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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 445/2011

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety¹, and in particular Article 14(6) and (8) thereof,

Whereas:

- (1) Directive (EU) 2016/798 aims to improve access to the market for rail transport services by defining common principles for the management, regulation and supervision of railway safety. Directive (EU) 2016/798 also provides for a framework to be put in place to ensure equal conditions for all entities in charge of maintenance for vehicles through application of the same certification requirements and conditions across the Union.
- (2) The purpose of the certification system is to provide a framework for harmonising requirements and methods to assess the ability of entities in charge of maintenance across the Union.
- (3) Following the positive evaluation of the current system of certification of entities in charge of maintenance for freight wagons addressed to the Commission on 11 March 2015 by the European Union Agency for Railways (the Agency), on 27 September 2018, the Agency issued Recommendation 007REC1004 on the revision of Commission Regulation (EU) No 445/2011².
- (4) Annex III to Directive (EU) 2016/798 sets out the requirements and assessment criteria for organisations applying for a certificate for entity in charge of maintenance ('ECM certificate') or for a certificate in respect of maintenance functions outsourced by an entity in charge of maintenance. In order to be fully applicable those requirements need to be further detailed and specified for the different maintenance functions as referred to in points (a) to (d) of Article 14(3) of that Directive.
- (5) Taking into account the wide variety of design and maintenance methods, that system of maintenance should be more oriented on the management requirements, such as the organisation of the entity in charge of maintenance, rather than a specific technical requirement.

¹ OJ L 138, 26.5.2016, p. 102.

² 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 653/2007 (OJ L 122, 11.5.2011, p. 22)

- (6) Safety-critical components require particular attention and priority in maintenance procedures. An exclusive definition of 'safety-critical component' would be beneficial to the system. However, the criticality aspects of any component are related to the particular design of the vehicle and to the particular functions of the component. It is therefore not possible to establish an exhaustive list of safety-critical components. The essential elements of safety-critical components should be set out.
- (7) When designing a new type of vehicle, the manufacturer should determine the criticality of the functions and components of their products by a risk-based analysis and record them in the technical file referred to in Article 15(4) of Directive (EU) 2016/797 of the European Parliament and of the Council³. The entity in charge of maintenance should have access to the relevant parts of the technical file to ensure it is fully aware of the criticality of the components for each type of vehicles under its responsibility. The entity in charge of maintenance should identify criticalities by observing and analysing the failures and tracing all its interventions, and be obliged to provide feedback at least on the safety-critical components identified as such by the manufacturer. Where the entity in charge of maintenance identifies new safety-critical components not yet included in the technical file, it should promptly inform the manufacturer, to allow it to take the necessary measures, including a revision of the technical file, if needed.
- (8) An entity or organisation taking on one or more maintenance functions as referred to in points (b) to (d) of Article 14(3) of Directive (EU) 2016/798 or part of those maintenance functions may apply the system of certification on a voluntary basis, based on the principles specified in Article 6. The aim of that certification is to ensure that maintenance is carried out within a controlled process that meets common quality standards in all its steps. Article 14(5) of Directive (EU) 2016/798 on the validity throughout the Union should also apply to those voluntary certificates.
- (9) As part of their activities, infrastructure managers may need to use trains, infrastructure inspection vehicles, on-track machines or other special vehicles for different purposes, such as transporting materials or staff for construction or infrastructure maintenance, performing maintenance on its infrastructure assets or managing emergency situations. In such situations, the infrastructure manager should be deemed to operate in the capacity of a railway undertaking under its safety management system. Assessing the infrastructure manager's capacity to operate vehicles for this purpose should be part of its assessment for a safety authorisation under Article 12 of Directive (EU) 2016/798.
- (10) In accordance with Directive (EU) 2016/798, an ECM certificate is to be valid throughout the Union. Certificates issued by bodies in third countries appointed pursuant to equivalent criteria and meeting equivalent requirements to those provided for in this Regulation should be accepted as being equivalent to the ECM certificates issued in the Union.
- (11) The assessment by a certification body of an application for an ECM certificate is an assessment of the applicant's ability to manage maintenance activities and to deliver the operational functions of maintenance either by itself or through contracts with other bodies, such as maintenance workshops, charged with delivering those functions or parts of those functions.

³ Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44).

