements of Annex III of Directive (EU) 2016/798 (article 11 of the ECM Regulation)²⁵,
- 8. Providing further indications of what the **ECM maintenance function certificates contains**, especially for the certificate of maintenance workshop (ECM F4).
- 9. Improving the link between the **safety management system** and the **maintenance management system** for those companies being at the same time RU/IM and ECM,
- 10. Avoiding that **national implementation and interpretation of the requirements of ECM Regulation** complicates the ECMs' activities when operating in different MSs,
- 11. Improving communication in relation to **functionalities** available in **ERADIS**, especially to address issues related to the lack of knowledge of their potential use (e.g. for requesting and/or consulting RfUs),
- 12. **Organising trainings** for all kind of stakeholders and authorities to ensure the understanding of the concepts of maintenance and maintenance management system²⁶.

It is considered appropriate to revise and integrate the clusters 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12 within the ECM guide and better promote and disseminate this guide among all stakeholders with the help of case studies and examples.

Concerning **cluster 3** of the actions above, it is worth mentioning that CEN/CENELEC WG48 is preparing a relevant paper.

²³ This guide provides explanations on the provisions contained in the ECM Regulation. However, it does not substitute for them. The guide is publicly available on the website of the European Union Agency for Railways: <u>Guidance on ECM certification process (europa.eu)</u>.

²⁴ In addition, there are also other elements in Annex III of Directive (EU) 2016/798.

²⁵ This proposed action has also implications on other activities carried out by the Agency not only strictly related to ECM guide and should be consider further.

²⁶ This proposed action has also implications on other activities carried out by the Agency not only strictly related to ECM guide and should be consider further.

Regarding **cluster 5** of the actions, in addition to the existing technical report 17696 by CEN/CENELEC, the suggestion is to integrate the ECM guide with examples of the management of SCCs.

With reference to **clusters 2, 8, 9** of actions, **RfUs** could be also developed.

Concerning **cluster 7** of the actions, for the development of the dedicated ERA guide's section aimed to share common / best practices regarding the NSAs' activities foreseen in article 11 of the ECM Regulation, it is considered useful to gather further evidence from both the monitoring of NSAs' activities carried out by the Agency and the cooperation among CBs facilitated by the Agency.

With reference to **cluster 10** of the actions, it is considered appropriate to gather further inputs related to national implementation through the CCB, NRB and NSA networks in order to include clarifications in the Agency's guide.

With recommendations of **cluster 12** professional training should be organised by the Agency or other entities facilitating for all stakeholders and authorities a deeper understanding of the concepts of maintenance and maintenance management system.

6.2.2 Actions regarding monitoring and supervision

The actions of the previous section should be complemented by the Agency's need for gathering information for the headline indicators listed below on the status of the implementation of ECM Regulation²⁷. Over time additional or amended indicators may be of relevance.

13. Gathering *information* from stakeholders to *design dedicated indicators* for monitoring and supervising purposes:

List of the main **headline indicators**:

- Overall level of correct implementation of the Regulation including the possible national peculiarities and the unbalanced application of the ECM Regulation across MSs stated by some railway stakeholders.
- Number of identified major non-compliances with the certification requirements per country and per application,
- Overall level of correct exchange of data between the main actors,
- Overall level of harmonisation of the requirements for ECMs concerning the SCCs,
- Overall level integration of the safety management system and the maintenance management system.

List of the main in-depth information requirements:

- Overall perceptions and experiences of ECM certification by stakeholders (CBs, NSAs, ECMs, keepers, maintenance workshops, RUs/IMs, leasing companies, manufacturers),
- Views on the implementation of specific elements of the Regulation (detected issues and advantages, non-anticipated results, etc.),
- Actual implementation costs (focusing on obtaining practical information about costs incurred by the different parties and distinguishing between "ECM vs. maintenance workshop" and "initial costs vs. annual costs"),

²⁷ In addition, within the future activities, it is also advisable to further decline the headline (synthetic) indicator with the use of dedicated sub-indicators, as well as their link with a timeline.

