

**Procedure for export of Food supplements containing botanicals originating in or consigned from India to EU in view of the Commission Implementing Regulations(EU) 2019/1793,2021/608,2021/1900and 2021/2246**

**Preamble-**By the Regulation entitled “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” (**hereinafter referred to as the “Commission Implementing Regulation (EU) 2021/2246”**), the European Commission has inter alia stated that due to the contamination risk by ethylene oxide, consignments of various products mentioned in the Implementing Regulation 2021/2246 including food supplements containing botanicals from India 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 the Commission Implementing Regulation (EU) 2019/1793 and that the results of the sampling and analysis should be attached to the said Official Certificate.Further, in order to ensure consistency and clarity, Annexes I and II to the Commission Implementing Regulation (EU) 2019/1793 has been replaced in its entirety by the text set out in the Annex to the Commission Implementing Regulation (EU) 2021/2246.Accordingly , entries of consignments of various products includingfood supplements containing botanicals, has been included by amending Annex II to Commission Implementing Regulation (EU) 2019/1793, with a frequency of identity and physical checks set at 20 %.

**Official Certificates were issued earlier in accordance with Article 11 and Annex IV to the COMMISSION IMPLEMENTING REGULATION (EU) 2019/1793 of 22<sup>nd</sup> 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” (hereinafter referred to as the “Commission Implementing Regulation (EU) 2019/1793”)**

**Thereafter, by the Regulation entitled “Commission Implementing Regulation (EU) 2021/608 of 14th April, 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) 2021/608”), the European Commission amended “Article 11- Official Certificate” of the Commission Implementing Regulation(EU) 2019/1793 dated 21st October, 2019 to ensure consistency with the new certification requirements in the Official Certificates for the entry into the Union laid down in Commission Implementing Regulation (EU) 2020/2235. Further the Annexes I, II, IIa and IV of the Commission Implementing Regulation (EU) 2019/1793 were also replaced by the text set out in the Annex to the Commission Implementing Regulation (EU)2021/608.Further,by the Regulation entitled “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” (hereinafter referred to as the “Commission Implementing Regulation (EU) 2021/1900”),the European Commission with a view to align the Official Certificates for the entry into the Union laid down in Commission Implementing Regulation (EU) 2020/2235 for different categories of goods and to ensure consistency with the new certification requirements in the Official Certificates, amended the model Official Certificate and the Notes on the completion of that certificate set out in Annex IV to Implementing Regulation (EU) 2019/1793.Further ,Annexes I,II,IIa and IV of the Commission Implementing Regulation (EU) 2019/1793 were replaced in its entirety by Annexes I,II,IIa and IV of the Commission Implementing Regulation (EU) 2021/1900.**

**Keeping in view the Commission Implementing Regulation(EU) 2021/2246 and the Commission Implementing Regulations (EU) 2019/1193, 2021/608 and 2021/1900 SHEFEXIL has prepared this document entitled “Procedure for export of food supplements containing botanicals from India originating in or consigned from India to EU by SHEFEXIL in view of the Commission Implementing Regulations(EU) 2019/1793,2021/608,2021/1900 and 2021/2246” bearing Reference No. SHEFEXIL/EU Botanicals/\_\_\_\_-\_\_\_\_\_ dated \_\_\_\_\_ for providing a synopsis of the aforesaid 4Commission Implementing Regulations and the procedure to be followed by the member exporters in accordance with the said 4 Commission Implementing Regulations.**

Schedule to this Procedure contains the following-

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## SCHEDULE A

### **The 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) 2017/625 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) <sup>(1)</sup>, 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 <sup>(2)</sup>, and in particular Article 53(1)(b) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 integrates into a single legislative framework the rules applicable to official controls on 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 <sup>(3)</sup> and other Union acts governing official controls in specific areas.
- (2) Pursuant to Regulation (EU) 2017/625, 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) 2017/625, 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 <sup>(4)</sup> (hereinafter, ‘the list’) and update the list as necessary to reflect any developments in that regard.

(1) OJ L 95, 7.4.2017, 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<sup>(5)</sup>, 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) 2017/625.
- (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<sup>(6)</sup>, (EU) 2015/175<sup>(7)</sup>, (EU) 2017/186<sup>(8)</sup>, (EU) 2018/1660<sup>(9)</sup> 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) 2017/625. 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.

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(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, 3.2.2017, 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 1881/2006 <sup>(10)</sup> and in feed by Directive 2002/32/EC of the European Parliament and of the Council <sup>(11)</sup>. The maximum levels for pesticide residues are established by Regulation (EC) No 396/2005 of the European Parliament and of the Council <sup>(12)</sup>. 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 <sup>(13)</sup> and in feed by Commission Regulation (EC) No 152/2009 <sup>(14)</sup>. The provisions on sampling for the official control of pesticide residues are established by Commission Directive 2002/63/EC <sup>(15)</sup>. 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) 2017/186 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.

