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Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Implementing Regulation (EU) 2017/555 of 24 March 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of several active substances listed in Part B of the Annex to Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme) ⁽¹⁾ 1**
- ★ **Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council ⁽¹⁾ 7**
- ★ **Commission Implementing Regulation (EU) 2017/557 of 24 March 2017 amending for the 263rd time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations 14**
- Commission Implementing Regulation (EU) 2017/558 of 24 March 2017 establishing the standard import values for determining the entry price of certain fruit and vegetables 16

DECISIONS

- ★ **Decision (EU) 2017/559 of the European Parliament and of the Council of 15 March 2017 on the mobilisation of the European Globalisation Adjustment Fund following an application from the Netherlands — EGF/2016/005 NL/Drenthe Overijssel Retail 18**
- ★ **Council Decision (EU) 2017/560 of 21 March 2017 on the position to be adopted on behalf of the European Union within the EU-Mexico Joint Committee relating to amendments to Annex III to Decision No 2/2000 of the EC-Mexico Joint Council of 23 March 2000 concerning the definition of the concept of originating products and methods of administrative cooperation (certain product-specific rules of origin for chemicals) 20**

⁽¹⁾ 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.

The titles of all other acts are printed in bold type and preceded by an asterisk.

★ Council Decision (EU) 2017/561 of 21 March 2017 on the position to be adopted on behalf of the European Union within the EU-Mexico Joint Committee relating to amendments to Annex III to Decision No 2/2000 of the EC-Mexico Joint Council of 23 March 2000 concerning the definition of the concept of originating products and methods of administrative cooperation (Andorra and San Marino, and certain product-specific rules of origin for chemicals)	26
★ Council Decision (EU) 2017/562 of 21 March 2017 appointing an alternate member, proposed by the Portuguese Republic, of the Committee of the Regions	32
★ Council Implementing Decision (EU) 2017/563 of 21 March 2017 authorising the Republic of Estonia to apply a special measure derogating from Article 287 of Directive 2006/112/EC on the common system of value added tax	33
★ Commission Implementing Decision (EU) 2017/564 of 23 March 2017 amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States (<i>notified under document C(2017) 1813</i>) ⁽¹⁾	35

Corrigenda

★ Corrigendum to Commission Delegated Regulation (EU) 2016/1824 of 14 July 2016 amending Delegated Regulation (EU) No 3/2014, Delegated Regulation (EU) No 44/2014 and Delegated Regulation (EU) No 134/2014 with regard, respectively, to vehicle functional safety requirements, to vehicle construction and general requirements and to environmental and propulsion unit performance requirements (OJ L 279, 15.10.2016)	46
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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/555

of 24 March 2017

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of several active substances listed in Part B of the Annex to Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme)

(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 ⁽¹⁾, and in particular the first paragraph of Article 17 and Article 78(2) thereof,

Whereas:

- (1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽²⁾ sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009.
- (2) Applications for the renewal of the approval of the active substances included in this Regulation were submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ⁽³⁾. However, the approval of those substances may expire for reasons beyond the control of the applicant before a decision has been taken on the renewal of their approval. It is therefore necessary to extend their approval periods in accordance with Article 17 of Regulation (EC) No 1107/2009.
- (3) In view of the time and resources necessary for completing the assessment of applications for the renewal of approvals of the large number of active substances the approvals of which are expiring between 2019 and 2021, Commission Implementing Decision C/2016/6104 ⁽⁴⁾ established a work programme grouping together similar active substances and setting priorities on the basis of safety concerns for human and animal health or the environment as provided for in Article 18 of Regulation (EC) No 1107/2009.
- (4) The presumed low-risk substances should be prioritised in accordance with Implementing Decision C/2016/6104. The approval of those substances should therefore be extended by a period as short as possible. Taking into account the distribution of responsibilities and work among Member States acting as rapporteurs and co-rapporteurs and the available resources necessary for assessment and decision-making, that period should be of 1 year for the active substances paraffin oil/(CAS 64742-46-7), paraffin oil/(CAS 72623-86-0), paraffin oil/(CAS 8042-47-5), paraffin oil/(CAS 97862-82-3) and sulphur.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ OJ L 153, 11.6.2011, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

⁽⁴⁾ Commission Implementing Decision of 28 September 2016 on the establishment of a work programme for the assessment of applications for the renewal of approvals of active substances expiring in 2019, 2020 and 2021 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ C 357, 29.9.2016, p. 9).

- (5) For active substances which do not fall in the prioritised categories in Implementing Decision C/2016/6104, the approval period should be extended by either 2 or 3 years, taking into account the present date of expiry, the fact that according to Article 6(3) of Implementing Regulation (EU) No 844/2012 the supplementary dossier for an active substance shall be submitted no later than 30 months before expiry of the approval, the need to ensure a balanced distribution of responsibilities and work among Member States acting as rapporteurs and co-rapporteurs, and the available resources necessary for assessment and decision-making. It is therefore appropriate to extend the approval periods for 2-phenylphenol (including its salts such as the sodium salt), chlormequat, dimethachlor, etofenprox, penconazole, propaquizafop, tetraconazole, tri-allate, and zeta-cypermethrin by 2 years, and to extend the approval periods of active substances bensulfuron, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and tebufenpyrad by 3 years.
- (6) The Commission received an application for the renewal of the approval of the active substance quizalofop-P (variant quizalofop-p-ethyl) and a separate application for the renewal of the approval of the active substance quizalofop-P (variant quizalofop-p-tefuryl). Given this fact and due to the different risk profiles of quizalofop-p-ethyl and quizalofop-p-tefuryl, it is appropriate to consider them as two different active substances for the purpose of the renewal procedure. The variant quizalofop-p-ethyl does not fall in the prioritised categories in Implementing Decision C/2016/6104. Therefore, and taking into account the reasons given in recital 5, it is appropriate to extend its approval period by 2 years.
- (7) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where no supplementary dossier in accordance with Implementing Regulation (EU) No 844/2012 is submitted no later than 30 months before the respective expiry date laid down in the Annex to this Regulation, the Commission will set the expiry date at the same date as before this Regulation or at the earliest date thereafter.
- (8) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where the Commission will adopt a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed because the approval criteria are not satisfied, the Commission will set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later. As regards cases where the Commission will adopt a Regulation providing for the renewal of an active substance referred to in the Annex to this Regulation, the Commission will endeavour to set, as appropriate under the circumstances, the earliest possible application date.
- (9) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (10) Taking into account that the approvals of some of the substances expire on 31 October 2019, and that applicants should submit supplementary dossiers 30 months before the expiry of the approval, this Regulation should enter into force as soon as possible.
- (11) 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 Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation

Article 2

This Regulation shall enter into force on the third 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, 24 March 2017.

For the Commission

The President

Jean-Claude JUNKER

ANNEX

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in the sixth column, expiration of approval, of row 271, Bensulfuron, the date is replaced by '31 October 2022';
- (2) in the sixth column, expiration of approval, of row 272, Sodium 5-nitroguaiacolate, the date is replaced by '31 October 2022';
- (3) in the sixth column, expiration of approval, of row 273, Sodium o-nitrophenolate, the date is replaced by '31 October 2022';
- (4) in the sixth column, expiration of approval, of row 274, Sodium p-nitrophenolate, the date is replaced by '31 October 2022';
- (5) in the sixth column, expiration of approval, of row 275, Tebufenpyrad, the date is replaced by '31 October 2022';
- (6) in the sixth column, expiration of approval, of row 276, Chlormequat, the date is replaced by '30 November 2021';
- (7) in the sixth column, expiration of approval, of row 278, Propaquizafop, the date is replaced by '30 November 2021';
- (8) in the sixth column, expiration of approval, of row 281, zeta-Cypermethrin, the date is replaced by '30 November 2021';
- (9) in the sixth column, expiration of approval, of row 284, Dimethachlor, the date is replaced by '31 December 2021';
- (10) in the sixth column, expiration of approval, of row 285, Etofenprox, the date is replaced by '31 December 2021';
- (11) in the sixth column, expiration of approval, of row 287, Penconazole, the date is replaced by '31 December 2021';
- (12) in the sixth column, expiration of approval, of row 288, Tri-allate, the date is replaced by '31 December 2021';
- (13) in the sixth column, expiration of approval, of row 292, Sulphur, the date is replaced by '31 December 2020';
- (14) in the sixth column, expiration of approval, of row 293, Tetraconazole, the date is replaced by '31 December 2021';
- (15) in the sixth column, expiration of approval, of row 294, Paraffin oils, the date is replaced by '31 December 2020';
- (16) in the sixth column, expiration of approval, of row 295, Paraffin oil, the date is replaced by '31 December 2020';
- (17) in the sixth column, expiration of approval, of row 299, 2-phenylphenol (including its salts such as the sodium salt), the date is replaced by '31 December 2021';

(18) entry 279 is replaced by the following:

279	Quizalofop-P					
	Quizalofop-P-tefuryl CAS No 119738-06-6 CIPAC No 641.226	(RS)-Tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate	≥ 795 g/kg	1 December 2009	30 November 2019	PART A Only uses as herbicide may be authorised. PART B
	Quizalofop-P-ethyl CAS No 100646-51-3 CIPAC No 641.202	ethyl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate	≥ 950 g/kg	1 December 2009	30 November 2021	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on quizalofop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the specification of the technical material as commercially manufactured which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material, — the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of non-target plants and ensure that conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate. Conditions of authorisation shall include risk mitigation measures, where appropriate.

