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⁽¹⁾ Text with EEA relevance.

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1658

of 5 November 2018

approving an amendment to the specification for a protected designation of origin or a protected geographical indication ('Côtes de Montravel' (PDO))

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⁾, and in particular Article 99 thereof,

Whereas:

- (1) The Commission has examined France's application for the approval of amendments to the specification for the protected designation of origin 'Côtes de Montravel', submitted under Article 105 of Regulation (EU) No 1308/2013.
- (2) The Commission published the application for approval of the amendments to the specification in the *Official Journal of the European Union* ⁽²⁾ as required by Article 97(3) of Regulation (EU) No 1308/2013.
- (3) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.
- (4) In accordance with Article 99 of Regulation (EU) No 1308/2013 the amendments to the specification should therefore be approved.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Côtes de Montravel' (PDO) are hereby approved.

Article 2

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

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ C 243, 11.7.2018, p. 3.

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

Done at Brussels, 5 November 2018.

*For the Commission,
On behalf of the President,
Phil HOGAN
Member of the Commission*

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1659**of 7 November 2018****amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605****(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 Article 19 thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 844/2012 ⁽²⁾ provides for the implementation of the renewal procedure for active substances as provided for in Regulation (EC) No 1107/2009.
- (2) Commission Regulation (EU) 2018/605 ⁽³⁾ introduced new scientific criteria for the determination of endocrine disrupting properties, which reflect the current state of scientific and technical knowledge. Those criteria are to apply as of 10 November 2018 to applications for the renewal of the approval of active substances in accordance with Regulation (EC) No 1107/2009, including pending applications.
- (3) Applications for the renewal of the approval of an active substance which are submitted before 10 November 2018 and for which, by that date, the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 has not voted on a draft Regulation concerning the renewal or non-renewal of the approval of that active substance, should be considered pending applications.
- (4) For such pending applications, it is possible that the information submitted by the applicant does not allow to conclude the assessment as regards whether the scientific criteria for the determination of endocrine disrupting properties set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are met or not and to conclude whether the approval criteria set out in those points are met or not. Therefore, the European Food Safety Authority ('the Authority') should be able to request additional information from the applicant in order to conclude whether the approval criteria set out in those points are met or not. Such additional information should be submitted within a time period set by the Authority, which should be as short as possible in order to avoid unjustified delays of the renewal procedure, and which should be based on the type of information to be submitted.
- (5) Within the period given to provide the additional information, applicants should also be able to apply for the derogation under Article 4(7) of Regulation (EC) No 1107/2009.
- (6) Where, based on the information already available, the Authority has been able to conclude that the substance meets the scientific criteria for the determination of endocrine disrupting properties, applicants should be able to submit additional information as regards the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 and/or be able to submit documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of that Regulation are met.
- (7) Where the Authority requires such additional information from the applicant, the period foreseen for the preparation of the conclusion by the Authority should be extended in order for that information to be taken into account.
- (8) When requesting additional information from the applicant, the Authority should consider that animal testing is to be minimised and tests on vertebrates are to be undertaken only as a last resort, in accordance with Article 62 of Regulation (EC) No 1107/2009.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ 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).

⁽³⁾ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

- (9) Taking into account that the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605 apply as of 10 November 2018, this Regulation should enter into force as soon as possible and apply from 10 November 2018.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) No 844/2012 is amended as follows:

- (1) The following Article is inserted after Article 11:

'Article 11a

For the purposes of assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 as amended by Commission Regulation (EU) 2018/605 (*), in relation to applications submitted in accordance with Article 1 before 10 November 2018 for which the draft renewal assessment report has not been submitted by that date, where the information available in the supplementary dossiers is not sufficient for the rapporteur Member State to conclude the assessment on whether these approval criteria are met and, where applicable, whether application of Article 4(7) is justified, the rapporteur Member State shall specify in the draft renewal assessment report, in a detailed way, the additional information which is necessary in order to make the assessment concerned.;

(*) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33)'.

- (2) The following paragraph is inserted after Article 13(3):

'3a. For the purposes of assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 as amended by Commission Regulation (EU) 2018/605, in relation to applications submitted in accordance with Article 1 before 10 November 2018, for which the draft renewal assessment report has been submitted but the conclusion by the Authority is not yet adopted by that date, where the information available in the dossier is not sufficient for the Authority to conclude the assessment on whether these approval criteria are met, the Authority shall, in consultation with the Member States, request from the applicant the additional information to be submitted to the rapporteur Member State, the other Member States, the Commission, and the Authority in the form of an updated supplementary dossier including the additional information. The Authority shall, in consultation with the rapporteur Member State and the applicant, set a period for the submission of that information. Such period shall be at least of 3 months, shall not exceed 30 months, and shall be justified in relation to the type of information which has to be submitted.

Within this period set by the Authority, the applicant may also submit where applicable, documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of Regulation (EC) No 1107/2009 are met.

Where the Authority, in consultation with the Member States, is able to conclude without requesting additional information that the scientific criteria for the determination of endocrine disrupting properties set out in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are met, it shall inform the applicant. Within 3 months after being informed by the Authority, the applicant may submit to the rapporteur Member State, the other Member States, the Commission, and the Authority, additional information to address the approval criteria set in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, and/or documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of that Regulation are met.

Where the first or third subparagraphs apply, the period referred to in paragraph 1 shall be extended by the period set for submission of the additional information.

Where no additional information is submitted in accordance with the first, second or third subparagraph within the period set for its submission, the Authority shall, without delay, inform the applicant, the rapporteur Member State, the Commission and the other Member States and conclude the assessment based on the available information.

