

COMMISSION IMPLEMENTING REGULATION (EU) 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****(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 feed and food imported from a third country in order to protect human health, animal health and the environment, where the risk cannot be contained satisfactorily by means of measures taken by the Member States individually.
- (2) Commission Regulation (EC) No 669/2009 ⁽³⁾ provides for an increased level of official controls on imports of certain feed and food of non-animal origin listed in Annex I to that Regulation. Betel leaves (*Piper betle* L.) originating from India are subject as of 1 April 2014 to an increased frequency of official controls as regards the presence of many *Salmonella* strains.
- (3) The results from the increased frequency of controls carried out by the Member States in the framework of Regulation (EC) No 669/2009 on those foodstuffs show a continuous high frequency of non-compliance with microbiological criteria for foodstuffs established in Union legislation. Since 2011, around 90 notifications ⁽⁴⁾ have been issued to the Rapid Alert System for Food and Feed due to the presence of a wide range of pathogenic *Salmonella* strains in foodstuffs containing or consisting of betel leaves originating in or consigned from India.
- (4) Those results provide evidence that the import of those foodstuffs constitutes a risk for human health. Despite the increased frequency of controls at Union borders in place the situation has been not improved. Furthermore, the Indian authorities have not provided a concrete and satisfactory action plan to remediate the shortcomings and deficiencies in the production and control systems, despite the European Commission's explicit request.
- (5) To protect human health in the Union, it is necessary to provide for additional guarantees in relation to those foodstuffs from India. Therefore all consignments of betel leaves from India should be accompanied by a health certificate stating that those foodstuffs were produced in line with the hygiene provisions set up in Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽⁵⁾, sampled and analysed for the presence of *Salmonella* and were found compliant with Union legislation, and by the results of the analytical tests.

⁽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⁾ From 2011 till 15 October 2015 (12 in 2011, 6 in 2012, 13 in 2013, 17 in 2014 and 43 on 15.10.2015).

⁽⁵⁾ 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).

- (6) It is appropriate to exclude non-commercial consignments from the application of the provisions of this Regulation.
- (7) The sampling and the analysis of consignments should be performed in accordance with the relevant Union legislation. Commission Regulation (EC) No 2073/2005 ⁽¹⁾ lays down both the microbiological criteria for foodstuffs and the provisions on sampling for the official control of microbiological criteria for foodstuffs applicable in the Union.
- (8) The Indian authorities have informed the Commission of the name of the competent authority whose authorised representative is entitled to sign the health certificate.
- (9) Regulation (EU) No 669/2009 should be amended accordingly.
- (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

Scope

1. This Regulation shall apply to consignments of foodstuffs containing or consisting of betel leaves (*Piper betle* L. commonly known as 'Paan leaf' or 'Betel quid') including those declared under CN codes 1404 90 00, originating in or consigned from India, set out in Annex I to this Regulation.
2. This Regulation shall not apply to consignments of foodstuffs referred to in paragraph 1 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 purpose of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002, Article 2 of Regulation (EC) No 882/2004 and Article 3 of Regulation (EC) No 669/2009 shall apply.

Article 3

Import into the Union

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

Consignments of such foodstuff may only enter the Union through the Designated Point of Entry (DPE) as defined in Regulation (EC) No 669/2009.

⁽¹⁾ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

*Article 4***Results of sampling and analysis**

1. Consignments of the foodstuff referred to in Article 1(1) shall be accompanied by the results of sampling and analysis performed by the competent authorities of India, to ascertain compliance with Union legislation on microbiological criteria of *Salmonella*, for the foodstuff referred to in Article 1(1).
2. The sampling referred to in paragraph 1 must be performed in accordance with Regulation (EC) No 2073/2005.

*Article 5***Health certificate**

1. The consignments shall also be accompanied by a health certificate in accordance with the model set out in Annex II.
2. The health certificate shall be completed, signed and verified by an authorised representative of the competent authority of India.
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 DPE is located. However, a Member State may consent to health certificates being drawn up in another official language of the Union.