						The Member States concerned shall ensure that the notifier submits to the Commission further information on the risk to non-target arthropods. They shall ensure that the notifier provides such information to the Commission by 30 November 2011.'
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COMMISSION IMPLEMENTING REGULATION (EU) 2017/556**of 24 March 2017****on the detailed arrangements for the good clinical practice inspection procedures pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC ⁽¹⁾, and in particular Article 78(7) thereof,

Whereas:

- (1) Regulation (EU) No 536/2014 lays down the legal framework for the conduct of clinical trials on medicinal products for human use in the Union to ensure that the rights, safety and well-being of the subjects are protected, and the data generated in clinical trials are robust and reliable. In particular, the sponsor of a clinical trial and the investigator are to ensure that the clinical trial is conducted in accordance with the relevant protocol and the principles of good clinical practice. Compliance with the applicable legal requirements, the protocol and the principles of good clinical practice, including with standards relating to data integrity and ethical conduct of the clinical trial, is to be verified by means of inspections conducted under the responsibility of the Member State where the inspection takes place.
- (2) The inspection in the context of clinical trials may concern good manufacturing practices as regards the manufacturing of the investigational medicinal products or good clinical practice as regards the conduct of clinical trials. Article 63 of Regulation (EU) No 536/2014 empowers the Commission to adopt delegated acts specifying the detailed arrangements for good manufacturing practice inspections as regards investigational medicinal products. Therefore, this Regulation should only lay down detailed arrangements for good clinical practice inspections procedures and requirements regarding training and qualifications of good clinical practice inspectors.
- (3) Member States may conduct inspections of clinical trials performed in third countries, either because a clinical trial is related to a clinical trial authorised in the Union or because the data of the clinical trial is being referred to in a clinical trial authorisation application in the Union. Those inspections should allow verifying whether such clinical trials were conducted in accordance with standards equivalent to Union standards. Inspections of clinical trials in third countries may also be conducted in order to verify whether the clinical trials, whose results are referred to in marketing authorisation applications in the Union, meet the ethical requirements set out in Regulation (EU) No 536/2014. Therefore, provisions on detailed arrangements for the inspection procedures should apply also to inspections conducted outside the Union in accordance with Regulation (EU) No 536/2014.
- (4) The International Conference on Harmonisation ('ICH') reached a consensus in 1995 to provide a harmonised approach for good clinical practice. Pursuant to Article 47 of Regulation (EU) No 536/2014, the ICH guidelines should be appropriately taken into account by the sponsor when drafting the clinical trial protocol and conducting the clinical trial. To the extent that those guidelines are compatible with the relevant Union law and EU guidelines, inspectors should refer to the ICH guidelines, taking into account the characteristics of each trial.
- (5) Member States should be required to set up quality systems to ensure that the inspection procedures are observed and consistently monitored. A well-functioning quality system should comprise an organisational structure, clear processes and procedures, including the standard operating procedures to be followed by inspectors when performing their tasks, clearly defined details of the inspectors' duties and responsibilities and ongoing training requirements, as well as adequate resources and mechanisms which aim at eliminating non-compliance.

⁽¹⁾ OJ L 158, 27.5.2014, p. 1.

- (6) It is necessary to enable inspectors to ensure the practical effectiveness of provisions on good clinical practice. That objective should be reflected in the minimum requirements for the qualification of inspectors, in particular as regards their education and training. For the same reasons, detailed rules on inspection procedures should be laid down.
- (7) In order to safeguard the effectiveness of inspection, the inspectors should be granted the necessary powers of access to the premises and data. This includes in particular any laboratory used for analysis in the clinical trial, any contract research organisation's facilities or the sponsor's premises. They should also be empowered to contact the trial subjects in justified cases.
- (8) In order to ensure the compliance with arrangements for good clinical practice inspections and in accordance with Article 77 of Regulation (EU) No 536/2014 Member States should take corrective measures if necessary. When during an inspection a major non-compliance or breach is identified, or the inspectors' investigatory powers are not recognised by the sponsors, Member States should have recourse to penalties.
- (9) In order to ensure the protection of confidential information, in particular personal data of clinical trial subjects related to their health as well as commercially confidential information, the inspectors and experts involved in inspections should be bound by the highest standards of confidentiality and the applicable requirements of the Union law, national laws and international agreements. The inspectors and experts involved in inspections should comply with the requirements of Directive 95/46/EC of the European Parliament and of the Council ⁽¹⁾ when processing personal data.
- (10) Commission Directive 2005/28/EC ⁽²⁾ should be repealed in order to ensure that only one set of rules applies to the conduct of good clinical practice inspections of clinical trials, including clinical trials governed by Directive 2001/20/EC of the European Parliament and of the Council ⁽³⁾. However, in order to ensure consistency with Article 98 of Regulation (EU) No 536/2014 setting up a transitional period maintaining, as regards certain requests for authorisation of a clinical trial, the applicability of Directive 2001/20/EC, Directive 2005/28/EC should, with the exception of its Chapters 5 and 6 referring to good clinical practice inspection procedures and inspectors, remain applicable during that transitional period to all clinical trials authorised on the basis of Directive 2001/20/EC.
- (11) This Regulation should become applicable at the same time as Regulation (EU) No 536/2014.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

This Regulation applies to inspections of:

- (a) clinical trials conducted in the Union, including clinical trial sites related to those trials but located outside the Union;

⁽¹⁾ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

⁽²⁾ Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirement for authorisation of the manufacturing or importations of such products (OJ L 91, 9.4.2005, p. 13).

⁽³⁾ Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

- (b) clinical trials referred to in the applications for clinical trial authorisations pursuant to Article 25(5) of Regulation (EU) No 536/2014;
- (c) clinical trials conducted in third countries and referred to in marketing authorisation applications in the Union.

Article 2

Time frame for inspections

Inspections may take place in any of the following circumstances:

- (a) before, during or after the conduct of a clinical trial;
- (b) as part of the verification of applications for marketing authorisation;
- (c) as a follow-up to the granting of a marketing authorisation.

Article 3

Quality system

1. Each Member State shall set up a properly designed quality system ensuring that the inspection procedures are observed and consistently monitored.

Member States shall maintain those quality systems up to date.

2. Each inspector shall have access to and comply with standard operating procedures, details of their duties, responsibilities and training requirements.

CHAPTER II

INSPECTORS

Article 4

Qualifications, training and experience

1. Inspectors shall have completed education at university level, or have equivalent experience, in medicine, pharmacy, pharmacology, toxicology or other fields relevant to the principles of good clinical practice.
2. Inspectors shall receive appropriate training, including participation in inspections. Their training needs, necessary to maintain or improve their skills, shall be assessed regularly by a person appointed for that task.
3. Inspectors shall have knowledge of principles and processes that apply to the development of medicinal products and clinical research and have knowledge of applicable Union and national legislation and guidelines on the conduct of clinical trials and the granting of marketing authorisations.
4. Inspectors shall have the ability to make professional judgments in relation to the compliance with applicable Union and national legislation and guidelines. They shall be able to assess data integrity as well as aspects related to ethical conduct of clinical trials.
5. Inspectors shall be familiar with the procedures and technical methods for the recording and management of clinical data, and with the organisation and regulation of the healthcare systems in the relevant Member States and, where appropriate, in third countries.

6. Inspectors shall be able to assess the degree of risk as regards the safety of the subjects enrolled in the clinical trial as well as the data integrity.
7. Inspectors shall be aware of the applicable rules as regards confidentiality and protection of personal data.
8. Member States shall keep records of the qualifications, training and experience of each inspector and maintain those records up-to-date for as long as inspector is in active duty.

Article 5

Conflict of interest and impartiality

1. Inspectors shall be free from any influence which could affect their impartiality or their judgement.
2. Inspectors shall not have conflicts of interest. In particular, they shall be independent of all of the following parties:
 - (a) the sponsor;
 - (b) the investigators involved in the clinical trial;
 - (c) persons financing the clinical trial;
 - (d) any other party involved in the conduct of the clinical trial.
3. Each inspector shall make an annual declaration of their financial interests and other links to the parties to be potentially inspected. That declaration shall be taken into consideration for the purposes of assigning an inspector to a specific inspection.

CHAPTER III

INSPECTION PROCEDURES

Article 6

Subject matter of inspections

Inspectors shall verify the compliance with the requirements of Regulation (EU) No 536/2014, including protection of the rights and well-being of the clinical trial subjects, the quality and integrity of data generated in clinical trial, the compliance with principles of good clinical practice, including the ethical aspects and the relevant national legislation.

Article 7

Procedures to be established by Member States

1. Member States shall establish the relevant procedures for at least the following:
 - (a) appointing experts to accompany inspectors, if additional expertise is required for an inspection;
 - (b) arranging inspections outside the Union;
 - (c) verification of good clinical practice compliance, including the modalities for examining the study management procedures and the conditions under which the clinical trial is planned, performed, monitored and recorded, as well as follow-up measures, such as a review of an analysis of the root cause of a significant non-compliance and verification of corrective and preventive actions implemented by the sponsor.

Member States shall make those procedures and rules publicly available.

2. Member States shall also define the powers of experts appointed to accompany inspectors.

*Article 8***Unannounced inspections**

The inspections may, where necessary, be carried out unannounced.

*Article 9***Collaboration between Member States**

1. Member States shall collaborate with each other, with the Commission and with the European Medicines Agency to develop and improve commonly recognised standards of good clinical practice inspections. This collaboration may take the form of joint inspections, agreed processes and procedures and sharing of experience and training.
2. The Commission shall make publicly available any guidance documents on the commonly recognised standards for the conduct of inspections, developed in collaboration with Member States and the European Medicines Agency.
3. The European Medicines Agency shall process and make available to Member States information on inspections that are envisaged, scheduled, or conducted, in order to assist Member States to ensure the most efficient use of inspection resources when planning their inspections.
4. Member States may request assistance from the national competent authority of another Member State in the matter of inspection.

*Article 10***Powers of inspectors**

1. Inspections shall be carried out by inspectors appointed by Member States.

In order to ensure the availability of necessary skills for each inspection, Member States may appoint teams of inspectors and appoint experts with appropriate qualifications to accompany inspectors.

