

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 <input type="checkbox"/> Vessel <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: Document:		I.16. Entry DPE Name:		
		I.17. Laboratory report Reference number: Date of issuance:		
I.21. Temperature of products Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>		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 <input type="checkbox"/>				
I.27. Release for internal market <input type="checkbox"/>				
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: