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## ANNEX

The Annex is amended as follows.

- (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
Arachidonic acid-rich oil from the fungus <i>Mortierella alpina</i>	Specified food category	Maximum levels	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'	
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013		
	Foods for special medical purposes for infants as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013		

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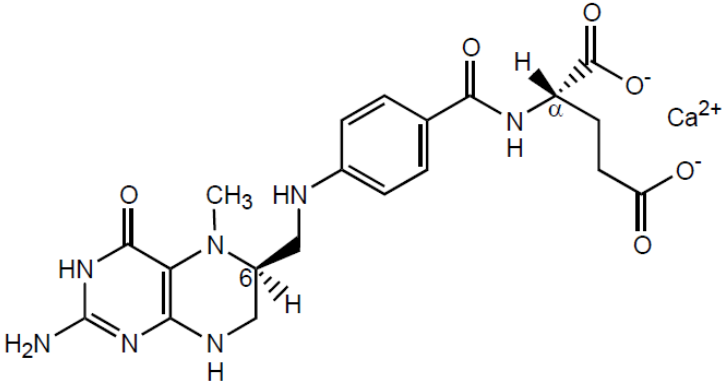
- (b) the following entry is inserted between the entry for ‘*Calanus finmarchicus* oil’ and the entry for ‘Chewing gum base (monomethoxypolyethylene glycol)’ in Tables 1 (Authorised novel foods) and 2 (Specifications):

Table 1

‘Calcium L-Methylfolate	Specified food category	Maximum levels <u>(expressed as folic acid)</u>	The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Calcium Methylfolate’.
	Foods for special medical purposes <u>and total dietary replacement for weight control</u> as defined in Regulation (EU) No 609/2013	1mg/day for adults	
	Infant formulae <u>and follow-on formula</u> as defined by Regulation (EU) No 609/2013	<u>28.6 µg/100 kcal</u>	
	<u>Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013</u>	<u>50 µg/100 kcal</u>	
	Food supplements as defined in Directive 2002/46/EC	1mg/day for adults	
	<u>Processed foods, except alcoholic beverages-Food as defined in Regulation (EC) No 1925/2006</u>	1mg/day for adults	

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Table 2

<p><b>‘Calcium L-Methylfolate</b></p>	<p><b>Definition</b></p> <p>Chemical formula: <math>\text{CaC}_{20}\text{H}_{23}\text{CaN}_7\text{O}_6</math></p> <p>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.</p> <p>CAS Numbers: 129025-21-4 (Calcium salt with an unspecified ratio of L-5-MTHF/<math>\text{Ca}^{2+}</math>) and 151533-22-1 (Calcium salt with specified 1:1 ratio of L-5-MTHF/<math>\text{Ca}^{2+}</math>).</p> <p>Molecular weight: 497.5 Daltons</p> <p>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.</p> <p>Structural formula:</p>  <p><b>Description</b></p> <p>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><b>Characteristics</b></p> <p>Purity: &gt; 95% w/w</p> <p>Water: ≤ 17.0%</p>
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	<p>Calcium (on anhydrous and solvent free basis): 7.0 - 8.5%</p> <p>D-methylfolate (6R, <math>\alpha</math>S isomer): <math>\leq 1.0\%</math></p> <p>Other folates and related substances: <math>\leq 2.5\%</math></p> <p>Ethanol: <math>\leq 0.5\%</math></p> <p>Lead: <math>\leq 20</math> mg/kg</p> <p>Boron: <math>\leq 20</math> mg/kg</p> <p><a href="#">Cadmium <math>\leq 0.5</math> mg/kg</a></p> <p><a href="#">Mercury <math>\leq 1.0</math> mg/kg</a></p> <p><a href="#">Arsenic <math>\leq 1.5</math> mg/kg</a></p> <p><a href="#">Platinum <math>\leq 2</math> mg/kg</a></p> <p><b>Microbiological criteria:</b></p> <p>Total viable aerobic counts: <math>\leq 1000</math> CFU/g</p>
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CFU: Colony Forming Units'

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(2) Annex I 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><b>Lacto-<i>N</i>-tetraose ('LNT') (microbial source)</b></p>	<p><b>Definition:</b>            Chemical formula: C<sub>26</sub>H<sub>45</sub>O<sub>21</sub>            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><b>Description:</b>            Lacto-<i>N</i>-tetraose is a purified, white to off-white amorphous powder that is produced by a microbial process.</p> <p><b>Source:</b> Genetically modified strain of <i>Escherichia coli</i> strain K-12 DH1</p> <p><b>Characteristics/Composition:</b>            Appearance: White to off white powder            Sum of lacto-<i>N</i>-tetraose, D-Lactose and lacto-<i>N</i>-triose II (% of dry matter): ≥ 90,0 % (w/w)            Lacto-<i>N</i>-tetraose (% of dry matter): ≥ 70,0 % (w/w)            D-Lactose: ≤ 12,0% (w/w)            Lacto-<i>N</i>-triose II: ≤ 10,0 % (w/w)            Para-lacto-<i>N</i>-hexaose-2: ≤ 3,5 % (w/w)            Lacto-<i>N</i>-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)</p> <p><b>Microbiological criteria:</b>            Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g  <i>Enterobacteriaceae</i>: ≤ 10 CFU/g  <i>Salmonella</i> sp.: Negative/25 g            Yeast: ≤ 100 CFU/g</p>
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	Mould: $\leq 100$ CFU/g Residual endotoxins: $\leq 10$ EU/mg
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CFU: Colony Forming Units'

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