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[...] (2026) **XXX** draft

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

of **XXX**

**amending Implementing Regulation (EU) 2019/1793 as regards the temporary increase
of official controls and emergency measures governing the entry into the Union of
arachidonic acid oil originating in China**

(Text with EEA relevance)

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

of **XXX**

amending Implementing Regulation (EU) 2019/1793 as regards the temporary increase of official controls and emergency measures governing the entry into the Union of arachidonic acid oil originating in China

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹, and in particular Article 53(1), 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)², and in particular Article 47(2), first subparagraph, point (b), and Article 54(4), first subparagraph, point (b), thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2019/1793³ lays down rules 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, microbiological contamination, Sudan dyes, and plant toxins listed in Annex II to that Implementing Regulation.
- (2) Notifications in the Rapid Alert System for Food and Feed ('RASFF') established by Regulation (EC) No 178/2002, together with follow-up investigations carried out by

¹ OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>.

² OJ L 95, 7.4.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/625/oj>.

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, ELI: http://data.europa.eu/eli/reg_impl/2019/1793/oj).

the competent authorities of the Member States concerned, have identified the presence of cereulide toxin in infant formula.

- (3) The follow-up investigations of the information received from RASFF notifications have provided evidence that arachidonic acid oil originating in China and used in the manufacture of infant formula constitutes the source of contamination.
- (4) Cereulide is an emetic toxin produced by certain strains of *Bacillus cereus*. It is resistant to common heat treatments, including pasteurisation and sterilisation, and therefore may remain active in food until the moment of consumption. Infant formula is a product intended for a particularly vulnerable population group. The consumption of infant formula contaminated by cereulide toxin, potentially leads to severe illness or even infant fatality. The detection of cereulide toxin in infant formula led to precautionary recalls in many Member States and third countries. Several Member States reported cases of infants with gastrointestinal symptoms following consumption of infant formula that were later part of the recalls. Moreover, the deaths of two infants, suspected to be linked to consumption of recalled infant formula, are under judicial investigation in a Member State.
- (5) Those elements provide evidence that arachidonic acid oil imported from China is likely to constitute a serious risk for human health.
- (6) It is therefore necessary to provide for an increased level of official controls and special conditions in relation to the importation of consignments of arachidonic acid oil from China. In particular, those consignments should be accompanied by an official certificate stating that all the results of sampling and analyses show the absence of cereulide toxin. The results of sampling and analyses should be attached to that certificate.
- (7) Therefore, arachidonic acid oil originating in China should be included in point 1 of Annex II to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by cereulide toxin, with a frequency of identity and physical checks set at 50 % of consignments entering the Union.
- (8) To ensure legal certainty for the entry into the Union of consignments that have already been dispatched from the country of origin or from another third country, if that country is different from the country of origin, when this Regulation enters into force, it is appropriate to provide for a transitional period of two months for consignments of arachidonic acid oil from China, which are not accompanied by the results of sampling and analyses and an official certificate. During this transitional period, public health protection is ensured for those consignments, since that commodity is subject to identity and physical checks at a frequency of 50 % of consignments entering the Union.
- (9) Implementing Regulation (EU) 2019/1793 should therefore be amended accordingly.
- (10) To ensure food safety and to avoid the entry into the Union of unsafe arachidonic acid oil originating in China, this Regulation should enter into force as a matter of urgency.
- (11) 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

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

1. in Article 1(1), point (b), the introductory wording is replaced by the following:
‘(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, microbiological contamination, cereulide toxin, Sudan dyes, and plant toxins, in accordance with Article 53(1), point (b), of Regulation (EC) No 178/2002.’;
2. Article 14 is replaced by the following:

‘Article 14

Transitional period

Consignments of arachidonic acid oil from China, which have been dispatched from the country of origin, or from another third country if that country is different from the country of origin, before the date of entry into force of Commission Implementing Regulation (EU) ...*, may enter the Union until ... [*same day as date of entry into force of this Regulation plus 2 months*] without being accompanied by the results of sampling and analyses and the official certificate provided for in Articles 10 and 11. [*OJ: Please insert in the text the number of this Regulation and insert the number, date, OJ reference and ELI number of this Regulation in the footnote, underneath.*]

* Commission Implementing Regulation (EU) ... of ... amending Implementing Regulation (EU) 2019/1793 as regards the temporary increase of official controls and emergency measures governing the entry into the Union of arachidonic acid oil originating in China (OJ L, ..., ..., ELI: ...).’;

3. Annex II is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN