Procedure framed by SHEFEXIL for Exports of Betel Leaves to EU & UK as per the Commission Implementing Regulation (EU) 2019/1793, 2021/608, 2021/1900, 2021/2246, 2023/174, 2024/1662 and 2024/120 Agriculture, England Food, England

A. Background

- A.1. As per Notification No. 30/2015-2020 dated 23.09.2021 issued by the Office of the Director General of Foreign Trade (DGFT), export of Betel Leaves to the European Union (imported under the ITC HS Code 1404 90 40 and CN Code Ex 140490 00) is subject to registration with Shellac & Forest Products Export Promotion Council(hereinafter referred to as the "Shefexil"), the designated Competent Authority for issuance of health certificate instead of APEDA. Shefexil has also been entrusted with the responsibility of issuing the Official Certificate in this regard, which is a prerequisite for entry of consignments of Betel Leaves to enter the European Union (hereinafter referred to as "EU")
- A.2. Import of Betel Leaves into the EU is monitored by the Regulations entitled –
- (i) Commission Implementing Regulation (EU) 2019/1793of 22nd October, 2019on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries Implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660 (hereinafter referred to as the "Commission Implementing Regulation (EU)2019/1793").;
- (ii) Commission Implementing Regulation (EU) 2021/608 of 14th April,2021amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council (hereinafter referred to as the "Commission Implementing Regulation (EU) 2021/608");
- (iii) Commission Implementing Regulation (EU) 2021/1900 of 27thOctober 2021 amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council (hereinafter referred to as the "Commission Implementing Regulation (EU) 2021/1900"); and
- (iv) Commission Implementing Regulation (EU) 2021/2246 of 15thDecember, 2021 amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No.178/2002 of the European Parliament and of the Council. (hereinafter referred to as the "Commission Implementing Regulation (EU) 2021/2246").
- A.3 Export of Betel Leaves to the EU will be governed by the provisions of the Commission Implementing Regulation (EU) 2019/1793, Commission Implementing Regulation (EU) 2021/608, Commission Implementing Regulation (EU) 2021/1900 and Commission Implementing Regulation (EU) 2021/2246.
- A.4. To facilitate the exporters to export the Betel Leaves to EU, Shefexil has prepared this document entitled "Procedure for Exports of Betel Leaves to EU" (hereinafter referred to as "this Procedure") bearing Ref. no. SHEFEXIL/ Betel leaves/ 21-22 dated 14.02.2022 with a view to control the contamination of Salmonella in the Betel Leaves consignments to be sent to EU & UK, and also to outline the procedures to be followed in order to ensure compliance of the provisions of the Commission Implementing Regulation (EU) 2019/1793 and Commission Implementing Regulation (EU) 2021/608, Commission Implementing Regulation (EU) 2021/1900 and Commission Implementing Regulation (EU) 2021/2246.

B. Objectives

- To establish a system for control of Salmonella and other microorganisms in exportable Betel Leaves
- To ensure that Betel Leaves exported from India meet the standards/specifications/ requirements of the European Union countries and the United Kingdom as well as countries following EU food safety standards and other importing countries having food safety compliance norms.
- To establish a mechanism to scrutinize and prevent contamination of Betel Leaves at any point
 of the value chain, thereby establishing complete traceability of the export products.
- To ensure that the testing and certification of the export products are done in a manner compliant to the provisions of the Commission Implementing Regulation (EU) 2019/1793 (as amended by Commission Implementing Regulation (EU) 2021/608 ,Commission Implementing Regulation(EU) 2021/1900 and Commission Implementing Regulation(EU) 2021/2246.

C. The System for Monitoring and evaluation

C.1. Monitoring at production level

• The exporters of Betel Leaves should ensure that the farms from which they procure Betel Leaves are registered with the State Horticulture Departments of respective States (i.e. states like Assam, Andhra Pradesh, Bihar, Karnataka, Maharashtra, Madhya Pradesh, Odisha and West Bengal).

C.2. Monitoring at the Pack Houses

- The Processing Center/Pack House for the Betel Leaves processing for the purpose of export to UK and EU should have FSSAI License with the accreditation of "Repacker General Manufacturing" and the operational system of the processing center/pack house should also have the FSSC 22000 certification (Food Safety Standard Certification 22000), the latest version of which is accredited by UKAS (United Kingdom Accreditation Service).
- The Pack Houses and processes requires to be mandatorily /compulsorily accredited as per the said UK accreditation authority UKAS.
- A dedicated Betel Leaves washing/processing room along with adequate infrastructure for washing/processing (on a stainless steel surface) needs to be maintained in the Pack Houses.
- The Pack Houses to ensure that the packing labels clearly indicates the Registration Code issued to the farm by the respective State Horticulture Department, and the lot numbers as originally indicated in the declaration/invoice.

C.3. Testing and certification of the export samples

- Testing will have to be done mandatorily, for every export shipment, at the NABL-accredited laboratories that fulfill the two following conditions:
 - The laboratories should have the ISO 17025 certification for Salmonella testing in Vegetables category; and
 - The most recent version of the analytical reference method EN ISO 6579-1 shall be used or a method validated against it in accordance with the protocol set out in EN ISO 16140-2to be used by the laboratories for checking Salmonella in the samples.
- Fulfilment of both the above conditions ISO 17025 accreditation for analytical reference method ISO 6579-1 and alternative method using VIDAS® Up Salmonella (SPT) are mandatory as per the provisions of the Commission Implementing Regulation (EU) 2019/1793 ,Commission Implementing Regulation (EU) 2021/608,Commission Implementing Regulation(EU) 2021/1900 and Commission Implementing Regulation(EU) 2021/2246.
- In this connection the format of sample slip, and label to be affixed in each box, are enclosed to this Procedure as Annexure 1 and Annexure 4 to this Procedure respectively.
- The laboratories approved for conducting sampling and analyses are mentioned in Annexure 2 to this Procedure.
- The laboratories conducting the tests shall give a analysis / test report which must contain full details of the sample drawn for inspection, e.g., the batch / lot number /identification id of the package, etc as outlined in Annexure 3 to this Procedure.

C.4. Drawing of samples

The sampling and the analyses for the control of Salmonella should be performed in accordance with the

sampling procedures and the analytical reference methods laid down in Article 3(e) and Annex III of the Commission Implementing Regulation (EU) 2019/1793.

According to Article 3 of the Commission Implementing Regulation (EU) 2019/1793 "sampling and analyses" should be carried out by competent authorities at border control posts or at control points referred to in Article 53(1)(a) of Regulation (EU) 2017/625, as part of physical checks on consignments of food and feed referred to in Article 1(1)(a) and (b) of the Commission Implementing Regulation (EU) 2019/1793, or in third countries for the purposes of the results of analyses which are required to accompany the consignments of food and feed referred to in Article 1(1)(b) as provided for in the Commission Implementing Regulation (EU) 2019/1793 shall be performed in accordance with the requirements set out in sub clauses(a) to (e) of Article 3 of the Commission Implementing Regulation (EU) 2019/1793. According to Article 3(e) of the Commission Implementing Regulation (EU) 2019/1793 for food listed in Annexes I and II due to the risk of presence of Salmonella, the "sampling and the analyses" for the control of Salmonella shall be performed in accordance with the sampling procedures and the analytical reference methods laid down in Annex III to the Commission Implementing Regulation (EU) 2019/1793.

Annexes I and II to the Commission Implementing Regulation (EU) 2019/1793 was replaced by Annexes I and II to the Commission Implementing Regulation (EU) 2021/608 and then by Annexes I and II to the Commission Implementing Regulation 2021/1900 and further replaced by Annexes I and II to the Commission Implementing Regulation (EU) 2021 / 2246.

Row 10 of Annex II to the Commission Implementing Regulation (EU)2021/2246 imposed the requirement of a 10% physical check of the consignments originating in India to find out whether the consignment is contaminated with Salmonella Row No. 10 of Annex II to the Commission Implementing Regulation (EU) 2021/2246, inter-alia, states as follows:-

Row	Country	Food and	CN code	TARIC sub-	Hazard	Frequency of
	of origin	feed(intended		division		identity and
		use)				physical
						checks(%)
10	India	Betel leaves	ex 140490 00	10	Salmonell	10
	(IN)	(Piper betel L.)			a	
		(Food)				

Annex III to the Commission Implementing Regulation (EU) 2019/1793 lays down sampling
procedures and analytical reference methods referred to in Article 3(e) to the Commission
Implementing Regulation (EU) 2019/1793 for the control of presence of Salmonella in food.
The procedure is given below:

$Sampling\ procedures\ and\ analytical\ reference\ methods\ for\ the\ control\ of\ presence\ of\ Salmonella\ in\ food:$

Annex III 1(b) states as follows:

(b) In the case where Annexes I or II to the Commission Implementing Regulation (EU) 2019/1793 for the application of the sampling procedures and analytical reference methods laid down in point 1(b) of Annex III to the Commission Implementing Regulation (EU) 2019/1793, the following rules shall apply:

Analytical reference method (1)	Weight of consignment	Number of sample units (n)	Sampling procedures	Analytical results required for each sample unit of the same consignment
EN ISO 6579-1	Any weight	5	n sample units are collected of a minimum of 100 g each. If batches are identified in the CHED, the sample units shall be collected from the different batches randomly chosen from the consignment. If batches cannot be identified, the sample units are collected randomly from the consignment. Pooling of sample units is not allowed. Each sample unit shall be tested separately.	No detection of Salmonella in 25 g

- (1) The most recent version of the analytical reference method shall be used or a method validated against it in accordance with the protocol set out in EN ISO 16140-2.
 - C.5 Method to be followed for the purpose of ascertaining the content of Salmonella in Betel Leaves
 - Annex III to the Commission Implementing Regulation (EU) 2019/1793 lays down sampling procedures and analytical reference methods referred to in Article 3(e) to the Commission Implementing Regulation (EU) 2019/1793 states that "The most recent version of the analytical reference method EN ISO 6579-1 shall be used or a method validated against it in accordance with the protocol set out in EN ISO 16140-2". As the product Betel leaves are perishable in nature, an alternative method using VIDAS® Up Salmonella (SPT) was found to be suitable. Reference to the Certificate reference No. BIO 12/32-10/11 issued by AFNOR confirms that the manufacturer validated by comparison to the reference method NF EN ISO 6579-1 (2017) and its amendment A1 (2020) and in accordance to the validation protocol NF EN ISO 16140-2 (2016).
 - (ii) Hence the laboratory shall use VIDAS® Up Salmonella (SPT) kit method as an alternative method to the analytical reference method EN ISO 6579-1 which is in compliance to Annex III to the Commission Implementing Regulation (EU) 2019/1793 lays down sampling procedures and analytical reference methods referred to in Article 3(e) for the purpose of ascertaining the presence of Salmonella content in Betel Leaves. However the laboratories shall have to carry out verification of this alternative method according to ISO 16140-3:2021.
 - (iii) Analytical reference method EN ISO 6579-1 and alternative method using VIDAS® Up Salmonella (SPT) kit shall be in the accredited scope of ISO 17025:2017.
 - (iv) If Salmonella is found to be present in the sample, the laboratory shall finally confirm using Analytical reference method EN ISO 6579-1
 - (v) The laboratories conducting the tests shall ensure that the Pack Houses/processing are having FSSAI License and FSSC 22000 Certification (Food Safety Standard Certification 22000), the latest version of which is accredited by UKAS. Further, the laboratories should also ensure that farms from which the Betel Leaves are procured are registered with State Horticulture Department of the respective states.
 - C.6. Special Conditions Governing the Entry into the Union of Certain food from Third countriesSection 3 of the Commission Implementing Regulation (EU) 2019/1793 deals with "Special Conditions
 Governing The Entry Into The Union Of Certain Food And Feed From Certain Third Countries" .For export of
 Betel Leaves to EU from India the following provisions of the Commission Implementing Regulation (EU)
 2019/1793 which is applicable to food products has to be complied with.
 - (i) In Article 2(1) to the Commission Implementing Regulation (EU) 2019/1793 is added Article 1(2) (c) of the Commission Implementing Regulation which inter alia states as follows "(2)in Article 2(1),the following point (c) is added:
 - '(c) "country of origin" means:

*** *** ***

- (ii) the country where the goods were produced, manufactured or wrapped where food and feed is listed in the Annexes due to the risk of presence of Salmonella or due to other hazards than those specified in point (i).';"
- (ii) Article 7 of Section 3 of the Commission Implementing Regulation (EU) 2019/1793 deals with "Entry into the Union". With respect to food, the said Article states as follows-
- Consignments of food listed in Annex II shall only enter into the Union in accordance with the conditions laid down in this section.
- The identification of the food referred to in paragraph 1 for official controls shall be made on the basis
 of the codes from the Combined Nomenclature and the TARIC sub-division indicated in Annex II.
- 3. Consignments referred to in paragraph 1 shall be subject to official controls at border control posts at their entry into the Union and at control points."
- (iii) Article 8 of Section 3 of the Commission Implementing Regulation (EU) 2019/1793 deals with "Frequency of identity checks and physical checks". With regard to food, the said provision states as follows-
- 1. The competent authorities at border control post and at control points referred to in Article 5 3(1)(a) of Regulation (EU) 2017/625 shall carry out identity and physical checks, including sampling and laboratory analyses, on consignments of food listed in Annex II, at the frequency set out in that Annex.
- 2. The frequency of identity and physical checks set out in an entry in Annex II shall be applied as an overall frequency for all products falling under that entry.
 - Paragraphs 3 and 4 of Article 8 of the Commission Implementing Regulation 2019/1793 has been replaced by Article 1(3) of the Commission Implementing Regulation(EU) 2021/1900. The said Article provides as follows-
 - "(3) in Article 8, paragraphs 3 and 4 are replaced by the following:
 - '3. Food consisting of two or more ingredients listed in Table 2 to Annex II which contains products falling only under one entry in Table 1 to Annex II shall be subject to the overall frequency of identity and physical checks set out in Table 1 to Annex II for that entry.
 - 4. Food consisting of two or more ingredients listed in Table 2 to Annex II which contains products falling under several entries for the same hazard in Table 1 to Annex II shall be subject to the highest overall frequency of identity and physical checks set out in Table 1 to Annex II for these entries."
- (iv) Article 9 of Section 3 of the Commission Implementing Regulation (EU) 2019/1793 deals with "Identification code". In connection with food, the said provision states as follows:-
- 1. Each consignment of food listed in Annex II shall be identified with an identification code.
- 2. Each individual bag or packaging form of the consignment shall be identified with that identification code.
- (v) Article 10 of Section 3 of the Commission Implementing Regulation (EU) 2019/1793 deals with "Results of sampling and analyses performed by the competent authorities of the third country". With

- respect to food, the said Article inter alia provides that-
- Each consignment of food in Annex II shall be accompanied by the results of sampling and analyses
 performed on that consignment by the competent authorities of the third country of origin or of the
 country where the consignment is consigned from if that country is different from the country of origin.
- 2. On the basis of the results referred to in paragraph 1, the competent authorities shall ascertain:

 (d) the absence of Salmonella in 25 g, for consignments of food listed in Annex II due to risk of microbiological contamination by Salmonella;

- 3. The results of sampling and analyses referred to in paragraph 1 shall bear the identification code of the consignment to which they relate referred to in Article 9(1).
- 4. The analyses referred to in paragraph 1 shall be performed by laboratories accredited in accordance with the standard ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories'."
- C.7. Issuance of 'official certificate' by SHEFEXIL
- (i) Each consignment of Betel Leaves should be accompanied by an 'Official Certificate' to be issued by the designated competent authority i.e. Shefexil in accordance with the provision contained in Article 1 of the Commission Implementing Regulation (EU) 2021/608.

The relevant portion of Article 1(1) of the Commission Implementing Regulation (EU) 2021/608 is set out below :

"Article 1

Amendments to Implementing Regulation (EU) 2019/1793

Implementing Regulation (EU) 2019/1793 is amended as follows:

(1) Article 11 is replaced by the following:

Article 11

Official Certificate

- 2. The official certificate shall comply with the following requirements:
 - (a) the official certificate shall be issued by the competent authority of the third country of origin or of the third country where the consignment is consigned from if that country is different from the country of origin;
 - (b) the official certificate shall bear the identification code of the consignment to which it relates, referred to in Article 9(1);
 - (c) the official certificate shall bear the signature of the certifying officer and the official stamp;
 - (d) where the official certificate contains multiple or alternative statements, the statements which are not relevant shall be crossed out, initialled and stamped by the certifying officer, or completely removed from the certificate;
 - (e) the official certificate shall consist of one of the following:
 - (i) a single sheet of paper;
 - (ii) several sheets of paper where all sheets are indivisible and constitute an integrated whole;

- (iii) a sequence of pages with each page numbered so as to indicate that it is a particular page in a finite sequence;
- (f) where the official certificate consists of a sequence of pages as referred to in point (e)(iii) of this paragraph, each page shall bear the unique code referred to in Article 89(1)(a) of Regulation (EU) 2017/625, the signature of the certifying officer and the official stamp;
- (g) the official certificate shall be presented to the competent authority of the border control post of entry into the Union where the consignment is subjected to official controls;
- (h) the official certificate shall be issued before the consignment to which it relates leaves the control of the competent authorities in the third country issuing the certificate;
- (i) the official certificate shall be drawn up in the official language, or in one of the official languages, of the Member State of the border control post of entry into the Union;
- (j) the official certificate shall be valid for not more than four months from the date of issue, but in any case no longer than six months from the date of the results of the laboratory analyses referred to Article 10(1).
- 3. By way of derogation from point (i) of paragraph 2, a Member State may consent to official certificates being drawn up in another official language of the Union and accompanied, if necessary, by an authenticated translation.
- 4. The colour of the signature and of the stamp other than an embossed or watermarked stamp, which are referred to in point (c) of paragraph 2, shall be different to the colour of the printing.
- 5. Points (c) to (g) of paragraph 2 and paragraph 4 shall not apply to electronic official certificates issued in accordance with the requirements of Article 39(1) of Commission Implementing Regulation (EU) 2019/1715.
- 6. Points (d), (e) and (f) of paragraph 2 shall not apply to official certificates issued in paper and completed in, and printed from, TRACES.
- 7. Competent authorities may issue a replacement official certificate only in accordance with the rules laid down in Article 6 of Commission Implementing Regulation (EU) 2020/2235.

The model Official Certificate and the Notes on the completion of that Certificate set out in Annex IV to the Commission Implementing Regulation (EU) 2019/1793 was replaced by the Commission Implementing Regulation (EU) 2021/608. Further the same has been replaced by the Commission Implementing Regulation (EU) 2021/1900.

In view of the above, SHEFEXIL should consider the following points before issuing an Official Certificate-

- Each consignment of Betel Leaves shall have to be accompanied by an Official Certificate to be
 prepared in accordance with Annex IV to the Commission Implementing Regulation (EU) 2021/1900
 and as specified in the format for EU and Great Britain mentioned in the Annexure –5 and 5A to this
 Procedure respectively.
- The Official Certificate will be issued based on the applications made by the exporters. The applications shall have to be accompanied by the sample analysis report of the laboratory. Shefexil will issue the Official Certificate only upon due verification of the documents submitted by the exporters and only after finding the documents submitted to be complete in all respect and satisfactory.

- The Official Certificate shall comply with the following requirements:
 - o the Official Certificate shall be issued by SHEFEXIL;
 - o the Official Certificate shall bear the identification code of the consignment to which it relates, referred to in Article 9(1);
 - o the Official Certificate shall bear the signature of the certifying officer and the official stamp;
 - where the Official Certificate contains multiple or alternative statements, the statements which are not relevant shall be crossed out, initialed and stamped by the certifying officer, or completely removed from the certificate:
 - o the Official Certificate shall consist of one of the following:
 - a single sheet of paper;
 - several sheets of paper where all sheets are indivisible and constitute an integrated whole;
 - a sequence of pages with each page numbered so as to indicate that it is a particular page in a finite sequence;
 - the Official Certificate shall have to be presented to the competent authority of the border control
 post of entry into the Union where the consignment is subjected to official controls;
 - the Official Certificate shall be issued before the consignment to which it relates leaves the control
 of the competent authorities in the third country issuing the certificate;
 - o the Official Certificate shall be drawn up in the official language, or in one of the official languages, of the Member State of the border control post of entry into the Union;
 - o the Official Certificate shall be valid for not more than four months from the date of issue, but in any case no longer than six months from the date of the results of the laboratory analyses referred to Article 10(1).
 - The notes mentioned below the format of Official Certificate in Annex IV of the Commission Implementing Regulation (EU) 2021/1900 states as follows:

"Notes

See notes for completion in this Annex.

Part II

- (i) Delete or cross out as appropriate (e.g. if food or feed)
- (ii) It applies only in the case of any stage of production, processing and distribution after primary production and related operations.
- (iii) Delete or cross out as appropriate in the case where you do not select this point for providing the certification.
- (iv) The colour of the signature shall be different to that of printing. The same rule applies to stamps other than those that are embossed or are a watermark.
- Annex IV to the Commission Implementing Regulation (EU) 2021/1900 provides the "MODEL OFFICIAL CERTIFICATE REFERRED TO IN ARTICLE 11 OF COMMISSION IMPLEMENTING REGULATION (EU) 2019/1793 FOR THE ENTRY INTO THE UNION OF CERTAIN FOOD OR FEED". The said Annex IV also provides the "NOTES FOR THE COMPLETION OF THE MODEL OFFICIAL CERTIFICATE REFERRED TO IN ARTICLE 11 OF COMMISSION IMPLEMENTING REGULATION (EU) 2019/1793 FOR THE ENTRY INTO THE UNION OF CERTAIN FOOD OR FEED".

The Notes governing the completion of such Official Certificate which is applicable to Betel Leaves as per the said Annex IV to the Commission Implementing Regulation (EU) 2021/1900 is set out in Annexure 6 to this Procedure.

- (v) The exporter applying for the 'Official Certificate' before SHEFEXIL shall have to submit the followings:
 - Copy of the FSSAI license and FSSC 22000 Certification (Food Safety Standard Certification 22000) the latest version of which is accredited by UKAS of Pack Houses.
 - Copy of the Certificate issued by respective State Horticulture Departments in favour of the farms from which Betel Leaves are procured.
 - Copy of pre-shipment inspection report.

C.8. Ensuring traceability

- Each consignment shall be identified with an identification code.
- Each individual bag or packaging form of the consignment shall be identified with that identification code.
- SHEFEXIL will trace the origin of the product from the documents submitted for obtaining the 'Official Certificate'.
- SHEFEXIL will work towards an online system to establish traceability and to do away with the requirement of production of certificates.

C.9. Penal Provision :-

- In the event of breach of instructions, SHEFEXIL may initiate action as per the provisions of Articles
 of Association of the Council in addition to the followings:-
 - (a) Cancellation of Registration-cum-Membership Certificate of the exporter.
 - (b) De recognition of the Authorized Agency and Recognized Laboratory.
 - (c) Notifying DGFT for cancellation of Import Export Code Number allocated to such exporters.
 - (d) Any other actions as it deem fit.
- D. The Relevant portion of the Commission Implementing Regulation (EU) 2019/1793 and Commission Implementing Regulation (EU) 2021/608, Commission Implementing Regulation (EU) 2021/1900 and the Commission Implementing Regulation (EU) 2021/2246 are set out in Annexures 7, 8, 9 and 10 to this Procedure respectively.

Date: 14.02.2022 Place: Kolkata (Sd/-)

Chairman - SHEFEXIL

List of Annexures:

Annexure 1: Sample slip for laboratories

Annexure 2: List of empaneled laboratories for pre-shipment inspection

Annexure 3: Format of laboratory analysis (pre-shipment inspection) certificate

Annexure 4: Format of labels to be affixed on each box meant for exports to EU

Annexure 5: Format of Official Certificate to EU

Annexure 5A: Format of official certificate to Great Britain / UK

Annexure 6: Notes on the Completion of the Model Official Certificate Referred to in Article 11 of Commission Implementing

Regulation (EU) 2019/1793 for The Entry Into The Union of Certain Food or Feed

Annexure 7: Relevant portion of Commission Implementing Regulation (EU) 2019/1793

Annexure 8: Relevant portion of Commission Implementing Regulation (EU) 2021/608

Annexure 9: Relevant portion of Commission Implementing Regulation (EU) 2021/1900.

Annexure 10: Relevant portion of Commission Implementing Regulation (EU) 2021/2246.

Sample slip for Laboratories

No.	Contents	<u>Details</u>
1.	Name and address of exporter	
2.	Name & address of the pack house	
3.	Pack houses Accreditation details &its validity	
4.	Betel Leave variety	
5.	Totalquantity(innumberofboxes,netweightandgrossweightdecla redbyexporter/pack house) covered in this sample slip	
6.	Pests and diseases condition of Betel Leaves	
7.	Weight of total sample	
8.	Weight of the laboratory sample (including control sample)	
9.	Date and time of drawl of sample at Pack house	

Signature of Exporter Name of exporter Signature of pack house representative Name of representative of pack house

Certificate

1. I,_			_(Name c	of th	ne sample	r of	the	lab)) has	drawn	this	sample	from	the	above	Pack
house	by adopt	ting the	e method	of	sampling	as	per	EU	Guid	lelines	of P	rocedur	e for	expo	ort of	Betel
Leaves																

- 2. This sample is taken from the above Packhouse, is intended to be exported by __(name of the exporter). There is no application fagri inputs, spray, irrigation, etc. between sampling and harvesting (in case of sample drawn from the Pack Houses).
- 3. I have also obtained copy of the pack house accreditation documents.
- 4. That, as on date, there cognition of this laboratory is valid.

Date:	Signature	:
Place:	Name of sampler of	
	Laboratory Official add	ress:

Laboratories for sampling and analysis of Betel Leaves

No.	Name and contact details of the laboratory
1	Vimta Labs Limited
	5, MN Park (Formerly Alexandria Knowledge
	Park), Genome Valley, Shamirpet, Medchal-
	Malkajigiri Dist.,
	Hyderabad - 500101, INDIA.
	Tel:+91 40 67404040, +91 40 67404501
	Fax: +91 40 2726 3657
	Email: bd@vimta.com
	https://www.vimta.com/contact
2	Geo Chem Laboratories
	Geo Chem House, 294, ShahidBhagat Singh
	Road, Fort, Mumbai 400001.
	Tel: +91 22 66383838
	Fax: +91 22 66383800
	E-mail: mumbai@geochem.net.in
	http://www.geochem.net.in/contact-us.html
3	Dr. Shalini Tripathi
	Assistant Director & BUMA
	Eurofins Analytical Services India Pvt. Ltd.
	157, Udyog Vihar, Phase-1, 122016, Gurugram, India
	Phone: +91-1246250301
	Mobile: +91-9582068017
	E-mail: ShaliniTripathi@eurofins.com
	Website: www.eurofins.in
4	Jyoti Sindhu
	Assistant Director-Lab
	Eurofins Analytical Services India Pvt. Ltd.
	540/1, Doddanekundi Industrial Area 2,
	Graphite India Road, Hoodi, Whitefield,
	560048, Bengaluru,
	India
	Phone: +91 8067223200
	Mobile: +91 8951854470
	1000HC. T/1 0/310344/0

SHEFEXIL will make changes in this list as and when new laboratories confirm their compliance with the EU guidelines.

Format of Laboratory Analysis Certificate for exports of Betel Leaves from India to EU

Issued To:Registration/ReportNo.COMPANY NAME (Exporter's name)Exporters Ref:Addressand date:

Ph:

Kind Attn: Mr./Mrs. Page 1 of 1

Customer Provided	Details :						
Sample Name:	Identification Id/ Batch/Lot Number:						
Test Required:	Salmonella in 5 sub samples	•					
Other Details if Any:	Shefexil RCMC No. & IE Code of the exporter: Name and address of Accredited Pack house: (sampled at pack house with seal no.) Pack house Accreditation details & validity:						
Sampling Details:	Sampled by: Authorized representative of						
Lab Provided Detail	s:						
Sample Received Date:		Sample Registration Date:					
Analysis Starting Date:		Analysis Completion Date:					
Received Quantity:	100 gms X 5 No						
Method of Testing:	SOP XXX using VIDAS® Up Salmonella (SPT) Kit alternative method to EN ISO 6579-1 (2017) and its amendment A1 (2020) and in accordance to the validation protocol EN ISO 16140-2 (2016)						
Other Details if Any:	SAMPLE TESTED AS RECEIVED						

Biological Food &agri products ULR No.

TEST RESULTS

S. No.	Test Parameters	UOM	Requirements as per EU Commission Implementing Regulation No. EU 2019/1793 dated 22nd October 2019	Results
1	Salmonella (sub sample-1)	per 25g	No detection in 25g	Not detected
2	Salmonella (sub sample-2)	per 25g	No detection in 25g	Not detected
3	Salmonella (sub sample-3)	per 25g	No detection in 25g	Not detected
4	Salmonella (sub sample-4)	per 25g	No detection in 25g	Not detected
5	Salmonella (sub sample-5)	per 25g	No detection in 25g	Not detected

Remarks:

The method used VIDAS® Up Salmonella (SPT) kit method is an alternative method to EN ISO 6579-1 (2017) and its amendment A1 (2020) and in accordance to the validation protocol EN ISO 16140-2 (2016) as certified by AFNOR. Further the method was verified in-house in the laboratory in accordance with verification protocol ISO 16140-3: 2021.

Conclusion: Sample conforms to the tests and limits specified in the Commission Implementing Regulation (EU) 2019/1793

- END OF THE TEST REPORT -

Annexure-4

Label to be affixed in each box meant for exports of Betel Leaves

(To be affixed by the exporter/ registered pack house)

Name of Pro	duce	Betel Leaves
Unique Ident	ificationCode	AAAPHL000F123

AAA: Three al	phabet codename of exporter
PHL:	Three alphabet pack house location code
000:	Three numeric pack house approval number codes
:	The Registration Code of the farms registered with the State Horticulture
	Department of the State of

Annexure - 5



शेलाक एण्ड फारेस्ट प्रोडाक्तस् ऐक्सपोर्ट प्रोमोशन कौंसिल

Shellac And Forest Products Export Promotion Council Formerly Shellac Export Promotion Council

(Sponsored by Ministry of Commerce & Industry, Govt of India)

"VANIJYA BHAWAN", INTERNATIONAL TRADE FACILITATION CENTRE, 1/1 WOOD STREET, 2ND FLOOR, KOLKATA - 700 016
Tel: 91-33-2283-4417, 2283-4697, 2283-4698 • Fax: 91-33-2283-4699
Email: shefexil@gmail.com • Website: www.shefexil.org

OFFICIAL CERTIFICATE REFERRED TO IN ARTICLE 11 OF COMMISSION IMPLEMENTING REGULATION (EU) 2019/1793 FOR THE ENTRY INTO THE UNION OF CERTAIN FOOD OR FEED

		CINION OF CERTAIN FOOD OR FEE		
	COUNTRY		12 6 15 1	Certificate to the EU
<u>+</u>	I.1 Consignor/Exporter		I.2 Certificate reference	I.2.a IMSOC reference No
je	Name			
틽	Address		I.3. Central Competent	
isi			Authority	QR CODE
S		ountry	I.4 Local Competent	
₽	Code		I	
Part I: Description of consignment	I.E. Considerate / Inconstant		Authority :	h
Ē	I.5 Consignee/Importer		I.6 Operator responsible for the	ne consignment
in g	Name		Name	
Ğ	Address		Address	
<u>:</u> :	Country ISO o	ountry	Country	ISO country code
ar	Code	· · · · · · · · · · · · · · · · · · ·		
-	I.7 Country of origin	ISO Country Code	I.9. Country of destination	ISO country
	, 3	•	code	•
			1.10	
-	. Place of dispatch		I.12. Place of destination	
	Name Registration/Ap	proval No	Name	Registration/Approval No.
	Name Registration/Ap	provarivo.	Name	Registration/Approvarito.
	Address		Address	
	Country ISO country Cod	la.	Country ISO coun	try Code
J	country 130 country coc	ic .	Country	ti y code
ļ	4.13. Place of loading		114 Data and time of deposition	
	1.13. Place of loading		I.14. Date and time of departure	2 :
	I.15. Means of transport		I.16 Entry Border Control Post	
	Aircraft	Vessel	I.17. Accompanying docu	
		<u> </u>	1.17. Accompanying docum	ments
	Railway	Road vehicle	Туре	Code
	,		Country	ICO accompting Condo
	Identification:		Country	ISO country Code
			Commercial docume	ent
			reference	
	I.18. Transport	Ambient	Chilled	Frozen
	conditions			<u></u>
	I.19. Container No/Seal number			
	Container No.	Seal No.		
	I.20. Certified as or for			
	Products for			
	Human consumption			
	Feedstuff			
	recustum			
İ	l.21.		I.22. F ernal market	
			1.23.	
		T	1227 1 1 1 1 1 1 1	
	I.24 Total number of packages	I.25 Total Quantity	1.26 Total net weight/gross v	weight (Kg)
	127.0			
	1.27. Description of consignment			
	CN code Species			
		Type of Pa		
		Number o	f packages Batch No.	
	For final			
	Consumer			
	Certifying officer:		Qualification and title : P.H.D., Ex	
	Name: DR. DEBJANI ROY		Shellac & Forest Products Export	Promotion Council
		Si	gnature:	
	Data			
	Date: Stamp			
	Smith			



शेलाक एण्ड फारेस्ट प्रोडाक्तस् ऐक्सपोर्ट प्रोमोशन कोंसिल

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	COUN	NTRY	Certificate for	the entry into the Union of food or feed
	II.	Health information	II.a Certificate reference No	II. b IMSOC reference
Part II : Certification	II. 1.	Regulation (EC) No 178/2002 principles and requirements or matters of food safety (OJ L 31 Regulation (EC) No. 852/2004 (OJ L 139, 30.4.2004, p.1), Regulation (EC) No. 183/2005 for feed hygiene (OJ L 35, 8.2. Regulation (EU) 2017/625 of official activities performed to plant protection products, am 1107/2009, (EU) No. 1151/20 the Council, Council Regulation 2007/43/EC, 2008/119/EC and European Parliament and of the 96/93/EC and 97/78/EC and certify that: the food of the consignment consignment referred to in Artivity with the requirements of Regulation in the case of any stage it has been handled and, where the second in the content of the consignment in the case of any stage it has been handled and, where the second in the case of any stage it comes from (an) establis	f food law, establishing the European For, 1.2.2002, p.1), f of the European Parliament and of the Council (EC) No. 1099/2014, (EU) 2016/429 and (EC) No. 1/2005 and (EC) No. 1099/2014 (EU) No. 1/2005 and (EC) No. 1099/2014 (EU) No. 1/2005 and (EC) No. 1099/2014 (EU) of Council Decision 92/438/EEC (Official Council Decision 92/438/EEC (Official Council Decision 92/438/EEC (Official Council Official Offici	council of 28 January 2002 laying down the general od Safety Authority and laying down procedures in council of 29 April 2004 on the hygiene of foodstuffs council of 12 January 2005 laying down requirements ocil of 15 March 2017 on official controls and other of the council of 15 March 2017 on official controls and other of the council of 15 March 2017 on official controls and other of the council of 15 March 2017 on official controls and other of the council of 15 March 2017 on official controls and other of the council of 15 March 2017 on official controls and other of the council of 15 March 2017 on official controls and other of 15 March 2017 on official controls and other of 15 March 2016 (EC) No. 396/2005, (EC) No. 1069/2009, (EC) No. 1069/2009, (EC) No. 854/2004 and (EC) No. 882/2004 of the 2019 of 15 March 2019 on official controls Regulation) (OJ L 95, 7.4.2017, p.1), and I could be comply of 15 March 2019 on official controls and in particular: Annex I to Regulation (EC) No. 852/2004 comply of Regulation (EC) No. 852/2004; after primary production and related operations: tored in a hygienic manner in accordance with the did on the hazard analysis and critical control points
		fying officer : e:DR. DEBJANI ROY		fication and title: P.H.D., Executive Director lac & Forest Products Export Promotion Council re:
	Date:			



शेलाक एण्ड फारेस्ट प्रोडाक्तस् ऐक्सपोर्ट प्रोमोशन कोंसिल

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Email: shefexil@gmail.com • Website: www.shefexil.org

	Country Certificate for the entry into the Union of food or feed		try into the Union of food or feed	
	II.	Health information	II.a Certificate reference No	II. b IMSOC reference
	II. 2.	Implementing Regulation controls and emergence countries implementing	y measures governing the entry into	2019 on the temporary increase of official the Union of certain goods from certain third EC) No. 178/2002 of the European Parliament
Part II : Certification	II.2.4 -	2019/1793, as well as f microbiological contam	for food consisting of two or more in hination lescribed above, samples were taken	annex II to Implementing Regulation (EU) ingredients listed in that Annex due to risk of in accordance with Annex III to
	-	in thethe hazards identified in	Annex II to Implementing Regulation	the laboratory) with methods covering at least
	II.3.	This certificate has been competent authority iss		hich it relates has left the control of the
	II. 4.	months from the date o	f the results of the last laboratory an	issue, but in any case no longer than six alyses.
	Part II		Aimex.	
	(1)		opropriate (e.g. if food or feed)	
	(2)	and related operations.		sing and distribution after primary production
	(3)	Delete or cross out as a certification.	oppropriate in the case where you do r	not selected this point for providing the
	(4)		are shall be different to that of the priossed or are a watermark.	inting. The same rule applies to stamps other
	Certifyi	ng officer :		Qualification and title : P.H.D., Executive Director
	Name	DR. DEBJANI ROY		Shellac & Forest Products Export Promotion Council gnature :
	Ι	Date :		
	S	Stamp		

Annexure - 5A



शेलाक एण्ड फारेस्ट प्रोडाक्तस् ऐक्सपोर्ट प्रोमोशन कोंसिल

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OFFICIAL CERTIFICATE REFERRED TO IN ARTICLE 11 OF RETAINED REGULATION (EU) 2019/1793, FOR THE ENTRY INTO GB OF CERTAIN FOOD OR FEED **GBHC176**

	COUNTRY		Official Certificate to the GB
¥	I.1 Consignor/ Exporter	I.2 Certificate reference	I.2.a IPAFF reference
mer	Name		
ig L	Address	I.3. Central Competent	
ons		Authority	QR CODE
o j e	Country ISO country	I.4 Local Competent	
ü	Code	Authority:	
Part I: Description of consignment	I.5 Consignee/Importer	I.6 Operator responsible for	the consignment
sscr	Name	Name	
ă.	Address	Address	100
핕	Country ISO country	Country	ISO country code
Pa	Code		
	1.7 Country of origin ISO Country Code	I.9. Country of destination	ISO country code
	.8	1.10	
	. Place of dispatch	I.12. Place of destination	
	Name Registration/Approval No.	Name	Registration/Approval No.
	7 11		registration, approval rec.
	Address	Address	
	Country ISO country Code	Country ISO cour	ntry Code
	I.13. Place of loading	I.14. Date and time of departur	re:
	I.15. Means of transport	I.16 Entry Border Control Post	
	Aircraft	117	
	The state of the s	I.17. Accompanying docu	uments
	Railway Road vehicle	Туре	Code
		Country	ISO country Code
	Identification:	Commercial docum	ent
		reference	
	I.18. Transport Ambient	Chilled	Frozen
	conditions 1.19. Container No/Seal number		
	Container No. Seal No.		
	I.20. Certified as or for		
	Products for		
	Human consumption		
	Feedstuff		
	1.21.	I.22. F ernal market	
		1.23.	
	I.24 Total number of packages I.25 Total Quantity	1.26 Total net weight/gross	weight (Kg)
	I.27. Description of consignment		
	CN code Species		
		Packaging Net weig	
		r of packages Batch No	D.
	For final		
	Consumer Certifying officer:	Qualification and title : P.H.D., E	Executive Director
	Name :DR. DEBJANI ROY	Shellac & Forest Products Expor	
	2	Signature:	
	Date:		
	Stamp		



शेलाक एण्ड फारेस्ट प्रोडाक्तस् ऐक्सपोर्ट प्रोमोशन कोंसिल

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	Regulation (EC) No 178/20 principles and requirements matters of food safety (OJ L Regulation (EC) No. 852/20 (OJ L 139, 30.4.2004, p.1), Regulation (EC) No. 183/20 for feed hygiene (OJ L 35, 8 Regulation (EU) 2017/625 official activities performed plant protection products, a 1107/2009, (EU) No. 1151/2 the Council, Council Regulation (EU) 2007/43/EC, 2008/119/EC are certify that:	s of food law, establishing to 31, 1.2.2002, p.1), 2004 of the European Parliam 2005 of the European Parliam 3.2.2005, p.1) and of the European Parliament to ensure the application of tamending Regulations (EC) 2012, (EU)No. 652/2014, (E ations (EC) No. 1/2005 and and 2008/120/EC and repea of the Council, Council Directed Council Decision 92/438/	provisions of Union tent and of the Countent and of the Council food and feed law, represent the No. 1099/2001, (ECU) 2016/429 and (ICU) 2016/429 and (ICU) 2016/429 and (ICU) 2016/429 and (ICU) No. 1099/200 ling Regulations (ICU) tives 89/608/EEC, SEEC (Official Content identification cooler i	uncil of 28 January 2002 laying down the general Safety Authority and laying down procedures and of 29 April 2004 on the hygiene of foodstuff and 12 January 2005 laying down requirements of 15 March 2017 on official controls and other rules on animal health and welfare, plant health at C. No.396/2005, (EC) No. 1069/2009, (EC) NEU) 2016/2031 of the European Parliament and on and Council Directives 98/58/EC, 1999/74/EEC) No. 854/2004 and (EC) No. 882/2004 of the 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/Eatrols Regulation) (OJ L 95, 7.4.2017, p.1), and the following the indicate the identification code for the safety of the safety and content of the safety of the safe
	Regulation (EC) No 178/20 principles and requirements matters of food safety (OJ L Regulation (EC) No. 852/20 (OJ L 139, 30.4.2004, p.1), Regulation (EC) No. 183/20 for feed hygiene (OJ L 35, 8 Regulation (EU) 2017/625 official activities performed plant protection products, a 1107/2009, (EU) No. 1151/2 the Council, Council Regulation (EU) 2007/43/EC, 2008/119/EC are certify that:	2002 of the European Parliams of food law, establishing to 231, 1.2.2002, p.1), 2004 of the European Parliams (2005 of the European Parliams (2005, p.1) and of the European Parliament to ensure the application of tamending Regulations (EC) (2012, (EU)No. 652/2014, (E) ations (EC) No. 1/2005 and and 2008/120/EC and repeat the Council, Council Directed Council Decision 92/438/	the European Food the European Food the European Food the European Food tent and of the Council and of the Council food and feed law, r. No 999/2001, (ECU) 2016/429 and (ICE) No. 1099/200 dling Regulations (ICE) tives 89/608/EEC, SEEC (Official Contest identification coofee identification Food	uncil of 28 January 2002 laying down the gene Safety Authority and laying down procedures noil of 29 April 2004 on the hygiene of foodstuncil of 12 January 2005 laying down requirement of 15 March 2017 on official controls and other rules on animal health and welfare, plant health at C. No.396/2005, (EC) No. 1069/2009, (EC) NEU) 2016/2031 of the European Parliament and O9 and Council Directives 98/58/EC, 1999/74/EC) No. 854/2004 and (EC) No. 882/2004 of the 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/Extrols Regulation) (OJ L 95, 7.4.2017, p.1), and the definition of the identification code for the safety of the safety and control of the identification code for the safety and control of the identification code for the safety and control of the identification code for the safety and control of the identification code for the safety and control of the identification code for the safety and control of the identification code for the safety and control of the identification code for the safety and control of the safety and control of the identification code for the safety and control of the safety a
[П.1.1 .	consignment referred to in A			
	 primary production of s with the general hygien and, in the case of any static thas been handled and, requirements of Annex it comes from (an) establishment 	gulations (EC) No. 178/2002 such food and associated open ne provisions laid down in parage of production, processing where appropriate, prepared II to Regulation (EC) No. 8.	and (EC) No.852/2 rations listed in An rt A of Annex I to F g and distribution aff I, packaged and stor 52/2004 and, programme based o	nnex I to Regulation (EC) No. 852/2004 comply Regulation (EC) No. 852/2004; ter primary production and related operations: red in a hygienic manner in accordance with the on the hazard analysis and critical control points
-	g officer : DR. DEBJANI ROY		•	and title: P.H.D., Executive Director orest Products Export Promotion Council



शेलाक एण्ड फारेस्ट प्रोडाक्तस् ऐक्सपोर्ट प्रोमोशन कोंसिल

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Email: shefexil@gmail.com • Website: www.shefexil.org

	Country				he Union of food or feed – GBHC176
	II.	Health information	II.a Certificate reference No		II. b IPAFF reference
	II. 2.	Implementing Regulation controls and emergence countries implementing	y measures governing the en	October try into 5 and (r 2019 on the temporary increase of official of the Union of certain goods from certain third EC) No. 178/2002 of the European Parliament
Part II : Certification	П.2.4	2019/1793, as well as f microbiological contam	or food consisting of two or ination escribed above, samples wer	more	Annex II to Implementing Regulation (EU) ingredients listed in that Annex due to risk of a in accordance with Annex III to
T.	-	in thethe hazards identified in	Annex II to Implementing R	ame of egulati	the laboratory) with methods covering at least
	II.3.	This certificate has been competent authority iss		ent to w	which it relates has left the control of the
	II. 4.	months from the date of	during four months from the f the results of the last labora		issue, but in any case no longer than six nalyses.
	Notes: See notes for completion in this Annex. Part II:				
	(4)		opropriate (e.g. if food or feed)	
	(5)				ssing and distribution after primary production
	(6)	Delete or cross out as ap certification.	opropriate in the case where y	ou do	not selected this point for providing the
	(4)		are shall be different to that o ossed or are a watermark.	f the pr	inting. The same rule applies to stamps other
		ng officer : DR. DEBJANI ROY		•	lification and title : P.H.D., Executive Director llac & Forest Products Export Promotion Council ture :
		Date : tamp			

NOTES FOR THE COMPLETION OF THE MODEL OFFICIAL CERTIFICATE REFERRED TO IN ARTICLE 11 OF COMMISSION IMPLEMENTING REGULATION (EU) 2019/1793 FOR THE ENTRY INTO THE UNION OF CERTAIN FOOD OR FEED

General

To positively select any option, please tick or mark the relevant box with a cross (X).

Only one of the options may be selected in boxes I.18, I.20.

Select among points II.2.1, II.2.2, II.2.3 and II.2.4, the point(s) corresponding to the category of product and the hazard(s) for which the certification is given.

Unless otherwise indicated, all boxes are compulsory.

If the consignee, the entry border control post (BCP) or the transport details (that is to say, the means and date) change after the certificate has been issued, the operator responsible for the consignment must advise the competent authority of the Member State of entry. Such a change shall not result in a request for a replacement certificate.

In case the certificate is submitted in the information management system for official controls (IMSOC), the following applies:

- the statements which are not relevant are crossed out,
- the entries or boxes specified in Part I constitute the data dictionaries for the electronic version of the official certificate,
- the sequences of boxes in Part I of the model official certificate and the size and shape of those boxes are indicative.
- where a stamp is required, its electronic equivalent is an electronic seal.

In case the official certificate is not submitted in the IMSOC, the statements which are not relevant must be crossed out, initialled and stamped by the certifying officer, or completely removed from the certificate.

PART I - DESCRIPTION OF CONSIGNMENT

Box	Description
	Country
	Indicate the name of the third country issuing the certificate.
I.1	Consignor/Exporter
	Indicate the name and address, country and ISO country code of the natural or legal person dispatching the consignment. This person shall be established in a third country, except for the re-entry of consignments originating in the Union.
1.2	Certificate reference
	Indicate the unique alphanumeric code assigned by the competent authority of the third country. This box is not compulsory for certificates submitted in the IMSOC. Repeated in box II.a
I.2a	IMSOC reference
	This is the unique alphanumeric code assigned by the IMSOC. Repeated in box II.b This box shall not be completed if the certificate is not submitted in the IMSOC.
1.3	Central competent authority
	Indicate the name of the central authority in the third country issuing the certificate.

1.4	Local competent authority
	Indicate, if applicable, the name of the local authority in the third country issuing the certificate.
1.5	Consignee/Importer
	Indicate the name and address of the natural or legal person to whom the consignment is destined in the Member State of destination.
1.6	Operator responsible for the consignment
	Indicate the name and address, country and ISO country code, of the natural or legal person in the Member State in charge of the consignment when presented at the Border Control Post (BCP) who makes the necessary declarations to the competent authorities as the importer or on behalf of the importer. This operator may be the same as indicated in box I.5.
	This box is optional.
1.7	Country of origin
	Indicate the name and ISO country code of the country where the goods originate from, were grown, harvested or produced for food and feed listed in the Annexes due to a possible risk of contamination by mycotoxins, including aflatoxins, or by plant toxins, or due to possible non-compliance with the maximum allowed levels of pesticide residues.
	Indicate the name and ISO country code of the country where the goods were produced, manufactured or wrapped for food and feed listed in the Annexes due to the risk of presence of <i>Salmonella</i> or due to other hazards than those specified in the first paragraph.
1.8	Region of origin
	Not applicable.
1.9	Country of destination
	Indicate the name and ISO country code of Member State of destination of the products.
I.10	Region of destination
	Not applicable.
I.11	Place of dispatch
	Indicate the name and address, country and ISO country code of the establishment(s) from where the products come from. Where required by Union legislation, indicate its registration or approval number.
	For other products: any unit of a company in the food or feed sector. Only the establishment shipping the products is to be named.
	In the case of trade involving more than one third country (triangular trade), the place of dispatch is the last third-country establishment of the export chain from which the final consignment is transported to the Union.
I.12	Place of destination
	Indicate the name and address, country and ISO country code, of the place where the consignment is being delivered for final unloading. Where applicable, also indicate the registration or approval number of the establishment of destination.
I.13	Place of loading
	Not applicable.
I.14	Date and time of departure
	Indicate the date when the means of transport departs (aircraft, vessel, railway or road vehicle).

I.15	Means of transport
	Select one or more of the following means of transport for goods leaving the country of dispatch, and indicate its identification:
	— aircraft (indicate the flight number);
	— vessel (indicate the vessel name and number);
	— railway (indicate the train identity and wagon number);
	— road vehicle (indicate the registration number with trailer number, if applicable).
	In the case of a ferry, tick "vessel" and identify the road vehicle(s) with registration number (with trailer number, if applicable), in addition to the name and number of the scheduled ferry.
I.16	Entry Border Control Post
	Indicate the name of the BCP of entry into the Union for certificates not submitted in the IMSOC or select the name of the BCP of entry into the Union and its unique alphanumeric code assigned by the IMSOC.
I.17	Accompanying documents
	Indicate the type of required document: analytical report/results of sampling and analyses referred to in Article 10 of Implementing Regulation (EU) 2019/1793, and indicate the unique code of required accompanying documents and country of issue.
	Other documents: indicate the type and reference number of document when a consignment is accompanied by other documents such as commercial documents (for example, the airway bill number, the bill of lading number or the commercial number of the train or road vehicle).
I.18	Transport conditions
	Indicate the category of required temperature during the transport of products (ambient, chilled, frozen).
I.19	Container number/Seal number
	Where applicable, indicate the container number and seal number (more than one possible).
	The container number must be provided if the goods are transported in closed containers.
	Only the official seal number must be stated. An official seal applies if a seal is affixed to the container, truck or rail wagon under the supervision of the competent authority issuing the certificate.
1.20	Certified as or for
	Select the intended use of goods as specified in the relevant Union legislation:
	Feedstuffs: concerns only products intended for animal feed.
	Products for human consumption: concerns only products intended for human consumption for which an official certificate is required by Union legislation.
I.21	For transit
	Not applicable.
1.22	For internal market
	Tick this box where consignments are intended to be placed on the Union market.
I.23	For re-entry
	Not applicable.
1.24	Total number of packages
1.05	Indicate the total number of packages in the consignment, where appropriate: In the case of bulk consignments, this box is optional.
I.25	Total quantity
	Not applicable.

1.26	Total net weight/gross weight (kg)
	The total net weight is the mass of goods themselves, without immediate containers or any packaging. It is automatically calculated by the IMSOC on the basis of the information entered in box I.27. The declared net weight of glazed food shall be exclusive of the glaze.
	Indicate the total gross weight, i.e. the aggregate mass of the goods, plus immediate containers and all their packaging, but excluding transport containers and other transport equipment.
1.27	Description of consignment
	Indicate the relevant Harmonised System (HS) code and the title defined by the World Customs Organisation as referred to in Council Regulation (EEC) No 2658/87
	This customs description shall be supplemented, if necessary, by additional information required to classify the products. In addition, state any specific requirements relating to the nature/processing of the products as defined in the relevant Union legislation.
	Indicate the species, and approval number of establishments when applicable together with ISO country code, number of packages, type of packaging, batch number, and net weight. Tick "final consumer" where products are packaged for final consumers.
	Species: indicate the scientific name or as defined in accordance with Union legislation.
	Type of packaging: identify the type of packaging according to the definition given in Recommendation No 21of UN/CEFACT (United Nations Centre for Trade Facilitation and Electronic Business).

PART II - Certification

Box	Description	
	Country	
	Indicate the name of the third country issuing the certificate.	
	Certificate model	
	This box refers to the specific title of each model of certificate.	
II	Health information	
	This box refers to the specific Union health requirements applicable to the nature of the	
	products and as defined in the equivalence agreements with certain third countries or in other	
	Union legislation, such as that for certification.	
II.2a	Certificate reference	
	This is the unique alphanumeric code indicated in box I.2.	
II.2b	IMSOC reference	
	This is the unique alphanumeric code indicated in box I.2a	
	Certifying officer	
	This box refers to the signature of the certifying officer as defined in point (26) of Article 3 of	
	Regulation (EU) 2017/625. Indicate the name in capital letters, qualification and title, where applicable, of the signatory, and the name and original stamp of the competent authority the signatory is attached to and date of signature.'	

• Relevant portion of the Commission Implementing Regulation (EU) 2019/1793 is set out below:

Quote

"COMMISSION IMPLEMENTING REGULATION (EU) 2019/1793 of 22 October 2019

on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 201 7/62 5 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 107/2009, (EU) No 115 1/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (1), and in particular Article 34(6)(a), Article 47(2)(b), Article 54(4)(a) and (b) and Article 90(c) thereof,

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 (2), and in particular Article 5 3(1)(b) thereof,

Whereas:

- (1) Regulation (EU) 201 7/62 5 integrates into a single legislative framework the rules applicable to official controlson animals and goods entering the Union in order to verify compliance with Union agri-food chain legislation. For that purpose, it repeals and replaces Regulation (EC) No 882/2004 of the European Parliament and of the Council (3) and other Union acts governing official controls in specific areas.
- (2) Pursuant to Regulation (EU) 201 7/62 5, certain categories of animals and goods from certain third countries are always to be presented at border control posts for official controls to be performed prior to their entry into the Union. In addition, Article 47(1)(d) and (e) of Regulation (EU) 2017/625 stipulate that goods subject to measures requiring a temporary increase of official controls or emergency measures respectively, should be subject to official controls at border control posts at their entry into the Union.
- (3) In that regard, pursuant to Regulation (EU) 201 7/62 5, certain goods from certain third countries should be subject to a temporary increase of official controls at border control posts in those cases where the Commission has decided, by means of implementing acts, that these controls are necessary due to a known or emerging risk or because there is evidence of widespread serious non-compliance with the Union agri-food chain legislation. To that effect, the Commission should establish the list of such goods, indicating their codes from the Combined Nomenclature (CN) as laid down in Annex I to Commission Regulation (EEC) No 2658/87 (4) (hereinafter, 'the list') and update the list as necessary to reflect any developments in that regard.

⁽¹⁾ OJ L 95, 7.4.201 7, p. 1.

⁽²⁾ OJ L 31, 1.2.2002, p. 1.

⁽³⁾ 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).

⁽⁴⁾ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

- (4) The list referred to in recital (3) should at this stage consist of an updated list of food and feed of non-animal origin set out in Commission Regulation (EC) No 669/2009 (5), which lays down rules concerning the increased level of official controls to be carried out at designated points of entry into the Union on imports of certain food and feed of non-animal origin from certain third countries. It is therefore appropriate to set out in Annex I to this Regulation the list of food and feed of non-animal origin from certain third countries to be subject to a temporary increase of official controls at the entry into the Union, in accordance with Article 47(2)(b) of Regulation (EU) 201 7/625.
- (5) Moreover, the Commission should establish rules on the frequency of identity checks and physical checks for the food and feed of non-animal origin from certain third countries subject to a temporary increase of controls, in accordance with Article 54(4)(a) of Regulation (EU) 2017/625, taking into account in particular the level of risk associated with the hazard under consideration and the frequency of border rejections.
- (6) Regulation (EU) 2017/625 and delegated and implementing acts adopted pursuant to Articles 47 to 64 of that Regulation, provide for one single system of official controls which applies to the areas covered by Commission Implementing Regulations (EU) No 884/2014 (⁶), (EU) 2015/175 (⁷), (EU) 2017/186 (⁸), (EU) 2018/1660 (⁹) and by Regulation (EC) No 669/2009. For this reason, and since the rules covered in these regulations are substantively linked, as they all concern the imposition of additional measures governing the entry into the Union of certain food and feed from certain third countries due to an identified risk and which apply depending on the gravity of the risk, it is appropriate to facilitate the correct and comprehensive application of the relevant rules by establishing in a single act the provisions concerning the temporary increase of official controls on certain food and feed of non-animal origin and the emergency measures currently set out in these Regulations.
- (7) The food and feed of non-animal origin subject to the emergency measures set out in Commission Implementing Regulations (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660 still pose a serious risk to public health which cannot be contained satisfactorily by means of measures taken by the Member States. It is therefore appropriate to set out in Annex II to this Regulation a list of food and feed of non-animal origin subject to emergency measures which consists of the updated lists of food and feed of non-animal origin laid down in Commission Implementing Regulations (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660. In addition, the scope of the entries in the aforementioned lists should be amended to include forms of the products other than the ones currently laid down therein, where those other forms present the same risk. It is therefore appropriate to amend all the entries concerning groundnuts to include oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil, as well as the entry concerning peppers from India to include roasted peppers (sweet or other than sweet).
- (8) With a view to ensure a proper control of the risks to public health, compound food containing any of the food of non-animal origin listed in Annex II to this Regulation due to the risk of contamination by aflatoxins, in a quantity above 20 % of either a single product or as the sum of products listed, and falling within the CN Codes laid down in Annex II should also be included in the list referred to in recital 7.
- (9) Moreover, the Commission should establish rules on the frequency of identity checks and physical checks for the food and feed subject to emergency measures pursuant to this Regulation, in accordance with Article 54(4)(b) of Regulation (EU) 201 7/62 5. It is therefore appropriate to establish such rules in this Regulation, taking into account in particular the level of risk associated with the hazard under consideration and the frequency of border rejections.

⁽⁵⁾ 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).

⁽⁶⁾ Commission Implementing Regulation (EU) No 884/2014 of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009 (OJ L 242, 14.8.2014, p. 4).

⁽⁷⁾ Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).

⁽⁸⁾ Commission Implementing Regulation (EU) 2017/186 of 2 February 2017 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 (OJ L 29, 3.2.201 7, p. 24).

⁽⁹⁾ 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 (OJ L 278, 8.11.2018, p. 7).