Where additional information is submitted in accordance with the first, second or third subparagraph within the period set for its submission, the rapporteur Member State shall, within 90 days from the date of receipt of the additional information evaluate the information received and send its evaluation to the Authority in the form of a revised draft renewal assessment report. The Authority shall conduct a consultation on the revised draft renewal assessment report with all the Member States and the applicant in accordance with Article 12. The Authority shall adopt the conclusion referred to in paragraph 1, within 120 days from the date of receipt of the revised draft renewal assessment report, using the guidance for identification of endocrine disruptors applicable at the date of the submission of the updated supplementary dossier referred to in the first subparagraph.;

(3) Paragraph 5 of Article 13 is replaced by the following:

‘5. Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the first subparagraph of paragraph 3 or in accordance with the first or third subparagraphs of paragraph 3a of this Article, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.’;

(4) The following paragraph is inserted after Article 14(1):

‘1a. For the purposes of assessment of the approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 as amended by Commission Regulation (EU) 2018/605, in relation to applications for which the conclusion by the Authority is adopted before 10 November 2018, and where the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 has not yet voted on a draft Regulation concerning the renewal or non-renewal of that active substance by that date, the Commission may consider that additional information is necessary to assess whether these approval criteria are met. In such cases, the Commission shall request that the Authority reassesses within a reasonable time period the available information and shall inform the applicant of that request.

When requested by the Commission in accordance with the first subparagraph, the Authority may, in consultation with the rapporteur Member State, decide whether additional information is required and request the applicant to submit such information to the rapporteur Member State, the other Member States, the Commission and the Authority in the form of an updated supplementary dossier including the additional information. The Authority shall, in consultation with the rapporteur Member State and the applicant, set a period for the submission of that information. Such period shall be at least of 3 months, shall not exceed 30 months, and shall be justified in relation to the type of information which has to be submitted.

Within this period set by the Authority, the applicant may also submit where applicable, documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of Regulation (EC) No 1107/2009 are met.

Where the Authority, in consultation with the Member States, is able to conclude without requesting additional information that the scientific criteria for the determination of endocrine disrupting properties set out in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 are met, it shall inform the applicant. Within 3 months after being informed by the Authority, the applicant may submit to the rapporteur Member State, the other Member States, the Commission, and the Authority, additional information to address the approval criteria set out in point 3.6.5 and/or point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, and/or documentary evidence showing that the conditions for the application of the derogation under Article 4(7) of that Regulation are met.

The rapporteur Member State shall, within 90 days from the date of receipt of the additional information evaluate the information received and send its evaluation to the Authority in the form of a revised draft renewal assessment report. The Authority shall conduct a consultation of the revised renewal assessment report with all the Member States and the applicant in accordance with Article 12.

The Authority shall adopt an addendum to the conclusion referred to in paragraph 1, within 120 days from the date of receipt of the revised draft renewal assessment report, using the guidance for identification of endocrine disruptors applicable at the date of the submission of the updated supplementary dossier referred to in the second subparagraph.

Where no additional information is submitted in accordance with the second, the third or the fourth subparagraph within the period set for its submission, the Authority shall, without delay, inform the applicant, the rapporteur Member State, the co-rapporteur Member State, the Commission and the other Member States and conclude the assessment based on the available information within 30 days from the expiry of the period referred to in the second or fourth subparagraph.

Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the second or fourth subparagraph of this Article, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.'

Article 2

The provisions of Implementing Regulation (EU) No 844/2012 inserted by Article 1 of this Regulation shall apply in addition to the other provisions of Implementing Regulation (EU) No 844/2012.

Article 3

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

It shall apply from 10 November 2018.

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

Done at Brussels, 7 November 2018.

For the Commission

The President

Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1660**of 7 November 2018****imposing special conditions governing the import of certain food of non-animal origin from certain third countries due to the risks of contamination with pesticides residues, amending Regulation (EC) No 669/2009 and repealing Implementing Regulation (EU) No 885/2014****(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 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽¹⁾, and in particular Article 53(1)(b)(ii) thereof,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ⁽²⁾, and in particular Article 15(5) thereof,

Whereas:

- (1) Article 53 of Regulation (EC) No 178/2002 provides for the possibility to adopt appropriate Union emergency measures for food and feed imported from a third country in order to protect public health, animal health or the environment, where it is evident that the food and feed concerned is likely to constitute a serious risk to human health and animal health and that such risk cannot be contained satisfactorily by means of measures taken by the Member States individually. Those Union emergency measures may consist of imposing special conditions of import for the products concerned.
- (2) Commission Regulation (EC) No 669/2009 ⁽³⁾ provides for an increased level of official controls on imports of the feed and food of non-animal origin listed in Annex I thereof. Vine leaves from Turkey and Pitahaya (dragon fruit) from Vietnam are included in that Annex and are therefore subject to an increased level of official controls.
- (3) The results from the official controls carried out by the Member States in the framework of Regulation (EC) No 669/2009, data resulting from notifications received through the Rapid Alert System for Food and Feed, as established by Regulation (EC) No 178/2002, audit reports by the Commission, reports received from third countries and exchanges of information between the Commission, Member States and the European Food Safety Authority show a continuous high frequency of non-compliance of vine leaves from Turkey with the maximum residue levels of pesticides set out in Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽⁴⁾. No improvement of the situation could therefore be observed even after increasing the frequency of controls at Union borders.
- (4) The results from the official controls carried out by the Member States in the framework of Regulation (EC) No 669/2009 show a high frequency of non-compliance of Pitahaya (dragon fruit) from Vietnam with the maximum residue levels of pesticides set out in Regulation (EC) No 396/2005. Moreover, an audit carried out by the Commission in Vietnam in March 2017 to evaluate controls of pesticides in food of plant origin intended for export to the European Union found that there is no official effective pesticide control system for food exported to the Union and that the authorities cannot ensure compliance of Vietnamese products with maximum residue levels for pesticide residues.
- (5) This provides evidence that the import of vine leaves from Turkey and of Pitahaya (dragon fruit) from Vietnam is likely to constitute a serious risk to health and that such risk cannot be contained satisfactorily by the measures currently in place. It is therefore necessary to establish special conditions of import for vine leaves from Turkey and Pitahaya (dragon fruit) from Vietnam.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 165, 30.4.2004, p. 1.

⁽³⁾ Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC (OJ L 194, 25.7.2009, p. 11).

