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## Legislation

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<sup>(1)</sup> Text with EEA relevance.

# EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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## II

(Non-legislative acts)

## INTERNATIONAL AGREEMENTS

**Notice concerning the entry into force of the Agreement between the European Union and its Member States, of the one part, and Iceland, of the other part, concerning Iceland's participation in the joint fulfilment of the commitments of the European Union, its Member States and Iceland for the second commitment period of the Kyoto Protocol to the United Nations Framework Convention on Climate Change**

The Agreement between the European Union and its Member States, of the one part, and Iceland, of the other part, concerning Iceland's participation in the joint fulfilment of the commitments of the European Union, its Member States and Iceland for the second commitment period of the Kyoto Protocol to the United Nations Framework Convention on Climate Change <sup>(1)</sup>, signed in Brussels on 1 April 2015, enters into force on 27 November 2018, in accordance with Article 11 of the Agreement, as the last instrument of ratification was deposited on 29 August 2018.

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<sup>(1)</sup> OJ L 207, 4.8.2015, p. 17.

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**Notice concerning the entry into force of the Agreement in the form of an Exchange of Letters between the European Union and the Kingdom of Norway concerning additional trade preferences in agricultural products**

The Agreement in the form of an Exchange of Letters between the European Union and the Kingdom of Norway concerning additional trade preferences in agricultural products <sup>(1)</sup> will enter into force on 1 October 2018, the procedure provided for in point (15) of the Agreement having been completed on 16 July 2018.

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<sup>(1)</sup> OJ L 129, 25.5.2018, p. 3.

# REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) 2018/1293

of 26 September 2018

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food lactitol

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 <sup>(1)</sup>, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 <sup>(2)</sup> was adopted, which establishes a Union list of authorised novel foods.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on the updating of the Union list.
- (4) Commission Implementing Decision (EU) 2017/450 <sup>(3)</sup> authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council <sup>(4)</sup>, the placing on the market of lactitol as a novel food to be used in capsule or tablet in food supplements intended for the adult population.
- (5) On 22 March 2018, the company DuPont Nutrition Biosciences ApS made a request to the Commission to change the conditions of use of the novel food lactitol within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to include powder as an allowed form of lactitol to be used in food supplements.
- (6) The Commission did not request an opinion from the European Food Safety Authority in accordance with Article 10(3) as the amendment of the conditions of use of the novel food lactitol by including powder, as an allowed form of lactitol to be used in food supplements is not liable to have an effect on human health.
- (7) The maximum level of lactitol authorised by Implementing Decision (EU) 2017/450 as a novel food to be used in capsule or tablet in food supplements is 20 g/day. The proposed use level of the novel food lactitol in powder form in the same food category corresponds to the maximum level that is currently authorized. Therefore, it is appropriate to amend the conditions of use of lactitol to authorise its use in powder form at the existing maximum authorised level.
- (8) The information provided in the application gives sufficient grounds to establish that the application for changing of the conditions of use of the novel food lactitol by including powder, as an allowed form of lactitol to be used in food supplements, comply with Article 12(2) of Regulation (EU) 2015/2283.

<sup>(1)</sup> OJ L 327, 11.12.2015, p. 1.

<sup>(2)</sup> Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

<sup>(3)</sup> Commission Implementing Decision (EU) 2017/450 of 13 March 2017 authorising the placing on the market of lactitol as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 69, 15.3.2017, p. 31).

<sup>(4)</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

- (9) Directive 2002/46/EC of the European Parliament and of the Council <sup>(1)</sup> lays down requirements on food supplements. The additional form of lactitol to be used in food supplements should be authorised without prejudice to that Directive.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

1. The entry in the Union list of authorised novel foods as provided for in Article 8 of Regulation (EU) 2015/2283 referring to the substance lactitol shall be amended as specified in the Annex to this Regulation.
2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.
3. The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

*Article 2*

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

*Article 3*

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

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

Done at Brussels, 26 September 2018.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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<sup>(1)</sup> Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

ANNEX

The entry for 'Lactitol' in Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470 is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Lactitol	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the food supplements containing it shall be "Lactitol"	
	Food Supplements as defined in Directive 2002/46/EC (capsules, tablets or powder) intended for the adult population	20 g/day		

**COMMISSION IMPLEMENTING REGULATION (EU) 2018/1294****of 26 September 2018****concerning the non-approval of Landes pine tar as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC <sup>(1)</sup>, and in particular Article 23(5) in conjunction with Article 13(2) thereof,