2. Inspectors shall be entitled to inspect the clinical trial sites, documents, facilities, records, including individual patients' records, quality arrangements, data and any other resources and entities that are deemed by the competent authority to be related to the clinical trial.
3. When performing an inspection, the inspectors shall be empowered to enter into sites, other related premises, and to access to data, including individual patients' records.
4. Inspectors shall be entitled to make copies of records and hard copies, print-outs of electronic records and take photos of premises and equipment.
5. Inspectors shall be entitled to ask any representative or member of staff of the inspected entity and any party involved in the clinical trial for explanations relating to the subject matter and purpose of the inspection and to record the answer.
6. Inspectors shall be empowered to contact the trial subjects directly, in particular in case of reasonable suspicion that they were not informed adequately of their participation in the clinical trial.
7. Member States shall provide inspectors with suitable means of their identification.
8. Member States shall establish a legal and administrative framework to ensure that inspectors from other Member States, on request and where appropriate, have access to sites, any premise of any entity related to the clinical trial as well as to related data.

*Article 11***Recognition of inspection conclusions**

Inspectors shall carry out inspections on behalf of the Union. The results of those inspections shall be recognised by all Member States.

In case of divergences between Member States in relation to the verification of compliance with the applicable legislation, the Member States, or the European Medicines Agency within the framework of its powers as provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽¹⁾, shall inform the Commission. The Commission, after consulting those Member States and the European Medicines Agency, may request a new inspection.

*Article 12***Resources**

Member States shall appoint an adequate number of inspectors to ensure effective verification of compliance of clinical trials with applicable requirements, as well as the timely reporting of inspection findings.

*Article 13***Inspection reports and records**

Without prejudice to the obligation to submit the inspection reports via the EU Portal in accordance with Article 78(6) of Regulation (EU) No 536/2014, Member States shall keep for at least 25 years relevant records of national inspections as well as of the inspections performed outside their territory, including information on the outcome of the inspection as regards good clinical practice compliance status as well as any action taken by the sponsor or Member State in the follow-up of the inspection. The inspection reports submitted through the EU portal shall not contain personal data of clinical trials' subjects.

*Article 14***Confidentiality**

The inspectors and experts appointed to the inspection team shall maintain the confidentiality of information to which they gain access as a result of good clinical practice inspections.

CHAPTER IV**FINAL PROVISIONS***Article 15***Repeal**

Directive 2005/28/EC is repealed from the date referred to in the second paragraph of Article 17.

*Article 16***Transitional provisions**

Directive 2005/28/EC, except for its Chapters 5 and 6, shall continue to apply to the clinical trials governed by Directive 2001/20/EC pursuant to Article 98 of Regulation (EU) No 536/2014.

⁽¹⁾ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

*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 6 months after the date of publication in the *Official Journal of the European Union* of the notice referred to in Article 82(3) of Regulation (EU) No 536/2014.

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

Done at Brussels, 24 March 2017.

For the Commission

The President

Jean-Claude JUNKER

**COMMISSION IMPLEMENTING REGULATION (EU) 2017/557
of 24 March 2017**

**amending for the 263rd time Council Regulation (EC) No 881/2002 imposing certain specific
restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh)
and Al-Qaida organisations**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations ⁽¹⁾, and in particular Article 7(1)(a) and Article 7a(5) thereof,

Whereas:

- (1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.
- (2) On 21 March 2017, the Sanctions Committee of the United Nations Security Council decided to amend two entries in its list of persons, groups and entities to whom the freezing of funds and economic resources should apply. Annex I to Regulation (EC) No 881/2002 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 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, 24 March 2017.

*For the Commission,
On behalf of the President,
Acting Head of the Service for Foreign Policy Instruments*

⁽¹⁾ OJ L 139, 29.5.2002, p. 9.

ANNEX

The identifying data for the following entries under the heading 'Natural persons' in Annex I to Regulation (EC) No 881/2002 are amended as follows:

- (a) 'Ri'ad Muhammad Hasan Muhammad Hijazi (*alias* (a) Hijazi, Raed M. (b) Al-Hawen, Abu-Ahmad (c) Al-Shahid, Abu-Ahmad (d) Raed Muhammad Hasan Muhammad Hijazi, (e) Al-Maghribi, Rashid (the Moroccan) (f) Al-Amriki, Abu-Ahmad (the American)). Date of birth: 30.12.1968. Place of birth: California, United States of America. Nationality: Jordanian. National identification No: 9681029476. Other information: (a) United States Social Security Number 548-91-5411; (b) In custody in Jordan as at March 2010; (c) Father's name is Mohammad Hijazi. Mother's name is Sakina. Date of designation referred to in Article 2a (4) (b): 17.10.2001.' is replaced by the following:

'Raed Muhammad Hasan Muhammad Hijazi (*alias* (a) Raed M. Hijazi, (b) Ri'ad Muhammad Hasan Muhammad Hijazi (as previously listed), (c) Rashid Al-Maghribi (the Moroccan), (d) Abu-Ahmad Al-Amriki (the American), (e) Abu-Ahmad Al-Hawen, (f) Abu-Ahmad Al-Shahid. Date of birth: 30.12.1968. Place of birth: California, United States of America. Nationality: (a) Jordanian (b) American. National identification No: Jordanian national number 9681029476. Other information: (a) United States Social Security Number 548-91-5411, (b) Father's name is Mohammad Hijazi. Mother's name is Sakina. Date of designation referred to in Article 7d(2)(i): 17.10.2001.'

- (b) 'Merai Zoghbi (*alias* (a) Mohamed Lebachir, (b) Meri Albdefattah Zgbye, (c) Zoghbi Merai Abdul Fattah, (d) Lazrag Faraj, (e) Larzg Ben Ila, (h) Muhammed El Besir, (f) Fraji di Singapore, (g) Fraji il Libico, (h) Farag, (i) Fredj). Date of birth: (a) 4.4.1969, (b) 4.4.1960, (c) 4.6.1960, (d) 13.11.1960, (e) 11.8.1960, (f) 13.11.1960, (g) 14.1.1968. Place of birth: (a) Bengasi, Libya, (b) Bendasi, Libya, (c) Morocco, (d) Libya. Other information: Member of Libyan Islamic Fighting Group. Date of designation referred to in Article 2a (4) (b): 2.8.2006.' is replaced by the following:

'Merai Abdefattah Khalil Zoghbi (*alias* (a) Mohamed Lebachir, (b) Meri Albdefattah Zgbye, (c) Zoghbi Merai Abdul Fattah, (d) Lazrag Faraj, (e) Larzg Ben Ila, (f) Muhammed El Besir, (g) Fraji di Singapore, (h) Fraji il Libico, (i) Farag, (j) Fredj, (k) Merai Zoghbi (as previously listed)). Date of birth: (a) 4.4.1969, (b) 4.4.1960, (c) 4.6.1960 (d) 13.11.1960, (e) 14.1.1968, (f) 11.08.1960. Place of birth: (a) Bengasi, Libya, (b) Bendasi, Libya, (c) Morocco, (d) Libya. Nationality: Libyan. Other information: Son of Wanisa Abdessalam. Date of designation referred to in Article 7d(2)(i): 2.8.2006.'

COMMISSION IMPLEMENTING REGULATION (EU) 2017/558**of 24 March 2017****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾,

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ⁽²⁾, and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.
- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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, 24 March 2017.

*For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General
Directorate-General for Agriculture and Rural Development*

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)		
CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	EG	145,6
	IL	234,5
	MA	102,7
	SN	213,0
	TR	109,2
	ZZ	161,0
0707 00 05	TR	180,4
	ZZ	180,4
0709 93 10	MA	53,9
	TR	151,1
	ZZ	102,5
0805 10 22, 0805 10 24, 0805 10 28	EG	45,3
	IL	80,4
	MA	50,0
	TN	55,5
	TR	73,7
	ZA	92,1
	ZZ	66,2
0805 50 10	AR	45,3
	EG	72,0
	TR	71,4
	ZZ	62,9
0808 10 80	CL	122,2
	CN	142,3
	ZA	111,8
	ZZ	125,4
0808 30 90	AR	117,5
	CL	139,7
	CN	77,7
	TR	148,9
	ZA	114,1
	ZZ	119,6

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

DECISIONS

DECISION (EU) 2017/559 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2017

on the mobilisation of the European Globalisation Adjustment Fund following an application from the Netherlands — EGF/2016/005 NL/Drenthe Overijssel Retail

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Regulation (EU) No 1309/2013 of the European Parliament and of the Council of 17 December 2013 on the European Globalisation Adjustment Fund (2014-2020) and repealing Regulation (EC) No 1927/2006 ⁽¹⁾, and in particular Article 15(4) thereof,

Having regard to the Interinstitutional Agreement of 2 December 2013 between the European Parliament, the Council and the Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management ⁽²⁾, and in particular point 13 thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The European Globalisation Adjustment Fund (EGF) aims to provide support for workers made redundant and self-employed persons whose activity has ceased as a result of major structural changes in world trade patterns due to globalisation, as a result of a continuation of the global financial and economic crisis, or as a result of a new global financial and economic crisis, and to assist them with their reintegration into the labour market.
- (2) The EGF is not to exceed a maximum annual amount of EUR 150 million (2011 prices), as laid down in Article 12 of Council Regulation (EU, Euratom) No 1311/2013 ⁽³⁾.
- (3) On 12 July 2016 the Netherlands submitted an application to mobilise the EGF, in respect of redundancies in 6 enterprises operating in the retail trade sector in 2 regions (Drenthe and Overijssel) in the Netherlands. It was supplemented by additional information provided in accordance with Article 8(3) of Regulation (EU) No 1309/2013. That application complies with the requirements for determining a financial contribution from the EGF as laid down in Article 13 of Regulation (EU) No 1309/2013.
- (4) The EGF should, therefore, be mobilised in order to provide a financial contribution of EUR 1 818 750 in respect of the application submitted by the Netherlands.
- (5) In order to minimise the time taken to mobilise the EGF, this decision should apply from the date of its adoption,

HAVE ADOPTED THIS DECISION:

Article 1

For the general budget of the Union for the financial year 2017, the European Globalisation Adjustment Fund shall be mobilised to provide the amount of EUR 1 818 750 in commitment and payment appropriations.