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(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) 2017/625 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) 2019/628 <sup>(16)</sup> 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 <sup>(17)</sup>, 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) 2017/625, the TRACES system is to be integrated into the Information Management System for Official Controls referred to in Article 131 of Regulation (EU) 2017/625 (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) 2017/625 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) 2019/628.
- (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) 2017/625 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 53(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 53(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) 2017/186, (EU) 2015/175 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).

## SECTION 1

**COMMON PROVISIONS***Article 1***Subject matter and scope**

1. 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) 2017/625;
  - (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 53(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) 2017/625;
  - (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 53(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) 2017/625.
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**

1. For the purposes of this Regulation, the following definitions shall apply:
  - (a) 'consignment' means 'consignment' as defined in Article 3(37) of Regulation (EU) 2017/625;
  - (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 2002/67/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 2002/63/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) 2017/625 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.

*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**

1. 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 1831/2003 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*.
3. 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 accordance with 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);
  - c) 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.
4. Competent authorities may issue a replacement official certificate only in accordance with the rules laid down in Article 5 of Implementing Regulation (EU) 2019/628.
5. 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**

1. 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) 2017/625.
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**

1. 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) 2017/186 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.
3. 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 Brussels, 22 October 2019.

*For the Commission*

*The President*

*Jean-Claude JUNCKER*

**Unquote**



## **SCHEDULE B**

The Relevant portion of the Commission Implementing Regulation(EU) 202 1/608 is set out below:-

Quote

COMMISSION IMPLEMENTING REGULATION (EU) 202 1/608

of 14 April 2021

amending Implementing Regulation (EU) 2019/1 793 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) 201 7/625 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, 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 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, 2008/1 19/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) 20 19/1793 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) 20 19/1793 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

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(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, 29.10.20 19, 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) 2020/2235 repeals 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.

(15) 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 2020 with 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 '*Sesamum* seeds (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) 2019/1 793

Implementing Regulation (EU) 20 19/1793 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").
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) 20 17/625, 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.

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(\*) 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) 20 16/429 and (EU) 20 17/625 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 21 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels, 14 April 2021.

For the Commission  
The President  
Ursula VON DER LEYE

Unquote

### **SCHEDULE C**

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

**Quote**

**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 <sup>(1)</sup>, and in particular Article 5 3(1)(b) thereof,

Having regard to Regulation (EU) 2017/625 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) <sup>(2)</sup>, 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 <sup>(3)</sup> 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.

<sup>(1)</sup>OJ L 31, 1.2.2002, p. 1.

<sup>(2)</sup>OJ L 95, 7.4.2017, p. 1.

<sup>(3)</sup>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 favourable trend 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.
- (17) 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 10(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.

- (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<sup>(4)</sup> 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.

<sup>(4)</sup> 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**

#### **SCHEDULE D**

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<sup>(1)</sup>

(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 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)<sup>(2)</sup>

(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:

- (1) Commission Implementing Regulation (EU) 2019/1793 <sup>(3)</sup> 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, 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, 7.4.2017, 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).

- (2) 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 Member States 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.

(6) 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 (*Cucumis melo 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 (*Solanum melongena*) 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.

(11) It is therefore necessary, in addition to the increased level of official controls, to provide for the imposition of special conditions in relation to aubergines (*Solanum melongena*) 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 (*Solanum melongena*) 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 (*Moringa oleifera*) 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 (*Centella asiatica*) and mukunuwenna (*Alternanthera sessilis*) 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 %.

(18) 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 %.

(24) 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 Table 1 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.

<sup>(5)</sup> 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).

(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 %.

(29) 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 (*Solanum melongena*), of sweet peppers (*Capsicum annuum*), of peppers of the genus *Capsicum* (other than sweet) and yardlong beans (*Vigna unguiculata* ssp. *sesquipedalis*, *Vigna unguiculata* ssp. *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 (*Solanum melongena*), of sweet peppers (*Capsicum annuum*), of peppers of the genus *Capsicum* (other than sweet) and yardlong beans (*Vigna unguiculata* ssp. *sesquipedalis*, *Vigna unguiculata* ssp. *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 2022 without 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

**Unquote**

## **Schedule E**

### **Synopsis of the 4 Commission Implementing Regulations of EU**

**(I) Recital 29 and 30 of the Commission Implementing Regulation(EU) 2021/2246 states as follows:**

**“(29) 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.**

**In view of the said Recitals of the Commission Implementing Regulations (EU) 2021/2246 consignments of various products including food supplements containing botanicals from India, will be subject to special conditions in addition to the increased level of official controls. In particular, as provided for in Article 10, Article 11 and Annex IV of the Commission Implementing Regulation (EU) 2019/1793 as amended by Article 1(1) and Annex IV of the Commission Implementing Regulation (EU) 2021/608, and further amendment by Annex IV of the Commission Implementing Regulations (EU) 2021/1900 each consignment of food supplements containing botanicals from India shall be accompanied by an Official Certificate issued in accordance with the format laid down in Annex IV to the Commission Implementing Regulation (EU) 2021/1900 in accordance with the Commission Implementing Regulations (EU) 2021/2246 stating that the product has been sampled and analysed for ethylene oxide and the results of sampling and analyses show compliance with Regulation (EC) No 396/2005 on maximum residue levels of ethylene oxide.**

(II) Row 10 of Annex II to the Commission Implementing Regulation (EU) 2021/2246 imposed the requirement of a 20% physical check of the consignments originating in India to find out whether the consignment is contaminated with Pesticide residues (Ethylene oxide (sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide) Row No. 10 of Annex II to the Commission Implementing Regulation (EU) 2021/2246, inter-alia, states as follows:-

Row	Country of origin	Food and feed(intended use)	CN code	TARI C sub-division	Hazard	Frequency of identity and physical checks(
-----	-------------------	-----------------------------	---------	---------------------	--------	--

						%)
10	India (IN)	Food supplements containing botanicals <b>(Food)</b>	— ex 1302 — ex 2106		Pestic ide residu es*	20%

\*Ethylene oxide (sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide)

### (III) Sampling, Analysis and Testing-

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 Ethylene oxide (sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide) in herbals or botanicals category; and
  - The method shall be utilizing GC-MS/MS and the limit of quantitation should be minimum of 0.01 mg/kg.
- The laboratories approved for conducting sampling and analyses are mentioned in Annexure 1 of this Procedure.
- The test report must maintain full details of the sample, e.g., the lot number, and identification id of the package, etc as outlined in Annexure 2 of this Procedure.

### (IV) Official Certificate-

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 format of Official Certificate as per the said Annex IV of the Commission Implementing Regulation (EU) 2021/1900 and Commission Implementing Regulation (EU) 2021/2246 and the Notes accompanying Annex IV to the Commission Implementing Regulation (EU) 2021/2246 with regard to completion of such Certificate which is applicable to food supplements containing botanicals are set out in Annexure III and IV respectively of this Procedure.

Further, the Official Certificate has to comply with the requirements set out in the Commission Implementing Regulation (EU) 2021/608 which inter alia provides as follows-

**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. 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.



Further, as mentioned above in accordance with the Commission Implementing Regulation 2021/2246 the Official Certificate shall state that all results of sampling and analysis shows compliance with Regulation (EC) No 396/2005 on maximum residue levels of ethylene oxide for consignments of food supplements containing botanicals (food).

**Penal provisions:**

**a) Cancellation of Registration-cum-Membership Certificate of the exporter.**

**b) Derecognition of the Authorized Agency and Recognized Laboratory.**

**c) Notifying to DGFT for cancellation of Import-Export Code Number allocated to such exporters.**

**d) Any other action as deemed fit.**

**Annexure-I****Laboratories for analysis of Ethylene oxide (sum of ethylene oxide and 2-chloroethanol expressed as ethylene oxide in food supplements containing Botanicals)**

No.	Name and contact details of the laboratory
1	<p>Shri Jagadeesh Kodali  Vice President - Food Division  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  Mobile : 91 9100136070  Fax : +91 40 2726 3657  Email : <a href="mailto:Jagadeesh.Kodali@vimta.com">Jagadeesh.Kodali@vimta.com</a>  <a href="https://www.vimta.com/contact">https://www.vimta.com/contact</a></p>
2	<p>Dr. Shalini Tripathi  Assistant Director &amp; BUMA  Eurofins Analytical Services India Pvt. Ltd.  157, Udyog Vihar, Phase-1,  122016, Gurugram,  India  Phone: +91-1246250301  Mobile: +91-9582068017  E-mail: <a href="mailto:ShaliniTripathi@eurofins.com">ShaliniTripathi@eurofins.com</a>  Website: <a href="http://www.eurofins.in">www.eurofins.in</a></p>
3.	<p>Envirocare Labs Pvt. Ltd.  Envirocare Labs Pvt. Ltd., Thane  Enviro House, A7, MIDC, Wagle Industrial Estate,  Main Road,Thane 400 604  Tel: +91 22 2583 8286,  Fax: +91 22 25838289  Website : <a href="http://www.enciocare.co.in">www.enciocare.co.in</a></p>
4.	<p>Eureka Analytical Services Pvt Ltd  Manekvadi, Near Overbridge,  Visnagar Rd, Unjha,  Gujarat 384170  Email : <a href="mailto:info@eurekaserv.com">info@eurekaserv.com</a>  Website : <a href="http://www.eurekaserv.com">www.eurekaserv.com</a></p>