Whereas:

- (1) On 22 December 2015, the Commission received an application from Progarein France SAS for the approval of Landes pine tar as a basic substance. That application was accompanied by the information required under the second subparagraph of Article 23(3) of Regulation (EC) No 1107/2009.
- (2) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance. The Authority provided the Commission with a technical report on Landes pine tar on 30 October 2017 <sup>(2)</sup>. The Commission presented the review report <sup>(3)</sup> and the draft of this Regulation on the non-approval of Landes pine tar to the Standing Committee on Plants, Animals, Food and Feed on 24 May 2018 and finalised them for the meeting of that Committee on 20 July 2018.
- (3) The documentation provided by the applicant does not show that Landes pine tar fulfils the criteria of a foodstuff as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(4)</sup>.
- (4) Specific concerns however were identified, in the technical report of the Authority, regarding Landes pine tar. Landes pine tar is a complex mixture, the exact composition of which is unknown. Landes pine tar should be considered as a substance of concern since it can contain substances of concern (e.g. furfurals, phenols). Furthermore the presence of substances of very high concern cannot be excluded (e.g. genotoxic carcinogens such as polycyclic aromatic hydrocarbons). Furthermore, assessment of the risk to operators, workers, bystanders and consumers could not be finalised based on the data available in the application.
- (5) No relevant evaluation, carried out in accordance with other Union legislation as referred to in Article 23(2) of Regulation (EC) No 1107/2009, was available.
- (6) The Commission invited the applicant to submit its comments on the technical report of the Authority and on the Commission's draft review report. The applicant submitted its comments, which have been carefully examined.
- (7) However, despite the arguments put forward by the applicant, the concerns related to the substance cannot be eliminated.
- (8) Consequently, as laid down in the Commission's review report, it has not been established that the requirements laid down in Article 23 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to approve Landes pine tar as a basic substance.
- (9) This Regulation does not prejudice the submission of a further application for the approval of Landes pine tar as a basic substance in accordance with Article 23(3) of Regulation (EC) No 1107/2009.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> EFSA (European Food Safety Authority), 2017. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for Landes pine tar for use in plant protection as protectant and repellent. EFSA supporting publication 2017:EN-1311. 57 pp.

<sup>(3)</sup> <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>.

<sup>(4)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

The substance Landes pine tar is not approved as a basic substance.

*Article 2*

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

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

Done at Brussels, 26 September 2018.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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**COMMISSION IMPLEMENTING REGULATION (EU) 2018/1295****of 26 September 2018****approving the basic substance Onion oil in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC <sup>(1)</sup>, and in particular Article 23(5) in conjunction with Article 13(2) thereof,

Whereas:

- (1) On 12 December 2016 the Commission received an application from Bionext, for the approval of Onion oil as a basic substance. That application was later completed by the information required by the second subparagraph of Article 23(3) of Regulation (EC) No 1107/2009.
- (2) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance. The Authority provided the Commission with a technical report on Onion oil on 31 October 2017 <sup>(2)</sup>.
- (3) The Commission presented the draft review report <sup>(3)</sup> on 25 May 2018 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 19 July 2018 and finalised them for the meeting of that Committee on 20 July 2018.
- (4) The documentation provided by the applicant shows that Onion oil fulfils the criteria of a foodstuff as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(4)</sup>. Moreover, it is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance. Consequently, it is to be considered as a basic substance.
- (5) It has appeared from the examinations made that Onion oil may be expected to satisfy, in general, the requirements laid down in Article 23 of Regulation (EC) No 1107/2009, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve Onion oil as a basic substance.
- (6) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions for the approval which are detailed in Annex I to this Regulation.
- (7) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(5)</sup> should be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1***Approval of a basic substance**

The substance Onion oil is approved as a basic substance as laid down in Annex I.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.<sup>(2)</sup> EFSA (European Food Safety Authority), 2017. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for onion oil for use in plant protection as repellent. EFSA supporting publication 2017:EN-1315. 36 pp. doi:10.2903/sp.efsa.2017.EN-1315.<sup>(3)</sup> <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>.<sup>(4)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).<sup>(5)</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

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*Article 2***Amendments to Implementing Regulation (EU) No 540/2011**

Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

*Article 3***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*.

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

Done at Brussels, 26 September 2018.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Specific provisions
Onion oil CAS No: 8002-72-0	Not applicable	Food grade	17 October 2018	Onion oil shall be used in accordance with the specific conditions included in the conclusions of the review report on Onion oil (SANTE/10615/2018) and in particular Appendices I and II thereto.

<sup>(1)</sup> Further details on identity, specification and manner of use of the basic substance are provided in the review report.

## ANNEX II

In Part C of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Specific provisions
'20	Onion oil CAS No: 8002-72-0	Not applicable	Food grade	17 October 2018	Onion oil shall be used in accordance with the specific conditions included in the conclusions of the review report on Onion oil (SANTE/10615/2018) and in particular Appendices I and II thereto.

<sup>(1)</sup> Further details on identity, specification and manner of use of basic substance are provided in the review report.

# DECISIONS

## COUNCIL DECISION (EU) 2018/1296

of 18 September 2018

**establishing the position to be adopted on behalf of the European Union at the 13th General Assembly of the Intergovernmental Organisation for International Carriage by Rail (OTIF) as regards certain amendments to the Convention concerning International Carriage by Rail (COTIF) and to the Appendices thereto**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91, in conjunction with Article 218(9), thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Union acceded to the Convention concerning International Carriage by Rail of 9 May 1980, as amended by the Vilnius Protocol of 3 June 1999 (the 'COTIF Convention'), pursuant to Council Decision 2013/103/EU <sup>(1)</sup>.
- (2) Decision 2013/103/EU specifies that the Commission is to represent the Union at the meetings of the Intergovernmental Organisation for International Carriage by Rail (OTIF).
- (3) The Member States, with the exception of Cyprus and Malta, are contracting parties to and apply the COTIF Convention.
- (4) The General Assembly of OTIF was set up in accordance with point (a) of Article 13(1) of the COTIF Convention (the 'General Assembly'). At its 13th session, due to take place from 25 to 26 September 2018, the General Assembly is expected to decide upon certain amendments to the COTIF Convention as well as to the Appendices E (Contract of Use of Infrastructure in International Rail Traffic — CUI) and G (Technical Admission of Railway Material used in International Traffic — ATMF) thereto. At this session, the General Assembly is also expected to decide upon the adoption of a new Appendix H to the COTIF Convention regarding the safe operation of trains in international traffic.
- (5) It is appropriate to establish the position to be adopted on behalf of the Union at the 13th General Assembly OTIF, as the envisaged amendments to the COTIF Convention and the Appendices thereto will be binding on the Union and capable of decisively influencing the content of Union law, namely Directives (EU) 2016/797 <sup>(2)</sup> and (EU) 2016/798 <sup>(3)</sup> of the European Parliament and of the Council.
- (6) The amendments to the Rules of Procedure of the General Assembly of OTIF aim to update certain provisions as a result of the accession of the Union to the COTIF Convention in 2011, in particular with regard to provisions governing the right to vote of the regional organisation and establishing the quorum.
- (7) The amendments to the COTIF Convention aim to improve and facilitate the procedure for revising the COTIF Convention with a view to the consistent and rapid implementation of amendments to the Appendices thereto, and in order to prevent adverse effects of the current lengthy revision procedure, including the risk of internal misalignment between amendments adopted by the Revision Committee and those adopted by the General Assembly, as well as external misalignment, in particular with Union law.

<sup>(1)</sup> Council Decision 2013/103/EU of 16 June 2011 on the signing and conclusion of the Agreement between the European Union and the Intergovernmental Organisation for International Carriage by Rail on the Accession of the European Union to the Convention concerning International Carriage by Rail (COTIF) of 9 May 1980, as amended by the Vilnius Protocol of 3 June 1999 (OJ L 51, 23.2.2013, p. 1).

<sup>(2)</sup> 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).

<sup>(3)</sup> Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (OJ L 138, 26.5.2016, p. 102).