- (10) Measures requiring a temporary increase of official controls and emergency measures set out in this Regulation should apply to food and feed intended for placing on the Union market since those goods represent a risk from a public health perspective.
- (11) As regards consignments sent as trade samples, laboratory samples or as display items for exhibitions, which are not intended to be placed on the market, consignments of a non-commercial nature intended for private use or consumption within the custom territory of the Union and consignment intended for scientific purposes, having regard to the low risk that such consignments pose to public health, it would be disproportionate to impose a requirement that these consignments be subject to official controls at border control posts and be accompanied by an official certificate or by the results of the sampling and laboratory analyses in accordance with this Regulation. However, in order to avoid misuse, this Regulation should apply to these consignments in the case where their gross weight exceeds a certain weight limit.
- (12) Measures requiring a temporary increase of official controls and emergency measures set out in this Regulation should not apply to food and feed on board means of transport operating internationally which are not unloaded and are intended for consumption by the crew and passengers since the placing on the Union market is very limited.
- (13) The maximum levels of mycotoxins, including of aflatoxins in food are established by Commission Regulation (EC) No 188 1/2006 (10) and in feed by Directive 2002/32/EC of the European Parliament and of the Council (11). The maximum levels for pesticide residues are established by Regulation (EC) No 396/2005 of the European Parliament and of the Council (12). The European Union Reference Laboratory for Dioxins and polychlorinated biphenyls (PCBs) in food and feed has carried out a study on the correlation between pentachlorophenol (PCP) and dioxins in contaminated guar gum from India. From this study it can be concluded that guar gum containing a level of PCP below the Maximum Residue Limit (MRL) of 0,01 mg/kg does not contain unacceptable levels of dioxins. Therefore compliance with the MRL on PCP, ensures in this specific case also a high level of human health protection as regards dioxins.
- (14) In relation to the rules referred to in recital (13), the provisions on sampling and analyses for the control of mycotoxins, including aflatoxins, in food are established by Commission Regulation (EC) No 401/2006 (¹³) and in feed by Commission Regulation (EC) No 152/2009 (¹⁴). The provisions on sampling for the official control of pesticide residues are established by Commission Directive 2002/63/EC (¹⁵). With a view to ensure uniform methods of sampling and laboratory analyses in third countries and Member States, the sampling and the analyses for food and feed required by this Regulation should be carried out in accordance with the aforementioned Union rules on sampling and analyses both in Member States and third countries.
- (15) Moreover, in order to ensure uniform sampling procedures and analytical reference methods for the control of Salmonella in food subject to this Regulation in third countries and Member States, this Regulation should lay down such sampling procedures and analytical reference methods.
- (16) Model official certificates for the entry into the Union of certain food and feed are laid down in Commission Implementing Regulations (EU) No 884/2014, (EU) 2015/175, (EU) 201 7/186 and (EU) 2018/1660. In order to facilitate the performance of official controls at the entry into the Union it is appropriate to establish a single model official certificate for the entry into the Union of food and feed subject to special conditions for the entry into the Union pursuant to this Regulation.

⁽¹⁰⁾ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

⁽¹¹⁾ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).

⁽¹²⁾ 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.).

⁽¹³⁾ Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs, OJ L 70, 9.3.2006, p. 12.

⁽¹⁴⁾ Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

⁽¹⁵⁾ 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).

- (17) Such official certificates should be issued either on paper or in electronic form. Therefore, it is appropriate to establish common requirements as regards issuance of official certificates in both cases, in addition to the requirements laid down in Chapter VII of Title II of Regulation (EU) 2017/625. In this regard, Article 90(f) of Regulation (EU) 201 7/62 5 makes provisions for the establishment by the Commission of rules for the issuance of electronic certificates and for the use of electronic signatures including in relation to official certificates issued in accordance with this Regulation. In addition, provisions should be made in this Regulation to ensure that the requirements for official certificates not submitted in IMSOC laid down in Commission Implementing Regulation (EU) 201 9/628 (16) also apply to official certificates issued in accordance with this Regulation.
- (18) Model certificates are included in the electronic system TRACES, set up by Commission Decision 2003/623/EC (17), to facilitate and accelerate administrative procedures at Union borders and to enable electronic communication between the competent authorities which helps preventing possible fraudulent or deceptive practices in respect of the official certificates. Since 2003, computer technology has evolved considerably and the TRACES system has been modified to improve the quality, processing and secure exchange of data. In accordance with Article 133(4) of Regulation (EU) 201 7/62 5, the TRACES system is to be integrated into the Information Management System for Official Controls referred to in Article 131 of Regulation (EU) 201 7/62 5 (IMSOC). The model official certificate laid down in this Regulation should therefore be adapted to IMSOC.
- (19) Point (c) of Article 90 of Regulation (EU) 201 7/625 empowers the Commission to lay down, by means of implementing acts, rules concerning the procedures to be followed for the issuance of replacement certificates. To avoid misuse and abuse, it is important to define the cases where a replacement official certificate may be issued and the requirements that need to be met by such certificate. Such cases have been laid down in Implementing Regulation (EU) 2019/628 in relation to official certificates issued in accordance with that Regulation. With a view to ensure a coherent approach, it is appropriate to provide that, in the case of issuing replacement certificates, official certificates issued in accordance with this Regulation should be replaced in accordance with the procedures for the replacement certificates laid down in Implementing Regulation (EU) 201 9/628.
- (20) Provisions should be established to regularly review whether modifications of the lists out in Annexes I and II to this Regulation, including of the frequency of identity and physical checks, are necessary. This should take into account new information related to risks and non-compliance, such as the data resulting from notifications received through the Rapid Alert System for Food and Feed (RASFF), data and information concerning consignments and the results of the documentary, identity and physical checks communicated by the Member States to the Commission, reports and information received from third countries, information resulting from the controls carried out by the Commission in third countries and information exchanged between the Commission and Member States and between the Commission and the European Food Safety Authority.
- (21) The rules to be established by the Commission in accordance with Articles 34(6)(a), 47(2)(b), and 54(4)(a) of Regulation (EU) 201 7/62 5 are substantively linked since they all concern requirements on official controls at the entry into the Union on certain goods from certain third countries subject to a temporary increase of official controls at their entry into the Union and should therefore apply from the same date. To facilitate the correct and comprehensive application of those rules, it is appropriate to establish them in a single act.
- (22) The rules to be established by the Commission in accordance with Articles 54(4)(b) and 90 (c) of Regulation (EU) 2017/625 and with Article 5 3(1)(b) of Regulation (EC) No 178/2002 are substantively linked since they all concern requirements for the entry into the Union of goods subject to emergency measures pursuant to Article 5 3(1)(b) of Regulation (EC) No 178/2002 and should therefore apply from the same date. To facilitate the correct and comprehensive application of those rules, it is appropriate to establish them in a single act.
- (23) For the purposes of simplification and rationalization, the rules laid down in Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 201 7/186, (EU) 2015/1 75 and (EU) 2018/1660 are consolidated into this Regulation. These Regulations should therefore be repealed and replaced with this Regulation.
- (24) 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:

⁽¹⁶⁾ Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates, OJ L 131, 17.5.2019, p. 101.

⁽¹⁷⁾ Commission Decision 2003/623/EC of 19 August 2003 concerning the development of an integrated computerised veterinary system known as Traces (OJ L 216, 28.8.2003, p. 58).

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SECTION 1

COMMON PROVISIONS

Article 1

Subject matter and scope

- This Regulation lays down:
- (a) the list of food and feed of non-animal origin from certain third countries subject to a temporary increase of official controls at their entry into the Union, established in Annex I, falling within the CN Codes and TARIC classifications laid down in that Annex, in accordance with Article 47(2)(b) of Regulation (EU) 201 7/625;
- (b) special conditions governing the entry into the Union of the following categories of consignments of food and feed due to the risk of contamination by mycotoxins, including aflatoxins, pesticide residues, pentachlorophenol and dioxins and microbiological contamination, in accordance with Article 5 3(1)(b) of Regulation (EC) No 178/2002:
 - (i) consignments of food and feed of non-animal origin from third countries or parts of those third countries listed in Table 1 to Annex II and falling within the CN Codes and TARIC classifications laid down in that Annex;
 - (ii) consignments of compound food containing any of the food listed in Table 1 to Annex II due to the risk of contamination by aflatoxins in a quantity above 20 % of either a single product or as the sum of those products and falling within the CN Codes laid down in Table 2 to that Annex;
- (c) rules on the frequency of identity checks and physical checks for the consignments of food and feed referred to in points (a) and (b) of this paragraph;
- (d) rules on the methods to be used for sampling and for laboratory analyses for the consignments of food and feed referred to in points (a) and (b) of this paragraph, in accordance with Article 34(6)(a) of Regulation (EU) 201 7/62 5;
- (e) rules concerning the model official certificate required to accompany consignments of food and feed referred to in point (b) of this paragraph and the requirements for such official certificate, in accordance with Article 5 3(1)(b) of Regulation (EC) No 178/2002;
- (f) rules for the issuance of replacement official certificates required to accompany consignments of food and feed referred to in point (b) of this paragraph, in accordance with Article 90(c) of Regulation (EU) 201 7/62 5.
- 2. This Regulation applies to consignments of food and feed referred to in points (a) and (b) of paragraph 1 intended for placing on the Union market.
- 3. This Regulation does not apply to the following categories of consignments of food and feed unless their gross weight exceeds 30 kg:
- (a) consignments of food and feed sent as trade samples, laboratory samples or as display items for exhibitions, which are not intended to be placed on the market;
- (b) consignments of food and feed which form part of passengers personal luggage and are intended for personal consumption or use;
- (c) non-commercial consignments of food and feed sent to natural persons which are not intended to be placed on the market;
- (d) consignments of food and feed intended for scientific purposes.
- 4. This Regulation does not apply to food and feed referred to in points (a) and (b) of paragraph 1 on board means of transport operating internationally which are not unloaded and are intended for consumption by the crew and passengers.
- 5. In case of doubt on the intended use of the food and feed referred in points (b) and (c) of paragraph (3), the burden of proof lies with the owner of the personal luggage and with the recipient of the consignment, respectively.

Article 2

Definitions

- For the purposes of this Regulation, the following definitions shall apply:
- (a) 'consignment' means 'consignment' as defined in Article 3(37) of Regulation (EU) 201 7/625;
- (b) 'placing on the market' means 'placing on the market' as defined in point (8) of Article 3 of Regulation (EC) No 178/2002.
- 2. However, for the purposes of Articles 7, 8, 9, 10 and 11 and of Annex IV, a 'consignment' means:
- (a) a 'lot' as referred to in Annex I to Regulation (EC) No 401/2006 and in Annex I to Regulation (EC) No 152/2009, in relation to food and feed listed in Annex II due to contamination risk by mycotoxins, including aflatoxins;
- (b) a 'lot' as referred to in the Annex to Directive 2 002/6 3/EC, in relation to food and feed listed in Annex II due to contamination risk by pesticides and pentachlorophenol.

Article 3

Sampling and analyses

The sampling and the analyses to be carried out by competent authorities at border control posts or at control points referred to in Article 5 3(1)(a) of Regulation (EU) 2017/625, as part of physical checks on consignments of food and feed referred to in Article 1(1)(a) and (b), or in third countries for the purposes of the results of analyses which are required to accompany the consignments of food and feed referred to in Article 1(1)(b) as provided for in this Regulation shall be performed in accordance with the following requirements:

- (a) for food listed in Annexes I and II due to possible contamination risk by mycotoxins, including aflatoxins, the sampling and the analyses shall be performed in accordance with Regulation (EC) No 401/2006;
- (b) for feed listed in Annexes I and II due to possible contamination risk by mycotoxins, including aflatoxins, the sampling and the analyses shall be performed in accordance with Regulation (EC) No 152/2009:
- (c) for food and feed listed in Annexes I and II due to possible non-compliance with the maximum allowed levels of pesticides residues the sampling shall be performed in accordance with Directive 2 002/6 3/EC;
- (d) for guar gum listed in Annex II due to possible contamination with pentachlorophenol and dioxins the sampling for the analysis of pentachlorophenol shall be performed in accordance with Directive 2002/63/EC and the sampling and analyses for the control of dioxins in feed shall be performed in accordance with Regulation (EC) No 152/2009;
- (e) for food listed in Annexes I and II due to the risk of presence of *Salmonella*, the sampling and the analyses for the control of *Salmonella* shall be performed in accordance with the sampling procedures and the analytical reference methods laid down in Annex III;
- (f) the methods of sampling and analyses referred to in the footnotes to Annexes I and II shall be applied in relation to hazards other than those referred to in points (a), (b), (c), (d) and (e).

Article 4

Release for free circulation

The custom authorities shall only allow the release for free circulation of consignments of food and feed listed in Annexes I and II upon presentation of a duly finalised Common Health Entry Document (CHED) as provided for in Article 5 7(2)(b) of Regulation (EU) 2017/625, which confirms that the consignment is in compliance with the applicable rules referred to in Article 1(2) of that Regulation.

SECTION 2

TEMPORARY INCREASE OF OFFICIAL CONTROLS AT BORDER CONTROL POSTS AND CONTROL POINTS ON CERTAIN FOOD AND FEED FROM CERTAIN THIRD COUNTRIES

Article 5

List of food and feed of non-animal origin

- 1. Consignments of food and feed listed in Annex I shall be subject to a temporary increase of official controls at border control posts at their entry into the Union and at control points.
- 2. The identification of the food and feed referred to in paragraph 1 for official controls shall be made on the basis of the codes from the Combined Nomenclature and the TARIC sub-division indicated in Annex I.

Article 6

Frequency of identity checks and physical checks

- 1. The competent authorities at border control posts and at control points referred to in Article 5 3(1)(a) of Regulation (EU) 201 7/62 5 shall carry out identity and physical checks, including sampling and laboratory analyses, on consignments of food and feed listed in Annex I at the frequency set out in that Annex.
- 2. The frequency of identity and physical checks set out in an entry in Annex I shall be applied as an overall frequency for all products falling under that entry.

SECTION 3

SPECIAL CONDITIONS GOVERNING THE ENTRY INTO THE UNION OF CERTAIN FOOD AND FEED FROM CERTAIN THIRD COUNTRIES

Article 7

Entry into the Union

- 1. Consignments of food and feed listed in Annex II shall only enter into the Union in accordance with the conditions laid down in this section.
- 2. The identification of the food and feed referred to in paragraph 1 for official controls shall be made on the basis of the codes from the Combined Nomenclature and the TARIC sub-division indicated in Annex II.
- 3. Consignments referred to in paragraph 1 shall be subject to official controls at border control posts at their entry into the Union and at control points.

Article 8

Frequency of identity checks and physical checks

- 1. The competent authorities at border control post and at control points referred to in Article 5 3(1)(a) of Regulation (EU) 2017/625 shall carry out identity and physical checks, including sampling and laboratory analyses, on consignments of food and feed listed in Annex II, at the frequency set out in that Annex.
- 2. The frequency of identity and physical checks set out in an entry in Annex II shall be applied as an overall frequency for all products falling under that entry.
- 3. Compound food listed in Table 2 to Annex II which contains products falling only under one entry in Table 1 to Annex II shall be subject to the overall frequency of identity and physical checks set out in Table 1 to Annex II for that entry.
- 4. Compound food listed in Table 2 to Annex II which contains products falling under several entries for the same hazard in Table 1 to Annex II shall be subject to the highest overall frequency of identity and physical checks set out in Table 1 to Annex II for these entries.

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Article 9

Identification code

- 1. Each consignment of food and feed listed in Annex II shall be identified with an identification code.
- 2. Each individual bag or packaging form of the consignment shall be identified with that identification code.
- 3. By way of derogation from paragraph 2, in case of consignments of food and feed listed in Annex II due to the risk of contamination by mycotoxins and where the packaging is combining several small packages, it is not necessary for the identification code of the consignment to be mentioned individually on all the separate small packages as long as it is mentioned at least on the package combining these small packages.