⁽¹⁾ OJ L 347, 20.12.2013, p. 855.

⁽²⁾ OJ C 373, 20.12.2013, p. 1.

⁽³⁾ Council Regulation (EU, Euratom) No 1311/2013 of 2 December 2013 laying down the multiannual financial framework for the years 2014-2020 (OJ L 347, 20.12.2013, p. 884).

Article 2

This decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 15 March 2017.

Done at Strasbourg, 15 March 2017.

For the European Parliament

The President

A. TAJANI

For the Council

The President

I. BORG

COUNCIL DECISION (EU) 2017/560**of 21 March 2017**

on the position to be adopted on behalf of the European Union within the EU-Mexico Joint Committee relating to amendments to Annex III to Decision No 2/2000 of the EC-Mexico Joint Council of 23 March 2000 concerning the definition of the concept of originating products and methods of administrative cooperation (certain product-specific rules of origin for chemicals)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207 in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Joint Declaration V ⁽¹⁾ to Decision No 2/2000 of the EC-Mexico Joint Council ⁽²⁾ established by the Economic Partnership, Political Coordination and Cooperation Agreement between the European Community and its Member States, of the one part, and the United Mexican States, of the other part, signed in Brussels on 8 December 1997 ⁽³⁾ ('the Agreement'), provides that the EC-Mexico Joint Committee established by the Agreement is to review the necessity to extend beyond 30 June 2003 the application of the rules of origin set out in Notes 2 and 3 of Appendix II(a) to Annex III to Decision No 2/2000 ('Notes 2 and 3'). That review concerns the product-specific rules in Appendix II to Annex III to Decision No 2/2000 for certain chemical products under the Harmonised System headings 2914 and 2915.
- (2) On 17 September 2010 the EU-Mexico Joint Committee adopted Decision No 1/2010 ⁽⁴⁾, extending the application of the rules of origin established in Notes 2 and 3 for the third time. Decision No 1/2010 applied until 30 June 2014.
- (3) It is appropriate to extend the application of the rules of origin established in Notes 2 and 3 on a temporary basis with effect from 1 July 2014 until 31 December 2019, in line with the principles of the modernisation of the Agreement, to ensure continuity with future product-specific rules.
- (4) Since the extension of the application of the rules of origin established in Notes 2 and 3 expired on 30 June 2014, it is appropriate to apply the new extension retroactively from 1 July 2014, in order to avoid disrupting existing economic conditions.
- (5) Appendix II to Annex III to Decision No 2/2000 should therefore be amended to extend the application of the rules of origin established in Notes 2 and 3 on a temporary basis with effect from 1 July 2014 until 31 December 2019.
- (6) For the purposes of the retroactive application, the time limit for presentation of the proof of origin by way of a EUR.1 movement certificate or an invoice declaration should be extended from 2 years to 3 years for the relevant chemical products imported into the Union in the period from 1 July 2014 to 30 June 2015.
- (7) Appendix V to Annex III to Decision No 2/2000 should therefore be replaced.
- (8) The position of the Union within the EU-Mexico Joint Committee should therefore be based on the attached draft Decision,

⁽¹⁾ OJ L 245, 29.9.2000, p. 1167.

⁽²⁾ Decision No 2/2000 of the EC-Mexico Joint Council of 23 March 2000 (OJ L 157, 30.6.2000, p. 10).

⁽³⁾ OJ L 276, 28.10.2000, p. 45.

⁽⁴⁾ Decision No 1/2010 of the EU-Mexico Joint Committee of 17 September 2010 relating to Annex III to Decision No 2/2000 of the EU-Mexico Joint Council concerning the definition of the concept of originating products and methods of administrative cooperation (OJ L 277, 21.10.2010, p. 30).

HAS ADOPTED THIS DECISION:

Article 1

1. The position to be adopted on behalf of the Union within the EU-Mexico Joint Committee relating to amendments to Annex III to Decision No 2/2000 of the EC-Mexico Joint Council shall be based on the draft Decision of the EU-Mexico Joint Committee attached to this Decision.
2. The representatives of the Union in the EU-Mexico Joint Committee may agree to minor changes to the draft Decision of the EU-Mexico Joint Committee referred to in paragraph 1 without further decision of the Council.

Article 2

The Decision of the EU-Mexico Joint Committee relating to amendments to Annex III to Decision No 2/2000 of the EC-Mexico Joint Council shall be published in the *Official Journal of the European Union*.

Done at Brussels, 21 March 2017.

For the Council
The President
E. SCICLUNA

DRAFT

DECISION No 1/2017 OF THE EU-MEXICO JOINT COMMITTEE**of ...****relating to amendments to Annex III to Decision No 2/2000 of the EC-Mexico Joint Council of 23 March 2000 concerning the definition of the concept of originating products and methods of administrative cooperation (certain product-specific rules of origin for chemicals)**

THE JOINT COMMITTEE,

Having regard to Decision No 2/2000 of the EC-Mexico Joint Council of 23 March 2000 ⁽¹⁾ and its Annex III, and in particular Article 38 of Annex III,

Whereas:

- (1) Annex III to Decision No 2/2000 ('Annex III') sets out the rules of origin for the products originating in the territory of the Parties to the Economic Partnership, Political Coordination and Cooperation Agreement between the European Community and its Member States, of the one part, and the United Mexican States, of the other part, signed in Brussels on 8 December 1997 ⁽²⁾ ('the Agreement').
- (2) The product-specific rules of origin set out in Appendix II to Annex III for products classified in Harmonized System headings 2914 and 2915 should be amended to allow the temporary application from 1 July 2014 to 31 December 2019 of the product-specific rules of origin set out in Notes 2 and 3 of Appendix II(a) to Annex III and should be updated to allow a modernised product-specific rule of origin in line with recent trade agreements. It is appropriate to apply the new extension retroactively from 1 July 2014 in order to avoid disruption in existing economic conditions.
- (3) Appendix V to Annex III sets out the time limit for each Party to accept an EUR.1 movement certificate issued retrospectively as referred to in Article 17(3) of Annex III, or for the exporter to present an invoice declaration to the customs authority of the importing Party after exportation of the products as provided for in Article 20(6) of Annex III.
- (4) For products falling under Harmonized System headings 2914 and 2915 imported into the EU in the period from 1 July 2014 to 30 June 2015, the period of presentation should be extended to three years to take into account the retroactive amendments to the product-specific rules of origin for those products.
- (5) The title of Appendix V to Annex III should be amended to align it with the changed time limit to accept EUR.1 movement certificates and to align it with Article 17(3) and Article 20(6) of Annex III.
- (6) Annex III should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

1. Appendix II to Annex III to Decision No 2/2000 is amended as set out in Annex I to this Decision.
2. Appendix V to Annex III to Decision No 2/2000 is replaced as set out in Annex II to this Decision.

⁽¹⁾ OJ L 157, 30.6.2000, p. 10.⁽²⁾ OJ L 276, 28.10.2000, p. 45.

Article 2

This Decision shall enter into force on the 45th day following the date of its adoption.

It shall apply with effect from 1 July 2014.

Done at ...,

For the Joint Committee

ANNEX I

Appendix II to Annex III to Decision No 2/2000 is amended as follows:

1. the following entry is inserted:

'HS heading	Description of product	Working or processing carried out on non-originating materials that confers originating status	
(1)	(2)	(3) or (4)	
ex 2914 (*)	— Diacetone alcohol — Methyl isobutyl ketone — Mesityl oxide	Manufacture from acetone	Manufacture in which a chemical reaction is made (**)

(*) Applicable from 1 July 2014 to 31 December 2019.

(**) A 'chemical reaction' is a process (including a biochemical process) which results in a molecule with a new structure by breaking intramolecular bonds and by forming new intramolecular bonds, or by altering the spatial arrangement of atoms in a molecule.

The following processes should not be considered for purposes of origin:

- (a) dissolving in water or other solvents;
- (b) the elimination of solvents including solvent water; or
- (c) the addition or elimination of water of crystallization.;

2. the entry for HS heading 2915 is replaced by the following:

'HS heading	Description of product	Working or processing carried out on non-originating materials that confers originating status	
(1)	(2)	(3) or (4)	
2915 (*)	Saturated acyclic monocarboxylic acids and their anhydrides, halides, peroxides and peroxyacids; their halogenated, sulphonated, nitrated or nitrosated derivatives, except for:	Manufacture from materials of any heading. However, the value of all the materials of headings 2915 and 2916 used may not exceed 20 % of the ex-works price of the product	Manufacture in which the value of all the materials used does not exceed 40 % of the ex-works price of the product
	— Acetic anhydride, ethyl and n-butyl acetate, vinyl acetate, isopropyl and methylamyl acetate, mono-, di- or trichloroacetic acids, their salts and esters	Manufacture from materials of any heading. However, the value of all the materials of heading 2916 used may not exceed 20 % of the ex-works price of the product	Manufacture in which a chemical reaction is made (**)

(*) Applicable from 1 July 2014 to 31 December 2019.

(**) A 'chemical reaction' is a process (including a biochemical process) which results in a molecule with a new structure by breaking intramolecular bonds and by forming new intramolecular bonds, or by altering the spatial arrangement of atoms in a molecule.