- (12) In accordance with Article 14(4) of Directive (EU) 2016/798, the certification bodies are accredited bodies, recognised bodies or the national safety authorities. A system of accreditation should provide a tool for managing risks by assuring that accredited bodies are competent to carry out the work they undertake. Furthermore, accreditation is a means to secure national and international recognition of ECM certificates issued by accredited bodies.
- (13) In order to have a system allowing certification bodies to perform checks on certified entities in charge of maintenance across the Union and to harmonise approaches to certification, it is important that all bodies able to award certificates to any entity in charge of maintenance ('certification bodies') cooperate with one another. Specific requirements for accreditation and recognition are to be developed and approved in accordance with Chapter II of Regulation (EC) No 765/2008 of the European Parliament and of the Council⁴.
- (14) Performance, organisation and decision-making procedures in the field of railway safety and interoperability vary substantially among the entities in charge of maintenance, with a detrimental effect on the smooth operation of the single European railway area. In particular, small and medium-sized enterprises wishing to enter the railway market in another Member State might be negatively affected by that. Therefore, strengthened coordination with a view to greater harmonisation at Union level is essential. In order to ensure that the entities in charge of maintenance and the certification bodies implement and apply consistently the different provisions of this Regulation, the European Union Agency for Railways ('the Agency') should, within its powers to monitor the overall safety performance of the Union rail system referred to in Article 35 of Regulation (EU) n° 2016/796, monitor the activities of the certification bodies through audit and inspections. To be able to perform this function, the Agency should collect information on the nature of the certification bodies active in that field and the number of certificates issued to entities in charge of maintenance. It is also important for the Agency to facilitate coordination of the certification bodies.
- (15) Pending the full application of the certification system of the entity in charge of maintenance provided for in this Regulation, the existing practices to certify entities in charge of maintenance and maintenance workshops for vehicles other than freight wagons should remain valid during a period of transition in order to ensure the uninterrupted provision of rail operation services, in particular at international level.
- (16) This Regulation provides for a system of certification for all types of vehicles, including freight wagons. Therefore, Commission Regulation (EU) No 445/2011⁵ should be repealed.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Committee referred to in Article 28(1) of Directive (EU) 2016/798,

⁴ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

⁵ 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 653/2007 (OJ L 122, 11.5.2011, p. 22).

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation establishes a system of certification of entities in charge of maintenance ('ECM certificate') and maintenance functions in accordance with Article 14(3) of Directive (EU) 2016/798.
2. It applies to all vehicles, and introduces the possibility for certification of outsourced maintenance functions.
3. This Regulation sets out the requirements to be met by the entities in charge of maintenance concerning safety-critical components.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (a) 'accreditation' means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008 of the European Parliament and of the Council⁶;
- (b) 'certification body' means a body, responsible for the certification of entities in charge of maintenance or for certification of the entity or organisation that fulfil maintenance functions referred to in points (b), (c) or (d) of Article 14(3) of Directive (EU) 2016/798, or parts of those functions;
- (c) 'release to service' means the justified and recorded assurance accompanied by documentation where appropriate, of by the entity in charge of maintenance to the fleet manager that maintenance has been delivered according to the maintenance orders;
- (d) 'return to operation' means a notice given to the user, such as a railway undertaking or a keeper, by the entity in charge of maintenance, based on a release to service, assuring that all appropriate maintenance works have been completed and the vehicle, previously removed from operation, is in a condition to be used safely, possibly subject to restrictions of use;
- (e) 'safety-critical component' means a component for which a single failure has a credible potential to lead directly to a serious accident.

Article 3

System of Certification

1. Without prejudice to Article 15(1) of Directive (EU) 2016/798, the mandatory system of ECM certification shall apply to any entity in charge of maintenance and in respect of all vehicles subject to Directive (EU) 2016/798.
2. The ECM certification of the entity in charge of maintenance shall be used to demonstrate the ability of a railway undertaking or infrastructure manager to comply

⁶ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

with the requirements set out respectively in points 5.2.4 and 5.2.5 both of Annex I and Annex II to Commission Delegated Regulation (EU) 2018/762⁷.

3. A vehicle for which a railway undertaking or an infrastructure manager is the keeper, may be exempted from the requirement of Paragraph 1, provided that:
 - 3.1. all maintenance concerning such vehicles is performed by the keeper of the vehicle without outsourcing maintenance activities, and
 - 3.2. concerning such vehicles, the safety management system of the keeper covers all maintenance functions required by Annex II, and is subject to a single safety certificate or a safety authorisation issued under Article 10 or Article 12 of Directive (EU) 2016/798 respectively, and
 - 3.3. the supervision of the continued compliance of the certified or authorised safety management system in respect to Annex II (of this Regulation) is ensured in accordance with Article 17 of Directive (EU) 2016/798.