Article 10

Results of sampling and analyses performed by the competent authorities of the third country

- Each consignment of food and feed listed in Annex II shall be accompanied by the results of sampling and analyses performed on that consignment by the competent authorities of the third country of origin or of the country where the consignment is consigned from if that country is different from the country of origin.
- 2. On the basis of the results referred to in paragraph 1, the competent authorities shall ascertain:
 - (a) compliance with Regulation (EC) No 1881/2006 and Directive 2002/32/EC on maximum levels of relevant mycotoxins, for consignments of food and feed listed in Annex II due to contamination risk by mycotoxins;
 - (b) compliance with Regulation (EC) No 396/2005 on maximum residue levels of pesticides, for consignments of food and feed listed in Annex II due to contamination risk by pesticide residues;
 - (c) that the product does not contain more than 0,01 mg/kg pentachlorophenol (PCP), for consignments of food and feed listed in Annex II due to contamination risk by pentachlorophenol and dioxins;
 - (d) the absence of Salmonella in 25 g, for consignments of food listed in Annex II due to risk of microbiological contamination by Salmonella.
- Each consignment of food and feed listed in Annex II due to contamination risk by pentachlorophenol and dioxins shall be accompanied by an analytical report which shall comply with the requirements set out in Annex II.
 - The analytical report shall include the results of the analyses referred to in paragraph 1.
- 4. The results of sampling and analyses referred to in paragraph 1 shall bear the identification code of the consignment to which they relate referred to in Article 9(1).
- 5. The analyses referred to in paragraph 1 shall 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 11

Official certificate

- 1. Each consignment of food and feed listed in Annex II shall be accompanied by an official certificate in accordancewith the model set out in Annex IV ('official certificate').
- 2. The official certificate shall comply with the following requirements:

- a) it shall be issued by the competent authority of the third country of origin or of the third country where the consignment is consigned from if that country is different from the country of origin;
- b) it shall bare the identification code of the consignment to which it relates referred to in Article 9(1);
- it shall be issued before the consignment to which it relates leaves the control of the competent authority of the third country issuing the certificate;
- d) it shall be valid for not more than four months from the date of issue, but in any case no longer than six months from the date of the results of the laboratory analyses referred to in paragraph 1 of Article 10.
- 3. An official certificate which is not submitted in the Information Management System for Official Controls referred to in Article 131 of Regulation (EU) 2017/625 (IMSOC) by the competent authority of the third country issuing the certificate shall also meet the requirements for model official certificates not submitted in IMSOC laid down in Article 3 of Implementing Regulation (EU) 2019/628.
- Competent authorities may issue a replacement official certificate only in accordance with the rules laid down in Article 5 of Implementing Regulation (EU) 201 9/628.
- The official certificate referred to in paragraph 1 shall be completed on the basis of the notes set out in Annex IV.

SECTION 4

FINAL PROVISIONS

Article 12

Updates to Annexes

The Commission shall review the lists set out in Annexes I and II on a regular basis not exceeding a period of six months, in order to take into account new information related to risks and non-compliance.

Article 13

Repeal

- Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2017/186, (EU) 2015/175 and (EU) 2018/1660 are repealed with effect from 14 December 2019.
- 2. References to Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2017/186, (EU) 2015/175 and (EU) 2018/1660 shall be construed as references to this Regulation.
- 3. References to 'the designated point of entry within the meaning of point (b) of Article 3 of Regulation (EC) No 669/2009' or to 'the designated point of entry' in acts other than those referred to in paragraph 1 shall be construed as references to a 'border control post' within the meaning of Article 3(38) of Regulation (EU) 2017/625.
- 4. References to 'the common entry document (CED) referred to in point (a) of Article 3 of Regulation (EC) No 669/2009', to 'the common entry document (CED) referred to in Annex II to Regulation (EC) No 669/2009' or to 'the common entry document (CED)' in acts other than those referred to in paragraph 1 shall be construed as references to the 'Common Health Entry Document (CHED)' referred to in Article 56 of Regulation (EU) 201 7/62 5.
- 5. References to the definition laid down in Article 3(c) of Regulation (EC) No 669/2009 in acts other than those referred to in paragraph 1 shall be construed as references to the definition of 'consignment' laid down in Article 3(37) of Regulation (EU) 2017/625.

Article 14

Transitional period

- The reporting obligations set out in Article 15 of Regulation (EC) No 669/2009, Article 13 of Regulation (EU) No 884/2014, Article 12 of Regulation (EU) 2018/1660, Article 12 of Regulation (EU) 2015/175 and Article 12 of Regulation (EU) 201 7/186 shall continue to apply until 31 January 2020.
 - Such reporting obligations shall cover the period until 31 December 2019.
- 2. The reporting obligations referred to in paragraph 1 shall be deemed to be satisfied where Member States have registered in TRACES the common entry documents issued by their respective competent authorities in accordance with Regulation (EC) No 669/2009, Regulation (EU) No 884/2014, Regulation (EU) 2015/175, Regulation (EU) 2017/186 and Regulation (EU) 2018/1660 during the reporting period set out in the provisions referred to in paragraph 1.
- Consignments of food and feed listed in Annex II accompanied by the relevant certificates issued before 14 February 2020 in accordance with the provisions of Regulation (EU) No 884/2014, Regulation (EU) 2018/1660, Regulation (EU) 2015/175 and Regulation (EU) 2017/186 respectively in force on 13 December 2019 shall be authorised for the entry into the Union until 13 June 2020.

]Article 15

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 14 December 2019.

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

Done at Brusels, 22 October 2019.

For the Commission

The President

Jean-Claude JUNCKER"

Unquote

Relevant portion of the Commission Implementing Regulation (EU) 2021/608 is set out below:-

Quote

amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council (Text with EEA relevance)

THE EUROPEAN COMMISSION.

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

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, and in particular Article 53(1)(b) thereof,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) and in particular point (b) of the first subparagraph of Article 47(2), points (a) and (b) of the first subparagraph of Article 54(4) and points (a), (b) and (c) of the first paragraph of Article 90 thereof.

Whereas:

- (1) Commission Implementing Regulation (EU) 2019/1793 lays down rules concerning the temporary increase of official controls at the entry into the Union on certain food and feed of non-animal origin from certain third countries listed in Annex I to that Implementing Regulation and special conditions governing the entry into the Union of certain food and feed from certain third countries due to the risk of contamination by mycotoxins, including aflatoxins, pesticide residues, pentachlorophenol and dioxins, and microbiological contamination, listed in Annex II to that Implementing Regulation.
- (2) Implementing Regulation (EU) 2019/1793 lays down requirements as regards the model official certificate for the entry into the Union of consignments of food and feed listed in Annex II to that Implementing Regulation and rules for the issuance of such certificate, both on paper and in electronic form. In accordance with Commission Implementing Regulation (EU) 2019/1715, TRACES is the component of the Information Management System for Official Controls (IMSOC) enabling the entire process of certificate production to be performed electronically, thus preventing possible fraudulent or deceptive practices in respect of official certificates. Therefore, Implementing Regulation (EU) 2019/1793 sets out a model official certificate that is compatible with TRACES

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 95, 7.4.2017, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660 (OJ L 277, 29.10.2019, p. 89).

⁽⁴⁾ Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components ('the IMSOC Regulation') (OJ L 261, 14.10.2019, p.37)

- (3) The certification requirements of Implementing Regulation (EU) 2019/1793 are consistent with the requirements laid down in Commission Implementing Regulation (EU) 2019/628 for official certificates for the entry into the Union. Commission Implementing Regulation (EU) 2020/2235repeals and replaces Implementing Regulation (EU) 2019/628 as of 21 April 2021, while amending and clarifying the requirements for model official certificates laid down in that Implementing Regulation.
- (4) In particular, Implementing Regulation (EU) 2020/2235 makes a distinction between official certificates issued on paper, electronic official certificates issued in accordance with the requirements of Article 39(1) of Implementing Regulation (EU) 2019/1715 and official certificates issued on paper and completed in, and printed from, TRACES. In addition, that Implementing Regulation lays down linguistic requirements for official certificates for the entry into the Union to facilitate official controls at the border control posts of introduction into the Union. To align the official certificates for different categories of goods and to ensure consistency with the new certification requirements in the official certificates for the entry into the Union laid down in Implementing Regulation (EU) 2020/2235, it is appropriate to amend Article 11 of Implementing Regulation (EU) 2019/1793.
- (5) Article 12 of Implementing Regulation (EU) 2019/1793 provides that the lists set out in its Annexes I and II are to be reviewed on a regular basis not exceeding a period of six months, in order to take into account new information related to risks and non-compliance with Union legislation.
- (6) The occurrence and relevance of recent food incidents notified through the Rapid Alert System for Food and Feed ('RASFF'), as established by Regulation (EC) No 178/2002, and information regarding official controls performed by Member States on food and feed of non-animal origin indicate that the lists set out in Annexes I and II to Implementing Regulation (EU) 2019/1793 should be amended.
- (7) In particular, due to the high frequency of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by *Salmonella* detected during official controls performed by Member States in accordance with Implementing Regulation (EU) 2019/1793 in 2019 and in the first semester of 2020 and due to the high number of notifications in the RASFF during that period, it is appropriate to increase, from 20 % to 50 %, the frequency of identity and physical checks to be performed on black pepper (*Piper nigrum*) from Brazil.
- (8) Due to the high frequency of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues detected during official controls performed by Member States in accordance with Implementing Regulation (EU) 2019/1793 in the second semester of 2019 and in the first semester of 2020, it is appropriate to increase, from 10 % to 20 %, the frequency of identity and physical checks to be performed on peppers of the *Capsicum* species (other than sweet) from Thailand.
- (9) Due to the high frequency of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by aflatoxins detected during official controls performed by Member States in accordance with Implementing Regulation (EU) 2019/1793 in the second semester of 2019 and in the first semester of 2020 and due to the high number of notifications in the RASFF in the first semester of 2020, it is appropriate to increase, from 10 % to 50 %, the frequency of identity and physical checks to be performed on groundnuts from India.

⁵⁾Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

⁽⁶⁾Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).

- (10) Sweet peppers (*Capsicum annuum*) from Turkey are already listed in Annex I to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by pesticide residues. For consignments of peppers of the *Capsicum* species (other than sweet) from Turkey, the data resulting from notifications received through the RASFF in the first semester of 2020 indicate the emergence of new risks to human health, due to possible pesticide residues contamination, requiring an increased level of official controls. The existing entry concerning sweet peppers (*Capsicum annuum*) from Turkey should therefore be amended to cover all peppers of the *Capsicum* species.
- (11) For goji berries from China listed in Annex I to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by pesticide residues, and for dried grapes from Turkey listed in that Annex due to the risk of contamination by ochratoxin A, the available information for the second semester of 2019 and the first semester of 2020 indicates an overall satisfactory degree of compliance with the relevant requirements provided for in Union legislation. As an increased level of official controls is therefore no longer justified for those commodities, the entries in Annex I to Implementing Regulation (EU) 2019/1793 concerning those commodities should be deleted.
- (12) For groundnuts from Brazil listed in Annex II to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by aflatoxins, the frequency of non-compliance with the relevant requirements provided for in Union legislation detected during official controls performed by Member States has decreased in the second semester of 2019 and remained at low levels in the first semester of 2020. It is therefore appropriate to delete the entry concerning groundnuts from Brazil from Annex II to Implementing Regulation (EU) 2019/1793, include it in Annex I to that Implementing Regulation and set the frequency of identity and physical checks at 10 %.
- (13) For groundnuts from China listed in Annex II to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by aflatoxins, the frequency of non-compliance with the relevant requirements provided for in Union legislation detected during official controls performed by Member States has decreased in the second semester of 2019 and in the first semester of 2020. It is therefore appropriate to delete the entry concerning groundnuts from China from Annex II to Implementing Regulation (EU) 2019/1793, include it in Annex I to that Implementing Regulation and set the frequency of identity and physical checks at 10 %. Due to the volume of trade in this commodity, that frequency is sufficient to ensure an appropriate level of monitoring.
- (14) For hazelnuts from Turkey listed in Annex II to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by aflatoxins, the frequency of non-compliance with the relevant requirements provided for in Union legislation detected during official controls performed by Member States has decreased in the second semester of 2019 and in the first semester of 2020. It is therefore appropriate to delete the entry concerning hazelnuts from Turkey from Annex II to Implementing Regulation (EU) 2019/1793, include it in Annex I to that Implementing Regulation and set the frequency of identity and physical checks at 5 %. Due to the volume of trade in this commodity, that frequency is sufficient to ensure an appropriate level of monitoring.
- Foodstuffs containing or consisting of betel leaves (*Piper betle*) originating in, or consigned from Bangladesh are listed in Annex IIa to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by *Salmonella*. Consequently, the importation into the Union of these products has been prohibited since June 2014. Bangladesh provided written guarantees by submitting a new action plan on 27 July 2020with measures covering all steps of the chain of production, which the Commission assessed as satisfactory. Following this assessment, it is appropriate to delete the entry concerning foodstuffs containing or consisting of betel leaves (*Piper betle*) originating in, or consigned from, Bangladesh from Annex IIa to Implementing Regulation (EU) 2019/1793, include it in Annex II to that Implementing Regulation and set the frequency of identity and physical checks at 50 %.
- (16) In order to ensure efficient protection against potential health risks arising from microbiological or chemical contamination of *Sesamum*seeds, in the columns referring to 'CN code'in the tables in Annexes I and II to Implementing Regulation (EU) 2019/1793 the CN code for roasted *Sesamum*seeds should be added in the rows referring to 'Sesamumseeds (food)'.
- 17) Part II of the model official certificate in Annex IV to Implementing Regulation (EU) 2019/1793 sets out the health information that the certifying officer is to provide when completing the certificate. In order to ensure legal certainty, it should be clarified that the health information for food or feed of non-animal origin can contain more than one certification, where such certification is mandatory pursuant to Article 11(1) of Implementing Regulation (EU) 2019/1793 in conjunction with Annex II to that Implementing Regulation.
- (18) Implementing Regulation (EU) 2019/1793 should therefore be amended accordingly. In order to ensure consistency and clarity, it is appropriate to replace Annexes I, II, IIa and IV to that Implementing Regulation in their entirety.

- (19) As Implementing Regulation (EU) 2020/2235 applies from 21 April 2021, Article 1(1) of this Regulation should also apply from that date.
- (20) 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

Amendments to Implementing Regulation (EU) 2019/1793

Implementing Regulation (EU) 2019/1793 is amended as follows: (1) Article 11 is replaced by the following:

'Article 11

Official certificate

- 1. Each consignment of food and feed listed in Annex II shall be accompanied by an official certificate in accordance with the model set out in Annex IV ("official certificate").
 - The official certificate shall comply with the following requirements:
 - (a) the official certificate shall be issued by the competent authority of the third country of origin or of the third country where the consignment is consigned from if that country is different from the country of origin;
 - (b) the official certificate shall bear the identification code of the consignment to which it relates, referred to in Article 9(1);
 - (c) the official certificate shall bear the signature of the certifying officer and the official stamp;
 - (d) where the official certificate contains multiple or alternative statements, the statements which are not relevant shall be crossed out, initialled and stamped by the certifying officer, or completely removed from the certificate;
 - (e) the official certificate shall consist of one of the following:
 - (i) a single sheet of paper;
 - (ii) several sheets of paper where all sheets are indivisible and constitute an integrated whole;
 - (iii) a sequence of pages with each page numbered so as to indicate that it is a particular page in a finite sequence;
 - (f) where the official certificate consists of a sequence of pages as referred to in point (e)(iii) of this paragraph, each page shall bear the unique code referred to in Article 89(1)(a) of Regulation (EU) 2017/625, the signature of the certifying officer and the official stamp;
 - (g) the official certificate shall be presented to the competent authority of the border control post of entry into the Union where the consignment is subjected to official controls;
 - (h) the official certificate shall be issued before the consignment to which it relates leaves the control of the competent authorities in the third country issuing the certificate;
 - (i) the official certificate shall be drawn up in the official language, or in one of the official languages, of the Member State of the border control post of entry into the Union;
 - (j) the official certificate shall be valid for not more than four months from the date of issue, but in any case no longer than six months from the date of the results of the laboratory analyses referred to Article 10(1).
- 3. By way of derogation from point (i) of paragraph 2, a Member State may consent to official certificates being drawn up in another official language of the Union and accompanied, if necessary, by an authenticated translation.
- 4. The colour of the signature and of the stamp other than an embossed or watermarked stamp, which are referred to in point (c) of paragraph 2, shall be different to the colour of the printing.