- Perceptions among ECMs on whether there are changes in resources used for applying for ECM certification and for preparing for the annual surveillance activities (gathering specific examples),
- Perceptions among CBs on whether there are changes in resources used for assessing ECM certification applications and for carrying out surveillance activities (gathering specific examples),
- Opinions from RUs/IMs and other stakeholders on the system established by ECMs to monitor their performance and the performance of their outsourcing partners,
- Views from ECMs, RUs/IMs, manufacturers, keepers and other stakeholders on the effectiveness of the exchange of information on the maintenance/operation of vehicles,
- Opinions from ECMs and maintenance workshops on the effectiveness of the exchange of views between NSAs and CBs to avoid duplication of assessments.

List of key data sources for these indicators would include:

- Triannual activity reports from all ECM certification bodies,
- Monitoring of NSAs' activities by the Agency,
- Cooperation among CBs facilitated by the Agency,
- Annual reporting by NSAs on ECM certification and supervision,
- Dedicated interviews/surveys issued through the NSA, NRB, ESG and CCBs Networks,
- ERADIS Register of the Agency.

For the indicators which are already being collected, the action is to consolidate the data collection and analysis, to be aimed to monitor in real-time the foreseen areas of improvement and anticipate potential issues related to the ECM Regulation implementation.

For indicators involving the collection of new data, the action is to design and implement a yearly monitoring system of the listed indicators / requirements, also using the mentioned data sources.

6.2.3 Medium-long term actions

To further strengthen and complement some of the mentioned actions (clusters 3, 4 and 10), with the support of the evidence gathered from the indicators (actions regarding monitoring and supervision) defined in section 6.2.2, the last action is aimed to:

- 14. Design and develop a **new Technical Specifications Interoperability (TSI) "Maintenance"** for the achievement among others:
 - Greater harmonisation related to the ECM-related responsibilities of RUs/IMs, keepers, manufacturers of vehicles and components, ECM and maintenance functions in various business organisation (integrated or non-integrated companies or large subcontracting for instance);
 - integration of the SMS and the maintenance management system;
 - common communication system between RU/IM, keepers, manufacturers of vehicles and components, ECM and maintenance functions' (including exchange of data and maintenance documentation);
 - the management of SCCs; and
 - the competences of staff performing maintenance activities.

Maintenance is the only one subsystem listed in the Annex 2 of the Directive (EU) 2016/797 without a TSI.

A new TSI Maintenance could be one of the options to achieve the harmonisation of practices when supporting efficiency to complete the existing regulatory framework as well as better understood and communicated to/across stakeholders; other options are also possible which require dedicated and further investigation.

It is important to note that according to Article 8 of the Agency Regulation, the Agency is obliged to conduct an impact assessment of its recommendations. Under this light, any design and development of a **new TSI "Maintenance"** would previously require (and for this, it is considered appropriate) a relevant impact assessment where costs and benefits for stakeholders are deeply analysed and quantified.

In addition, the findings of this first implementation report of the ECM Regulation could also contribute to the future activities of the Agency (e.g. CSM).

Annexes

Annex 1 – Overview of the Agency's implementation report 2015 for Commission Regulation (EU) No 445/2011

<u>Background</u>

The certification of ECMs maintaining freight wagons was made mandatory in the EU since 31 May 2011 when the Commission Regulation (EU) No 445/2011²⁸ entered into force. Shortly afterwards the certification was extended to the OTIF member countries when the ATMF Annex A²⁹ entered into force on 1 May 2012.

The Article 14a (7) of the Railway Safety Directive³⁰ requires the Agency to evaluate the Commission Regulation (EU) No 445/2011 3 years after its the entry into force. A similar provision was included in the ECM Regulation 2019/779 forming the legal basis for the present report.

On this basis the Agency launched the preparation of the implementation report in 2014 and this work was completed in 2015.

It was noted in the 2015 implementation report that Article 14a was introduced in the Railway Safety Directive in 2008 not because of an overall lack of safety related to maintenance within the railway system, but as a measure to make feasible the control of risks associated to supply of maintenance.

