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

of **XXX**

laying down specific conditions applicable to the introduction into the Union of consignments from certain third countries due to microbiological contamination and amending Regulation (EC) No 669/2009

(Text with EEA relevance)

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

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laying down specific conditions applicable to the introduction into the Union of consignments from certain third countries due to microbiological contamination and amending Regulation (EC) No 669/2009

(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 safety¹, 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 rules², 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 imported from a third country in order to protect human health, animal health and the environment, where it is evident that there is a serious risk that cannot be contained satisfactorily by means of measures taken by the Member States individually.
- (2) Article 11 of that Regulation requires that food imported into the Union for placing on the market within the Union is to comply with the relevant requirements of food law or conditions recognised by the Union to be at least equivalent thereto or, where a specific agreement exists between the Union and the exporting country, with requirements contained therein.
- (3) Regulation (EC) No 852/2004 of the European Parliament and of the Council³ lays down general rules for food business operators on the hygiene of foodstuffs.
- (4) Article 11 of Regulation (EC) No 882/2004 sets the requirements for sampling and analysis methods used in the context of official controls.

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

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 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

- (5) Article 14 of Regulation (EC) No 178/2002 provides that unsafe food products are not to be placed on the market. According to Regulation (EC) No 882/2004, the Competent Authorities are to verify the food business operators' compliance with Union legislation.
- (6) Commission Regulation (EC) No 669/2009⁴ lays down rules concerning the increased level of official controls on imports of certain feed and food of non-animal origin listed in Annex I to that Regulation.
- (7) For many years, there has been a high frequency of non-compliance with microbiological safety issues in sesame seeds ('Sesamum seeds') and betel leaves ('Piper betle L.') from India. An increased frequency of official controls on import of those foods has therefore been established in 2014 with regard to the presence of Salmonella spp. Nonetheless these increased controls confirmed the high frequency of non-compliance of those foods with microbiological safety due to Salmonella spp. The import of those foods constitutes therefore a serious risk to public health within the Union and it is therefore necessary to adopt Union emergency measures.
- (8) Guarantees from the competent authorities of exporting countries that those foods have been produced in line with the hygiene provisions set up in Regulation (EC) No 852/2004 are necessary to protect human health in the Union. In order to ensure harmonised enforcement of import controls across the Union, all consignments of such foods should be accompanied by a health certificate signed by the competent authorities of exporting countries and by the results of analytical tests guaranteeing that they have been sampled and analysed with satisfactory results for the presence of microbiological pathogens.
- (9) Article 6 of Commission Regulation (EC) No 669/2009 requires the food business operators, responsible for consignments, to give prior notification of the arrival and nature of such consignments at the designated point of entry (DPE).
- (10) Article 8 of Commission Regulation (EC) No 669/2009 requires, with regard to the increased level of official controls, those controls to cover documentary, identity and physical checks. Documentary checks are to be carried out without undue delay on all consignments within 2 working days from the time of arrival at the DPE and identity and physical checks, including laboratory analysis, at the frequencies set out in Annex I to that Regulation.
- (11) In order to ensure an efficient organisation and harmonised import controls at Union level with regard to the presence of microbiological pathogens in certain foods from certain third countries, specific import conditions for such foods should be laid down. For legal clarity, it is appropriate to gather all foods from third countries subject to specific conditions because of microbiological risks into one Regulation. Therefore the provisions regarding Betel leaves from India laid down in Commission Implementing Regulation (EU) No 2016/166⁵ should be inserted into this Regulation and Regulation (EC) No 669/2009 should be amended accordingly.

⁴ 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).

⁵ Commission Implementing Regulation (EU) No 2016/166 of 8 February 2016 laying down specific conditions applicable to the import of foodstuffs containing or consisting of betel leaves ('Piper betle') from India and amending Regulation (EC) No 669/2009.

- (12) Commission Implementing Regulation (EU) No 2016/166 should be repealed and replaced simultaneously by a more general Regulation laying down the provisions as regards import of certain foods from certain third countries due to microbiological contamination
- (13) 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
Subject matter and scope

This Regulation shall apply to the introduction of the foods listed in Annex I to this Regulation.

Article 2
Definitions

For the purpose of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002, in Article 2 of Regulation (EC) No 882/2004 and in Article 3 of Regulation (EC) No 669/2009 shall apply.

Article 3
Introduction into the Union

The FBO shall ensure that:

1. Consignments of foods referred to in Annex I ("food") shall only be introduced into the Union in accordance with the procedures laid down in this Regulation.
2. Consignments of foods shall only be introduced into the Union through the designated point of entry ("DPE").

Article 4
Results of sampling and analysis accompanying the consignment

1. Each consignment of foods shall be accompanied by the results of sampling and analysis performed by either the competent authority of the third country of origin, or the competent authority of the third country where the consignment was consigned from if that third country is different from the country of origin verifying the absence of the hazard specified in Annex I.
2. The sampling and the analysis referred to in paragraph 1 of this Article shall be performed in accordance with Chapter III "Sampling and analysis" of Regulation (EC) No 882/2004. In particular, the sampling shall be performed in accordance with the relevant standards of the ISO (International Organisation for Standardisation) and the guidelines of the Codex Alimentarius used as reference and the analysis for *Salmonella* shall be performed according to the reference method EN/ISO 6579 (the latest updated version of the detection method) or a method validated against it in accordance with the protocol set out in EN/ISO 16140 or other internationally accepted similar protocols.