**SAMPLING PROCEDURE FOR ANALYSIS OF ETHYLENE OXIDE (SUM OF ETHYLENE OXIDE AND 2-CHLOROETHANOL EXPRESSED AS ETHYLENE OXIDE) & NAME OF THE AGENCY AUTHORIZED FOR DRAWAL OF SAMPLE FOR EXPORT OF FOOD SUPPLEMENTS CONTAINING BOTANICALS IN OR CONSIGNED FROM INDIA TO THE EUROPEAN UNION**

**Ref : EU COMMISSION DIRECTIVE 2002/63/EC of 11 July 2002**

**Scope**

The objective of the sampling procedure is to enable representative sample to be obtained from a lot, for analysis of Ethylene oxide (sum of Ethylene oxide and 2-chloroethanol expressed as Ethylene oxide) to determine compliance with Commission implementing regulation (EU) 2021/2246 of 15 Dec 2021 amending Implementing Regulation (EU) 2019/1793 for the MRLs specified in as per Commission regulation (EU) 2015/868 amending Annexes II, III and V to Regulation (EC) No 2005/396.

**Sampling Device**

A tool such as a scoop, dipper, borer, knife or spear, used to remove a unit from bulk material, from packages

**Sampling officer**

Sampling to be carried out by the person trained in sampling procedures and where required, authorized by the appropriate authorities to take samples.

**Lot**

A quantity of a food material delivered at one time and known, or presumed, by the sampling officer to have uniform characteristics such as origin, producer, variety, packer, type of packing, markings, consignor, etc.

*Notes:*

- a) Where a consignment is comprised of lots which can be identified as originating from different growers, etc., each lot should be considered separately.*
- b) A consignment may consist of one or more lots.*
- c) Where the size or boundary of each lot in a large consignment is not readily established, each one of a series of wagons, lorries, ships bays, etc., may be considered to be a separate lot.*
- d) A lot may be mixed by grading or manufacturing processes, for example.*

**Note: Each consignment shall be considered as separate lot and sampled separately. If a lot is subdivided and sent to different customers in different consignments, then each subdivided lot shall be sampled and analysed separately.**

### **Primary sample/incremental sample**

One or more units taken from one position in a lot.

*Notes: a) The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot.*

### **Bulk sample/aggregate sample**

For products other than meat and poultry, the combined and well-mixed aggregate of the primary samples taken from a lot

*Notes: a) The primary samples must contribute sufficient material to enable all laboratory samples to be withdrawn from the bulk sample.*

*b) Where separate laboratory samples are prepared during collection of the primary sample(s), the bulk sample is the conceptual sum of the laboratory samples, at the time of taking the samples from the lot.*

### **Laboratory sample**

The sample sent to, or received by, the laboratory. A representative quantity of material removed from the bulk sample.

*Notes: a) The laboratory sample may be the whole or a part of the bulk sample.*

*b) Units should not be cut or broken to produce the laboratory sample(s)*

*c) Replicate laboratory samples may be prepared.*

### **Precautions to be taken**

Contamination and deterioration of samples must be prevented at all stages, because they may affect the analytical results. Each lot to be checked for compliance must be sampled separately. Handling of the sample shall be carried out with care in order to avoid changes in the characteristics of the sample.

### **Procedure for sampling**

#### **Determining the laboratory sample weight**

The laboratory sample shall be in minimum size of (ref. Table 4)

Commodity classification	Minimum size of each laboratory sample
Products of high value	0.1Kg*
Solid product of low bulk	0.2Kg

*\*Note: A smaller laboratory sample may be taken from a product of exceptionally high value but the reason for doing so should be noted in the sampling record.*

### **Determining bulk sample weight and primary/incremental sample weight.**

The weight of bulk sample in Kg = 3\* x laboratory sample weight

*\*Note: One for laboratory sample, second one for control sample, third one for customer sample*

### **Minimum number of primary/incremental samples to be taken from a lot (ref. Table-1)**

Products, packaged or in bulk

#### Based on weight

Weight of lot, kg	Minimum number of primary/incremental samples to be taken from the lot
<50 kg	3
50-500 kg	5
>500 kg	10