⁽⁴⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

- (6) Curry leaves from India are currently subject to the special conditions of import set out in Commission Implementing Regulation (EU) No 885/2014 ⁽¹⁾. Special conditions of import for this product should be maintained, in light of the data resulting from notifications received through the Rapid Alert System for Food and Feed and of the results from the official controls carried out by the Member States in the framework of Implementing Regulation (EU) No 885/2014, which show a continuous high frequency of non-compliance.
- (7) It is therefore appropriate to require that curry leaves from India, vines leaves from Turkey and Pitahaya (dragon fruit) from Vietnam be subject to official controls before export to the Union, including sampling and analysis, so as to ensure that those products comply with the relevant legal requirements. All consignments of such products should be accompanied by a health certificate stating that the products have been sampled in accordance with Commission Directive 2002/63/EC ⁽²⁾.
- (8) In order to ensure an efficient organisation and a degree of uniformity at the Union level of the controls at import with regard to the presence of pesticides residues in and on curry leaves from India, vines leaves from Turkey and Pitahaya (dragon fruit) from Vietnam, it is appropriate to provide in this Regulation for control procedures which are at least equivalent to those provided for in Regulation (EC) No 669/2009.
- (9) In order to take into account the specific nature of non-compliance with documentary requirements, it is appropriate to lay down rules on the action to be taken where the consignment is not accompanied by both the results of sampling and analysis and the health certificate or where those results or that health certificate do not comply with the requirements laid down in this Regulation.
- (10) Regulation (EC) No 882/2004 requires competent authorities to notify the Commission and other Member States of border rejections. As regards pesticides, it is appropriate to clarify that where the competent authorities reject a consignment of food listed in this Regulation, such notification should be made where a maximum residue level set out in Regulation (EC) No 396/2005 has not been complied with, irrespective of whether the acute reference dose has been exceeded.
- (11) In order to collect data for continuous risk evaluation in relation to the goods covered by this Regulation and adapt existing measures as necessary, it is appropriate to require Member States to submit to the Commission biannually a report on all analytical results of official controls carried out under this Regulation. Certain Member States register the common entry document pertaining to certain feed and food of non-animal origin on a voluntary basis in the Trade Control and Expert System (TRACES) established by Commission Decisions 2003/24/EC ⁽³⁾ and 2004/292/EC ⁽⁴⁾, thus providing the Commission with information on the number of consignments imported and the results of the checks provided for in this Regulation. That reporting obligation should therefore be deemed to be satisfied where Member States register in TRACES the common entry documents issued in accordance with this Regulation.
- (12) The measures provided for in this Regulation should be reviewed before 31 October 2019 in order to assess whether they are still necessary.
- (13) Adequate financial resources should be available for organising official controls in accordance with this Regulation. Hence, costs resulting from such official controls should be borne by the food business operators responsible for the consignments.
- (14) For the sake of transparency and consistency of the applicable rules, all specific conditions governing the import of curry leaves from India, of vine leaves from Turkey and of Pitahaya (dragon fruit) from Vietnam with regard to the presence of pesticide residues should be set out in this Regulation. Therefore the entries for vine leaves from Turkey and for Pitahaya (dragon fruit) from Vietnam should be removed from Annex I to Regulation (EC) No 669/2009 and Implementing Regulation (EU) No 885/2014 concerning curry leaves from India should be repealed.

⁽¹⁾ Commission Implementing Regulation (EU) No 885/2014 of 13 August 2014 laying down specific conditions applicable to the import of okra and curry leaves from India and repealing Implementing Regulation (EU) No 91/2013 (OJ L 242, 14.8.2014, p. 20).

⁽²⁾ Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC (OJ L 187, 16.7.2002, p. 30).

⁽³⁾ Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system (OJ L 8, 14.1.2003, p. 44).

⁽⁴⁾ Commission Decision 2004/292/EC of 30 March 2004 on the introduction of the Traces system and amending Decision 92/486/EEC (OJ L 94, 31.3.2004, p. 63).

- (15) In order to give operators sufficient time to adapt to the requirements set out in this Regulation, this Regulation should apply from 8 December 2018. In the interest of legal certainty, it is appropriate to provide that Member States should authorise during a transitional period the import of consignments of vine leaves from Turkey, of Pitahaya (dragon fruit) from Vietnam and of curry leaves from India which left their country of origin or the country of consignment if that country is different from the country of origin, prior to 8 December 2018 provided that those consignments fulfil the requirements of Regulation (EC) No 669/2009 in force on 7 December 2018 and Implementing Regulation (EU) No 885/2014 respectively.
- (16) 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

Scope

1. This Regulation shall apply to consignments of the food of non-animal origin which is listed in Annex I.

This Regulation shall also apply to compound food, containing any of the food listed in Annex I in a quantity above 20 %.

2. This Regulation shall not apply to consignments of food which are destined to a private person for personal consumption and use only. In case of doubt, the burden of proof lies with the recipient of the consignment.

Article 2

Definitions

For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 and in Article 2 of Regulation (EC) No 882/2004 shall apply.

The definitions of 'common entry document' and 'designated point of entry' set out in points (a) and (b) respectively of Article 3 of Regulation (EC) No 669/2009 shall also apply.

For the purposes of this Regulation, a 'consignment' means a 'lot' as defined in Directive 2002/63/EC.

For the purposes of Article 11(3), the definitions set out in Regulation (EC) No 396/2005 shall apply.

Article 3

Import into the Union

Consignments of food referred to in Article 1(1) may only be imported into the Union in accordance with the procedures laid down in this Regulation.

Such consignments can only enter the Union through a designated point of entry.

Article 4

Results of sampling and analysis

1. Each consignment of food referred to in Article 1(1) shall be accompanied by the results of sampling and analysis performed by the competent authorities of the country of origin as referred to in Annex I or of the third country where the consignment is consigned from if that country is different from the country of origin, to ascertain compliance with Union legislation on maximum residue levels of pesticides.

2. The sampling referred to in paragraph 1 must be performed in accordance with Directive 2002/63/EC.

3. The analysis referred to in paragraph 1 must be performed by laboratories accredited in accordance with the standard ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories'.