- (8) The amendments to Appendix E (CUI) to the COTIF Convention aim to clarify the scope of application of the CUI Uniform Rules to ensure that those rules are more systemically applied for their intended purpose, namely in international railway traffic such as in freight corridors or for international passenger trains.
- (9) The amendments to Appendix G (ATMF) to the COTIF Convention aim to achieve harmonisation between the OTIF rules and the Union rules, in particular after the adoption of the fourth railway package by the Union in 2016.
- (10) Most of the proposed amendments are in line with the law and the strategic objectives of the Union, and should therefore be supported by the Union.
- (11) The position of the Union at the 13th General Assembly of OTIF should therefore be based on the Attachment,

HAS ADOPTED THIS DECISION:

*Article 1*

1. The position to be adopted on behalf of the Union at the 13th General Assembly of the Intergovernmental Organisation for International Carriage by Rail (OTIF) is set out in the Attachment.
2. Minor changes to the positions set out in the Attachment may be agreed by the representatives of the Union at the General Assembly without further decision of the Council.

*Article 2*

The Decisions of the 13th General Assembly, once adopted, shall be published in the *Official Journal of the European Union*, indicating the date of their entry into force.

*Article 3*

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 18 September 2018.

*For the Council*  
*The President*  
G. BLÜMEL

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## ATTACHMENT

## 1. INTRODUCTION

The 13th session of the General Assembly of the Intergovernmental Organisation Convention for International Carriage by Rail (OTIF) will take place on 25 and 26 September 2018. The meeting documents are available on the website of OTIF at the following link: [http://extranet.otif.org/en/?page\\_id=1071](http://extranet.otif.org/en/?page_id=1071).

## 2. COMMENTS ON AGENDA ITEMS

**Agenda Item 1 – Election of the Chair and Vice-Chair**

*Document(s):* None

*Competence:* Union (shared)

*Exercise of voting rights:* Member States

*Position:* None

**Agenda Item 2 – Adoption of the agenda**

*Document(s):* SG-18028-AG 13/2.1; SG-18047-AG 13/2.2

*Competence:* Union (shared and exclusive), without prejudice to the competences of the Member States in respect of agenda item 9

*Exercise of voting rights:* Union, without prejudice to the competences of the Member States in respect of agenda item 9

*Position:* In favour of the adoption of the agenda

**Agenda Item 3 – Formation of the Credentials Committee**

*Document(s):* None

*Competence:* Union (shared)

*Exercise of voting rights:* Member States

*Position:* None

**Agenda Item 4 – Organisation of the work and designation of any Committees considered necessary**

*Document(s):* None

*Competence:* Union (shared)

*Exercise of voting rights:* Member States

*Position:* None

**Agenda Item 5 – Modification of the Rules of Procedure**

*Document(s):* SG-18030-AG 13/5

*Competence:* Union (shared and exclusive)

*Exercise of voting rights:* Union

*Position:* Support the amendments to the Rules of Procedure of the General Assembly.

The proposed draft amendments to the Rules of Procedure of the General Assembly of OTIF relate to the deadlines for submitting and dispatching documents, the participation of independent experts and clarification of the provisions relating to the exercising of rights by regional organisations. The current version of the Rules of Procedure predates the Union's accession to the COTIF Convention; certain provisions need therefore to be updated, in particular the provisions establishing the quorum and governing the rights to vote of the Union (Articles 20 and 21), which have to be modified in order to comply with Article 38 of the COTIF Convention and with the EU-OTIF Agreement. The other modifications proposed aim to ensuring orderly proceedings of the General Assembly on the basis of the best available international practice and OTIF's practice; they should also be supported.

**Agenda Item 6 – Election of a Secretary-General for the period from 1 January 2019 to 31 December 2021**

*Document(s):* Restricted distribution

*Competence:* Union (shared)

*Exercise of voting rights:* Member States

*Position:* None

**Agenda Item 7 – Membership of OTIF – general situation**

*Document(s):* SG-18032-AG 13/7

*Competence:* Union (shared)

*Exercise of voting rights:* not applicable

*Position:* None

**Agenda Item 8 – Cooperation with international organisations and associations**

*Document(s):* SG-18048-AG 13/8

*Competence:* Union (shared and exclusive)

*Exercise of voting rights:* Union

*Position:*

Oppose the proposal from the OTIF Secretariat that the General Assembly should authorise the Administrative Committee to establish and dissolve consultative contact groups with other international organisations and associations, and supervise the functioning of contact groups.

Propose that, in accordance with Article 13 § 2 of the COTIF Convention, the General Assembly decides to establish temporarily, i.e. for a period of four years, an *ad hoc* committee entrusted with the task to establish and dissolve consultative contact groups with other international organisations and associations, and supervise the functioning of contact groups. The Union should be entitled to participate in the work of the *ad hoc* Committee in accordance with 5(1) of the Accession agreement. The activities of the Committee should be guided by and in line with OTIF's work programme.

The proposal from the OTIF Secretariat consists in a decision of the General Assembly authorising the Administrative Committee to be empowered to establish and dissolve consultative contact groups with other international organisations and associations, and to supervise the functioning of such groups. At this stage, the Union shares the objective, namely to allow for a degree of flexibility in the matters concerned. However, it cannot accept the proposal as such, since it amounts to conferring a new task upon the Administrative Committee, beyond those set out in Article 15 § 2 of the COTIF Convention, without formal amendment of the latter, operated in accordance with the applicable procedures.

Since the Union shares the general objective, however, it suggests the General Assembly to establish temporarily an *ad hoc* committee, in accordance with Article 13 § 2 of the Convention, with the task to establish and dissolve consultative contact groups with other international organisations and associations, and to supervise the functioning of such groups. In this respect, it is important to bear in mind that such tasks have practical implications for the development of policies at OTIF level in all areas. It is thus necessary to guarantee that the Union is fully involved in these activities, in accordance with Article 5(1) of the Accession Agreement.

A period of four years should be appropriate, so as to judge, prior to its expiration, whether the experience gained is satisfactory. In the affirmative, and following due preparation, an amendment of the Convention could be envisaged for a structural solution, in compliance with the guarantees for the Union established by Article 5(1) of the Accession Agreement.

**Agenda Item 9 – Budget framework**

*Document(s):* Restricted distribution

*Competence:* Member States

*Exercise of voting rights:* Member States

*Position:* None

Pursuant to Article 4 of the EU-OTIF Agreement, 'The Union shall not contribute to the budget of OTIF and shall not take part in decisions concerning that budget.'



**Agenda Item 10 – Partial revision of the base Convention: amendment of the procedure for revising COTIF**

*Document(s):* SG-18035-AG 13/10

*Competence:* Union (shared)

*Exercise of voting rights:* Member States

*Position:* Support the amendment to Article 34 §§ 3 to 6 of the COTIF Convention and approve the modifications to the Explanatory Report.

In line with the outcome of the discussion on this topic at the 26th session of the Revision Committee, it is necessary and appropriate to support the proposed amendment to the COTIF Convention, in order to provide for a fixed time period (36 months) for the entry into force of amendments to the Appendices adopted by the General Assembly, including the clause of flexibility to extend such a deadline on a case-by-case basis, where so decided by the General Assembly by the majority provided for under Article 14 § 6 of COTIF Convention.

The proposal aims at improving and facilitating the procedure for revising the COTIF Convention with a view to the consistent and rapid implementation of amendments to the Convention and its Appendices, and in order to prevent adverse effects of the current lengthy revision procedure, including the risk of internal misalignment between amendments adopted by the Revision Committee and those adopted by the General Assembly, as well as external misalignment, particularly with Union law.

**Agenda Item 11 – Partial revision of the CIM UR – Secretary General's report**

*Document(s):* SG-18036-AG 13/11

*Competence:* Union (shared and exclusive)

*Exercise of voting rights:* Union (in case a vote takes place)

*Position:* Take note of the Secretary General's report and instruct the Secretary-General to submit to the 14th General Assembly a report on the progress of work on customs issues and the digitalisation of freight transport documents and, if necessary, to submit proposals to amend the CIM UR.

**Agenda Item 12 – Partial revision of the CUI UR**

*Document(s):* SG-18037-AG 13/12

*Competence:* Union (shared)

*Exercise of voting rights:* Member States

*Position:*

Support the amendments to the Title and Articles 1, 3, 5 (§ 1), 5 bis (§§ 1 and 2), 7 (§ 2), 8, 9 (§1) and 10 (§3) of the CUI UR, and approve the modifications to the Explanatory Report.

Support, for the purpose of the modifications to the CUI UR, the amendments to Articles 2 (§ 1, letter a), No 3) and 6 (§ 1, letter e)) of the COTIF Convention.

In line with the amendments approved during the 26th session of the Revision Committee in February 2018, the proposed modifications aim essentially at clarifying the scope of the CUI UR by introducing a definition in Article 3 of 'international railway traffic' to mean 'traffic which requires the use of an international train path or several successive national train paths situated in at least two States and coordinated by the infrastructure managers concerned', and by amending Article 1 (Scope) accordingly, while keeping the link with CIV and CIM UR. The objective is to ensure that the CUI UR are more systemically applied for their intended purpose, i.e. in international railway traffic.

The draft amendments are consistent with the definitions and provisions of the Union *acquis* regarding the management of rail infrastructure and the coordination between infrastructure managers (e.g. Articles 40, 43 and 46 of Directive 2012/34/EU (recast)). As regards the draft amendment proposed to Article 8 (Liability of the manager), this is essentially editorial and does not affect the scope or substance of the provision. The draft amendments proposed to Article 9 as well as to Articles 3, 5, 5bis, 7 and 10 are strictly editorial.

**Agenda Item 13 – Partial revision of the ATMF UR**

*Document(s):* SG-18038-AG 13/13

*Competence:* Union (exclusive)

*Exercise of voting rights:* Union

*Position:* Support the partial revision of the ATMF UR as proposed by the OTIF Secretariat.

A partial revision of the ATMF UR was adopted at the 26th session of the Revision Committee for the reasons described in the following paragraph. This revision however also implied some minor changes of editorial or linguistic nature to Articles 1, 3 and 9 of ATMF UR, which are outside the competence of the Revision Committee. They should thus be adopted by the General Assembly.

The provisions of the ATMF UR are compatible with the provisions of the European Union's Interoperability Directive 2008/57/EC and with part of the Safety Directive 2009/49/EC. With the adoption of the fourth railway package, the Union changed several provisions of this *acquis*. On the basis of an analysis by the Commission, the OTIF Secretariat and the relevant working group prepared modifications concerning Articles 2, 3a, 5, 6, 7, 10, 10b, 11 and 13 of the ATMF UR. These modifications are necessary in order to harmonise some terminology with the new EU provisions and to take into account some procedural changes in the EU, in particular the fact that the EU Agency for Railways will be competent to issue vehicle authorisations. The basic concept of ATMF is not affected by the proposed changes.

**Agenda Item 14 – New Appendix H regarding the safe operation of trains in international traffic**

*Document(s):* SG-18039-AG 13/14.1; SG-18040-AG 13/14.2

*Competence:* Union (exclusive)

*Exercise of voting rights:* Union

*Position:*

Support (SG-18039-AG 13/14.1) the inclusion of a new Appendix H to the COTIF Convention regarding the safe operation of trains in international traffic and approve the modifications to the Explanatory Report.

Support (SG-18040-AG 13/14.2), for the purpose of the inclusion of a new Appendix H, the modifications to Articles 2 (§ 1), 6 (§ 1), 20 (§§ 1 and 2), 33 (§§ 4 and 6) and 35 (§§4 and 6) of the COTIF Convention and approve the modifications to the Explanatory Report.

The draft new Appendix H sets out provisions to regulate the safe operation of trains in international traffic with the objective to harmonise the COTIF Convention with the Union's *acquis* and support interoperability beyond the European Union. The proposed text is in line with the provisions of the new safety Directive (EU) 2016/798 and the related secondary legislation. As indicated, it is also necessary to modify certain provisions of the COTIF Convention for the purpose of the inclusion of this new Appendix H.

The proposed texts are submitted to the General Assembly pursuant to a decision of the 26th session of the Revision Committee and are fully in line with the Union position that was defined ahead of the Revision Committee.

**Agenda Item 15 – General discussion regarding the need to harmonise access conditions**

*Document(s):* SG-18041-AG 13/15

*Competence:* Union (exclusive)

*Exercise of voting rights:* Union

*Position:* Support the proposal from the OTIF Secretariat to mandate the Secretary-General to continue the work on the development of a non-binding legal framework on international railway network access conditions, in accordance with the guidelines set out section VI of document SG-18041-AG 13/15, within the framework of the working group of legal experts and in cooperation with competent international organisations and associations.

The subject matter – railway network access conditions – is regulated at EU level by Directive 2012/34/EC (recast) of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area. In line with the discussion that took place on this topic during the 26th session of the Revision Committee in February 2018, it is appropriate to continue supporting the initiative on the development by OTIF of a non-binding legal framework on railway network access conditions, as a means to facilitate and improve international railway traffic beyond the EU.

**Agenda Item 16 – Unified Railway Law – Secretary General’s report**

*Document(s):* SG-18042-AG 13/16

*Competence:* Union (shared)

*Exercise of voting rights:* Member States

*Position:*

Take note of the Secretary General’s report and instruct the Secretary-General to continue cooperation with UNECE on the Unified Railway Law initiative.

Mandate the Administrative Committee to follow up the UNECE initiative on Unified Railway Law and issue its advisory opinion on general policy issues, where feasible, and mandate the Working Group of Legal experts to follow up the UNECE initiative on Unified Railway Law and issue its advisory opinion on legal matters, where feasible.

Instruct the Secretary-General and the Working Group of Legal Experts, in consultation with the Administrative Committee, to consider and propose solutions for appropriate OTIF involvement in the management of binding legal instruments which could take over the Draft Legal Regime on the contract of carriage of goods as developed within the framework of the UNECE initiative on Unified Railway Law, and instruct the Secretary-General to submit a report to the 14th General Assembly.

While a single international legal regime may provide benefits for rail transport across the Eurasian continent in comparison to the two legal systems that exist at present, such a single regime could be developed only with the clear commitment and participation of OSJD and OTIF and their members – otherwise a third international legal regime will be developed and international railway regulation will be further fragmented. Consequently, a prior political decision by the existing organisations to coordinate this aim is necessary before any comprehensive legal system can be put in place. It is therefore necessary and appropriate to ensure that OTIF continues to be involved in this process, notably through the activities of its Administrative Committee and its Working Group of Legal Experts, and reports on the progress of the work at UNECE at the next meeting of the General Assembly.

**Agenda Item 17 – Working group of legal experts**

*Document(s):* SG-18046-AG 13/17

*Competence:* Union (shared)

*Exercise of voting rights:* Member States

*Position:*

Endorse the setting up of an advisory working group of legal experts to: prepare draft amendments or supplements to the Convention; provide legal advice and assistance, promote and facilitate the functioning and implementation of the COTIF Convention, monitor and assess the application and implementation of the COTIF Convention, act as a forum for OTIF’s members to raise and discuss relevant legal issues.

Mandate the Secretary-General to submit conclusions and proposals made by the working group to the competent organs of OTIF for consideration and/or decision.

Instruct the Secretary-General to submit a report on the working group’s activities at the 14th meeting of the General Assembly.

In line with the outcome of the discussion on this topic at the 26th session of the Revision Committee in February 2018, it is appropriate to endorse the creation of a standing group of legal experts within OTIF to assist and facilitate the functioning of the existing organs in the legal field and to ensure the effective management of the COTIF Convention.

**Agenda Item 18 – Report on the activities of the Administrative Committee in the period between 1 October 2015 and 30 September 2018**

*Document(s):* Restricted distribution

*Competence:* Union (shared)

*Exercise of voting rights:* Member States

*Position:* Take note of the report

**Agenda Item 19 – Election of the Administrative Committee for the period between 1 October 2018 and 30 September 2021 (composition and chair)**

*Document(s):* Restricted distribution

*Competence:* Union (shared)

*Exercise of voting rights:* Member States

*Position:* None

**Agenda Item 20 – Provisional date of the 14th General Assembly**

*Document(s):* None

*Competence:* not applicable

*Exercise of voting rights:* not applicable

*Position:* None

**Agenda Item 21 – Any other business**

*Document(s):* Not available

*Competence:* Not applicable

*Exercise of voting rights:* Not applicable

*Position:* None

**Agenda Item 22 – Any General Assembly mandates**

*Document(s):* None

*Competence:* Union (shared and exclusive)

*Exercise of voting rights:* Union

*Position:* Mandates in accordance with agenda item 8

**Agenda Item 23 – Committee reports, if necessary**

*Document(s):* Not available

*Competence:* Not applicable

*Exercise of voting rights:* Not applicable

*Position:* None

**Agenda Item 24 – Adoption of decisions, mandates, recommendations and other General Assembly documents (final document)**

*Document(s):* Not available

*Competence:* Union (shared and exclusive)

*Exercise of voting rights:* Union

*Position:* As specified under relevant agenda items.

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**COMMISSION IMPLEMENTING DECISION (EU) 2018/1297****of 25 September 2018****on a derogation from mutual recognition of the authorisation of biocidal products containing creosote by France in accordance with Article 37 of Regulation (EU) No 528/2012 of the European Parliament and of the Council***(notified under document C(2018) 5412)***(Only the French text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products <sup>(1)</sup>, and in particular Article 37(2)(b) thereof,

Whereas:

- (1) The companies Bilbaina de Alquitranes, SA, Koppers International BV and Rain Carbon BVBA ('the applicants') submitted complete applications to France for mutual recognition of three authorisations granted by Sweden in respect of three biocidal product families of wood preservatives containing the active substance creosote ('the products'). Sweden authorised the products for the treatment of poles for overhead electricity and telecommunication ('transmission poles') and railway sleepers by professional users.
- (2) Creosote is classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council <sup>(2)</sup> as carcinogen category 1B. Creosote also meets the criteria for being a persistent, bioaccumulative and toxic substance (PBT substance), or a very persistent and very bioaccumulative substance (vPvB substances) according to Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council <sup>(3)</sup>. Therefore, it meets the exclusion criteria set out in points (a) and (e) of Article 5(1) of Regulation (EU) No 528/2012. In accordance with the third subparagraph of Article 5(2) of Regulation (EU) No 528/2012, the use of biocidal products containing creosote is to be restricted to Member States in which at least one of the conditions set out in that paragraph is met.
- (3) France considered that none of the conditions of Article 5(2) of Regulation (EU) No 528/2012 were satisfied concerning the treatment of transmission poles in its territory and that refusal of authorisation for this use was justified on grounds of the protection of the environment and of the health and life of humans, as referred to in points (a) and (c) of Article 37(1) of Regulation (EU) No 528/2012, respectively. Therefore, pursuant to Article 37(2) of that Regulation, France informed the applicants about its intention to adjust the terms and conditions of the authorisations to be granted in France by not authorising the products for the treatment of transmission poles ('the restricted use').
- (4) Two of the applicants disagreed with the proposed adjustment and one of them did not reply within 60 days of that communication. As a result, on 22 November 2017, France informed the Commission in accordance with the second subparagraph of Article 37(2) of Regulation (EU) No 528/2012.
- (5) From the arguments put forward by France, it follows that the risk to humans or the environment from the exposure to creosote associated with the restricted use of the products cannot be considered negligible. France also pointed out that other wood preservatives containing active substances not meeting the exclusion criteria referred to in Article 5(1) of Regulation (EU) No 528/2012 are available on the French market for the restricted use. Thus, not authorising the restricted use would not have any disproportionate negative impact on the French society. According to France, the restricted use is not essential to control any serious danger to human health, animal health or the environment.

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

<sup>(3)</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

- (6) Therefore, none of the conditions of Article 5(2) of Regulation (EU) No 528/2012 are satisfied for the restricted use in France. With a view to achieving a high level of protection of human health, animal health and the environment, Regulation (EU) No 528/2012 lays down that the authorisation of biocidal products containing active substances with the worst hazard profiles shall be restricted to specific situations. Moreover, pursuant to the second subparagraph of Article 37(1) of that Regulation, Member States may, in particular, propose on the grounds referred to in the first subparagraph of that Article to refuse to grant an authorisation or to adjust the terms and conditions of the authorisations to be granted for biocidal products containing an active substance to which Article 5(2) or Article 10(1) of that Regulation applies. Creosote meets several of the exclusion criteria referred to in Article 5(1) of that Regulation both in terms of hazardous properties for the environment and for human health.
- (7) The Commission therefore considers that the derogation from mutual recognition proposed by France is justified on the grounds referred to in points (a) and (c) of Article 37(1) of that Regulation.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

*Article 1*

1. The derogation from mutual recognition proposed by France for the biocidal product families referred to in paragraph 2 is justified on the grounds of the protection of the environment and of the health and life of humans as referred to in points (a) and (c) of Article 37(1) of Regulation (EU) No 528/2012, in conjunction with the second subparagraph of Article 37(1) of Regulation (EU) No 528/2012.

2. Paragraph 1 applies to the biocidal product families identified by the following case numbers, as provided for by the Register for Biocidal Products:

BC-WK024516-27;

BC-DQ024492-36;

BC-EU013041-45.

*Article 2*

This Decision is addressed to the French Republic.

Done at Brussels, 25 September 2018.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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**CORRIGENDA**

**Corrigendum to Council Decision 2009/477/EC of 28 May 2009 publishing in consolidated form the text of the Customs Convention on the international transport of goods under cover of TIR carnets (TIR Convention) of 14 November 1975 as amended since that date**

*(Official Journal of the European Union L 165 of 26 June 2009)*

On page 44, Annex 4, point 8:

*for:* 'Nom et adresse',

*read:* 'Name and address'.

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