

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1318

of 9 August 2021

correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods, Decision 2008/968/EC authorising the placing on the market of arachidonic acid-rich oil from *Mortierella alpina* as a novel food ingredient and Implementing Regulation (EU) 2020/484 authorising the placing on the market of lacto-N-tetraose as a novel food

(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 1852/2001 ⁽¹⁾, 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 Council ⁽²⁾.
- (2) The Union list of novel foods authorised or notified under Regulation (EC) No 258/97 was established by Commission Implementing Regulation (EU) 2017/2470 ⁽³⁾.
- (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 alpina*' was authorised under certain conditions of use by Commission Decision 2008/968/EC ⁽⁴⁾, by the Dutch competent authority ⁽⁵⁾, and also pursuant to Article 5 of Regulation (EC) No 258/97. The related 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 refer to infants without being restricted to premature infants. Therefore, it is necessary to correct Article 1 of the Decision 2008/968/EC and the entry 'Arachidonic acid-rich oil from the fungus *Mortierella alpina*' in Table 1 of the Annex to Implementing Regulation (EU) 2017/2470.

⁽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).

⁽⁵⁾ Letter of 19 December 2011 (https://ec.europa.eu/food/system/files/2016-10/novel-food_authorisation_2011_auth-letter_arachidonic_acid_rich_oil_en.pdf).

- (5) The novel food 'Calcium L-Methylfolate' was authorised under certain conditions of use by the Irish competent authority in January 2008 under the provisions of Regulation (EC) No 258/97, on the basis of a favourable opinion on the safety of the novel food by the European Food Safety Authority ⁽⁶⁾. The novel food was erroneously not included in the initial Union list. It is therefore appropriate that 'Calcium L-Methylfolate' is added to the Union list of authorised novel foods, taking also into account that 'Calcium L-Methylfolate' was authorised as a source of folate in infant formula, follow-on formula, processed cereal-based food and baby food by Commission Delegated Regulation (EU) 2021/571 ⁽⁷⁾.
- (6) The novel food 'Lacto-N-tetraose (LNT) (microbial source)' was authorised under certain conditions of use by Commission Implementing Regulation (EU) 2020/484 ⁽⁸⁾. In the specifications, the chemical formula of Lacto-N-tetraose was erroneously referred to as C₂₆H₄₅O₂₁ instead of the correct C₂₆H₄₅NO₂₁. In the description of Lacto-N-tetraose, the wording of 'or agglomerates' was erroneously omitted, and 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 the chemical formula of Lacto-N-tetraose and to lacto-N-tetraose II in Table 2 of the Annex to Implementing Regulation (EU) 2020/484 and Implementing Regulation (EU) 2017/2470 should be corrected accordingly.
- (7) Decision 2008/968/EC and Implementing Regulations (EU) 2017/2470 and (EU) No 2020/484 should be corrected accordingly.
- (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 second paragraph of Article 1 of the Decision 2008/968/EC is corrected as follows:

'The addition of fungal oil from *Mortierella alpina* to infant formulae and follow-on formulae shall be limited by its content of arachidonic acid according to the rules specified in Annex I, 5.7 and in Annex II, 4.7 to Directive 2006/141/EC. Its use in formulae for infants shall be in accordance with the provisions of Council Directive 89/398/EEC ^(*) on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses.

^(*) Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ L 186, 30.6.1989, p. 27).'

Article 2

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

Article 3

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

⁽⁶⁾ <https://doi.org/10.2903/j.efsa.2004.135>.

⁽⁷⁾ Commission Delegated Regulation (EU) 2021/571 of 20 January 2021 amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the list of substances that may be added to infant and follow-on formula, baby food and processed cereal-based food (OJ L 120, 8.4.2021, p. 1).

⁽⁸⁾ 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).

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*.

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

Done at Brussels, 9 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

(1) The Annex to Implementing Regulation (EU) 2017/2470 is corrected as follows:

(a) the entry for 'Arachidonic acid-rich oil from the fungus *Mortierella alpina*' in Table 1 (Authorised novel foods) is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
	<i>Specified food category</i>	<i>Maximum levels</i>		
"Arachidonic acid-rich oil from the fungus <i>Mortierella alpina</i>"	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from <i>Mortierella alpina</i> ' or ' <i>Mortierella alpina</i> oil'	
	Foods for special medical purposes for infants as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013		

(b) the following entry is inserted between the entry for '*Calanus finmarchicus* oil' and the entry for 'Chewing gum base (monomethoxypolyethylene glycol)' in Table 1 (Authorised novel foods) and Table 2 (Specifications):

— Table 1:

"Calcium L-Methylfolate"	<i>Specified food category</i>	<i>Maximum levels (expressed as folic acid)</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Calcium L-Methylfolate'."	
	Foods for special medical purposes and total diet replacement for weight control as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013		
Infant formulae and follow-on formula as defined by Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			
Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	In accordance with Directive 2002/46/EC			
Food fortified in accordance with Regulation (EC) No 1925/2006	In accordance with Regulation (EU) No 1925/2006			

<p>“Calcium L-Methylfolate</p>	<p>Description: The novel food is produced by chemical synthesis starting from folic acid. It is a white to light yellowish, almost odourless, crystalline powder, sparingly soluble in water and very slightly soluble or insoluble in most organic solvents.</p> <p>Definition: Chemical formula: $C_{20}H_{23}CaN_7O_6$ Systematic name: N-{4-[[[(6S)-2-amino-1,4,5,6,7,8-hexahydro-5-methyl-4-oxo-6-pteridiny]methyl]amino]benzoyl}-L-glutamic acid, calcium salt. CAS Numbers: 129025-21-4 (Calcium salt with an unspecified ratio of L-5-MTHF/Ca^{2+}) and 151533-22-1 (Calcium salt with specified 1:1 ratio of L-5-MTHF/Ca^{2+}). Molecular weight: 497,5 Daltons Synonyms: L-methylfolate, calcium; L-5-methyltetrahydrofolic acid, calcium salt [(L-5-MTHF-Ca)]; (6S)-5-methyltetrahydrofolic acid, calcium salt [(6S)-5-MTHF-Ca]; (6S)-5-methyl-5,6,7,8-tetrahydropteroyl-L-glutamic acid, calcium salt, and L-5-methyl-tetrahydrofolic acid (L-5-MTHF) without the cation specified. Structural formula:</p> <p>Characteristics Purity: > 95 % (Dry basis) Water: ≤ 17.0 % Calcium (on anhydrous and solvent free basis): 7.0 – 8.5 % Calcium D-methylfolate (6R, αS isomer): ≤ 1.0 %</p>
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	<p>Other folates and related substances: ≤ 2.5 %</p> <p>Ethanol: ≤ 0.5 %</p> <p>Lead: ≤ 1 mg/kg</p> <p>Boron: ≤ 10 mg/kg</p> <p>Cadmium ≤ 0.5 mg/kg</p> <p>Mercury ≤ 1.0 mg/kg</p> <p>Arsenic ≤ 1.5 mg/kg</p> <p>Platinum ≤ 2 mg/kg</p> <p>Microbiological criteria:</p> <p>Total viable aerobic counts: ≤ 1 000 CFU/g</p> <p>Total yeast and mould count: ≤ 100 CFU/g</p>
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CFU: Colony Forming Units”

(2) Point (2) of the Annex to Implementing Regulation (EU) 2020/484 is corrected as follows:

The entry for ‘Lacto-N-tetraose (‘LNT’) (microbial source)’ in Table 2 (Specifications) is replaced by the following:

<p>“Lacto-N-tetraose (‘LNT’) (microbial source)</p>	<p>Definition: Chemical formula: C₂₆H₄₅NO₂₁ Chemical name: β-D-Galactopyranosyl-(1 → 3)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1 → 3)-β-D-galactopyranosyl-(1 → 4)-D-glucopyranose Molecular mass: 707.63 Da CAS No 14116-68-8</p> <p>Description: Lacto-N-tetraose is a purified, white to off-white amorphous powder or agglomerates that is produced by a microbial process.</p> <p>Source: Genetically modified strain of <i>Escherichia coli</i> strain K-12 DH1</p> <p>Characteristics/Composition: Appearance: White to off white powder or agglomerates Sum of lacto-N-tetraose, D-Lactose and lacto-N-triose II (% of dry matter): ≥ 90.0 % (w/w) Lacto-N-tetraose (% of dry matter): ≥ 70.0 % (w/w) D-Lactose: ≤ 12.0 % (w/w)</p>
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Lacto-N-triose II: ≤ 10.0 % (w/w)
Para-lacto-N-hexaose-2: ≤ 3.5 % (w/w)
Lacto-N-tetraose fructose isomer: ≤ 1.0 % (w/w)
Sum of other carbohydrates: ≤ 5.0 % (w/w)
Moisture: ≤ 6.0 % (w/w)
Ash, sulfated: ≤ 0.5 % (w/w)
pH (20 °C, 5 % solution): 4.0 -6.0
Residual protein: ≤ 0.01 % (w/w)
Microbiological criteria:
Aerobic mesophilic bacteria total plate count: $\leq 1\ 000$ CFU/g
Enterobacteriaceae: ≤ 10 CFU/g
Salmonella spp.: Negative/25 g
Yeast: ≤ 100 CFU/g
Mould: ≤ 100 CFU/g
Residual endotoxins: ≤ 10 EU/mg

CFU: Colony Forming Units”