<u>Work undertaken</u>

The implementation report was prepared using a number of different information sources as inputs, incl.:

- ECM dissemination workshops;
- Interactions with stakeholders in the context of the preparation of the accreditation scheme and guidelines;
- Exchanges as part of the cooperation of (ECM) certification bodies;
- ECM monitoring activities;
- Discussions within The Freight Focus Group;
- Other exchanges and meetings (e.g. NRB and NSA network meetings).

Moreover, to gather specific feedback from all railway actors regarding the implementation of Commission Regulation (EU) No 445/2011 and to get information for the extension of this Regulation to other vehicles, the Agency launched a questionnaire to the railway actors at the beginning of 2014. The questionnaire aimed at getting feedbacks from the experience of the railway actors who apply the ECM system or who are impacted by the ECM certification. In particular, the following aspects have been addressed:

²⁸ Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2077.

²⁹ COTIF 1999, appendix G. ATMF Annex A - Uniform Rules set out in accordance with Article 15 § 2 - Certification and auditing of Entities in Charge of Maintenance (ECM).

³⁰ Directive 2004/49/EC on safety on the Community's railways as amended by Directive 2008/110/EC. Article 14(a) was introduced in this amendment with Para 7 providing that '...The Agency shall evaluate the certification process implemented in accordance with paragraph 5 by submitting a report to the Commission, no later than three years after the entry into force of the relevant measure.

- Evidence on the experiences of the ECM Certification Scheme;
- Overview of how scheme is working in practice;
- Perception of the railway actors;
- Assessment on costs and benefits;
- Identification of pertinent amendments;
- Suggestions regarding the possible extension of scope to all vehicles.

This questionnaire resulted in some 210 responses from a variety of stakeholders from across Europe. This high level of responses was the result of several factors including a strong support from external stakeholders.

<u>Main findings</u>

(A) Findings from the stakeholder questionnaire

Below, key findings from the 2014 ECM questionnaire are outlined:

The main **strengths** of ECM certification put forward by respondents included:

- Harmonisation of processes and procedures on maintenance of vehicles all over Europe increase overall safety;
- Clearer definition of responsibilities and targets through legal framework;
- ECM certification is a basis for a common language between RUs and other actors regarding maintenance of freight wagons;
- Improve the organisation of maintenance;
- Reduction in inter-organisations assessments. The efforts for supplier assessment can be reduced for each company;
- ECM certification supports the introduction of legal provisions for risk management (CSM risk assessment and CSM on monitoring).

The main **weaknesses** of ECM certification put forward by respondents included:

- Divergent interpretations of the ECM legal framework remain between MSs;
- Absence of processes/procedures related to the management of relations between ECMs and manufacturers (return on experience);
- Additional administrative burden for companies of particular importance for Small and Medium sized Enterprises (SMEs).

Influence of ECM Certification on problems concerning maintenance tasks for wagons:

- 112 respondents perceived a positive influence from ECM Certification on problems linked to the maintenance tasks for wagons (either strongly, 38 or weakly, 74);
- 7 respondents perceived a negative influence from ECM Certification on problems linked to maintenance tasks for wagons;
- 34 respondents perceived no influence from ECM Certification.

Influence of ECM Certification on problems concerning maintenance control and supervision:

- 42 respondents had the view that the influence was strongly positive while 56 respondents selected weakly positive;
- 7 respondents had a negative perception of ECM certification influence on these problems;
- 42 respondents mentioned that ECM certification had no influence on problems regarding maintenance control / supervision.

Influence of ECM certification on railway safety:

- 141 respondents perceived a positive influence (51 perceived a strongly positive influence while 90 perceived a weakly positive influence);
- 3 respondents perceived a weakly negative influence (none of the respondents viewed there to be strongly negative influence);
- 29 respondents considered that there had been no influence.

Views on the need to make any changes / adjustments to Commission Regulation (EU) No 445/2011:

- 92 respondents considered that there was a need for changes / adjustments to the regulation;
- 62 respondents did not perceive a need for change;
- 40 respondents answered that they didn't know;
- 5 respondents left the question unanswered.