Article 5

Health certificate

1. Each consignment of food referred to in Article 1(1) shall be accompanied by the original version of a health certificate, in accordance with the model set out in Annex II.

2. The health certificate shall be completed, signed and verified by the competent authority of the country of origin or of the country where the consignment is consigned from if that country is different from the country of origin.
3. The health certificate shall be drawn up in the official language, or in one of the official languages, of the Member State where the designated point of entry is located. However, a Member State may consent to health certificates being drawn up in another official language of the Union.
4. The health certificate must be issued before the consignment to which it relates leaves the control of the competent authority issuing it.
5. The health certificate shall only be valid during four months from the date of issue.
6. The original health certificate shall be presented to, and kept by, the competent authorities of the designated point of entry.

Article 6

Identification

Each consignment of food referred to in Article 1(1) shall be identified with an identification code which corresponds to the identification code mentioned on the results of the sampling and analysis referred to in Article 4 and the health certificate referred to in Article 5. Each individual bag, or other packaging form, of the consignment shall be identified with that identification code.

Article 7

Prior notification of consignments

1. Food business operators or their representatives shall give prior notification of the estimated date and time of physical arrival of consignments of food referred to in Article 1(1) to the competent authorities at the designated point of entry and of the nature of the consignment.
2. For the purpose of prior notification, food business operators or their representatives shall complete Part I of the common entry document (CED) and transmit that document to the competent authorities at the designated point of entry, at least one working day prior to the physical arrival of the consignment.
3. For the completion of the CED pursuant to this Regulation, food business operators or their representatives shall take into account the notes for guidance for the CED laid down in Annex II to Regulation (EC) No 669/2009.

Article 8

Official controls

1. The competent authorities at the designated point of entry shall carry out documentary checks in relation to each consignment of food referred to in Article 1(1) to ascertain compliance with the requirements laid down in Articles 4 and 5.
2. Member States shall carry out identity and physical checks on consignments, including sampling and analysis, in accordance with Articles 8(1), 9 and 19 of Regulation (EC) No 669/2009 at the frequency set out in Annex I to this Regulation.
3. After completion of the checks, the competent authorities shall:
 - (a) complete the relevant entries of Part II of the CED;
 - (b) join the results of sampling and analysis carried out in accordance with paragraph 2 of this Article to the CED;
 - (c) provide and fill the CED reference number on the CED;
 - (d) stamp and sign the original of the CED;
 - (e) make and retain a copy of the signed and stamped CED.
4. The competent authorities of the designated point of entry shall issue the operator responsible for the consignment with an authenticated copy of the health certificate or, if the consignment is split, with individually authenticated copies of such certificate.
5. The original of the CED shall accompany the consignment during its transport until it is released for free circulation.

*Article 9***Splitting of a consignment**

1. The consignment shall not be split until all official controls have been completed, and the CED has been fully completed by the competent authorities as provided for in Article 8.
2. In the case of subsequent splitting of the consignment, an authenticated copy of the CED shall accompany each part of the consignment during its transport until it is released for free circulation.

*Article 10***Release for free circulation**

The release for free circulation of consignments shall be subject to the presentation by the food business operators or their representative to the custom authorities of a CED duly completed by the competent authority once all official controls have been carried out. The custom authorities shall only release the consignment for free circulation if a favourable decision by the competent authority is indicated in box II.14 of the CED and the CED is signed in box II.21 thereof.

*Article 11***Non-compliance**

1. Where the official controls carried out in accordance with Article 8 establish non-compliance with the relevant Union legislation, including this Regulation, the competent authority shall complete Part III of the CED and action shall be taken pursuant to Articles 19, 20 and 21 of Regulation (EC) No 882/2004.
2. Where a consignment is not accompanied by both the results of sampling and analysis referred to in Article 4 and the health certificate referred to in Article 5 or if those results or that health certificate do not comply with the requirements laid down in this Regulation, the consignment shall not be imported into the Union and shall be re-dispatched outside the Union or destroyed.
3. Where the competent authority at the designated point of entry does not permit the introduction of a consignment of food referred to in Article 1(1) due to non-compliance with a maximum residue level set out in Regulation (EC) No 396/2005, it shall immediately notify such border rejection in accordance with Article 19(3) of Regulation (EC) No 882/2004.

*Article 12***Reports**

1. Member States shall submit to the Commission biannually, by the end of the month following each semester, a report of all analytical results of official controls carried out on consignments of food pursuant to this Regulation.

That report shall include the following information:

- (a) the number of consignments imported;
- (b) the number of consignments subjected to sampling for analysis;
- (c) the results of the checks as provided for in Article 8(2).

2. The reporting obligations set out in paragraph 1 shall be deemed to be satisfied where Member States register in TRACES the CEDs issued by their respective competent authorities in accordance with this Regulation.

*Article 13***Review**

This Regulation shall be reviewed before 31 October 2019.

*Article 14***Costs**

All costs resulting from the official controls including sampling, analysis, storage and any measures taken following non-compliance shall be borne by the food business operators responsible for the consignment.

*Article 15***Amendment to Regulation (EC) No 669/2009**

Annex I to Regulation (EC) No 669/2009 is amended as follows:

- (a) in the entries for Turkey, the entry referring to 'Vine leaves' is deleted.
- (b) in the entries for Vietnam, the entry referring to 'Pitahaya (dragon fruit)' is deleted.

*Article 16***Repeal**

Implementing Regulation (EU) No 885/2014 is repealed.

*Article 17***Transitional measures**

For a period of three months from the date of entry into force of this Regulation, Member States shall continue to authorise the introduction of consignments of curry leaves originating from India which left the country of origin, or the country of consignment if that country is different from the country of origin, prior to 8 December 2018 provided that those consignments fulfil the requirements of Implementing Regulation (EU) No 885/2014.

For a period of three months from the date of entry into force of this Regulation, Member States shall continue to authorise the introduction of consignments of vine leaves originating from Turkey and of Pitahaya (dragon fruit) originating from Vietnam which left the country of origin, or the country of consignment if that country is different from the country of origin, prior to 8 December 2018 provided that those consignments fulfil the requirements of Regulation (EC) No 669/2009 in force on 7 December 2018.

