

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

of **XXX**

correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods, Implementing Regulation (EU) 2023/2210 authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of *Escherichia coli* K-12 DH1 as a novel food, and Implementing Regulation (EU) 2022/1365 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food *Schizochytrium* sp. oil rich in DHA and EPA

(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 Articles 8 and 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 ensuring the proper implementation and use of the Union list of novel foods.

¹ OJ L 327, 11.12.2015, p. 1. ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>.

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). ELI: <http://data.europa.eu/eli/reg/1997/258/oj>.

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). ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj.

- (4) The conditions of use of 3-Fucosyllactose (3-FL) produced by a derivative strain of *Escherichia coli* K-12 DH1 authorised as a novel food by Implementing Regulation (EU) 2023/2210⁴ did erroneously not include foods for special medical purposes as defined in Regulation (EU) 609/2013 of the European Parliament and of the Council⁵ intended for infants and young children purposes which was requested by the applicant and was assessed by the European Food Safety Authority ('the Authority') in its opinion⁶ on this novel food. In that opinion the authority concluded that the use of 3-FL in food for special medical purposes intended for infants and young children should not be higher than the maximum levels specified for the proposed uses in the corresponding food categories for this group of the population which would be the 1.75 g/L maximum levels authorised in infant formula and follow on formula. It is therefore appropriate that this use is added in the conditions of use of this novel food and Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 and Implementing Regulation (EU) 2023/2210 are corrected accordingly.
- (5) Pursuant to Article 4(2) of Regulation (EC) No 258/97⁷, *Schizochytrium* sp. oil rich in DHA and EPA was first authorised in 2012 by the competent authority of the United Kingdom to be placed on the market as a novel food for use in a number of foods, including food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council⁸ intended for 'normal population' at levels of 250 mg/day, and in food supplements intended for pregnant and lactating women at 450 mg/day. The normal population is to be considered as the general population. However, it should be noted that the application included an intake assessment concerning the general population, excluding children below 18 months of age.
- (6) In 2015, Commission Implementing Decision (EU) 2015/546⁹ authorised a change of the conditions of use of *Schizochytrium* sp. oil rich in DHA and EPA concerning an increase of maximum levels of DHA and EPA in food supplements for the adult population, excluding pregnant and lactating women, to 3 000 mg/day.

⁴ Commission Implementing Regulation (EU) 2023/2210 of 20 October 2023 authorising the placing on the market of 3-Fucosyllactose produced by a derivative strain of *Escherichia coli* K-12 DH1 as a novel food and amending Implementing Regulation (OJ L 2023/2210, 23.10.2023 ELI: http://data.europa.eu/eli/reg_impl/2023/2210/oj.

⁵ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35) ELI: <http://data.europa.eu/eli/reg/2013/609/oj>.

⁶ Safety of 3-fucosyllactose (3-FL) produced by a derivative strain of *Escherichia coli* K-12 DH1 as a novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal 2023;21(6):8026.

⁷ 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).

⁸ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51) ELI: <http://data.europa.eu/eli/dir/2002/46/oj>.

⁹ Commission Implementing Decision (EU) 2015/546 of 31 March 2015 authorising an extension of use of DHA and EPA-rich oil from the micro-algae *Schizochytrium* sp. as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 90, 2.4.2015) p. 11. ELI: http://data.europa.eu/eli/dec_impl/2015/546/oj.

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

- (7) When the initial Union list of novel foods was established by Implementing Regulation (EU) 2017/2470, the use of this novel food in food supplements for children from 18 months to 18 years of age at levels of 250 mg/day was erroneously omitted. In addition, although the conditions of use of *Schizochytrium* sp. oil rich in DHA and EPA were amended by Commission Implementing Regulation (EU) 2022/1365, this amendment did not include the use of this novel food in food supplements for children from 18 months to 18 years of age at levels of 250 mg/day. It is therefore necessary to correct Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 and Implementing Regulation (EU) 2022/1365¹⁰ to include the use of the novel food *Schizochytrium* sp. oil rich in DHA and EPA in food supplements for children from 18 months to 18 years of age at levels of 250 mg/day.
- (8) 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 Annex I to this Regulation.

Article 2

Implementing Regulation (EU) 2022/1365 is corrected in accordance with Annex II to this Regulation.

Article 3

Implementing Regulation (EU) 2023/2210 is corrected in accordance with Annex III to this Regulation.

¹⁰ Commission Implementing Regulation (EU) 2022/1365 of 4 August 2022 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food *Schizochytrium* sp. oil rich in DHA and EPA. (OJ L 205, 5.6.2022, p. 230). ELI: http://data.europa.eu/eli/reg_impl/2022/1365/oj

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Article 4

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

Done at Brussels,

*For the Commission
The President
Ursula von der LEYEN*

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