Among the **areas in need of adjustment** the following were mentioned by respondents:

- Clearer rules and more precision of the current Commission Regulation (EU) No 445/2011, to allow no room for interpretation, and some modifications as well;
- Extending the scope of certification to include vehicles other than wagons;
- Common interpretation of the ECM Regulation by different countries;
- Less paperwork, No administrative overkill;
- Better exchange of information;
- To make the ECM certification the standard in all Europe for safety certification (in most European countries, national behaviour is still standard).

Changes in ongoing resources linked to maintenance management:

• Overall, the experiences put forward by the respondents suggest that most (107) experienced an increase in resources linked to maintenance management, while only (2) experienced a decrease.

Improvement in the **efficiency of operations** due to the harmonised management system:

• 95 respondents did not experience any change so far. On the other hand, 51 respondents experienced an increase in efficiency compared to 15 having experienced a decrease in efficiency. Some 47 respondents did not answer the question.

Changes in **certification costs**:

• Most respondents experienced an increase in certification costs (107) compared to 42 respondents that did not experience any change and 1 respondent with a decrease in certification costs.

Changes in **workload** (in terms of days) for initial preparation in order to enter the process of ECM certification:

• A significant majority of respondents experienced an increase in workload (133), while 14 respondents experienced no change, and 2 respondents had a decrease in workload.

Business of **exchanging wagons or renting wagons** short term / long term affected by Commission Regulation (EU) No 445/2011:

- 31 respondents indicated that there was a positive influence;
- 13 respondents indicated that there was a negative influence;
- 76 respondents indicated that there was no influence.

Overall conclusions

The 2015 ECM Implementation Report offered the following conclusions:

- The implementation of the Commission Regulation (EU) No 445/2011 is a success as the ECM certification has been widely adopted by the railway sector.
- Nevertheless there are matters of reflexion and improvements related to the implementation in the different countries, the certification bodies, the maturity of implementation of the CSM RA (Risk Evaluation and Assessment) and the CSM MO (Monitoring) and the exchange of information between the railway actors, mainly RUs, keepers and ECMs.
- Finally, the Agency considered that the certification system developed for freight wagons was sufficiently mature to start the revision of the Commission Regulation (EU) No 445/2011 to extend the scope to all vehicles.

ECM Certification Bodies:
24 organisations & 35 participants
A3CERT
APNCF
CERTIFER
Consumer Protection and Technical Regulatory
Authority
NSA FR
IISCERT
Inspectie Leefomgeving en Transport
ITALCERTIFER
ITSA
Kentriki - Savills Hellas
Ministry of Serbia, Directorate for Railways
M-ZERO
NSA LU
NSA LV
NSA SI
OBB
Republic of Serbia, Directorate for Railways
Sconrail
SEGURIDAD FERROVIARIA
SQS
TÜV Rheinland Europe
TUV SUD
UTK PL
VIACARE

Annex 2 – List of participating entities

National Safety Authorities:
16 organisations & 28 participants
NSA CH
NSA DE
NSA DK
NSA ES
NSA FR
NSA GR
NSA IE
NSA IT
NSA LU
NSA NO
NSA RO
NSA SE
NSA SK
NSA SL
NSA UK
Rail Sector:

67 organisations & 86 participants
AERRL
AKIEM
ALSTOM GROUP
ARETZ WAGGON
AZVI
BAHNVERSTAND
BANE NOR
BEACON RAIL
BLS
CARGO WAGON
CER
CFL
CFL CARGO
CP
EAV SRL
ELECNOR
EUCORAIL FEDECRAIL
GEFER
HITACHI RAIL
INFRABEL / EIM
INTERPORTO BOLOGNA
ILSA
KNORR BREMSE
KOLEJ BALTICKA
LFI
LOC MAINT
MERCITALIA INTERMODAL
MERMEC
MODALIS
MOSOLF
MULTI MARITIME
NB RAIL
NETWORK RAIL
NORWEGIAN RAILWAY ASSOCIATION NJK
NS NL
OBB ONLINE.NO
RAIL SUPPORT AS
RAIL SUPPORT AS
REF RENT
RENFE
SACYR
onorm