*Article 18***Entry into force and date of application**

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 8 December 2018.

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

Done at Brussels, 7 November 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Food of non-animal origin subject to special conditions regarding their import into the European Union

Food (intended use)	CN code ⁽¹⁾	TARIC sub-division	Country of origin	Hazard(s)	Frequency of physical and identity checks (%) at import
Pitahaya (dragon fruit) (Food — fresh or chilled)	ex 0810 90 20	10	Vietnam (VN)	Residues of pesticides listed in the control programme adopted in accordance with Article 29(2) of Regulation (EC) No 396/2005 (pesticides to be monitored in/on products of plant origin only) ⁽²⁾ and residues of dithiocarbamates ⁽³⁾ (dithiocarbamates expressed as CS ₂ , including maneb ⁽³⁾ , mancozeb ⁽³⁾ , metiram ⁽³⁾ , propineb ⁽³⁾ , thiram ⁽³⁾ and ziram ⁽³⁾), Phenthoate ⁽²⁾ and Quinalphos ⁽²⁾ .	10
Curry leaves (<i>Bergera/Murraya koenigii</i>) (Food — fresh, chilled, frozen or dried)	ex 1211 90 86	10	India (IN)	Residues of pesticides listed in the control programme adopted in accordance with Article 29(2) of Regulation (EC) No 396/2005 (pesticides to be monitored in/on products of plant origin only) ⁽²⁾ and residues of acephate ⁽²⁾ .	20
Vine leaves (Food)	ex 2008 99 99	11, 19	Turkey (TR)	Residues of pesticides listed in the control programme adopted in accordance with Article 29(2) of Regulation (EC) No 396/2005 (pesticides to be monitored in/on products of plant origin only) ⁽²⁾ and residues of dithiocarbamates ⁽³⁾ (dithiocarbamates expressed as CS ₂ , including maneb ⁽³⁾ , mancozeb ⁽³⁾ , metiram ⁽³⁾ , propineb ⁽³⁾ , thiram ⁽³⁾ and ziram ⁽³⁾) and metrafenone ⁽²⁾ .	20

⁽¹⁾ Where only certain products under any CN code are required to be examined and no specific subdivision under that code exists in the good nomenclature, the CN code is marked 'ex'.

⁽²⁾ Pesticide residues analysed with multiresidue methods based on CG-MS and LC-MS.

⁽³⁾ Pesticide residues analysed with single residue methods.

ANNEX II

Country:

Health Certificate

Part I: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Country Phone		I.2. Certificate reference number		
			I.3. Central Competent Authority		
			I.4. Local Competent Authority		
	I.5. Consignee/Importer Name Address Country Phone		I.6. Operator responsible for the consignment in EU (where known) Name Address Postal code		
	I.7. Country of origin, ISO code		I.9. Country of destination, ISO code		
	I.11. Place of origin Name Address		I.12. Place of destination (where known) Name Address		
	I.13. Place of dispatch Address		I.14. Date of departure		
	I.15. Means of transport Aeroplane ☐ Vessel ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Document:		I.16. Entry DPE Name: I.17. Laboratory report Reference number: Date of issuance:		
	I.21. Temperature of products Ambient ☐ Chilled ☐ Frozen ☐		I.20. Quantity Total net weight (Kg) Total gross weight (Kg)		I.22. Total Number of Packages
	I.23. Seal/Container No.				
I.25. Commodity certified for: Human consumption ☐					
I.27. Release for internal market ☐					
I.28. Identification of the commodity CN Code: TARIC subdivision: Nature of commodity Number of packages Net weight Identification code					

Country:

Food of non-animal origin subject to special conditions regarding
their import into the EU**II. Health information****II.a. Certificate reference number**

Part II: Certification

I, the undersigned authorised representative of the competent authority, declare that I am aware of the relevant provisions of Regulation (EC) No 852/2004 and Regulation (EC) No 396/2005, and hereby certify that:

- II.1. The food of the consignment described under Part I has been produced under conditions which comply with the maximum residue levels of pesticides set out in Regulation (EC) No 396/2005 and produced, sorted, handled, processed, packaged and transported in line with good hygiene practices.
- II.2. From this consignment, sampling and analysis were carried out in accordance with Article 4 of Commission Implementing Regulation (EU) 2018/1660 on (date), subjected to pesticide laboratory analysis on (date) in the (name of laboratory) with methods covering at least the hazards identified in Annex I to this Regulation.
- II.3. The details of sampling, methods of analysis used and all results are attached and show compliance with Union legislation on maximum residue levels of pesticides.
- II.4. This certificate has been issued before the consignment to which it relates has left the control of the competent authority.
- II.5. This certificate is valid during four months from the date of issue.

Authorised representative of the competent authority

Name (in capital letters):

Qualification and title:

Date:

Signature:

Stamp:

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1661**of 7 November 2018****amending Council Regulation (EC) No 1210/2003 concerning certain specific restrictions on economic and financial relations with Iraq**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1210/2003 of 7 July 2003 concerning certain specific restrictions on economic and financial relations with Iraq and repealing Regulation (EC) No 2465/96 ⁽¹⁾, and in particular Article 11(b) thereof,

Whereas:

- (1) Annex III to Regulation (EC) No 1210/2003 lists public bodies, corporations and agencies and natural and legal persons, bodies and entities of the previous government of Iraq covered by the freezing of funds and economic resources that were located outside Iraq on the date of 22 May 2003 under that Regulation.
- (2) On 2 November 2018, the Sanctions Committee of the United Nations Security Council decided to remove one entry from the list of persons or entities to whom the freezing of funds and economic resources should apply.
- (3) Annex III to Regulation (EC) No 1210/2003 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1210/2003 is amended as set out in 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, 7 November 2018.

For the Commission,

On behalf of the President,

Head of the Service for Foreign Policy Instruments

⁽¹⁾ OJ L 169, 8.7.2003, p. 6.

ANNEX

In Annex III to Regulation (EC) No 1210/2003, the following entry is deleted:

‘76. MAYSAN SUGAR STATE ENTERPRISE. Addresses: (a) P.O. Box 9, Amara, Maysan, Iraq; (b) P.O. Box 3028, Maysan, Iraq.’

DECISIONS

POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2018/1662

of 25 October 2018

extending the mandate of the Head of Mission of the European Union Advisory Mission for Civilian Security Sector Reform Ukraine (EUAM Ukraine) (EUAM UKRAINE/1/2018)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular the third paragraph of Article 38 thereof,

Having regard to Council Decision 2014/486/CFSP of 22 July 2014 on the European Union Advisory Mission for Civilian Security Sector Reform Ukraine (EUAM Ukraine) ⁽¹⁾, and in particular Article 7(1) thereof,

Whereas:

- (1) Pursuant to Decision 2014/486/CFSP, the Political and Security Committee (PSC) is authorised, in accordance with Article 38 of the Treaty, to take the relevant decisions for the purpose of exercising the political control and strategic direction of the European Union Advisory Mission for Civilian Security Sector Reform Ukraine (EUAM Ukraine), including the decision to appoint a Head of Mission.
- (2) On 07 January 2016, the PSC adopted Decision (CFSP) 2016/49 ⁽²⁾, appointing Mr Kęstutis LANČINSKAS as Head of Mission of EUAM Ukraine from 1 February 2016 to 31 January 2017.
- (3) On 10 January 2017, the PSC adopted Decision (CFSP) 2017/113 ⁽³⁾, extending the mandate of Kęstutis LANČINSKAS as Head of Mission of EUAM Ukraine from 1 February 2017 to 30 November 2017.
- (4) On 10 November 2017, the PSC adopted Decision (CFSP) 2017/2106 ⁽⁴⁾, extending the mandate of Kęstutis LANČINSKAS as Head of Mission of EUAM Ukraine from 1 December 2017 to 30 November 2018.
- (5) The High Representative of the Union for Foreign Affairs and Security Policy has proposed to extend the mandate of Kęstutis LANČINSKAS as Head of Mission of EUAM Ukraine from 1 December 2018 to 31 May 2019,

HAS ADOPTED THIS DECISION:

Article 1

The mandate of Kęstutis LANČINSKAS as Head of Mission of EUAM Ukraine is hereby extended until 31 May 2019.

⁽¹⁾ OJ L 217, 23.7.2014, p. 42.

⁽²⁾ Political and Security Committee Decision (CFSP) 2016/49 of 7 January 2016 on the appointment of the Head of Mission of the European Union Advisory Mission for Civilian Security Sector Reform Ukraine (EUAM Ukraine) (EUAM UKRAINE/1/2016) (OJ L 12, 19.1.2016, p. 47).

⁽³⁾ Political and Security Committee Decision (CFSP) 2017/113 of 10 January 2017 extending the mandate of the Head of Mission of the European Union Advisory Mission for Civilian Security Sector Reform Ukraine (EUAM Ukraine) (EUAM UKRAINE/1/2017) (OJ L 18, 24.1.2017, p. 48).

⁽⁴⁾ Political and Security Committee Decision (CFSP) 2017/2106 of 10 November 2017 extending the mandate of the Head of Mission of the European Union Advisory Mission for Civilian Security Sector Reform Ukraine (EUAM Ukraine) (EUAM UKRAINE/2/2017) (OJ L 303, 18.11.2017, p. 10).

Article 2

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

Done at Brussels, 25 October 2018.

For the Political and Security Committee
The Chairperson
S. FROM-EMMESBERGER

COUNCIL DECISION (EU) 2018/1663**of 6 November 2018**

on the position to be taken on behalf of the European Union within the European Committee for drawing up standards in the field of inland navigation and within the Central Commission for the Navigation of the Rhine concerning the adoption of European standards for professional qualifications in inland navigation

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91(1), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Revised Convention for Rhine Navigation (the 'Convention') entered into force on 14 April 1967.
- (2) Pursuant to Article 46 of the Convention, the Central Commission for the Navigation of the Rhine (CCNR) is able to adopt resolutions which are binding for its members.
- (3) The European Committee for drawing up standards in the field of inland navigation (CESNI) was created on 3 June 2015 in the framework of the CCNR in order to develop technical standards for inland waterways in various fields, in particular as regards vessels, information technology and crew.
- (4) CESNI will adopt European standards for professional qualifications in inland navigation ('standards for professional qualifications') during its meeting on 8 November 2018. A plenary session of the CCNR is likely to adopt a resolution that will incorporate those standards into the Regulations for Rhine navigation personnel.
- (5) It is appropriate to establish the position to be taken on the Union's behalf in CESNI and the CCNR, as the standards for professional qualifications will decisively influence the content of Union law, namely Directive (EU) 2017/2397 of the European Parliament and of the Council ⁽¹⁾, and will have legal effect by virtue of the rules governing the CCNR when it adopts those standards.
- (6) It is important that the technical requirements for crew members be as harmonised as possible under different legal regimes in Europe in order to facilitate mobility, to ensure the safety of navigation and to ensure the protection of human life and the environment. In particular, Member States which are also members of the CCNR should be authorised to support decisions harmonising the CCNR rules with those applied in the Union.
- (7) The standards for professional qualifications developed by CESNI provide for minimum harmonised European standards and include standards for competences, standards for practical examinations, standards for medical fitness and standards for the approval of simulators.
- (8) With effect from 18 January 2022, Article 32 of Directive (EU) 2017/2397 refers directly to standards for professional qualifications as being those established by CESNI. The Commission is empowered to include the entire text of those standards in delegated acts, to make or update relevant references and to set the date of application.
- (9) The Union's position should be expressed by the Member States of the Union that are members of CESNI and the CCNR, acting jointly,

HAS ADOPTED THIS DECISION:

Article 1

1. The position to be taken on behalf of the Union within the European Committee for drawing up standards in the field of inland navigation (CESNI) on 8 November 2018 shall be to agree to the adoption of the European standards for professional qualifications in inland navigation (references cesni (18)_29 to cesni (18)_42).

