

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

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

of **XXX**

correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods and Implementing Regulation (EU) 2020/484 authorising the placing on the market of lacto-N-tetraose as a novel food under Regulation (EU) 2015/2283

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001¹, and in particular Article 12 thereof,

Whereas:

- (1) Pursuant to Article 8 of Regulation (EU) 2015/2283, the Commission was to establish, by 1 January 2018, the Union list of novel foods authorised or notified under Regulation (EC) No 258/97 of the European Parliament and of the Council².
- (2) The Union list of novel foods authorised or notified under Regulation (EC) No 258/97 was established by Commission Implementing Regulation (EU) 2017/2470³.
- (3) The Commission has identified errors in the Annex to Implementing Regulation (EU) 2017/2470. Corrections are needed in order to provide clarity and legal certainty to food business operators and to the Member States' competent authorities, thus providing for the proper implementation and use of the Union list of novel foods.
- (4) The novel food 'Arachidonic acid-rich oil from the fungus *Mortierella alpine*' was authorised under certain conditions of use by Commission Decision 2008/968/EC⁴ and

¹ OJ L 327, 11.12.2015, p. 1.

² Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

³ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁴ Commission Decision 2008/968/EC of 12 December 2008 authorising the placing on the market of arachidonic acid-rich oil from *Mortierella alpina* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 344, 20.12.2008, p. 123).

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by the Dutch competent authority⁵. The food category ‘Foods for special medical purposes for premature infants as defined in Regulation (EU) No 609/2013’ erroneously refers only to premature infants although the authorisation in the food category concerned should cover infants without being restricted to premature infants. Therefore, a correction of the entry ‘Arachidonic acid-rich oil from the fungus *Mortierella alpin*~~ae~~’ in Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.

- (5) The novel food ‘Calcium L-Methylfolate’ was authorised under certain conditions of use by the Irish competent authority in January 2008. The novel food was erroneously omitted in the Union list. Therefore, a new entry should be added to Tables 1 and 2 of the Annex to Implementing Regulation (EU) 2017/2470.
- (6) The novel food ‘Lacto-N-tetraose (‘LNT’) (microbial source)’ was authorised under certain conditions of use by Commission Implementing Regulation (EU) 2020/484⁶. In the specifications, the minor ingredient ‘lacto-N-triose II’ is erroneously referred to as ‘lacto-N-tetraose II’. Therefore, the specifications of the ‘Lacto-N-tetraose (‘LNT’) (microbial source)’ relating to lacto-N-tetraose II in Table 2 of the Annex to Implementing Regulations (EU) 2020/484 and (EU) 2017/2470 should be corrected accordingly.
- (7) Implementing Regulations (EU) 2017/2470 and (EU) 2020/484 should be corrected accordingly.
- (8) Sacha inchi oil (inclusion in FS)
- (7)(9) Clarification on Ilex guayusa (where appropriate)
- (8)(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2017/2470 is corrected in accordance with the Annex to this Regulation.

Article 2

The Annex to Implementing Regulation (EU) 2020/484 is corrected in accordance with the Annex to this Regulation.

⁵ Letter of 11 December 2011 (https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_authorisation_2011_auth-letter_arachidonic_acid_rich_oil_en.pdf)

⁶ Commission Implementing Regulation (EU) 2020/484 of 2 April 2020 authorising the placing on the market of lacto-N-tetraose as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 103, 3.4.2020, p. 3).

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Article 3

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

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

Done at Brussels,

*For the Commission
The President
Ursula von der LEYEN*