Or

#### Based on number of cans, cartons or other containers in the lot

Number of cans, cartons or other containers	Minimum number of primary/incremental samples to be taken from the lot
1-25	1
26-100	5
>100	10

### **Primary/incremental sample weight to be taken**

= Determined bulk sample weight/ Minimum number of primary/incremental samples to be taken from the lot

Ex: If laboratory sample required from above tables is 0.2kg, bulk sample weight is 0.6kg (3x 0.2kg),

If the consignment weight is 50-500kg then number of primary/incremental samples to be taken at random locations is 5 and each incremental sample weight is  $0.6\text{kg}/6 = 0.12\text{kg}$

Hence the sampling sample be done from 5 random locations each 0.12 kg, aggregate to 0.6kg and divide to 3 portions (One for laboratory sample, second one for control sample, third one for customer sample)

### **Sampling request**

Sampling request shall be done by exporter in the prescribed format in Annexure-III to the authorized laboratory.

### **Sampling Record (Sample slip)**

The sampling officer must record the nature and origin of the lot; the owner, supplier or carrier of it; the date and place of sampling; and other any other information. **Each consignment shall be considered as separate lot and sampled separately. If a lot is subdivided and sent to different customers in different consignments, then each subdivided lot shall be sampled and analysed separately. HACCP compliance certificate shall be verified by laboratory sampling officer.** Any departure from the recommended method of the sampling must be recorded. A sign copy of the sample slip must accompany each laboratory sample and a copy should be retained by the sampling officer with one control sample. A copy of the sampling record should be given to the exporter of the lot or a representative of the exporter along with one control sample. Sampling record format given in Annexure-IV

### **Packing and Labeling of the samples**

The laboratory sample must be placed in a clean, inert container which provides secure protection from contamination, damage and leakage. The sample must be delivered to the laboratory thru the courier service as soon as practicable. Spoilage in transit must be avoided. The samples shall be protected from light during storage as far as possible.

### **Dispatch of Sample**

Samples shall be dispatched to Vimta Labs Ltd., Hyderabad for the analysis.

### **References :**

- 1) 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.
- 2) Commission Implementing Regulation (EU) 2019/1793 of 22nd October, 2019.
- 3) 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

**Annexure-III**

**APPLICATION FOR DRAVAL OF SAMPLES OF  
FOOD SUPPLEMENTS CONTAINING BOTANICALS FOR  
SAMPLING & LABORATORY TESTING**

**(To be filled in by the applicant exporter/manufacturer on their letter head)**

1.	Name & Address of the Exporter	
2.	Name & Address of the Manufacturer	
3.	Plant Location	
4.	Consignment details: Sample Description/Product  Lot/Batch Nos. No. of Bags/packages Type of Packing  Quantity (MT)  Consignment code	

**Note: Each consignment shall be considered as separate lot and sampled separately. If a lot is subdivided and sent to different customers in different consignments, then each subdivided lot shall be sampled and analysed separately.**

**DECLARATION**

It is certified that, to the best of my knowledge and belief, the above information is true and correct in all respects.

Date:

Signature of Exporter

Place:

(Name of Exporter with company seal)



**SAMPLE SLIP FOR FOOD SUPPLEMENTS CONTAINING BOTANICALS****Sample Slip no:**

<b>A.</b>	<b>Sample Details as per customer letter</b>		
1.	Name and address of customer		
2.	Customer Ref. letter		
3.	Test request for sampling		
	a. Product (sample description)		
	b. Lot details/Type of packing		
	Consignment code		
<b>B.</b>	<b>Sampling Details</b>		
1.	Place & address of sampling(location)		
2.	Marks on the bags if any		
3.	Date & Time of sampling		
4.	Lot/Consignment/ details	Lot No.	
		Date of Packing	
		Total no of bags.	
5.	No. of Bags selected for sampling		
6.	Hologram/ Sticker/ seal nos affixed on sampled bags (If any)		
7.	Total quantity of sample drawn (in gms)		
8.	Laboratory sample (in gms)		
9.	To be tested for		
10.	Sampling procedure adopted		
11.	Seal No. On Laboratory sample		
12.	Seal No. On Counter sample		
13.	Seal No. On the Customer sample		

**Note: Each consignment shall be considered as separate lot and sampled separately. If a lot is subdivided and sent to different customers in different consignments, then each subdivided lot shall be sampled and analysed separately.**

This is to certify that; I have drawn the subjected sample personally from the above mentioned address as per the prescribed sampling procedure in line with 2002/63/EC guidelines in the presence of customer representative.

Date:

(Signature)

(Signature)

Place:

Name:  
Authorized representative who  
has drawn the sample

Name:  
Authorized representative of  
customer

**Label for samples of food supplements containing botanicals**

Laboratory name / logo	Sample slip no.  Lab / counter / customer sample
Sample description	
Lot no	
Lot quantity  Consignment quantity	
Customer name, location	
Test requested	MAXIUM PESTICIDE RESIDUE LEVEL OF ETHYLENE OXIDE
Date of sampling	
Name and signature of sampler	
Name and signature of customer	

**Annexure-V****Test report template**

Issued To:  
COMPANY NAME  
Address

Registration/Report No.

Ph:XXXXXXXXXXXXXXXXXXXXXXX

Kind Attn: Mr. YYYY

Page 1 of 1

<b>Customer Provided Details :</b>			
Sample Name:			
Manufacturer:		Batch/Lot Number:	
Mfg. Date:		Exp. Date:	
Test Required:	Pesticide Residues (Sum of Ethylene oxide and 2-chloroethanol expressed as Ethylene oxide)		
Other Details if Any:	Total lot quantity& consignment quantity shall be specified mandatorily.		
Sampling Details:			
<b>Lab Provided Details :</b>			
Sample Received Date:		Sample Registration Date:	
Analysis Starting Date:		Analysis Completion Date:	
Received Quantity:			
Method of Testing:	For Ethylene oxide: Validated method XXXXXXXXXXX		
Other Details if Any:	SAMPLE TESTED AS RECEIVED		

**Chemical**  
**Residues in Food Products**

**TEST RESULTS**

S. No.	Test Parameters	UOM	Requirements as per Commission regulation (EU) 2015/868 amending Annexes II, III and V to Regulation (EC) No 396/2005	Results
2	Ethylene oxide (sum of Ethylene oxide and 2-chloroethanol expressed as Ethylene oxide)	mg/kg	Max 0.020	Not detected

Remarks: Instrument used :GC-MS/MS, Quantification Limit : 0.01 mg/kg;

**Conclusion:** Sample conforms to the EU MRLs for the tests specified in the Commission implementing regulation (EU) 2021/2246 of 15 Dec2021amending Implementing Regulation (EU) 2019/1793

**- END OF THE TEST REPORT -**

Name and Designation of Authorized Signatory



## Annexure VI

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

Part I : Description of consignment	<b>COUNTRY</b>		<b>Certificate to the EU</b>	
	<b>1.1 Consignor/ Exporter</b> Name Address  Country ISO country code		<b>1.2. Certificate reference No</b> SHEFEXIL/RCMC/___/Extracts /OC/21-22/	<b>1.2.a</b> <b>IMSOCreference</b> QR Code
			<b>1.3. Central Competent Authority</b> SHELLAC AND FOREST PRODUCTS EXPORT PROMOTION COUNCIL	
			<b>1.4 Local Competent Authority :</b>	
	<b>1.5 Consignee / Importer</b> Name Address  Country ISO country code		<b>1.6 Operator responsible for the consignment</b> Name Address  Country ISO country code	
	<b>1.7 Country of origin</b> ISO country code		<b>1.9 Country of destination</b> ISO country code	
	<b>1.8</b>		<b>1.10</b>	
	<b>1.11. Place of dispatch</b> Name Registration/Approval No  Address-  Country ISO country code		<b>1.12. Place of Destination</b> Name Registration/Approval No  Address-  Country ISO country code	
	<b>1.13.</b>		<b>1.14. Date and time of departure :</b>	
	<b>1.15. Means of transport</b> <input type="checkbox"/> Aircraft <input type="checkbox"/> Vessel <input type="checkbox"/> Railway <input type="checkbox"/> Road Vehicle Identification :		<b>1.16 Entry Border Control Post</b>	
<b>1.18. Transport conditions :</b> Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>		<b>1.17. Accompanying documents</b> Type    Code  Country    ISO country code Commercial document reference		
<b>1.19. Container No/Seal No.</b> Container No :    Seal No:				
<b>1.20. Certified as or for</b> <input type="checkbox"/> Products for Human consumption <input type="checkbox"/> Feedstuff				
<b>1.21.</b>		<b>1.22. <input type="checkbox"/> For internal market</b>		
<b>1.23.</b>		<b>1.23.</b>		
<b>1.24 Total number of packages</b>	<b>1.25 Total Quantity</b>	<b>1.26 Total net weight / gross weight (Kg)</b>		
<b>1.27. Description of consignment</b> CN Code    Species    Type of packaging    Net weight Number of packages    Batch No.  <input type="checkbox"/> For final consumer				
Certifying officer : Qualification and title : P.H.D., Executive Director Name : <b>DR. DEBJANI ROY</b> Shellac & Forest Products Export Promotion Council Signature :  Date : Stamp				

COUNTRY		Certificate for the entry into the Union of food or feed	
II. Health information	II.a Certificate reference No <b>SHEFEXIL/RCMC/___/Extracts/OC/21-22/</b>	II. b <b>IMSOC</b> reference	
Part II : Certification	<p>II. 1. I, the undersigned, declare that I am aware of the relevant provisions of Union legislation :</p> <ul style="list-style-type: none"> <li>- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p.1),</li> <li>- Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p.1),</li> <li>- Regulation (EC) No. 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p.1) and</li> <li>- Regulation (EU) 2017/625 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) (OJ L 95, 7.4.2017, p.1), and I certify that :</li> </ul>		
	<p>[II.1.1. <input type="checkbox"/> The food of the consignment described above with the identification code _____ (indicate the identification code for the consignment referred to in Article 9(1) of Commission Implementing Regulation (EU) 2019/1793) was produced in accordance with the requirements of Regulations (EC) No. 178/2002 and (EC) No.852/2004 and in particular :</p> <ul style="list-style-type: none"> <li>- Primary production of such food and associated operations listed in Annex I to Regulation (EC) No. 852/2004 comply with the general hygiene provisions laid down in part A of Annex I to Regulation (EC) No. 852/2004;</li> <li>- And, in the case of any stage of production, processing and distribution after primary production and related operations :</li> <li>- It has been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No. 852/2004 and,</li> <li>- It comes from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Regulation (EC) No.852/2004;]</li> </ul>		
<p>Certifying officer : Qualification and title : P.H.D., Executive Director</p> <p>Name : <b>DR. DEBJANI ROY</b> Shellac &amp; Forest Products Export Promotion Council</p> <p>Signature :</p> <p>Date :</p> <p>Stamp</p>			

Country			Certificate for the entry into the Union of food or feed		
II.	Health information	II.a Certificate reference No SHEFEXIL/RCMC/___/Extracts/OC/21-22/	II. b IMSOC reference No		
<p>II. 2. I, the undersigned, declare that I am aware of the relevant provisions of Commission</p> <ul style="list-style-type: none"> <li>- 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 (OJ L277, 29.10.2019, p. 89) and I certify that :-</li> </ul> <p>[II.2.2] Certification for food and feed of non-animal origin listed in Annex II to Implementing Regulation (EU) 2019/1793, as well as for food consisting of two or more ingredients listed in that Annex, due to contamination risk by pesticide residues</p> <ul style="list-style-type: none"> <li>- from the consignment described above, samples were taken in accordance with Commission Directive 2002/63/EC/on ..... (date), subject to laboratory analyses on ..... (date) in the ..... (name of the laboratory) with methods covering at least the hazards identified in Annex II to Implementing Regulation (EU) 2019/1793</li> <li>- the products have been sampled and analysed for ethylene oxide and the results of sampling and analyses 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.</li> <li>- The details of the methods of laboratory analyses and all results are attached and show compliance with Union legislation on maximum residue levels of pesticides.]</li> </ul> <p>II.3. This certificate has been issued before the consignment to which it relates has left the control of the competent authority issuing it.</p> <p>II. 4. This certificate is valid during four months from the date of issue, but in any case no longer than six months from the date of the results of the last laboratory analyses.</p> <p>Notes :</p> <p>See notes for completion in this Annex.</p> <p>Part II :</p> <ol style="list-style-type: none"> <li>(1) Delete or cross out as appropriate (e.g. if food or feed)</li> <li>(2) It applies only in the case of any stage of production, processing and distribution after primary production and related operations.</li> <li>(3) Delete or cross out as appropriate in the case where you do not selected this point for providing the certification.</li> <li>(4) The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those that are embossed or are a watermark.</li> </ol> <p>Certifying officer : Qualification and title : P.H.D., Executive Director</p> <p>Name : <b>DR. DEBJANI ROY</b> Shellac &amp; Forest Products Export Promotion Council</p> <p>Signature :</p> <p>Date :</p> <p>Stamp</p>					

## ANNEX VII

**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
<b>Country</b>	
	Indicate the name of the third country issuing the certificate.
<b>I.1</b>	<b>Consignor/Exporter</b>
	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.
<b>I.2</b>	<b>Certificate reference</b>
	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
<b>I.2a</b>	<b>IMSOC reference</b>
	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.
<b>I.3</b>	<b>Central competent authority</b>
	Indicate the name of the central authority in the third country issuing the certificate.
<b>I.4</b>	<b>Local competent authority</b>
	Indicate, if applicable, the name of the local authority in the third country issuing the certificate.
<b>I.5</b>	<b>Consignee/Importer</b>
	Indicate the name and address of the natural or legal person to whom the consignment is destined in the Member State of destination.