SBB
SIEMENS
SJ
SLOVAK RAIL
SNCF
SZ VIT
TESMEC
TKP SILESIA
TRAFIKVERKET
TRANSCHEM
TRANSITO
TRENITALIA
TRENITALIA TPER
TSZ GREDELJ
TUV SUD
ТҮСКА GT
UIB
UIC
UIP RAIL
VIB EUROPE
ZRK-DOM POZNAN
ZS CARGO

Other actors (bilateral exchanges):
4 organisations
One NIB
One NSA
Ingenieurbüro Severin Dünnbier
AKIEM



Moving Europe towards a sustainable and safe railway system without frontiers.

Annex 3 3 – Full results of the survey carried out by the Agency

The main characteristics of the survey are listed below:

- The survey was carried out via EUSurvey and sent to ESG members.
- Total number of questionnaires received (on 15th September 2023): # 399
- Total number of questionnaires after data cleaning: # 373
- The results are presented by section of the questionnaire: [1] Organisation information, and [2] Evaluation questions.

Preliminary and final findings of the survey were presented at different CCB, NSA, NRB and ESG meetings, as shown in Table 1.

Type of meeting	Date	Details		
NSA network meeting	27/09/2023	Preliminary aggregated results		
ESG meeting 11/10/2023		Disaggregated final results by stakeholder type		
CCB meeting	18/10/2023	Disaggregated final results by stakeholder type		
NSA network meeting	7-8/11/2023	Disaggregated final results by stakeholder type		
NRB network meeting	28/11/2023	Disaggregated final results by stakeholder type		
NSA-NRB network meeting	14/03/2023	State of play and next steps		
ESG meeting	17/04/2024	State of play and next steps		

Table 1 – Overview of the presentations of the survey's findings

Organisation information are reported below:



Figure 2 – Please indicate what type of role(s) your organisation performs

Figure 3 – Please specify the type of vehicles you are an ECM for





Figure 4 – Please specify the additional ECM functions, if any, that you perform in-house



Figure 5 – Primary location of respondents with international/domestic only activities

The 19 evaluation questions are organized in three clusters as shown in Figure 6.

Figure 6 – Overview of the survey's evaluation questions.

IMPLEMENTATION, OUTCOME **IMPROVEMENTS FUNCTIONING & FEATURES** GENERIC: GENERIC: .. has implemented and applied consistently, • Overall advantages of the ECM Regulation • No changes / adjustments to the current outweigh any disadvantages. ECM Regulation are needed. make use of Art. 3(4) allowing compliance with the ECM Regulation through the Safety SPECIFIC: Management System instead of through an • .. has reduced the problems associated with SPECIFIC: ECM certification, maintenance tasks for vehicles, .. the scope extension of the ECM scheme to Our liability, real or perceived, is reduced if • .. has facilitated maintenance other types of vehicles than freight wagons. maintenance is outsourced to a certified ECM, control/supervision, • .. has positively influenced railway safety, . use the ERADIS database to input and • .. has reduced the time and resources interrogate ECM information, required for customers to search and select a suitable ECM, .. check regularly the Safety Alert IT Tool (SAIT) to input and access information, • .. has decreased costs and resources for maintenance management, • .. has decreased certification costs, • .. has facilitated the harmonisation of often change our ECM certification body depending on the vehicle types, requirements and methods to assess the ability of ECMs for vehicles, • .. has increased the number of maintenance providers have started operations, use of an ECM certification body outside our main country of operations.

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... has influenced the business setup of

maintenance providers.