The following processes should not be considered for purposes of origin:

- (a) dissolving in water or other solvents;
- (b) the elimination of solvents including solvent water; or
- (c) the addition or elimination of water of crystallization.;

ANNEX II

Appendix V to Annex III to Decision No 2/2000 is replaced by the following:

‘Appendix V

PERIOD OF TIME FOR ACCEPTANCE BY THE CUSTOMS AUTHORITY OF AN EUR.1 MOVEMENT CERTIFICATE
ISSUED RETROSPECTIVELY IN ACCORDANCE WITH ARTICLE 17(3) OF ANNEX III AND FOR THE PRESENTATION
OF AN INVOICE DECLARATION IN ACCORDANCE WITH ARTICLE 20 (6) OF ANNEX III

1. For imports into the European Union: The period of time is two years from the time when the products to which the EUR.1 movement certificate relates are imported. For products falling under HS heading ex 2914 and 2915 as set out in Appendix II, having entered the European Union between 1 July 2014 and 30 June 2015, the period of time is three years from the time when the products to which the EUR.1 movement certificate relates are imported.
 2. For imports into Mexico: The period of time is one year from the time when the products to which the EUR.1 movement certificate relates are imported.’.
-

COUNCIL DECISION (EU) 2017/561**of 21 March 2017**

on the position to be adopted on behalf of the European Union within the EU-Mexico Joint Committee relating to amendments to Annex III to Decision No 2/2000 of the EC-Mexico Joint Council of 23 March 2000 concerning the definition of the concept of originating products and methods of administrative cooperation (Andorra and San Marino, and certain product-specific rules of origin for chemicals)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207 in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Annex III to Decision No 2/2000 of the EC-Mexico Joint Council ⁽¹⁾ established by the Economic Partnership, Political Coordination and Cooperation Agreement between the European Community and its Member States, of the one part, and the United Mexican States, of the other part ⁽²⁾, signed in Brussels on 8 December 1997 ('the Agreement'), sets out the rules of origin for the products originating in the territory of the Parties to the Agreement. Article 38 of Annex III to Decision No 2/2000 allows the EU-Mexico Joint Committee to amend that Annex.
- (2) The European Union has in place a customs union with the Principality of Andorra for products falling within Chapters 25 to 97 of the Harmonized System and with the Republic of San Marino for products falling within Chapters 1 to 97 of the Harmonized System. This customs union allows goods originating in Mexico to benefit from preferential treatment under Decision No 2/2000 also when exported to Andorra and San Marino.
- (3) It has been agreed that Mexico will accept products falling within Chapters 25 to 97 of the Harmonized System originating in the Principality of Andorra and products falling within Chapters 1 to 97 of the Harmonised System originating in the Republic of San Marino as products originating in the EU within the meaning of Annex III to Decision No 2/2000.
- (4) An Appendix VI should therefore be added to Annex III to Decision No 2/2000 to allow those products to be treated, when imported into Mexico, in a similar way to products originating in the Union, and to lay down provisions regarding the application of Annex III to those products.
- (5) Joint Declaration V ⁽³⁾ to Decision No 2/2000 provides that the EC-Mexico Joint Committee established by the Agreement is to review the necessity to extend beyond 30 June 2003 the application of the rules of origin set out in Notes 2 and 3 of Appendix II(a) to Annex III to Decision No 2/2000 ('Notes 2 and 3'). That review concerns the product-specific rules in Appendix II to Annex III to Decision No 2/2000 for certain chemical products under the Harmonised System headings 2914 and 2915.
- (6) The EU-Mexico Joint Committee is to adopt a Decision, extending the application of the rules of origin established in Notes 2 and 3 for the fourth time. That Decision is to apply until 31 December 2019.
- (7) It is appropriate to extend the application of the rules of origin established in Notes 2 and 3 on a permanent basis, because they are in line with the principles of the modernisation of the Agreement.
- (8) Appendix II to Annex III to Decision No 2/2000 should therefore be amended to extend the application of the rules of origin established in Notes 2 and 3 on a permanent basis.

⁽¹⁾ Decision No 2/2000 of the EC-Mexico Joint Council of 23 March 2000 (OJ L 157, 30.6.2000, p. 10).

⁽²⁾ OJ L 276, 28.10.2000, p. 45.

⁽³⁾ OJ L 245, 29.9.2000, p. 1167.

- (9) The position of the Union within the EU-Mexico Joint Committee should therefore be based on the attached draft Decision,

HAS ADOPTED THIS DECISION:

Article 1

1. The position to be adopted on behalf of the Union within the EU-Mexico Joint Committee relating to amendments to Annex III to Decision No 2/2000 of the EC-Mexico Joint Council shall be based on the draft Decision of the EU-Mexico Joint Committee attached to this Decision.
2. The representatives of the Union in the EU-Mexico Joint Committee may agree to minor changes to the draft Decision of the EU-Mexico Joint Committee referred to in paragraph 1 without further decision of the Council.

Article 2

The Decision of the EU-Mexico Joint Committee relating to amendments to Annex III to Decision No 2/2000 of the EC-Mexico Joint Council shall be published in the *Official Journal of the European Union*.

Done at Brussels, 21 March 2017.

For the Council
The President
E. SCICLUNA

DRAFT

DECISION No 2/2017 OF THE EU-MEXICO JOINT COMMITTEE**of ...****relating to amendments to Annex III to Decision No 2/2000 of the EC-Mexico Joint Council of 23 March 2000 concerning the definition of the concept of originating products and methods of administrative cooperation (Andorra and San Marino, and certain product-specific rules of origin for chemicals)**

THE JOINT COMMITTEE,

Having regard to Decision No 2/2000 of the EC-Mexico Joint Council of 23 March 2000 ⁽¹⁾ and its Annex III, and in particular Article 38 of Annex III,

Whereas:

- (1) Annex III to Decision No 2/2000 ('Annex III') sets out the rules of origin for the products originating in the territory of the Parties to the Economic Partnership, Political Coordination and Cooperation Agreement between the European Community and its Member States, of the one part, and the United Mexican States, of the other part, signed in Brussels on 8 December 1997 ⁽²⁾ ('the Agreement').
- (2) The European Union has in place customs unions with the Principality of Andorra and with the Republic of San Marino, respectively, and, as a result, goods originating in Mexico benefit from preferential treatment when exported to those two countries.
- (3) It has been agreed that Mexico will accept products falling within Chapters 25 to 97 of the Harmonized System originating in the Principality of Andorra and products falling within Chapters 1 to 97 of the Harmonised System originating in the Republic of San Marino as products originating in the European Union within the meaning of Annex III.
- (4) An Appendix VI should therefore be added to Annex III to allow those products to be treated, when imported into Mexico, in a similar way to products originating in the European Union, and to establish provisions regarding the application of Annex III to those products.
- (5) On ... the Joint Committee adopted Decision No 1/2017 ⁽³⁾ *, which extends the application of the rules of origin established in Notes 2 and 3 of Appendix II(a) to Annex III ('Notes 2 and 3') for the fourth time. The extension provided for in Decision No 1/2017 applies until 31 December 2019.
- (6) It is appropriate to extend the application of the rules of origin established in Notes 2 and 3 on a permanent basis, because they are in line with the principles of the modernisation of the Agreement.
- (7) Annex III should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

1. Appendix II to Annex III to Decision No 2/2000 is amended as set out in Annex I to this Decision.

⁽¹⁾ OJ L 157, 30.6.2000, p. 10.

⁽²⁾ OJ L 276, 28.10.2000, p. 45.

⁽³⁾ Decision No 1/2017 of the EU-Mexico Joint Committee of ... relating to amendments to Annex III to Decision No 2/2000 of the EC-Mexico Joint Council of 23 March 2000 concerning the definition of the concept of originating products and methods of administrative cooperation (certain product-specific rules of origin for chemicals) (OJ L ...).

* OJ: Please insert in the text the date of Decision No 1/2017 of the EU-Mexico Joint Committee and complete the corresponding footnote.

2. An Appendix VI is added to Annex III to Decision No 2/2000 as set out in Annex II to this Decision.

Article 2

This Decision shall enter into force on the first day of the second month following the date on which the Parties have notified each other of the completion of the procedures necessary for this purpose.

Done at ...,

For the Joint Committee

ANNEX I

In Appendix II to Annex III to Decision No 2/2000, the entries for HS headings 2914 and 2915 are replaced by the following:

'HS heading	Description of product	Working or processing carried out on non-originating materials that confers originating status	
(1)	(2)	(3) or (4)	
ex 2914	— Diacetone alcohol — Methyl isobutyl ketone — Mesityl oxide	Manufacture from acetone	Manufacture in which a chemical reaction is made (*)
2915	Saturated acyclic monocarboxylic acids and their anhydrides, halides, peroxides and peroxyacids; their halogenated, sulphonated, nitrated or nitrosated derivatives, except for:	Manufacture from materials of any heading. However, the value of all the materials of headings 2915 and 2916 used may not exceed 20 % of the ex-works price of the product	Manufacture in which the value of all the materials used does not exceed 40 % of the ex-works price of the product
	— Acetic anhydride, ethyl and n-butyl acetate, vinyl acetate, isopropyl and methylamyl acetate, mono-, di- or trichloroacetic acids, their salts and esters	Manufacture from materials of any heading. However, the value of all the materials of heading 2916 used may not exceed 20 % of the ex-works price of the product	Manufacture in which a chemical reaction is made (*)

(*) A "chemical reaction" is a process (including a biochemical process) which results in a molecule with a new structure by breaking intramolecular bonds and by forming new intramolecular bonds, or by altering the spatial arrangement of atoms in a molecule. The following processes should not be considered for purposes of origin:

- (a) dissolving in water or other solvents;
- (b) the elimination of solvents including solvent water; or
- (c) the addition or elimination of water of crystallization.