- 5. Points (c) to (g) of paragraph 2 and paragraph 4 shall not apply to electronic official certificates issued in accordance with the requirements of Article 39(1) of Commission Implementing Regulation (EU) 2019/1715 (*).
- 6. Points (d), (e) and (f) of paragraph 2 shall not apply to official certificates issued in paper and completed in, and printed from, TRACES.
- 7. Competent authorities may issue a replacement official certificate only in accordance with the rules laid down in Article 6 of Commission Implementing Regulation (EU) 2020/2235 (**).
- 8. The official certificate shall be completed on the basis of the notes set out in Annex IV.
- (*) Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components ("the IMSOC Regulation") (OJ L 261, 14.10.2019, p. 37).
- (**) Commission Implementing Regulation (EU) 2020/2235 of 16 December, 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).';
- (2) Annexes I, II, IIa and IV are replaced by the text set out in the Annex to this Regulation.

Article 2

Entry into force and application

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

Article 1(1) shall apply from 21stApril,2021.

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

Done at Brussels, 14th April, 2021.

For the Commission The President Ursula VON DER LEYEN

Unquote

The relevant portion of the Commission Implementing Regulation (EU) 2021/1900 is set out below:

Ouote

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1900

of 27 October 2021

amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (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 5 3(1)(b) thereof,

Having regard to Regulation (EU) 201 7/62 5 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (²), and in particular Article 47(2)(b), Article 54(4)(a) and (b) and Article 90(a), (b) and (c) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2019/1793 (3) lays down rules on the temporary increase of official controls at the entry into the Union on certain food and feed of non-animal origin from certain third countries listed in Annex I to that Implementing Regulation, on special conditions governing the entry into the Union of certain food and feed from certain third countries due to the risk of contamination by mycotoxins, including aflatoxins, pesticide residues, pentachlorophenol and dioxins, and microbiological contamination, listed in Annex II to that Implementing Regulation, and on the suspension of entry into the Union of certain food and feed from certain third countries, listed in Annex IIa to that Implementing Regulation.
- (2) Since the term 'compound food' in Article 1(1)(b)(ii), Article 8, in Table 2 of Annex II and in Annex IV to Implementing Regulation (EU) 2019/1793 is not used with the same understanding as in other Union legislation, it is appropriate to replace this term by 'food consisting of two or more ingredients'.
- (3) In order to ensure uniform understanding and application of Implementing Regulation (EU) 2019/1793, it is appropriate to add the definition of 'country of origin' to Article 2 of that Implementing Regulation.
- (4) Article 12 of Implementing Regulation (EU) 2019/1793 provides that the lists set out in its Annexes I and II are to be reviewed at regular intervals not exceeding six months, in order to take into account new information related to risks and non-compliance with Union legislation.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 95, 7.4.201 7, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660 (OJ L 277, 29.10.2019, p. 89).

- (5) Annex IIa to Implementing Regulation (EU) 2019/1793 lists food and feed from certain third countries subject to suspension of entry into the Union, as referred to in Article 1 1a of that Regulation.
- (6) Given that Implementing Regulation (EU) 2019/1793 does not explicitly provide for a period of applicability of the emergency measures for the products listed in Annex IIa and considering that these measures are to be withdrawn or modified where new information related to risks and to non-compliance with Union legislation becomes available, the list set out in Annex IIa to this Regulation should also be regularly reviewed. It is therefore appropriate to amend Article 12 of Implementing Regulation (EU) 2019/1793.
- (7) The occurrence and relevance of recent food incidents notified through the Rapid Alert System for Food and Feed ('RASFF'), as established by Regulation (EC) No 178/2002, and information regarding official controls performed by Member States on food and feed of non-animal origin in the second semester of 2020 indicate that the lists set out in Annexes I and II to Implementing Regulation (EU) 2019/1793 should be amended in order to protect human health in the Union.
- (8) In particular, for consignments of lemons from Turkey, the data resulting from notifications in the RASFF and information regarding official controls performed by Member States indicate the emergence of new risks to human health, due to a possible contamination by pesticide residues, requiring an increased level of official controls. In addition, for consignments of groundnuts from Brazil, information regarding official controls performed by Member States indicate the emergence of new risks to human health, due to a possible contamination by pesticide residues, requiring an increased level of official controls. Entries on both of those commodities should therefore be included in Annex I to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 20 %.
- (9) Due to the frequency of non-compliance with the relevant requirements provided for in Union legislation as regards contamination by pesticide residues detected during official controls performed by Member States in accordance with Implementing Regulation (EU) 2019/1793, and due to the high number of notifications in the RASFF, it is appropriate to increase to 20 % the frequency of identity and physical checks to be performed on oranges, mandarins, clementines, wilkings and similar citrus hybrids, and sweet peppers and peppers of the genus Capsicum (other than sweet) from Turkey.
- (10) Due to the high frequency of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues detected during official controls performed by Member States in accordance with Implementing Regulation (EU) 2019/1793, it is appropriate to increase to 50 % the frequency of identity and physical checks to be performed on jackfruit from Malaysia and on peppers of the genus Capsicum (other than sweet) from Uganda.
- (11) Due to notifications in the RASFF concerning contamination by residues of ethylene oxide, as regards certain consignments of okra from India, ethylene oxide should be added to the analysis to be performed on this commodity and the frequency of physical and identity checks for the presence of pesticide residues, including ethylene oxide, to be performed on okra from India at the Union borders, should be increased to 20 %.
- (12) Due to the frequency of non-compliance with the relevant requirements provided for in Union legislation as regards contamination by aflatoxins detected during official controls performed by Member States in accordance with Implementing Regulation (EU) 2019/1793, and due to the high number of notifications in the RASFF, it is appropriate to increase to 20 % the frequency of identity and physical checks to be performed on groundnuts from the United States.
- (13) Due to the high frequency of non-compliance with the relevant requirements provided for in Union legislation as regards contamination by *Salmonella* detected during official controls performed by Member States in accordance with Implementing Regulation (EU) 2019/1793, it is appropriate to increase to 50 % the frequency of identity and physical checks to be performed on *Sesamum* seeds from Sudan.

- (14) Due to the high frequency of non-compliance with the relevant requirements provided for in Union legislation as regards contamination by pesticide residues detected during official controls performed by Member States in accordance with Implementing Regulation (EU) 2019/1793, it is appropriate to increase to 50 % the frequency of identity and physical checks to be performed on vine leaves from Turkey.
- (15) For hazelnuts and products produced from hazelnuts from Georgia, the available information indicates a favourabletrend of the degree of compliance with the relevant requirements provided for in Union legislation as regards contamination by aflatoxins. It is appropriate to decrease to 20 % the frequency of identity and physical checks to be performed on hazelnuts and products produced from hazelnuts from Georgia. Hazelnuts and products produced from hazelnuts from Turkey and from Azerbaijan are listed in Annex II to Implementing Regulation (EU) 2019/1793 due to risk of contamination by aflatoxins. For the purpose of ensuring consistency in mitigating risks, it is appropriate to amend the existing entry on hazelnuts and products produced from hazelnuts from Georgia to cover the same products as those originating from Turkey and from Azerbaijan.
- (16) Sesamum seeds from Ethiopia have been subject to an increased level of official controls due to the risk of contamination by Salmonella since January 2019. The official controls carried out on those foodstuffs by the Member States show a persistent high rate of non-compliance since the establishment of the increased level of official controls. Those results provide evidence that the entry of those foodstuffs into the Union constitutes a serious risk for human health.
- (1 7) It is therefore necessary, in addition to the increased level of official controls, to provide for special conditions in relation to Sesamum seeds from Ethiopia. In particular, all consignments of Sesamum seeds from Ethiopia should be accompanied by an official certificate stating that all results of sampling and analysis show the absence of Salmonella in 25 g as provided in Article 1 0(2)(d) of Implementing Regulation (EU) 2019/1793. The results of the sampling and analysis should be attached to that certificate. Therefore, the entry on Sesamum seeds from Ethiopia in Annex I to Implementing Regulation (EU) 2019/1793 should be deleted and an entry on those seeds should be inserted in Annex II to that Implementing Regulation.
- (18) Peppers of the genus Capsicum (sweet or other than sweet) from Sri Lanka have been subject to an increased level of official controls as regards the presence of aflatoxins since July 2017. The official controls carried out on these foodstuffs by the Member States show a persistent high rate of non-compliance since the establishment of the increased level of official controls. Those results provide evidence that the entry of those foodstuffs into the Union constitutes a serious risk for human health.
- (19) It is therefore necessary, in addition to the increased level of official controls, to provide for special conditions for peppers of the genus *Capsicum* (sweet or other than sweet) from Sri Lanka. In particular, all consignments of that commodity from Sri Lanka should be accompanied by an official certificate stating that the products have been sampled and analysed for aflatoxins and all results show that the relevant maximum levels of aflatoxins have not been exceeded. The results of the sampling and analysis should be attached to that certificate. Therefore, the entry on peppers of the genus *Capsicum* (sweet or other than sweet) from Sri Lanka in Annex I to Implementing Regulation (EU) 2019/1793 should be deleted and an entry on those peppers should be inserted in Annex II to that Implementing Regulation.
- (20) As regards pistachios from the United States, listed in Annex I to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by aflatoxins, the available information indicates an overall satisfactory degree of compliance with the relevant requirements provided for in Union legislation. Therefore, an increased level of official controls is no longer justified for this commodity and its entry in Annex I to Implementing Regulation (EU) 2019/1793 should be deleted.
- (21) In order to ensure efficient protection against potential health risks arising from contamination of groundnuts by aflatoxins, in the columns referring to 'Food and feed (intended use)' and 'CN code' in Table 1 of Annex II to Implementing Regulation (EU) 2019/1793, the terms 'including mixtures' and the CN codes for mixtures should be added in the rows referring to groundnuts (peanuts), otherwise prepared or preserved.

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- (22) It is appropriate to provide a transitional period for consignments of Sesamum seeds from Ethiopia and consignments of peppers of the genus Capsicum (sweet or other than sweet) from Sri Lanka, which are not accompanied by an official certificate, but which were already subject to official controls at the border control post in accordance with harmonised frequency rates for identity and physical checks in accordance with Implementing Regulation (EU) 2019/1793 before the amendment by this Regulation.
- (23) Implementing Regulation (EU) 2019/1793 lays down requirements as regards the model official certificate for the entry into the Union of consignments of food and feed listed in Annex II to that Implementing Regulation.
- (24) To align the official certificates for the entry into the Union laid down in Commission Implementing Regulation (EU) 2020/2235(4) for different categories of goods and to ensure consistency with the new certification requirements in the official certificates, it is appropriate to amend the model official certificate and the notes on the completion of that certificate set out in Annex IV to Implementing Regulation (EU) 2019/1793.
- (25) In order to ensure consistency and clarity, it is appropriate to replace Annexes I, II, IIa, and IV to Implementing Regulation (EU) 2019/1793 in their entirety.
- (26) Implementing Regulation (EU) 2019/1793 should therefore be amended accordingly.
- (27) 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

Amendments to Implementing Regulation (EU) 2019/1793

Implementing Regulation (EU) 2019/1793 is amended as follows:

- (1) in Article 1, point (1)(b)(ii) is replaced by the following:
 - '(ii) consignments of food consisting of two or more ingredients, containing any of the food listed in Table 1 to Annex II due to the risk of contamination by aflatoxins in a quantity above 20 % of either a single product or as the sum of those products and falling within the CN codes laid down in Table 2 to that Annex;';
- (2) in Article 2(1), the following point (c) is added:
 - '(c) "country of origin" means:
 - (i) the country where the goods originate from, were grown, harvested or produced, where food and feed is listed
 in the Annexes due to a possible risk of contamination by mycotoxins, including aflatoxins, or by plant toxins,
 or due to possible non-compliance with maximum allowed levels of pesticide residues;
 - (ii) the country where the goods were produced, manufactured or wrapped where food and feed is listed in the Annexes due to the risk of presence of Salmonella or due to other hazards than those specified in point (i).';
- (3) in Article 8, paragraphs 3 and 4 are replaced by the following:
 - '3. Food consisting of two or more ingredients listed in Table 2 to Annex II which contains products falling only under one entry in Table 1 to Annex II shall be subject to the overall frequency of identity and physical checks set out in Table 1 to Annex II for that entry.
- (4) Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).

4. Food consisting of two or more ingredients listed in Table 2 to Annex II which contains products falling under several entries for the same hazard in Table 1 to Annex II shall be subject to the highest overall frequency of identity and physical checks set out in Table 1 to Annex II for these entries.';

(4) Article 12 is replaced by the following:

'Article 12

Updates to Annexes

The Commission shall review the lists set out in Annexes I, II and IIa on a regular basis not exceeding a period of six months, in order to take into account new information related to risks and non-compliance.';

(5) Article 14 is replaced by the following:

'Article 14

Transitional period

Consignments of Sesamum seeds from Ethiopia and consignments of peppers of the genus Capsicum (sweet or other than sweet) from Sri Lanka which are not accompanied by an official certificate and the results of sampling and analysis in accordance with this Regulation shall be accepted for entry into the Union until 13 January 2022.';

(6) Annexes I, II, IIa and IV are replaced by the text set out in the Annex to this Regulation.

Article 2

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, 27 October 2021.

For the Commission The President Ursula VON DER LEYEN

Unquote

The relevant portion of the Commission Implementing Regulation (EU) 2021/2246 is set out below:

Quote

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2246 of 15 December 2021

amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council

> (Text with EEA relevance) THE EUROPEAN COMMISSION,

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

Having regard to Regulation (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)

(1) OJ L 31, 1.2.2002, p. 1., and in particular Article 53(1), point (b)(ii), thereof,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)(2)

(2) OJ L 95, 7.4.2017, p. 1., and in particular Article 47(2), point (b), and Article 54(4), points (a) and (b), thereof,

Whereas:

Commission Implementing Regulation (EU) 2019/1793 (3) lays down rules on the temporary (1) increase of official controls at the entry into the Union on certain food and feed of nonanimal origin from certain third countries listed in Annex I to that Implementing Regulation, and on the imposition of special conditions governing the entry into the Union of certain consignments of food and feed from certain third countries due to the risk of contamination by mycotoxins, including aflatoxins, pesticide residues, pentachlorophenol and dioxins, and microbiological contamination, listed in Annex II to that Implementing Regulation.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 95, 7.4.201 7, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660 (OJ L 277, 29.10.2019, p. 89).