Article 4

Safety-critical components

1. Safety-critical components shall be identified based on a risk assessment at any point during the lifecycle of the vehicle.
2. Safety-critical components of a new type of vehicle shall be recorded by its manufacturer in the technical files of subsystems referred to in Article 15(4) of Directive (EU) 2016/797.
3. If the risk assessment of a safety-critical component is modified or a new safety-critical component is identified during the maintenance of the vehicle the entity in charge of maintenance shall record that fact in the maintenance file or documentation referred to in Article 14 of Directive (EU) 2016/798.
4. In addition, the entity in charge of maintenance shall inform the manufacturer of new or modified safety critical componenets without delay, to allow it to take the necessary measures, including ensuring the revision of the technical file referred to in Article 15(4) of Directive (EU) 2016/797.
5. For managing safety-critical components, the entity in charge of maintenance shall give feedback to the railway undertakings and infrastructure managers operating the vehicles, keepers and manufacturers of vehicles, subsystems or components, as most appropriate and shall in particular, inform them of exceptional maintenance findings beyond wear and tear.
6. At the request of the entity in charge of maintenance or of the keeper of the vehicle, the manufacturers shall provide technical and engineering support for safety-critical components and their safe integration.

⁷ Commission Delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010 (OJ L 129, 25.5.2018, p. 26).

Article 5

Obligations of parties involved in the maintenance process

1. The entity in charge of the maintenance of the vehicle shall deliver information on the operation of a vehicle on the maintenance of a vehicle, to the railway undertakings or infrastructure managers at request, either directly or via the keeper.
2. The railway undertaking or the infrastructure manager shall deliver information on the operation of a vehicle to the entity in charge of maintenance at request, either directly or via the keeper of the vehicle.
3. All parties involved in the maintenance process such as railway undertakings, infrastructure managers, keepers, entities in charge of maintenance, as well as manufacturers of vehicles, subsystems or components, shall exchange relevant information about maintenance in accordance with the criteria listed in Sections I.7 and I.8 of Annex II.
4. Where any involved party, in particular a railway undertaking or an infrastructure manager, has evidence that an entity in charge of maintenance does not comply with Article 14 of Directive (EU) 2016/798 or with the certification requirements of this Regulation, it shall without delay inform the certification body or the relevant national safety authority thereof. The certification body shall take appropriate action to check whether the claim of non-compliance is justified.
5. Where there is a change of entity in charge of maintenance, the keeper, in accordance with Article 47(6) of Directive (EU) 2016/797, shall inform without delay the registration entity referred to in Article 4(1) of Commission Decision 2007/756/EC⁸ and request the update of the vehicle register. In that situation:
 - (i) the former entity in charge of maintenance shall without delay deliver the maintenance documentation to the keeper;
 - (ii) the former entity in charge of maintenance shall be relieved of its obligations when it is removed from the vehicle register;
 - (iii) in the absence of a new entity in charge of maintenance the registration of the vehicle shall be suspended.

Article 6

Certification bodies

1. Member States shall provide the Agency with the following information concerning the certification bodies :
 1. name
 2. address
 3. contact details
 4. areas of activities

⁸ Commission Decision 2007/756/EC of 9 November 2007 adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC (OJ L 305, 23.11.2007, p. 30).

5. the nature of their empowerment in accordance with Article 14 of Directive (EU) 2016/798 (accreditation, recognition or if they have taken on the task as the national safety authority)
6. Member States shall inform the Agency about any change in the situation within one month of the occurrence of that change.
7. Member States shall ensure that the certification bodies comply with the general criteria and principles set out in Annex I and with any specific sectoral accreditation schemes laid down by the relevant Union legislation.
8. Member States shall ensure that decisions taken by the certification bodies are subject to judicial review.
9. In order to harmonise approaches to the assessment of applications, the certification bodies shall cooperate with one another both within the Member States and across the Union.
10. The Agency shall organise and facilitate cooperation between the certification bodies.
11. The certification bodies shall deliver an activity report in an electronic form every 3 years to the Agency. The content of such a report shall be defined by the Agency (in collaboration with the certification bodies) and made available [*insert date — 18 months from the date of entry into force of the Regulation*] and in accordance with any specific sectoral accreditation schemes laid down by the relevant Union legislation. The Agency shall publish the reports on its website.
12. A national safety authority, a national investigation body or the Agency may request any certification body on the situation concerning an individual ECM certification. The certification body shall reply within 2 weeks at the latest.

Article 7

Certification of entities in charge of maintenance

1. The entity in charge of maintenance shall apply for ECM certification to a certification body. It shall use the relevant form in Annex III and provide documentary evidence for the requirements and procedures set out in Annex II. The application shall include the description of the system of surveillance to ensure continued compliance with the requirements set out in Annex II, after the award of the ECM certification.
2. The application for ECM certification may be limited to a specified type of vehicles.
3. The applicant shall submit supplementary information and documentation at the request of the certification body within 2 weeks or any longer delay indicated by the certification body.
4. The certification body shall verify the fulfilment of the requirements set out in Annex II. To that end, it may undertake site visits of the entity in charge of maintenance.
5. The certification body shall take a decision to award or refuse ECM certification at the latest 4 months after all the information and documentation has been submitted and received.

6. The certification body shall give the reasons for its decisions. It shall notify its decision to the entity in charge of maintenance, with an indication of the appeal process, the time limit for an appeal and the contact details of the appeal body.
7. The decision to award the ECM certification shall be notified using the relevant form set out in Annex IV.
8. An ECM certification shall be valid for a maximum period of 5 years. The certified entity in charge of maintenance shall inform the certification body of any changes that might have an impact on the validity of its certification without delay.

Article 8

Compliance of entities in charge of maintenance

1. The certification body shall conduct surveillance activities in respect of the entity in charge of maintenance to verify continued compliance with the requirements set out in Annex II. It shall conduct site visits at least once every 18 months, which may be limited to one site of each certified entity. The choice regarding the nature of surveillance activities and sites to be visited shall aim at ensuring overall continuing compliance and shall be based on a geographical and functional balance. It shall take account of previous surveillance activities of the entity in charge of maintenance surveilled.
2. Where the certification body finds that an entity in charge of maintenance no longer complies with the requirements on the basis of which it issued the ECM certification, it shall agree an improvement plan with the entity in charge of maintenance, or decide to limit the scope of the ECM certification, or suspend or revoke the certification, depending on the extent of non-compliance.
3. Where the entity in charge of maintenance does not follow the improvement plan or continuously not to compliance with the requirements set out in Annex II, the certification body shall decide to limit the scope of or revoke the ECM certification, depending on the degree of non-compliance.
4. In case of revocation of an ECM certification, the entity in charge of the national or European vehicle register shall ensure suspension of the registration of vehicles affected by the revocation, until a new entity in charge of maintenance is registered for the vehicles concerned.
5. Each entity in charge of maintenance shall submit an annual report of its activities to its certification body and make it available to the national safety authority and to the Agency upon request. The requirements for this report are set out in Annex V.

Article 9

Outsourcing maintenance functions

1. One or more of the functions referred to in points (b), (c) and (d) of Article 14(3) of Directive (EU) 2016/798, or parts thereof, may be outsourced and the certification body shall be informed thereof.
2. The entity in charge of maintenance shall demonstrate to the certification body how it complies with all the requirements and assessment criteria set out in Annex II with regard to the functions it decided to outsource.

3. The entity in charge of maintenance shall remain responsible for the outcome of the outsourced maintenance activities and shall establish a system to monitor their performance.

Article 10

Certification for outsourced maintenance functions

1. A certification may be requested by any entity or organisation taking on one or more maintenance functions as referred to in points (b), (c) and (d) of Article 14(3). Such a voluntary certification shall imply that the maintenance carried out by the entity or organisation concerned of one or more of those functions complies with the relevant requirements set out in Annex II.
2. Certification bodies shall apply the procedures set out in Articles 6, 7, 8 and 13(4) adapted to the specific case of the applicant.

In assessing applications for certification in respect of outsourced maintenance functions or parts thereof, certification bodies shall apply:

- (a) the requirements and assessment criteria set out in Section I of Annex II, adapted to the organisation's type and extent of service;
- (b) the requirements and assessment criteria describing the specific maintenance function or functions.

Article 11

Role of the national safety authorities

If a national safety authority has knowledge that an entity in charge of maintenance does not comply with the requirements of Annex III of Directive (EU) 2016/798 or with the certification requirements of this Regulation, it shall inform the national authorities responsible for the accreditation or recognition and the Agency.

Article 12

Monitoring of the certification bodies

1. The Agency shall support the harmonised system of certification through the provision of:
 - (a) assistance to national accreditation bodies and to the relevant national authorities recognising the certification bodies;
 - (b) cooperation on appropriate accreditation and certification schemes. Those schemes shall set out evaluation criteria and procedures to assess compliance of certification bodies with the requirements set out in Annex I (via the European accreditation infrastructure pursuant to Article 14 of Regulation (EC) No 765/2008).
2. The Agency may audit the capacity of certification bodies to meet the requirements set out in Annex I. In the case of accredited certification bodies, the Agency shall cooperate with the relevant national accreditation bodies. In the case of certification bodies, which are not accredited, the Agency shall cooperate with the relevant national authorities that recognised the certification bodies. The criteria and procedure for audits shall be adopted by the Management Board of the Agency.