ANNEX II

The following Appendix is added to Annex III to Decision No 2/2000:

'Appendix VI

THE PRINCIPALITY OF ANDORRA AND THE REPUBLIC OF SAN MARINO

1. Products originating in the Principality of Andorra falling within Chapters 25 to 97 of the Harmonized System shall be accepted by Mexico under the same customs regime as that which applies to products imported from and originating in the European Union, as long as the customs union established by Council Decision 90/680/EEC of 26 November 1990 ⁽¹⁾ remains in force.
2. Products originating in Mexico falling within Chapters 25 to 97 of the Harmonized System benefit from the same preferential tariff treatment when imported into Andorra as they receive when imported into the European Union, as long as the customs union established by Decision 90/680/EEC remains in force.
3. Products originating in the Republic of San Marino falling within Chapters 1 to 97 of the Harmonized System shall be accepted by Mexico under the same customs regime as that which applies to products imported from and originating in the European Union, as long as the Agreement on Cooperation and Customs Union between the European Economic Community and the Republic of San Marino, done at Brussels on 16 December 1991 ⁽²⁾, remains in force.
4. Products originating in Mexico falling within Chapters 1 to 97 of the Harmonized System benefit from the same preferential tariff treatment when imported into San Marino as they receive when imported into the European Union, as long as the Agreement on Cooperation and Customs Union between the European Economic Community and the Republic of San Marino, done at Brussels on 16 December 1991, remains in force.
5. Annex III shall apply *mutatis mutandis* to the trade of the products referred to in points 1 to 4.
6. The exporter or his authorised representative shall enter "Mexico" as well as either "the Principality of Andorra" or "the Republic of San Marino" in Box 2 of the EUR.1 movement certificate or on the invoice declaration. In addition, that information shall be entered in Box 4 of the EUR.1 movement certificate, or on the invoice declaration in the case of products originating in the Principality of Andorra or the Republic of San Marino.
7. The European Union shall send to Mexico samples of the EUR.1 movement certificates, the stamps to be used by the Principality of Andorra and the Republic of San Marino, and the addresses of the authorities responsible for the verification process in the Principality of Andorra and the Republic of San Marino.
8. If the competent governmental authority of the Principality of Andorra or the Republic of San Marino does not comply with the provisions of Annex III, Mexico may take the case to the Special Committee on Customs Cooperation and Rules of Origin established by Article 17 of Decision No 2/2000, in order for appropriate measures to be determined to resolve the issue.'

⁽¹⁾ Council Decision 90/680/EEC of 26 November 1990 on the conclusion of an agreement in the form of an exchange of letters between the European Economic Community and the Principality of Andorra (OJ L 374, 31.12.1990, p. 13).

⁽²⁾ OJ L 84, 28.3.2002, p. 43.

COUNCIL DECISION (EU) 2017/562**of 21 March 2017****appointing an alternate member, proposed by the Portuguese Republic, of the Committee of the Regions**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Portuguese Government,

Whereas:

- (1) On 26 January 2015, 5 February 2015 and 23 June 2015, the Council adopted Decisions (EU) 2015/116 ⁽¹⁾, (EU) 2015/190 ⁽²⁾ and (EU) 2015/994 ⁽³⁾ appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020.
- (2) An alternate member's seat on the Committee of the Regions has become vacant following the end of the term of office of Mr Rodrigo VASCONCELOS DE OLIVEIRA,

HAS ADOPTED THIS DECISION:

Article 1

The following is hereby appointed as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2020:

— Mr Rui Jorge DA SILVA LEITE DE BETTENCOURT, *Secretário Regional Adjunto da Presidência para as Relações Externas do Governo Regional dos Açores*.

Article 2

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

Done at Brussels, 21 March 2017.

For the Council
The President
E. SCICLUNA

⁽¹⁾ Council Decision (EU) 2015/116 of 26 January 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 20, 27.1.2015, p. 42).

⁽²⁾ Council Decision (EU) 2015/190 of 5 February 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 31, 7.2.2015, p. 25).

⁽³⁾ Council Decision (EU) 2015/994 of 23 June 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 159, 25.6.2015, p. 70).

COUNCIL IMPLEMENTING DECISION (EU) 2017/563**of 21 March 2017****authorising the Republic of Estonia to apply a special measure derogating from Article 287 of Directive 2006/112/EC on the common system of value added tax**

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax ⁽¹⁾, and in particular Article 395 thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) By letter registered with the Commission on 18 May 2016, Estonia requested authorisation to apply a special measure derogating from Article 287 of Directive 2006/112/EC (‘the special measure’), allowing Estonia to exempt from value added tax (VAT) taxable persons whose annual turnover is no higher than EUR 40 000 as of 1 January 2018.
- (2) In accordance with Article 395(2) of Directive 2006/112/EC, the Commission informed the other Member States by letter dated 4 October 2016 of the request made by Estonia. The Commission notified Estonia by letter dated 5 October 2016 that it had all the information necessary to consider the request.
- (3) Under point 8 of Article 287 of Directive 2006/112/EC, Estonia may exempt from VAT taxable persons whose annual turnover is no higher than the equivalent in national currency of EUR 16 000 at the conversion rate on the day of its accession.
- (4) The requested special measure is in line with the objectives of Commission Communication of 25 June 2008, entitled “Think small first” — a “Small Business Act” for Europe’.
- (5) Given that the special measure will result in reduced VAT obligations for smaller businesses, Estonia should be authorised to apply it for a limited period of time, until 31 December 2020. Taxable persons should still be able to opt for the normal VAT arrangements.
- (6) As Articles 281 to 294 of Directive 2006/112/EC governing the special scheme for small enterprises are subject to review, it is possible that a directive amending those provisions of Directive 2006/112/EC will enter into force before 31 December 2020.
- (7) Based on information provided by Estonia, the increased threshold will have a negligible impact on the overall amount of tax revenue collected at the stage of final consumption.
- (8) The derogation has no impact on the Union’s own resources accruing from VAT,

HAS ADOPTED THIS DECISION:

Article 1

By way of derogation from point 8 of Article 287 of Directive 2006/112/EC, Estonia is authorised to exempt from VAT taxable persons whose annual turnover is no higher than EUR 40 000.

⁽¹⁾ OJ L 347, 11.12.2006, p. 1.

Article 2

This Decision shall take effect on the day of its notification.

This Decision shall apply from 1 January 2018 until 31 December 2020, or until the entry into force of a directive amending Articles 281 to 294 of Directive 2006/112/EC governing the special scheme for small enterprises, whichever date is earlier.

Article 3

This Decision is addressed to the Republic of Estonia.

Done at Brussels, 21 March 2017.

For the Council
The President
E. SCICLUNA

COMMISSION IMPLEMENTING DECISION (EU) 2017/564**of 23 March 2017****amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States***(notified under document C(2017) 1813)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽¹⁾, and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market ⁽²⁾, and in particular Article 10(4) thereof,

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ⁽³⁾, and in particular Article 4(3) thereof,

Whereas:

- (1) Commission Implementing Decision 2014/709/EU ⁽⁴⁾ lays down animal health control measures in relation to African swine fever in certain Member States. The Annex to that Implementing Decision demarcates and lists certain areas of those Member States in Parts I, II, III and IV thereof differentiated by the level of risk based on the epidemiological situation. That list includes, amongst others, certain areas of Lithuania.
- (2) Since November 2016, no outbreaks of African swine fever in domestic pigs have been notified in certain areas of Lithuania which are listed in Part III of the Annex to Implementing Decision 2014/709/EU. In addition, supervision of biosecurity measures has been implemented in a satisfactory manner in holdings in those areas based on the national programme for biosecurity aimed at the prevention of the spread of African swine fever. These facts indicate an improvement in the epidemiological situation. Accordingly, those areas of Lithuania should now be listed in Part II, instead of Part III, of the Annex to Implementing Decision 2014/709/EU.
- (3) The evolution of the current epidemiological situation of African swine fever in the affected domestic and feral pig populations in the Union should be taken into account in the assessment of the animal health risk posed by that situation as regards that disease in Lithuania. In order to focus the animal health control measures provided for in Implementing Decision 2014/709/EU and to prevent the further spread of African swine fever, while preventing any unnecessary disturbance to trade within the Union and avoiding unjustified barriers to trade by third countries, the Union list of areas subject to the animal health control measures set out in the Annex to that Implementing Decision should be amended to take into account the changes in the current epidemiological situation as regards that disease in Lithuania.
- (4) The Annex to Implementing Decision 2014/709/EU should therefore be amended accordingly.
- (5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 395, 30.12.1989, p. 13.

⁽²⁾ OJ L 224, 18.8.1990, p. 29.

⁽³⁾ OJ L 18, 23.1.2003, p. 11.

⁽⁴⁾ Commission Implementing Decision 2014/709/EU of 9 October 2014 concerning animal health control measures relating to African swine fever in certain Member States and repealing Implementing Decision 2014/178/EU (OJ L 295, 11.10.2014, p. 63).

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision 2014/709/EU is replaced by the text set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 23 March 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

‘ANNEX

PART I

1. Estonia

The following areas in Estonia:

- the maakond of Hiiumaa.

2. Latvia

The following areas in Latvia:

- in the novads of Bauskas, the pagasti of Īslīces, Gailīšu, Brunavas and Ceraukstes,
- in the novads of Dobeles, the pagasti of Bikstu, Zebrenes, Annenieku, Naudītes, Penkules, Auru and Krimūnu, Dobeles, Berzes, the part of the pagasts of Jaunbērzes located to the west of road P98, and the pilsēta of Dobeļe,
- in the novads of Jelgavas, the pagasti of Glūdas, Svētes, Platones, Vircavas, Jaunsvirlaukas, Zaļenieku, Vilces, Lielplatones, Elejas and Sesavas,
- in the novads of Kandavas, the pagasti of Vānes and Matkules,
- in the novads of Kuldīgas, the pagasti of Rendas and Kabiles,
- in the novads of Saldus, the pagasti of Jaunlutriņu, Lutriņu and Šķēdes,
- in the novads of Talsu, the pagasts of Ģibuļu,
- in the novads of Ventspils, the pagasti of Vārves, Užavas, Jūrkalnes, Piltenes, Zīru, Ugāles, Usmas and Zlēku, the pilsēta of Piltene,
- the novads of Brocēnu,
- the novads of Rundāles,
- the novads of Tērvetes,
- the part of the novads of Stopiņu located to the west of roads V36, P4 and P5, streets Acones, Dauguļupes and river Dauguļupīte,
- the pilsēta of Bauska,
- the pilsēta of Talsi,
- the republikas pilsēta of Jelgava,
- the republikas pilsēta of Ventspils.

3. Lithuania

The following areas in Lithuania:

- in the rajono savivaldybė of Jurbarkas, the seniūnijos of Raudonės, Veliuonos, Seredžiaus and Juodaičių,
- in the rajono savivaldybė of Pakruojis, the seniūnijos of Klovainių, Rozalimo and Pakruojis,
- in the rajono savivaldybė of Panevėžys, the part of the Krekenavos seniūnija located to the west of the river Nevėžis,
- in the rajono savivaldybė of Pasvalys, the seniūnijos of Joniškėlio apylinkių, Joniškėlio miesto, Namišių, Pasvalio apylinkių, Pumpėnų, Pušaloto, Saločių and Vaškų,
- in the rajono savivaldybė of Raseiniai, the seniūnijos of Ariogalos, Ariogalos miestas, Betygalos, Pajūrių and Šiluvos,
- in the rajono savivaldybė of Šakiai, the seniūnijos of Plokščių, Kriūkų, Lekėčių, Lukšių, Griškabūdžio, Barzdų, Žvirgždaičių, Sintautų, Kudirkos Naumiesčio, Slavikų, Šakių,
- the miesto savivaldybė of Pasvalys,
- the rajono savivaldybė of Radviliškis,

- the rajono savivaldybė of Vilkaviškis,
- the savivaldybė of Kalvarija,
- the savivaldybė of Kazlų Rūda,
- the savivaldybė of Marijampolė.

4. Poland

The following areas in Poland:

In the województwo warmińsko-mazurskie:

- the gminy of Kalinowo and Prostki in the powiat ełcki,
- the gmina of Biała Piska in powiat piski.

In the województwo podlaskie:

- the gminy Juchnowiec Kościelny, Suraż, Turośń Kościelna, Łapy and Poświętne in the powiat białostocki,
- the gminy of Brańsk with the city of Brańsk, Boćki, Rudka, Wyszki, the part of the gmina of Bielsk Podlaski located to the west of the line created by road number 19 (going northwards from the city of Bielsk Podlaski) and prolonged by the eastern border of the city of Bielsk Podlaski and road number 66 (going southwards from the city of Bielsk Podlaski), the city of Bielsk Podlaski, the part of the gmina of Orla located to the west of road number 66, in the powiat bielski,
- the gminy of Drohiczyn, Dziadkowice, Grodzisk and Perlejewo in the powiat siemiatycki,
- the gminy of Grabowo and Stawiski in the powiat kolneński,
- the gminy of Kołaki Kościelne, Szumowo, Zambrów with the city Zambrów in powiat zambrowski,
- the gminy of Rutka-Tartak, Szypliszki, Suwałki, Raczki in the powiat suwalski,
- the gminy Sokoły, Kulesze Kościelne, Nowe Piekuty, Szepietowo, Klukowo, Ciechanowiec, Wysokie Mazowieckie with the city of Wysokie Mazowieckie, Czyżew in powiat wysokomazowiecki,
- the powiat augustowski,
- the powiat łomżyński,
- the powiat M. Białystok,
- the powiat M. Łomża,
- the powiat M. Suwałki,
- the powiat sejneński.

In the województwo mazowieckie:

- the gminy of Cerańów, Jabłonna Lacka, Sterdyń and Repki in the powiat sokołowski,
- the gminy of Korczew, Przesmyki, Paprotnia, Suchożebry, Mordy, Siedlce and Zbuczyn in the powiat siedlecki,
- the powiat M. Siedlce,
- the gminy of Rzekuń, Troszyn, Czerwin and Goworowo in the powiat ostrołęcki,
- the gminy of Olszanka, Łosice and Platerów in the powiat łosicki,
- the powiat ostrowski.

In the województwo lubelskie:

- the gmina of Hanna in the powiat włodawski,
- the gminy of Kąkolewnica Wschodnia and Komarówka Podlaska in the powiat radzyński,
- the gminy of Międzyrzec Podlaski with the city of Międzyrzec Podlaski, Drelów, Rossosz, Sławatycze, Wisznica, Sosnówka, Łomazy and Tucznia in the powiat bialski.

PART II

1. Estonia

The following areas in Estonia:

- the linn of Elva,
- the linn of Võhma,
- the linn of Kuressaare,
- the linn of Rakvere,
- the linn of Tartu,
- the linn of Viljandi,
- the maakond of Harjumaa (excluding the part of the vald of Kuusalu located to the south of road 1 (E20), the vald of Aegviidu and the vald of Anija),
- the maakond of IDA-Virumaa,
- the maakond of Läänemaa,
- the maakond of Pärnumaa,
- the maakond of Põlvamaa,
- the maakond of Võrumaa,
- the maakond of Valgamaa,
- the maakond of Raplamaa,
- the vald of Suure-Jaani,
- the part of the vald of Tamsalu located to the north-east of the Tallinn-Tartu railway,
- the vald of Tartu,
- the vald of Abja,
- the vald of Alatskivi,
- the vald of Haaslava,
- the vald of Haljala,
- the vald of Tarvastu,
- the vald of Nõo,
- the vald of Ülenurme,
- the vald of Tähtvere,
- the vald of Rõngu,
- the vald of Rannu,
- the vald of Konguta,
- the vald of Puhja,
- the vald of Halliste,
- the vald of Kambja,
- the vald of Karksi,
- the vald of Kihelkonna,
- the vald of Kõpu,
- the vald of Lääne-Saare,
- the vald of Laekvere,
- the vald of Leisi,
- the vald of Luunja,
- the vald of Mäksa,
- the vald of Meeksi,

- the vald of Muhu,
- the vald of Mustjala,
- the vald of Orissaare,
- the vald of Peipsiääre,
- the vald of Piirissaare,
- the vald of Pöide,
- the vald of Rägavere,
- the vald of Rakvere,
- the vald of Ruhnu,
- the vald of Salme,
- the vald of Sõmeru,
- the vald of Torgu,
- the vald of Vara,
- the vald of Vihula,
- the vald of Viljandi,
- the vald of Vinni,
- the vald of Viru-Nigula,
- the vald of Võnnu.

2. Latvia

The following areas in Latvia:

- in the novads of Apes, the pagasti of Trapenes, Gaujienas and Apes and the pilsēta of Ape,
- in the novads of Balvu, the pagasti of Vīksnas, Bērzkālnes, Vectilžas, Lazdulejas, Briežuciema, Tilžas, Bērzpils and Krišjāņu,
- in the novads of Bauskas, the pagasti of Mežotnes, Codes, Dāviņu and Vecsaules,
- in the novads of Daugavpils the pagasti of Vaboles, Liksnas, Sventes, Medumu, Demenas, Kalkūnes, Laucesas, Tabores, Maļinovas, Ambeļu, Biķernieku, Naujenes, Vecsalienas, Salienas and Skrudalienas,
- in the novads of Dobeles, the part of the pagasts of Jaunbērzes located to the east of road P98,
- in the novads of Gulbenes the pagasts of Līgo,
- in the novads of Ikšķiles, the part of pagasts of Tīnūžu located to the south-east of road P10, the pilsēta of Ikšķile,
- in the novads of Jelgavas the pagasti of Kalnciema, Līvānāžu and Valgundes,
- in the novads of Kandavas, the pagasti of Cēres, Kandavas, Zemītes and Zantes, the pilsēta of Kandava,
- in the novads of Krimuldas, the part of pagasts of Krimuldas located to the north-east of roads V89 and V81 and the part of pagasts of Lēdurgas located to the north-east of roads V81 and V128,
- in the novads of Limbažu, the pagasti of Skultes, Limbažu, Umurgas, Katvaru, Pāles, Viļķenes and the pilsēta of Limbaži,
- in the novads of Preiļu the pagasts of Saunas,
- in the novads of Raunas, the pagasts of Raunas,
- in the novads of Riebiņu, the pagasti of Sīļukalna, Stabulnieku, Galēnu and Silajāņu,
- in the novads of Rugāļu the pagasts of Lazdukalna,
- in the novads of Siguldas, the pagasts of Mores and the part of the pagasts of Allažu located to the south of the road P3,

- in the novads of Smiltenes, the pagasti of Brantu, Blomes, Smiltenes, Bilskas and Grundzāles, the pilsēta of Smiltene,
- in the novads of Talsu, the pagasti of Ķūļciema, Balgales, Vandzenes, Laucienes, Virbu, Strazdes, Lubes, Īves, Valdgales, Laidzes, Ārlavas, Lībagu and Abavas, the pilsētas of Sabile, Stende and Valdemārpils,
- in the novads of Ventspils, the pagasti of Ances, Tārgales, Popes and Puzes,
- the novads of Ādažu,
- the novads of Aglonas,
- the novads of Aizkraukles,
- the novads of Aknīstes,
- the novads of Alojas,
- the novads of Alūksnes,
- the novads of Amatas,
- the novads of Babītes,
- the novads of Baldones,
- the novads of Baltnavas,
- the novads of Beverīnas,
- the novads of Burtnieku,
- the novads of Carnikavas,
- the novads of Cēsu,
- the novads of Cesvaines,
- the novads of Ciblas,
- the novads of Dagdas,
- the novads of Dundagas,
- the novads of Engures,
- the novads of Ērgļu,
- the novads of Iecavas,
- the novads of Ilūkstes,
- the novads of Jaunjelgavas,
- the novads of Jaunpils,
- the novads of Jēkabpils,
- the novads of Kārsavas,
- the novads of Ķeguma,
- the novads of Ķekavas,
- the novads of Kocēnu,
- the novads of Kokneses,
- the novads of Krāslavas,
- the novads of Krustpils,
- the novads of Lielvārdes,
- the novads of Līgatnes,
- the novads of Līvānu,
- the novads of Lubānas,
- the novads of Ludzas,
- the novads of Madonas,
- the novads of Mālpils,
- the novads of Mārupes,

