

COMMISSION IMPLEMENTING REGULATION (EU) 2022/202
of 14 February 2022
correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods
(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 8 thereof,

After consulting the Standing Committee on Plants, Animals, Food and Feed,

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 ensuring the proper implementation and use of the Union list of novel foods.
- (4) The novel food '*Cistus incanus* L. *Pandalis* herb' was authorised under certain conditions of use by the Czech competent authority pursuant to Article 5 of Regulation (EC) No 258/97. The specifications for this novel food erroneously omitted that the novel food consists of the dried and cut aerial parts (young shoots with woody parts) of *Cistus incanus* L. *Pandalis*. Furthermore, the specifications erroneously added detailed composition information on the novel food that the applicant had submitted as complementary information, which was not included in the opinion delivered by the Czech competent authority and is not needed for the safety assessment or the product characterisation. This information should thus be removed. Therefore, the specifications concerning '*Cistus incanus* L. *Pandalis* herb' in Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 should be corrected.

⁽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).

- (5) Commission Implementing Regulation (EU) 2021/1318 ⁽⁴⁾ corrected the Union list of authorised novel foods to include the novel food 'Calcium L-Methylfolate' which, although authorised in January 2008 by the Irish competent authority under certain conditions of use in accordance with Regulation (EC) No 258/97, was erroneously not included in the Union list when the initial list was established. The conditions of use of 'Calcium L-Methylfolate' in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽⁵⁾, that were included in the Union list, erroneously excluded infants and young children from the targeted users' group, whereas the original authorisation did authorise that use. Therefore, a correction of the entry 'Calcium L-Methylfolate' in Table 1 of the Annex to Implementing Regulation (EU) 2017/2470 is necessary.
- (6) The specification limits for mercury ($\leq 1,0$ mg/kg) and platinum (≤ 2 mg/kg) for 'Calcium L-Methylfolate' laid down in Implementing Regulation (EU) 2021/1318 refer to the limits in the specifications of this novel food 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 ⁽⁶⁾. However, the specification limits of $\leq 1,5$ mg/kg for mercury and ≤ 10 mg/kg for platinum were also originally authorised by the Irish competent authority in 2008, based on a favourable opinion on the safety of the novel food by the European Food Safety Authority ⁽⁷⁾. It is therefore necessary to correct Table 2 of the Annex to Implementing Regulation (EU) 2017/2470 accordingly.
- (7) Implementing Regulation (EU) 2017/2470 containing Union list of novel foods should be corrected accordingly.

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

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, 14 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁴⁾ 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 (OJ L 286, 10.8.2021, p. 5).

⁽⁵⁾ 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).

⁽⁶⁾ 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).

⁽⁷⁾ The EFSA Journal (2004) 135, 1-20.

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

(1) the entry for 'Calcium L-Methylfolate' is replaced by the following:

(a) in Table 1 (Authorised novel foods):

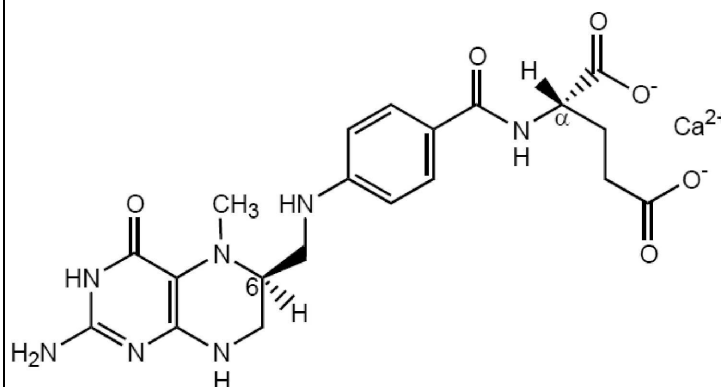
Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'Calcium L-Methylfolate'	<i>Specified food category</i>	<i>Maximum levels (expressed as folic acid)</i>	The designation of the novel food on the labelling of the foodstuffs 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	In accordance with Directive 2002/46/EC		
	Food fortified in accordance with Regulation (EC) No 1925/2006	In accordance with Regulation (EC) No 1925/2006		

and

(b) in Table 2 (Specifications):

Authorised Novel Food	Specifications
'Calcium L-Methylfolate'	<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: $C_{20}H_{23}CaN_7O_6$</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.
 CAS Numbers: 129025-21-4 (Calcium salt with an unspecified ratio of L-5-MTHF/Ca²⁺) and 151533-22-1 (Calcium salt with specified 1:1 ratio of L-5-MTHF/Ca²⁺).
 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:



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 %

Other folates and related substances: ≤ 2,5 %

Ethanol: ≤ 0,5 %

Contaminants

Infants and young children	General population excluding infants and young children
Lead: ≤ 1 mg/kg	Lead: ≤ 1 mg/kg
Boron: ≤ 10 mg/kg	Boron: ≤ 10 mg/kg
Cadmium ≤ 0,5 mg/kg	Cadmium ≤ 0,5 mg/kg
Mercury ≤ 1,0 mg/kg	Mercury ≤ 1,5 mg/kg

	Arsenic ≤ 1,5 mg/kg	Arsenic ≤ 1,5 mg/kg
	Platinum ≤ 2 mg/kg	Platinum ≤ 10 mg/kg
	Microbiological criteria: Total viable aerobic counts: ≤ 1 000 CFU/g Total yeast and mould count: ≤ 100 CFU/g	
CFU: Colony Forming Units'		

(2) the entry for '*Cistus incanus* L. Pandalis herb' in Table 2 (Specifications) is replaced by the following:

Authorised Novel Food	Specifications
' <i>Cistus incanus</i> L. Pandalis herb'	Description: <i>Cistus incanus</i> L. Pandalis herb; species belonging to the Cistaceae family and native to the Mediterranean region, Chalkidiki Peninsula. The novel food consists of the dried and cut aerial parts (young shoots with woody parts) of <i>Cistus incanus</i> L. Pandalis'