Figure 7 – The introduction of ECM certification has reduced the problems associated with maintenance tasks for vehicles

🔳 1. Fully disagree 📕 2. Rather disagree 🔳 3. Neither agree nor disagree 🔳 4. Rather agree 🔳 5. Fully agree 💻 Don't know / Not applicable

Figure 8 – The introduction of ECM certification has facilitated maintenance control/supervision

■ 1. Fully disagree ■ 2. Rather disagree ■ 3. Neither agree nor disagree ■ 4. Rather agree ■ 5. Fully agree ■ Don't know / Not applicable





Figure 9 – The ECM certification has positively influenced railway safety

Figure 10 – The ECM certification has reduced the time and resources required for customers to search and select a suitable ECM

■ 1. Fully disagree ■ 2. Rather disagree ■ 3. Neither agree nor disagree ■ 4. Rather agree ■ 5. Fully agree ■ Don't know / Not applicable





Figure 11 – Costs and resources for maintenance management have decreased by the ECM Regulation

Figure 12 – Certification costs have decreased since the introduction of the ECM framework

🔳 1. Fully disagree 📕 2. Rather disagree 📕 3. Neither agree nor disagree 📕 4. Rather agree 📕 5. Fully agree 📮 Don't know / Not applicable





Figure 13 – The ECM certification bodies have implemented and applied consistently the different provisions of the ECM Regulation

Figure 14 – Overall advantages of the ECM Regulation outweigh any disadvantages

■ 1. Fully disagree ■ 2. Rather disagree ■ 3. Neither agree nor disagree ■ 4. Rather agree ■ 5. Fully agree ■ Don't know / Not applicable

AGGREGATED RESULTS - ALL	3 <mark>% 6%</mark> 18%	40%	29% <mark>3%</mark>
National Safety Authority acting as an ECM Certification Body	25%	75%	
Recognised ECM Certification Body	25%	75%	
National Safety Authority	20%	70%	10%
Accredited ECM Certification Body	11%	44%	44%
Component manufacturer	<mark>6%0%</mark> 41%		47% 6%
Manufacturer	<mark>3%</mark> 20%	20%	57%
ECM	3 <mark>% 6%</mark> 19%	43%	27% <mark>2</mark> %
Infrastructure manager	2 <mark>% 8% 20%</mark>	40%	26% <mark>4%</mark>
Vehicle keeper	<mark>4%</mark> 7% 22%	38%	26% <mark>4%</mark>
Railway Undertaking	<mark>4% 8%</mark> 21%	40%	24% <mark>3%</mark>
Other	14% 14	% 32%	29% <mark>4%</mark>
Leasing company	44%	38%	19%





Figure 16 – Since the ECM Regulation a higher number of maintenance providers have started operations compared to the number of maintenance providers that have closed



Figure 17 – The ECM Regulation has influenced the business setup of maintenance providers (merging with other companies, selling divisions, etc.)



1. Fully disagree 2. Rather disagree 3. Neither agree nor disagree 4. Rather agree 5. Fully agree Don't know / Not applicable

Figure 18 – The scope extension of the ECM scheme to other types of vehicles than freight wagons has been an advantage



Figure 19 – No changes / adjustments to the current ECM Regulation are needed 120 Rue Marc Lefrance | BP 20392 | FR-59307 Valenciennes Cedex Tel. +33 (0)327 09 65 00 | era.europa.eu



1. Fully disagree 2. Rather disagree 3. Neither agree nor disagree 4. Rather agree 5. Fully agree Don't know / Not applicable

Figure 20 – We make use of Art. 3(4) allowing compliance with the ECM Regulation through the Safety Management System instead of through an ECM certification



Figure 21 – Our liability, real or perceived, is reduced if maintenance is outsourced to a certified ECM



🔳 1. Fully disagree 📕 2. Rather disagree 🔳 3. Neither agree nor disagree 📕 4. Rather agree 🔳 5. Fully agree 📮 Don't know / Not applicable

Figure 22 – We use the ERADIS database to input and interrogate ECM information



Figure 23 – We regularly check the Safety Alert IT Tool (SAIT) to input and access information



🔳 1. Fully disagree 📕 2. Rather disagree 🔳 3. Neither agree nor disagree 📕 4. Rather agree 📕 5. Fully agree 📕 Don't know / Not applicable

Figure 24 – We often change our ECM certification body depending on the vehicle types

🔳 1. Fully disagree 📕 2. Rather disagree 🔳 3. Neither agree nor disagree 📕 4. Rather agree 📕 5. Fully agree 💻 Don't know / Not applicable





Figure 25 – We make use of an ECM certification body outside our main country of operations