- the novads of Mazsalacas,
- the novads of Mērsraga,
- the novads of Naukšēnu,
- the novads of Neretas,
- the novads of Ogres,
- the novads of Olaines,
- the novads of Ozolnieki,
- the novads of Pārgaujas,
- the novads of Pļaviņu,
- the novads of Priekule,
- the novads of Rēzeknes,
- the novads of Rojas,
- the novads of Rūjienas,
- the novads of Salacgrīvas,
- the novads of Salas,
- the novads of Saulkrastu,
- the novads of Skrīveru,
- the novads of Strenču,
- the novads of Tukuma,
- the novads of Valkas,
- the novads of Varakļānu,
- the novads of Vecpiebalgas,
- the novads of Vecumnieku,
- the novads of Viesītes,
- the novads of Viļakas,
- the novads of Viļānu,
- the novads of Zilupes,
- the part of the novads of Garkalnes located to the north-west of road A2,
- the part of the novads of Ropažu located to the east of road P10,
- the republikas pilsēta of Daugavpils,
- the republikas pilsēta of Jēkabpils,
- the republikas pilsēta of Jūrmala,
- the republikas pilsēta of Rēzekne,
- the republikas pilsēta of Valmiera.

3. Lithuania

The following areas in Lithuania:

- in the rajono savivaldybė of Biržai, the seniūnijos of Nemunėlio Radviliškio, Pabiržės, Pačeriaukštės and Parovėjos,
- in the rajono savivaldybė of Kupiškis, the seniūnijos of Noriūnų, Skapiškio, Subačiaus and Šimonių,
- in the rajono savivaldybė of Panevėžys the seniūnijos of Naujamiesčio, Pajstrio, Panevėžio, Ramygalos, Smilgių, Uptytės, Vadoklių, Velžio and the part of Krekenavos seniūnija located to the east of the river Nevėžis,
- the miesto savivaldybė of Alytus,
- the miesto savivaldybė of Biržai,
- the miesto savivaldybė of Jonava,
- the miesto savivaldybė of Kaišiadorys,

- the miesto savivaldybė of Kaunas,
- the miesto savivaldybė of Panevėžys,
- the miesto savivaldybė of Prienai,
- the miesto savivaldybė of Vilnius,
- the rajono savivaldybė of Alytus,
- the rajono savivaldybė of Anykščiai,
- the rajono savivaldybė of Ignalina,
- the rajono savivaldybė of Jonava,
- the rajono savivaldybė of Kaišiadorys,
- the rajono savivaldybė of Kaunas,
- the rajono savivaldybė of Kėdainiai,
- the rajono savivaldybė of Lazdijai,
- the rajono savivaldybė of Molėtai,
- the rajono savivaldybė of Prienai,
- the rajono savivaldybė of Rokiškis,
- the rajono savivaldybė of Šalčininkai,
- the rajono savivaldybė of Širvintos,
- the rajono savivaldybė of Švenčionys,
- the rajono savivaldybė of Trakai,
- the rajono savivaldybė of Ukmergė,
- the rajono savivaldybė of Utena,
- the rajono savivaldybė of Varėna,
- the rajono savivaldybė of Vilnius,
- the rajono savivaldybė of Zarasai,
- the savivaldybė of Birštonas,
- the savivaldybė of Druskininkai,
- the savivaldybė of Elektrėnai,
- the savivaldybė of Visaginas.

4. Poland

The following areas in Poland:

In the województwo podlaskie:

- the gmina of Dubicze Cerkiewne, the parts of the gminy of Kleszczele and Czeremcha located to the east of road number 66, in the powiat hajnowski,
- the gmina of Rutki in the powiat zambrowski,
- the gmina Kobylin-Borzymy in the powiat wysokomazowiecki,
- the gminy of Czarna Białostocka, Dobrzyniewo Duże, Gródek, Michałowo, Supraśl, Tykocin, Wasilków, Zabłudów, Zawady and Choroszcz in the powiat białostocki,
- the part of the gmina of Bielsk Podlaski located to the east of the line created by road number 19 (going northwards from the city of Bielsk Podlaski) and prolonged by the eastern border of the city of Bielsk Podlaski and road number 66 (going southwards from the city of Bielsk Podlaski), the part of the gmina of Orla located to the east of road number 66, in the powiat bielski,
- the powiat sokółski.

In the województwo lubelskie:

- the gminy of Piszczac and Kodeń in the powiat bialski.

PART III

1. Estonia

The following areas in Estonia:

- the maakond of Jõgevamaa,
- the maakond of Järvamaa,
- the part of the vald of Kuusalu located to the south of road 1 (E20),
- the part of the vald of Tamsalu located to the south-west of the Tallinn-Tartu railway,
- the vald of Aegviidu,
- the vald of Anija,
- the vald of Kadrina,
- the vald of Kolga-Jaani,
- the vald of Kõo,
- the vald of Laeva,
- the vald of Laimjala,
- the vald of Pihitla,
- the vald of Rakke,
- the vald of Tapa,
- the vald of Väike-Maarja,
- the vald of Valjala.

2. Latvia

The following areas in Latvia:

- in the novads of Apes, the pagasts of Virešu,
- in the novads of Balvu, the pagasti of Kubuļu, Balvu and the pilsēta of Balvi,
- in the novads of Daugavpils the pagasti of Nīcgales, Kalupes, Dubnas and Višķu,
- in the novads of Gulbenes, the pagasti of Beļavas, Galgauskas, Jaungulbenes, Daukstu, Stradu, Litenes, Stāmerienas, Tirzas, Druvienas, Rankas, Lizuma and Lejasciema and the pilsēta of Gulbene,
- in the novads of Ikšķiles, the part of the pagasts of Tīnūžu located to the north-west of road P10,
- in the novads of Krimuldas the part of pagasts of Krimuldas located to the south-west of roads V89 and V81 and the part of pagasts of Lēdurgas located to the south-west of roads V81 and V128,
- in the novads of Limbažu the pagasts of Vidrižu,
- in the novads of Preiļu the pagasti of Preiļu, Aizkalnes and Pelēču, the pilsēta of Preiļi,
- in the novads of Raunas, the pagasts of Drustu,
- in the novads of Riebiņu the pagasti of Riebiņu and Rušonas,
- in the novads of Rugāju the pagasts of Rugāju,
- in the novads of Siguldas the pagasts of Siguldas and the part of pagasts of Allažu located to the north of road P3 and the pilsēta of Sigulda,
- in the novads of Smiltenes, the pagasti of Launkalnes, Variņu and Palsmanes,
- the novads of Inčukalna,
- the novads of Jaunpiebalgas,
- the novads of Salaspils,
- the novads of Sējas,

- the novads of Vārkavas,
- the part of the novads of Garkalnes located to the south-east of road A2,
- the part of the novads of Ropažu located to the west of road P10,
- the part of the novads of Stopiņu located to the east of roads V36, P4 and P5, streets Acones, Daugulupes and river Daugulupīte.

3. Lithuania

The following areas in Lithuania:

- in the rajono savivaldybė of Biržai, the seniūnijos of Vabalninko, Papilio and Širvenos,
- in the rajono savivaldybė of Kupiškis, the seniūnijos of Alizavos and Kupiškio,
- in the rajono savivaldybė of Panevėžys, the seniūnijos of Miežiškių, Raguvos and Karsakiškio,
- in the rajono savivaldybė of Pasvalys, the seniūnijos of Daujėnų and Krinčino.

4. Poland

The following areas in Poland:

In the województwo podlaskie:

- the powiat grajewski,
- the powiat moniecki,
- the gminy of Czyże, Białowieża, Hajnówka with the city of Hajnówka, Narew, Narewka and the parts of the gminy of Czeremcha and Kleszczele located to the west of road number 66 in the powiat hajnowski,
- the gminy of Mielnik, Milejczyce, Nurzec-Stacja, Siemiatycze with the city of Siemiatycze in the powiat siemiatycki.

In the województwo mazowieckie:

- the gminy of Sarnaki, Stara Kornica and Huszlew in powiat łosicki.

In the województwo lubelskie:

- the gminy of Konstantynów, Janów Podlaski, Leśna Podlaska, Rokitno, Biała Podlaska, Zalesie and Terespol with the city of Terespol in the powiat bialski,
- the powiat M. Biała Podlaska.

PART IV

Italy

The following areas in Italy:

- all areas of Sardinia.'
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CORRIGENDA

Corrigendum to Commission Delegated Regulation (EU) 2016/1824 of 14 July 2016 amending Delegated Regulation (EU) No 3/2014, Delegated Regulation (EU) No 44/2014 and Delegated Regulation (EU) No 134/2014 with regard, respectively, to vehicle functional safety requirements, to vehicle construction and general requirements and to environmental and propulsion unit performance requirements

(Official Journal of the European Union L 279 of 15 October 2016)

On page 3, in Article 2 amending Delegated Regulation (EU) No 44/2014, point (1):

for: ‘(1) in Article 3(2), “Manufacturers” is replaced by “Manufacturers of parts and equipment”’;

read: ‘(1) in Article 3(3), “Manufacturers” is replaced by “Manufacturers of parts and equipment”’.