- Article 12 of Implementing Regulation (EU) 2019/1793 provides that the lists set out in Annexes I and II to that Implementing Regulation are to be reviewed at regular intervals not exceeding 6 months, in order to take into account new information related to risks to human health and non-compliance with Union legislation, such as the data resulting from notifications received through the rapid alert system established by Regulation (EC) No 178/2002, as well as data and information concerning consignments and the results of the documentary, identity and physical checks communicated by the Member States to the Commission.
- (3) The occurrence and relevance of recent food incidents notified through the Rapid Alert System for Food and Feed ('RASFF') indicating the existence of a serious direct or indirect risk to human health deriving from food or feed, as established by Regulation (EC) No 178/2002, and information regarding official controls performed by MemberStates on food and feed of non-animal origin in the first semester of 2021 indicate that the lists set out in Annexes I and II to Implementing Regulation (EU) 2019/1793 should be amended in order to protect human health in the Union.
- (4) Groundnuts and products produced from groundnuts from Argentina have been subject to an increased level of official controls due to the risk of contamination by aflatoxins since January 2019. The official controls carried out by the Member States and available information show improvement in compliance with the relevant requirements provided for in Union legislation. Those results provide evidence that the entry of those foodstuffs into the Union does not constitute a serious risk for human health. As a consequence, it is not necessary to continue to provide that each consignment is accompanied by an official certificate stating that all results of sampling and analysis show compliance with Regulation (EC) No 396/2005 of the European Parliament and of the Council (4)
- (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). At the same time, Member States should continue to carry out controls to ensure that the current level of compliance will be maintained. Therefore, the entry concerning groundnuts from Argentina in Annex II to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex I to that Implementing Regulation, maintaining the level of frequency of identity and physical checks at 5 % of consignments entering the Union.
- (5) Hazelnuts and products produced from hazelnuts from Azerbaijan have been subject to an increased level of official controls due to the risk of contamination by aflatoxins since January 2019. The official controls carried out by the Member States and available information show improvement in compliance with the relevant requirements provided for in Union legislation. Those results provide evidence that the entry of those foodstuffs into the Union does not constitute a serious risk for human health. As a consequence, it is not necessary to continue to provide that each consignment has been accompanied by an official certificate stating that all results of sampling and analysis show compliance with the Regulation (EC) No 396/2005. At the same time, Member States should continue to carry out controls to ensure that the current level of compliance will be maintained. Therefore, the entry concerning hazelnuts from Azerbaijan in Annex II to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex I to that Implementing Regulation, maintaining the level of frequency of identity and physical checks at 20 % of consignments entering the Union.

- Black pepper (*Piper nigrum*) from Brazil has been subject to an increased level of official controls due to the risk of contamination by *Salmonella* since January 2019. The official controls carried out on those foodstuffs by the Member States show a persistent high rate of non-compliance since the establishment of the increased level of official controls. Those results provide evidence that the entry of those foodstuffs into the Union constitutes a serious risk for human health.
- (7) It is therefore necessary, in addition to the increased level of official controls, to provide for special conditions in relation to the importation of black pepper (*Piper nigrum*) from Brazil. In particular, all consignments of black pepper from Brazil should be accompanied by an official certificate stating that all results of sampling and analysis show the absence of *Salmonella* in 25 g. The results of the sampling and analysis should be attached to that certificate. Therefore, the entry on black pepper from Brazil in Annex I to Implementing Regulation (EU) 2019/1793 should be transferred to Annex II to that Implementing Regulation with a frequency of identity and physical checks set at 50 % of consignments entering the Union.
- (8) In relation to consignments of Galia melons (*Cucumismelo var. reticulatus*) from Honduras, the data resulting from notifications in the RASFF and information regarding official controls performed by Member States indicate the emergence of new risks to human health, due to a possible contamination by *Salmonella Braenderup*. It is therefore necessary to require an increased level of official controls on entries of those commodities from Honduras. Such commodities should therefore be included in Annex I to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 10 % of consignments entering the Union.
- (9) Sweet peppers (Capsicum annum) from China have been subjected to an increased level of official controls due to the risk of contamination by Salmonella since January 2019. The official controls carried out by the Member States and available information show improvement in compliance with the relevant requirements provided for in Union legislation. Therefore, an increased level of official controls at the level of 20 % of consignments entering the Union is no longer justified for this commodity. However, Member States should continue to carry out controls to ensure that the current level of compliance will be maintained. The corresponding entry in Annex I to Implementing Regulation (EU) 2019/1793 should be modified and the frequency of identity and physical checks decreased to 10 % of consignments entering the Union.
- (10) Aubergines (*Solanummelongena*) from the Dominican Republic have been subject to an increased level of official controls due to the risk of contamination by pesticide residues since January 2019. The official controls carried out on those foodstuffs by the Member States show a persistent high rate of non-compliance since the establishment of the increased level of official controls. Those results provide evidence that the entry of those foodstuffs into the Union constitutes a serious risk for human health.
- It is therefore necessary, in addition to the increased level of official controls, to conditions provide for the imposition of special in relation aubergines (Solanummelongena) from the Dominican Republic. In particular, all consignments of that commodity from the Dominican Republic should be accompanied by an official certificate stating that all results of sampling and analysis show compliance with Regulation (EC) No 396/2005 on maximum residue levels of pesticides for consignments of food and feed listed in Annex II to Implementing Regulation (EU) 2019/1793 due to the contamination risk by pesticide residues. The results of the sampling and analysis should be attached to that certificate. Therefore, the entry on aubergines (Solanummelongena) from the Dominican Republic in Annex I to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to

- Annex II to that Implementing Regulation, with a frequency of identity and physical checks maintained at 50 % of consignments entering the Union.
- (12) Peppers of the genus *Capsicum* and Yardlong beans from the Dominican Republic have been subject to an increased level of official controls due to the risk of contamination by pesticide residues since January 2010. The official controls carried out on those foodstuffs by the Member States show a persistent high rate of non-compliance since the establishment of the increased level of official controls. Those results provide evidence that the entry of those foodstuffs into the Union constitutes a serious risk for human health.
- (13) It is therefore necessary, in addition to the increased level of official controls, to provide for the imposition of special conditions in relation to peppers of the genus *Capsicum* and Yardlong beans from the Dominican Republic. In particular, all consignments of peppers of the genus *Capsicum* and Yardlong beans from the Dominican Republic should be accompanied by an official certificate stating that all results of sampling and analysis show compliance with Regulation (EC) No 396/2005 on maximum residue levels of pesticides for consignments of food and feed listed in Annex II to Implementing Regulation (EU) 2019/1793 due to the contamination risk by pesticide residues. The results of the sampling and analysis should be attached to that certificate. Therefore, the entry on peppers of the genus *Capsicum* and Yardlong beans from the Dominican Republic in Annex I to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex II to that Implementing Regulation, with a frequency of identity and physical checks maintained at 50 %.
- (14) In relation to consignments of drumsticks (*Moringaoleifera*) from India, the data resulting from notifications in the RASFF and information regarding official controls performed by Member States indicate the emergence of new risks to human health, due to a possible contamination by pesticide residues. It is therefore necessary to require an increased level of official controls on entries of this commodity from India. Such commodities should therefore be included in Annex I to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 10 %.
- (15) In relation to consignments of peppers of the genus *Capsicum* (other than sweet) from India, a high frequency of non- compliance with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues was detected during official controls performed by Member States in accordance with Annex II to Implementing Regulation (EU) 2019/1793. It is therefore appropriate to increase the frequency of identity and physical checks to be performed on such consignments to 20 %.
- (16) In relation to consignments of rice from India and Pakistan, the data resulting from notifications in the RASFF and information regarding official controls performed by Member States indicate the emergence of new risks to human health, due to a possible contamination by aflatoxins and ochratoxine A. It is therefore necessary to require an increased level of official controls on entries of such consignments. Entries of those commodities from India and Pakistan should therefore be included in Annex I to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 10 %.
- (17) In relation to consignments of gotukola (*Centellaasiatica*) and mukunuwenna (*Alternantherasessilis*) from Sri Lanka, the data resulting from notifications in the RASFF and information regarding official controls performed by Member States indicate the emergence of new risks to human health, due to a possible contamination by pesticide residues. It is therefore necessary to require an increased level of official controls on entries of such consignments. Entries of those commodities from Sri Lanka should therefore be included in Annex I to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 10 %.

- Hazelnuts and products produced from hazelnuts from Turkey have been subject to an increased level of official controls due to the risk of contamination by aflatoxins April 2021. The official controls carried out on those foodstuffs by the Member States indicate an overall satisfactory degree of compliance with the relevant requirements provided for in Union legislation. Therefore, an increased level of official controls is no longer justified for this commodity and its entry in Annex I to Implementing Regulation (EU) 2019/1793 should be deleted.
- (19) In relation to consignments of grapefruits from Turkey, the data resulting from notifications in the RASFF and information regarding official controls performed by Member States indicate the emergence of new risks to human health, due to a possible contamination by pesticide residues. It is therefore necessary to require an increased level of official controls on entries of such consignments. Entries of that commodity from Turkey should therefore be included in Annex I to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 10 %.
- (20) Mandarins (including tangerines and satsumas), clementines, wilkings and similar citrus hybrids and oranges from Turkey have been subject to an increased level of official controls due to the risk of contamination by pesticide residues since January 2020. The official controls carried out on those foodstuffs by the Member States show a persistent high rate of non-compliance since the establishment of the increased level of official controls. Those results provide evidence that the entry of those foodstuffs into the Union constitutes a serious risk for human health.
- (21) It is therefore necessary, in addition to the increased level of official controls, to provide for the imposition of special conditions in relation to mandarins and oranges from Turkey. In particular, all consignments of mandarins (including tangerines and satsumas), clementines, wilkings and similar citrus hybrids and oranges from Turkey should be accompanied by an official certificate stating that all results of sampling and analysis show compliance with Regulation (EC) No 396/2005 on maximum residue levels of pesticides for consignments of food and feed listed in Annex II to Implementing Regulation (EU) 2019/1793 due to the contamination risk by pesticide residues. The results of the sampling and analysis should be attached to that certificate. Therefore, the entry on mandarins and oranges from Turkey in Annex I to Implementing Regulation (EU) 2019/1793 should be deleted and transferred to Annex II to that Implementing Regulation with a frequency of identity and physical checks raised to 20 %.
- (22) In relation to consignments of cumin seeds and dried oregano from Turkey, the data resulting from notifications in the RASFF and information regarding official controls performed by Member States indicate the emergence of new risks to human health, due to a possible contamination by pyrrolizidine alkaloids. It is therefore necessary to require an increased level of official controls on entries of such consignments. Entries of these commodities from Turkey should therefore be included in Annex I to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 10 % of consignments entering the Union.
- (23) In relation to *pitahaya*(dragon fruit) from Vietnam, a high frequency of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues was detected during official controls performed by Member States in accordance with Annex II to Implementing Regulation (EU) 2019/1793. It is therefore appropriate to increase the frequency of identity and physical checks to be performed on such consignments to 20 %.

- The risk arising from contamination of groundnuts by aflatoxins is associated as well with groundnuts paste. Therefore to ensure efficient protection against potential health risks arising from contamination of groundnuts paste by aflatoxins, in the columns referring to 'Food and feed (intended use)' and 'CN code' in Annex I and in Table1 of Annex II to Implementing Regulation (EU) 2019/1793, the category 'groundnuts paste' and relevant CN codes for groundnuts paste should be added for the entries relating to groundnuts for Argentina, Bolivia, Brazil, China, Madagascar, Senegal and for the United States in Annex I and for Egypt, Ghana, Gambia, India and Sudan in Annex II.
- (25) Sesamum seeds from India have been subjected to an increased level of official controls in view of a risk of contamination by pesticide residues including ethylene oxide since October 2020. The official controls carried out by Member States and available information show improvement in compliance with the relevant requirements in Union legislation regarding pesticide residues other than ethylene oxide. Therefore, an increased level of official controls of consignments of sesamum seed for the possible contamination with pesticide residues that can be analysed with multi-residues methods is no longer necessary for this commodity. Therefore the corresponding entry in Annex II to Implementing Regulation (EU) 2019/1793 should be modified accordingly.
- (26) Data resulting from notifications in the RASFF and information regarding official controls performed by Member States indicate the emergence of new risks to human health, due to a possible contamination by ethylene oxide, requiring an increased level of official controls. Ethylene oxide is classified as a mutagen, category 1B, a carcinogen, category 1B, and a reproductive toxicant, category 1B, in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council(5)Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1). Moreover, ethylene oxide is not approved as an active substance for use in plant protection products in the Union.
- (27) In relation to consignments of locust beans (carob), mucilages and thickeners, whether or not modified, derived from locust beans or locust bean seeds from Morocco, spice paste from Mexico and peppers of the genus *Capsicum* (other than sweet) from Uganda, results from official controls performed by Member States show occurrences of contamination by ethylene oxide.
- (28) Therefore, in order to ensure efficient protection against potential health risks arising from contamination of those commodities, consignments of locust beans (carob), mucilages and thickeners, whether or not modified, derived from locust beans or locust bean seeds from Morocco, spice paste from Mexico and peppers of the genus *Capsicum* (other than sweet) from Uganda should therefore be included in Annex I to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 10 %.

⁽⁵⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

- Taking into account the number of RASFF notifications received, it is appropriate to provide for special conditions for consignments of xanthan gum from China, locust beans (including mucilages and thickeners derived from locust beans), Guar gum, several spices, Calcium carbonate and food supplements containing botanicals from India, food supplements containing botanicals and instant noodles from South Korea, locust beans (including mucilages and thickeners derived from locust beans) from Malaysia and Turkey, and instant noodles from Vietnam. Due to the contamination risk by ethylene oxide, consignments of those products should be accompanied by an official certificate stating that all results of sampling and analysis show compliance with Regulation (EC) No 396/2005 on maximum residue levels of ethylene oxide for consignments of food and feed listed in Annex II to Implementing Regulation (EU) 2019/1793. The results of the sampling and analysis should be attached to that certificate. Therefore, entries of consignments of xanthan gum from China, locust beans (including mucilages and thickeners derived from locust beans), Guar gum, several spices, Calcium carbonate and food supplements containing botanicals from India, food supplements containing botanicals and instant noodles from South Korea, locust beans (including mucilages and thickeners derived from locust beans) from Malaysia and Turkey, and instant noodles from Vietnam should be included in Annex II to Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 20 %.
- (30) In order to ensure consistency and clarity, it is appropriate to replace Annexes I and II to Implementing Regulation (EU) 2019/1793 in their entirety by the text set out in the Annex to this Regulation.
- (31) It is appropriate to provide for a transitional period for consignments of black pepper (*Piper nigrum*) from Brazil, of aubergines (*Solanummelongena*), of sweet peppers (*Capsicum annuum*), of peppers of the genus *Capsicum* (other than sweet) and yardlong beans (*Vignaunguiculatassp. sesquipedalis, Vignaunguiculatassp. unguiculata*) from the Dominican Republic and of mandarins (including tangerines and satsumas), clementines, wilkings and similar citrus hybrids and oranges from Turkey, which are not accompanied by an official certificate, but which were already subject to official controls at the border control post in accordance with Union legislation in force at the time.
- (32) Implementing Regulation (EU) 2019/1793 should therefore be amended accordingly.
- (33) 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

Article 14 is replaced by the following:

'Article 14

Transitional period

Consignments of black pepper (*Piper nigrum*) from Brazil, of aubergines (*Solanummelongena*), of sweet peppers (*Capsicum annuum*), of peppers of the genus *Capsicum* (other than sweet) and yardlong beans (*Vignaunguiculatassp. sesquipedalis, Vignaunguiculatassp. unguiculata*) from the Dominican Republic and of mandarins (including tangerines and satsumas), clementines, wilkings and similar citrus hybrids and oranges from Turkey, which were already subject to increased official controls before the entry into force of this Regulation, may be authorised to entry into the Union until 26 January 2022without being accompanied by an official certificate and the results of sampling and analysis.';

2. Annexes I and II are replaced by the text set out in the Annex to this Regulation.

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*.

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

Done at Brussels, 15 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

EN Official Journal of the European Union L 453/10 17.12.2021

Unquote