*Article 6***Identification**

Each consignment of the foodstuff 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 the foodstuff referred to in Article 1(1) to the competent authorities at the DPE and of the nature of the consignment.
2. For the purpose of prior notification, they shall complete Part I of the common entry document (CED) laid down in Article 3(a) to Regulation (EC) No 669/2009 and transmit that document to the competent authority at the DPE, at least one working day prior to the physical arrival of the consignment.
3. For the completion of the CED in application of this Regulation, food business operators shall take into account for the foodstuff referred to in Article 1(1), 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 authority at the DPE shall carry out documentary checks on each consignment of the foodstuff referred to in Article 1(1) to ascertain compliance with the requirements laid down in Articles 4 and 5.
2. The identity and physical checks on the foodstuff referred to in Article 1(1) of this Regulation 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 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;
 - (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 original of the CED and of the health certificate with the accompanying results of sampling and analysis referred to in Article 4 shall accompany the consignment during its transport until it is released for free circulation. For foodstuff referred to in Article 1(1), 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 for that purpose.

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

1. Consignments 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 (physically or electronically) 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 and favourable results from physical checks, where such checks are required, are known. 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 and signed in box II.21 of the CED.

*Article 11***Non-compliance**

If the official controls establish non-compliance with the relevant Union legislation, 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.

*Article 12***Reports**

Member States shall submit to the Commission every three months a report of all analytical results of official controls on consignments of foodstuff pursuant to this Regulation. That report shall be submitted during the month following each quarter.

The report shall include the following information:

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

*Article 13***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.

*Article 14***Transitional measures**

By way of derogation from Articles 4(1) and 5(1), Member States shall authorise the imports of consignments of food referred to in Article 1(1) which left the country of origin prior to the entry into force of this Regulation without being accompanied by a health certificate and the results of sampling and analysis.

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

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

*Article 16***Entry into force**

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

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

Done at Brussels, 8 February 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Food of non-animal origin subject to the measures provided for in this Regulation:

Feed and food (intended use)	CN code (*)	TARIC sub- division	Country of origin or dispatch	Hazard	Frequency of physical and iden- tity checks (%) at import
Betel leaves (<i>Piper betle</i> L.) — (Food)	ex 1404 90 00	10	India (IN)	Salmonella (**)	10

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

(**) Reference method EN/ISO 6579 or a method validated against it as referred to in Article 5 of Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

ANNEX II

Health Certificate for the importation into the European Union of

..... (1)
Consignment Code Certificate Number

According to the provisions of Commission Implementing Regulation (EU) 2016/166 laying down specific conditions applicable to the import of Betel leaves ('Piper betle') from India the

..... (Competent authority referred to in Article 5(2) of Regulation (EU) 2016/166)

CERTIFIES that the (insert food referred to in Article 1(1) of Regulation (EU) 2016/166)

of this consignment composed of:

..... (description of consignment, product, number and type of packages, gross or net weight)

embarked at (embarkation place)

by (identification of transporter)

going to (place and country of destination)

which comes from the establishment (name and address of establishment)

have been produced, under conditions which comply with Regulation (EC) No 852/2004.

From this consignment, samples were taken in accordance with Regulation (EC) No 2073/2005 in view to check the presence of salmonella strains

on (date), subjected to laboratory analysis on

(date) in the

(name of laboratory). The details of sampling, methods of analysis used and all results are attached.

Done at on

Stamp and signature of authorised representative of competent authority referred to in Article 5(2) of Regulation (EU) 2016/166

(1) Product and country of origin.

ANNEX III

In Annex I to Regulation (EC) No 669/2009, the following entry is deleted:

Feed and food (intended use)	CN code ⁽¹⁾	TARIC sub- division	Country of origin	Hazard	Frequency of physical and iden- tity checks (%)
'Betel leaves (<i>Piper betle</i> L.) — (Food)	ex 1404 90 00	10	India (IN)	Salmonella ⁽¹⁰⁾	50'

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

⁽¹⁰⁾ Reference method EN/ISO 6579 or a method validated against it as referred to in Article 5 of Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).