⁽¹⁾ Directive (EU) 2017/2397 of the European Parliament and of the Council of 12 December 2017 on the recognition of professional qualifications in inland navigation and repealing Council Directives 91/672/EEC and 96/50/EC (OJ L 345, 27.12.2017, p. 53).

2. The position to be taken on behalf of the Union at the meeting of the plenary session of the Central Commission for the Navigation of the Rhine (CCNR) where the European standards for professional qualifications in inland navigation (references cesni (18)_29 to cesni (18)_42) are decided upon shall be to support all proposals aligning the requirements of the Regulations for Rhine navigation personnel with those of the European standards for professional qualifications in inland navigation.

Article 2

1. The position of the Union as set out in Article 1(1) shall be expressed by the Member States that are members of CESNI, acting jointly.
2. The position of the Union as set out in Article 1(2) shall be expressed by the Member States that are members of the CCNR, acting jointly.

Article 3

Minor technical changes to the positions set out in Article 1 may be agreed upon without a further decision of the Council.

Article 4

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

Done at Brussels, 6 November 2018.

For the Council

The President

H. LÖGER

COUNCIL DECISION (EU) 2018/1664**of 6 November 2018****amending Decision 1999/70/EC concerning the external auditors of the national central banks, as regards the external auditors of Lietuvos bankas**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to Protocol No 4 on the Statute of the European System of Central Banks and of the European Central Bank, annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union, and in particular Article 27.1 thereof,

Having regard to the Recommendation of the European Central Bank of 4 October 2018 to the Council of the European Union on the external auditors of Lietuvos bankas (ECB/2018/23) ⁽¹⁾,

Whereas:

- (1) The accounts of the European Central Bank (ECB) and of the national central banks of the Member States whose currency is the euro are to be audited by independent external auditors recommended by the Governing Council of the ECB and approved by the Council of the European Union.
- (2) The mandate of the external auditors of Lietuvos bankas expired following the audit for the financial year 2017.
- (3) By means of its Recommendation of 18 May 2018 (ECB/2018/15) ⁽²⁾, the ECB recommended that UAB Deloitte Lietuva be appointed as external auditors of Lietuvos bankas for the financial years 2018 to 2021. UAB Deloitte Lietuva did not take up the appointment. It is therefore necessary to appoint external auditors for the financial years 2018 to 2021.
- (4) The Governing Council of the ECB has recommended that UAB Ernst & Young Baltic be appointed as the external auditors of Lietuvos bankas for the financial years 2018 to 2021.
- (5) Council Decision 1999/70/EC ⁽³⁾ should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

In Article 1 of Decision 1999/70/EC, paragraph 19 is replaced by the following:

‘19. UAB Ernst & Young Baltic are hereby approved as the external auditors of Lietuvos bankas for the financial years 2018 to 2021.’.

Article 2

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

Article 3

This Decision is addressed to the European Central Bank.

Done at Brussels, 6 November 2018.

For the Council

The President

H. LÖGER

⁽¹⁾ OJ C 370, 12.10.2018, p. 1.

⁽²⁾ Recommendation of the European Central Bank of 18 May 2018 to the Council of the European Union on the external auditors of Lietuvos bankas (ECB/2018/15) (OJ C 181, 28.5.2018, p. 1).

⁽³⁾ Council Decision 1999/70/EC of 25 January 1999 concerning the external auditors of the national central banks (OJ L 22, 29.1.1999, p. 69).

COUNCIL DECISION (EU, Euratom) 2018/1665**of 6 November 2018****appointing a member, proposed by the Grand Duchy of Luxembourg, of the European Economic and Social Committee**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 302 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a thereof,

Having regard to the proposal of the Luxembourg Government,

Having regard to the opinion of the European Commission,

Whereas:

- (1) On 18 September 2015 and 1 October 2015, the Council adopted Decisions (EU, Euratom) 2015/1600 ⁽¹⁾ and (EU, Euratom) 2015/1790 ⁽²⁾ appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020.
- (2) A member's seat on the European Economic and Social Committee has become vacant following the end of the mandate of Mr Christophe HANSEN,

HAS ADOPTED THIS DECISION:

Article 1

Ms Claudine OTTO, *Conseiller en affaires européennes, avis et affaires juridiques à la Chambre de Commerce*, is hereby appointed as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2020.

Article 2

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

Done at Brussels, 6 November 2018.

For the Council

The President

H. LÖGER

⁽¹⁾ Council Decision (EU, Euratom) 2015/1600 of 18 September 2015 appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020 (OJ L 248, 24.9.2015, p. 53).

⁽²⁾ Council Decision (EU, Euratom) 2015/1790 of 1 October 2015 appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020 (OJ L 260, 7.10.2015, p. 23).

COUNCIL DECISION (EU) 2018/1666**of 6 November 2018****appointing two members and five alternate members, 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) Two members' seats on the Committee of the Regions have become vacant following the end of the term of office of Mr António BRAGANÇA FERNANDES and Mr Luís GOMES.
- (3) Five alternate members' seats on the Committee of the Regions have become vacant following the end of the term of office of Mr Francisco LOPES, Ms Isaura MORAIS, Mr Américo PEREIRA, Mr António PEREIRA and Mr Aníbal REIS COSTA,

HAS ADOPTED THIS DECISION:

Article 1

The following are hereby appointed to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2020:

(a) as members:

- Mr Ricardo Bruno ANTUNES MACHADO RIO, *Presidente da Câmara de Braga*,
- Mr Aires Henrique DO COUTO PEREIRA, *Presidente da Câmara da Póvoa de Varzim*;

(b) as alternate members:

- Ms Berta FERREIRA MILHEIRO NUNES, *Presidente da Câmara de Alfândega da Fé*,
- Mr Pedro Miguel César RIBEIRO, *Presidente da Câmara de Almeirim*,
- Mr Hélder António GUERRA DE SOUSA E SILVA, *Presidente da Câmara de Mafra*,
- Mr Rui Miguel DA SILVA ANDRÉ, *Presidente da Câmara de Monchique*,
- Mr Carlos SILVA SANTIAGO, *Presidente da Câmara de Sernancelhe*.

Article 2

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

Done at Brussels, 6 November 2018.

For the Council

The President

H. LÖGER

⁽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 DECISION (EU) 2018/1667**of 6 November 2018****appointing an alternate member, proposed by the Kingdom of the Netherlands, 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 Government of the Netherlands,

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. On 11 July 2017, by Council Decision (EU) 2017/1335 ⁽⁴⁾, Ms Ingrid VAN ENGELSHOVEN was replaced by Ms Saskia BRUINES as an alternate member.
- (2) An alternate member's seat on the Committee of the Regions has become vacant following the end of the term of office of Ms Saskia BRUINES,

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 R.J. (Robert) VAN ASTEN, *Wethouder (alderman: member of the executive council) of the municipality 's-Gravenhage*.

Article 2

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

Done at Brussels, 6 November 2018.

For the Council

The President

H. LÖGER

⁽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).

⁽⁴⁾ Council Decision (EU) 2017/1335 of 11 July 2017 appointing an alternate member, proposed by the Kingdom of the Netherlands, of the Committee of the Regions. (OJ L 185, 18.7.2017, p. 46).

COMMISSION IMPLEMENTING DECISION (EU) 2018/1668**of 6 November 2018**

amending Annex I to Decision 2006/766/EC as regards the entry for the United States of America in the list of third countries and territories from which imports of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption are permitted

(notified under document C(2018) 7207)

(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 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ⁽¹⁾, and in particular Article 11(1) thereof,

Whereas:

- (1) Regulation (EC) No 854/2004 provides that products of animal origin are to be imported only from a third country or part of a third country that appears on a list drawn up in accordance with that Regulation.
- (2) Regulation (EC) No 854/2004 also provides that when drawing up and updating such lists, account is to be taken of the results of Union controls in third countries. Regulation (EC) No 882/2004 of the European Parliament and of the Council ⁽²⁾ provides that third countries are to appear on such lists only if their competent authorities provide appropriate guarantees as regards compliance or equivalence with Union feed and food law and animal health rules.
- (3) Commission Decision 2006/766/EC ⁽³⁾ lists those third countries and territories which satisfy the criteria referred to in Regulation (EC) No 854/2004 and are therefore able to guarantee that the products referred to in Decision 2006/766/EC meet the sanitary conditions laid down in Union legislation to protect the health of consumers and can accordingly be exported to the Union. In particular, Annex I to that Decision sets out a list of third countries from which imports of bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption are permitted. That list also indicates restrictions concerning such imports from certain third countries.
- (4) The most recent Union controls in the United States of America to evaluate the control system in place governing the production of bivalve molluscs intended for export to the Union took place in 2015. Those controls, together with assurances provided by the competent authorities of the United States of America, indicate that the conditions for the production of bivalve molluscs, applicable in the States of Massachusetts and Washington, offer guarantees equivalent to those laid down in the relevant Union legislation. As a result, imports from the States of Massachusetts and Washington in the United States of America of bivalve molluscs, tunicates, echinoderms and marine gastropods should be permitted. The Commission will establish the specific conditions for the export of those products in a public health certificate.
- (5) Decision 2006/766/EC should therefore be amended accordingly.
- (6) 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 139, 30.4.2004, p. 206.

⁽²⁾ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

⁽³⁾ Commission Decision 2006/766/EC of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted (OJ L 320, 18.11.2006, p. 53).

HAS ADOPTED THIS DECISION:

Article 1

In Annex I to Decision 2006/766/EC, the entry for the United States of America is replaced by the following:

'US	United States of America	States of Massachusetts and Washington'
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Article 2

This Decision is addressed to the Member States.

Done at Brussels, 6 November 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2018/1669**of 6 November 2018****repealing Decision 2006/80/EC granting certain Member States the derogation provided for in Article 3(2) of Council Directive 92/102/EEC on the identification and registration of animals***(notified under document C(2018) 7239)***(Only the Czech, French, Italian, Portuguese, Slovakian and Slovenian text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs ⁽¹⁾, and in particular Article 3(2) thereof,

Whereas:

- (1) Directive 2008/71/EC sets out the minimum requirements for the identification and registration of pigs.
- (2) Pursuant to Article 3(1) of Directive 2008/71/EC, Member States are to ensure that the competent authority has an up-to-date list of all the holdings which keep animals covered by that Directive and are situated on their territory.
- (3) Article 3(2) of Directive 2008/71/EC provides the possibility to authorise Member States to exclude from the list of holdings required by Article 3(1) of that Directive natural persons who keep one single pig which is intended for their own use or consumption, provided that this animal is subjected to the controls laid down in that Directive before any movement.
- (4) Commission Decision 2006/80/EC ⁽²⁾ authorises the Czech Republic, France, Italy, Portugal, Slovenia and Slovakia to apply the derogation now provided for in Article 3(2) of Directive 2008/71/EC as regards holdings with one single pig.
The Czech Republic, France, Italy, Portugal, Slovenia and Slovakia have confirmed that they no longer apply the derogation provided for in Article 3(2) of Directive 2008/71/EC as regards holdings with one single pig.
- (5) Decision 2006/80/EC should therefore be repealed.
- (6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2006/80/EC is repealed.

Article 2

This Decision is addressed to the Czech Republic, to the French Republic, to the Italian Republic, to the Portuguese Republic, to the Republic of Slovenia and to the Slovak Republic.

Done at Brussels, 6 November 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

⁽¹⁾ OJ L 213, 8.8.2008, p. 31.

⁽²⁾ Commission Decision 2006/80/EC of 1 February 2006 granting certain Member States the derogation provided for in Article 3(2) of Council Directive 92/102/EEC on the identification and registration of animals (OJ L 36, 8.2.2006, p. 50).