Article 5
Health certificate

1. The consignments of foods listed in Annex I shall be accompanied by a health certificate in accordance with the model set out in Annex III.
2. The health certificate shall be signed and stamped by an authorised representative of either the competent authority of the third country of origin, or the competent authority of the third country where the consignment is consigned from if that third country is different from the country of origin.
3. The health certificate and its attachments shall be drawn up in the official language, or in one of the official languages, of the Member State where the DPE is located. However, the Member State of the DPE may consent to health certificates being drawn up in another official language of the Union.
4. The health certificate shall be valid for a period of four months from the date of issue, but no longer than six months from the date of the last microbiological laboratory analysis.

Article 6
Identification

Each consignment of foods shall be identified with an identification code (consignment code) which corresponds to the identification code referred to 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 and of the nature of the consignment to the competent authority of the DPE.
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 authority of the DPE, at least one working day prior to the physical arrival of the consignment.
3. For the completion of the CED, 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.
4. CEDs shall be drawn up in the official language, or in one of the official languages, of the Member State where the DPE is located. However, a Member State of the DPE may consent to CEDs being drawn up in another official language of the Union.

Article 8
Official controls

1. The competent authority at the DPE shall carry out documentary checks for each consignment of food to ascertain compliance with the requirements laid down in Articles 4 and 5.

2. The identity checks and physical checks on food shall be carried out in accordance with Articles 8, 9 and 19 of Regulation (EC) No 669/2009 at the frequency set out in Annex II to this Regulation.
3. Where a consignment of food is not accompanied by the results of sampling and analysis referred to in Article 4 and the health certificate referred to in Article 5 or where 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 to the third country of origin or destroyed.
3. After completion of the identity checks and physical checks, the competent authorities shall:
 - (a) Complete the relevant entries of Part II of the CED;
 - (b) Attach the results of sampling and analysis carried out, in accordance with paragraph 2 of this Article;
 - (c) Provide the CED with the CED reference number;
 - (d) Stamp and sign the original of the CED;
 - (e) Make and retain a copy of the signed and stamped CED.
4. The originals of the CED and the health certificate referred to in Article 5 with the accompanying results of sampling and analysis referred to in Article 4 shall accompany the consignment during transportation and until it is released for free circulation. In case of authorisation of onward transportation of the consignments pending the results of the physical checks, a certified copy of the original CED shall be issued. Where authorisation is given, the competent authority at the DPE shall notify the competent authority at the point of destination and appropriate arrangements shall be put in place to ensure that the consignment remains under the continuous control of the competent authorities and cannot be tampered with in any manner pending the results of the physical checks.

Article 9
Splitting of a consignment

1. Consignments shall not be split until all checks have been completed, and the CED has been fully filled in by the competent authorities of the PDE 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 and until it is released for free circulation.

Article 10
Release for free circulation

The release for free circulation of consignments of food listed in Annex I shall be subject to the presentation (physically or electronically) by the food business operators or their representatives to the customs authorities of a CED duly filled in by the competent authority of the DPE once all official controls have been carried out and favourable results from physical checks, where such checks are required, are known. The customs authorities shall only release the consignment for free circulation if a favourable decision by the competent authority is indicated in box II.14 and signed in box II.21 of the CED.

Article 11
Non-compliance

If the official controls establish non-compliance with the relevant provisions of Regulation (EC) No 852/2004 Union legislation, the competent authority of the DPE shall complete Part III of the CED and shall take actions as laid down in provisions of Articles 19, 20 and 21 of Regulation (EC) No 882/2004.

Article 12
Reports

Member States shall submit to the Commission a report of all analytical results on consignments of foods taken in accordance with Article 8.

That report shall cover a period of six months and shall be submitted biannually by the end of the month following each semester.

The report shall include the following information:

- (a) Number of consignments introduced, including size in terms of net weight and country of origin of each consignment;
- (b) Number of consignments subjected to sampling for analysis;
- (c) Results of the identity checks and physical checks referred to in Article 8(2).

Article 13
Costs

All costs resulting from the official controls provided for in Article 8, including sampling, analysis, storage and any measures taken in case of non-compliance as referred to in Article 11, shall be borne by the food business operators.

Article 14
Transitional measures

Member States shall authorise introduction of consignments of food which left either the third country of origin, or the third country where the consignment is consigned from if that third country is different from the third country of origin, prior to the date of entry into force of this Regulation without being accompanied by a health certificate as referred to in Article 5 and the results of sampling and analysis as referred to in Article 4.

Article 15
Repeal

Regulation (EC) No 2016/166 is repealed.

Article 16
Amendment of Regulation (EC) No 669/2009

Regulation (EC) No 669/2009 is amended in accordance with Annex IV to this Regulation.

Article 17
Entry into force

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

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

Done at Brussels,

For the Commission
The President
Jean Claude JUNCKER