3. If the Agency considers that the deficiencies identified pursuant to paragraph 2 prevent the certification body concerned from effectively performing tasks set out in this Regulation, the Agency shall issue a recommendation requesting the national accreditation body to take appropriate steps, within a mutually agreed time limit, taking into account the seriousness of the deficiency. The national accreditation body shall request the certification body to adopt appropriate measures to solve the deficiencies. If the certification body fails to take such measures within the time limit indicated by the accreditation body, its accreditation shall be revoked.
4. The Agency shall be entitled to conduct pre-announced or unannounced inspections of certification bodies, to verify specific areas of their activities, including in alleged cases of non-compliance. The Agency shall be given access to all relevant documents and records. In the case of accredited certification bodies, the Agency shall cooperate with the relevant national accreditation bodies. In the case of certification bodies which are not accredited, the Agency shall cooperate with the relevant national authorities that recognised the certification bodies concerned.
5. Inspections shall be conducted in accordance with the policy, working methods and procedures adopted by the Management Board of the Agency.
6. The duration of an inspection shall not exceed two days. The certification bodies shall facilitate the work of the Agency's staff.
7. The Agency shall address reports of audits or inspections to the certification body and the national accreditation body or to the Member State concerned. Each report shall include the concrete circumstances and scope of the audit/inspection activities and where appropriate, the list of deficiencies identified by the Agency and proposals for remedies to rectify deficiencies.
8. The Agency shall publish a comprehensive report on its audit and inspection activities, including experience drawn from these activities, on its website, by [*insert date — three years from the date of entry application*] and every 2 years thereafter.

Article 13

Provision of information

1. The Agency shall collect, record and publish basic information on certification bodies and certified entities in charge of maintenance. The Agency shall create an IT tool for delivering this task.
2. In case of recognition or when the national safety authority carries out the tasks of a certification body, Member States shall notify the Agency of the recognised certification bodies by providing their names, addresses and contact details.
3. In case of accreditation, the accreditation bodies shall notify the Agency of the accredited certification bodies by providing their names, addresses and contact details. Any change in the situation of the certification bodies shall be notified to the Agency within one month following the occurrence of that change.
4. Certification bodies shall notify the Agency of all issued, amended, renewed, suspended or revoked ECM certifications or of all certifications for functions as referred to in points (b), (c) and (d) of Article 14(3) of Directive (EU) 2016/798, within one week from its decision, using the forms set out in Annex IV.

Article 14

Reporting

The Agency shall address to the Commission a first report on the implementation of this Regulation five years following its entry into force. The Agency shall address subsequent reports on the implementation of this Regulation every three years following the first report.

Article 15

Transitional provisions

1. Certification bodies accredited or recognised pursuant to Regulation (EU) 445/2011 shall be deemed accredited or recognised in accordance with this Regulation under the conditions for which those certification bodies have been accredited or recognised.
2. The certification for an entity in charge of maintenance for vehicles other than freight wagons, issued by the certification body on the basis of national laws, applicable in the field governed by this Regulation, before [*insert date — one year from the date of entry into force of the Regulation*] shall be recognised as being equivalent to ECM certification for their original period of validity or at the latest, until [*insert date — 4 years from the date of entry into force of the Regulation*].
3. Attestations of conformity with the principles and criteria equivalent to the requirements of Annex III of Regulation (EU) 445/2011 issued by a certification body by [*insert date — the date of entry into force of the Regulation*] at the latest, shall be deemed equivalent to ECM certifications issued under this Regulation for their original period of validity or at the latest, until [*insert date — 4 years from the date of entry into force of the Regulation*].
4. Certificates for outsourced maintenance functions for vehicles other than freight wagons, issued by the certification body by [*insert date — three year from the date of entry into force of the Regulation*] at the latest, on the basis of national laws applicable in the field governed by this Regulation before its entry into force shall be deemed equivalent to ECM certifications for outsourced maintenance functions issued under this Regulation for their original period of validity or at the latest, until [*insert date — 6 years from the date of entry into force of the Regulation*].

Article 16

Repeal

Regulation (EU) No 445/2011 is repealed with effect from [*insert date — one year after the date of entry into force of the Regulation*].

Certificates issued under Regulation (EU) 445/2011 by a certification body shall be deemed equivalent to certificates issued under this Regulation for their original period of validity.

Article 17

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*insert date — one year from the date of entry into force of the Regulation*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission
The President
Jean-Claude Juncker*

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