<b>I.6</b>	<b>Operator responsible for the consignment</b>
<p>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.</p> <p>This box is optional.</p>	
<b>I.7</b>	<b>Country of origin</b>
<p>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.</p> <p>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.</p>	
<b>I.8</b>	<b>Region of origin</b>
Not applicable.	
<b>I.9</b>	<b>Country of destination</b>
Indicate the name and ISO country code of Member State of destination of the products.	
<b>I.10</b>	<b>Region of destination</b>
Not applicable.	
<b>I.11</b>	<b>Place of dispatch</b>
<p>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.</p> <p>For other products: any unit of a company in the food or feed sector. Only the establishment shipping the products is to be named.</p> <p>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.</p>	
<b>I.12</b>	<b>Place of destination</b>
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.	
<b>I.13</b>	<b>Place of loading</b>
Not applicable.	
<b>I.14</b>	<b>Date and time of departure</b>
Indicate the date when the means of transport departs (aircraft, vessel, railway or road vehicle).	
<b>I.15</b>	<b>Means of transport</b>

<p>Select one or more of the following means of transport for goods leaving the country of dispatch, and indicate its identification:</p> <ul style="list-style-type: none"> <li>— aircraft (indicate the flight number);</li> <li>— vessel (indicate the vessel name and number);</li> <li>— railway (indicate the train identity and wagon number);</li> <li>— road vehicle (indicate the registration number with trailer number, if applicable).</li> </ul> <p>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.</p>	
<b>I.16</b>	<b>Entry Border Control Post</b>
<p>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.</p>	
<b>I.17</b>	<b>Accompanying documents</b>
<p>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.</p> <p>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).</p>	
<b>I.18</b>	<b>Transport conditions</b>
<p>Indicate the category of required temperature during the transport of products (ambient, chilled, frozen).</p>	
<b>I.19</b>	<b>Container number/Seal number</b>
<p>Where applicable, indicate the container number and seal number (more than one possible).</p> <p>The container number must be provided if the goods are transported in closed containers.</p> <p>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.</p>	
<b>I.20</b>	<b>Certified as or for</b>
<p>Select the intended use of goods as specified in the relevant Union legislation:</p> <p>Feedstuffs: concerns only products intended for animal feed.</p> <p>Products for human consumption: concerns only products intended for human consumption for which an official certificate is required by Union legislation.</p>	
<b>I.21</b>	<b>For transit</b>
<p>Not applicable.</p>	

<b>I.22</b>	<b>For internal market</b>
Tick this box where consignments are intended to be placed on the Union market.	
<b>I.23</b>	<b>For re-entry</b>
Not applicable.	
<b>I.24</b>	<b>Total number of packages</b>
Indicate the total number of packages in the consignment, where appropriate: In the case of bulk consignments, this box is optional.	
<b>I.25</b>	<b>Total quantity</b>
Not applicable.	
<b>I.26</b>	<b>Total net weight/gross weight (kg)</b>
<p>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.</p> <p>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.</p>	
<b>I.27</b>	<b>Description of consignment</b>
<p>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.</p> <p>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.</p> <p>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.</p> <p>Species: indicate the scientific name or as defined in accordance with Union legislation.</p> <p>Type of packaging: identify the type of packaging according to the definition given in Recommendation No 21 of UN/CEFACT (United Nations Centre for Trade Facilitation and Electronic Business).</p>	

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**PART II – Certification**

<b>Box</b>	<b>Description</b>
<b>Country</b>	

Indicate the name of the third country issuing the certificate.	
<b>Certificate model</b>	
This box refers to the specific title of each model of certificate.	
<b>II</b>	<b>Health information</b>
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.	
<b>II.2a</b>	<b>Certificate reference</b>
This is the unique alphanumeric code indicated in box I.2.	

<b>II.2b</b>	<b>IMSOC reference</b>
This is the unique alphanumeric code indicated in box I.2a	
<b>Certifying officer</b>	
<p>This box refers to the signature of the certifying officer as defined in point (26) of Article 3 of Regulation (EU) 2017/625.</p> <p>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.'</p>	

C. Penal provisions:

In the event of breach of these instructions, SHEFEXIL may initiate action as per the provisions of the Articles of Association of the Council, in addition to the followings:

- a) Cancellation of Registration-cum-Membership Certificate of the exporter.
- b) Derecognition of the Authorized Agency and Recognized Laboratory.
- c) Notifying to DGFT for cancellation of Import-Export Code Number allocated to such exporters.
- d) Any other action as deemed fit.