

Official Journal of the European Union

L 286



English edition

Legislation

Volume 64

10 August 2021

Contents

II Non-legislative acts

REGULATIONS

- ★ **Commission Regulation (EU) 2021/1317 of 9 August 2021 amending Regulation (EC) No 1881/2006 as regards maximum levels of lead in certain foodstuffs ⁽¹⁾** 1
- ★ **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 ⁽¹⁾** 5
- ★ **Commission Implementing Regulation (EU) 2021/1319 of 9 August 2021 authorising changes in the specifications of the novel food Coriander seed oil from *Coriandrum sativum* and amending Implementing Regulation (EU) 2017/2470 ⁽¹⁾** 12

DECISIONS

- ★ **Council Decision (EU) 2021/1320 of 30 July 2021 appointing an alternate member, proposed by the Hellenic Republic, of the Committee of the Regions** 16
- ★ **Commission Implementing Decision (EU) 2021/1321 of 6 August 2021 amending the Annex to Decision 2007/453/EC as regards the BSE status of Canada and Ireland (notified under document C(2021) 5789) ⁽¹⁾** 17

⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2021/1317

of 9 August 2021

amending Regulation (EC) No 1881/2006 as regards maximum levels of lead in certain foodstuffs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ⁽¹⁾, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006 ⁽²⁾ sets maximum levels for lead (Pb) in a range of foodstuffs.
- (2) On 18 March 2010, the European Food Safety Authority ('the Authority') adopted an opinion on lead in food ⁽³⁾. The Authority identified that lead can cause developmental neurotoxicity in young children and cardiovascular issues and nephrotoxicity in adults. The risk assessment for lead was based on these potentially critical adverse effects. The Authority concluded that there was no evidence for a threshold for a number of critical endpoints, including developmental neurotoxicity and adult nephrotoxicity. Therefore, it was not appropriate to derive a tolerable weekly intake. The Authority expressed a concern that there was potential that the current levels of dietary exposure to lead might affect neurodevelopment in fetuses, infants and children.
- (3) The Authority's conclusions were confirmed by the conclusions of the report of the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (FAO/WHO) in 2010 ⁽⁴⁾.
- (4) Taking into account the most recent occurrence data, the Codex Alimentarius Commission at its 41th Session ('CAC41') lowered the Codex maximum level for lead in salt (excluding salt from marshes) from 2 mg/kg to 1 mg/kg.
- (5) Taking into account the most recent occurrence data, the Codex Alimentarius Commission at its 42nd Session ('CAC42') lowered the Codex maximum levels of 0,5 mg/kg for edible offal to 0,2 mg/kg for edible offal from cattle, 0,15 mg/kg for edible offal from pigs and 0,1 mg/kg for edible offal from poultry. It also lowered the maximum levels for 'wine made from grapes' from 0,2 mg/kg to 0,1 mg/kg and set a maximum level for fortified/liqueur 'wines made from grapes' at 0,15 mg/kg. Both maximum levels apply to wine made from grapes harvested after the date the CAC42 adopted the maximum levels.

⁽¹⁾ OJ L 37, 13.2.1993, p. 1.

⁽²⁾ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

⁽³⁾ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2010. Scientific Opinion on lead in food. *EFSA Journal* 2010;8(4):1570, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2010.1570>

⁽⁴⁾ Evaluation of Certain Food Additives and Contaminants. Seventy-third report of the joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 960.

- (6) In light of these developments and of the most recent occurrence data, the dietary exposure to lead in food should be reduced within the Union by lowering the existing maximum levels or setting additional maximum levels for foodstuffs for which lower levels of lead are reasonably achievable, namely offal, certain foods for infants and young children, salt and wild fungi. For the same reasons, the maximum levels for lead in wines should be reduced and a maximum level for liqueur wine should be established as regards those products produced from future harvests. Finally, for those same reasons, but also to help fight fraudulent practices, such as the addition of lead chromate to turmeric, maximum levels for spices should be established.
- (7) Regulation (EC) No 1881/2006 should therefore be amended accordingly.
- (8) Given that lead is a weak indirect genotoxic carcinogen, and consequently its presence is a higher risk for public health, products not complying with the new maximum levels for lead and placed on the market before the entry into force of this Regulation should only be allowed to remain on the market for a short period of time.
- (9) 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 Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation.

Article 2

Foodstuffs listed in the Annex that were lawfully placed on the market before the entry into force of this Regulation may remain on the market until 28 February 2022.

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, 9 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Section 3: Metals of the Annex to Regulation (EC) No 1881/2006, subsection 3.1. (Lead) is replaced by the following:

	Foodstuffs ⁽¹⁾	Maximum level (mg/kg wet weight)
3.1	Lead	
3.1.1	Raw milk ⁽⁶⁾ , heat-treated milk and milk for the manufacture of milk-based products	0,020
3.1.2	Infant formulae, follow-on formulae and young child formulae ⁽⁵⁷⁾	
	marketed as powder ⁽³⁾ ⁽²⁹⁾	0,020
	marketed as liquid ⁽³⁾ ⁽²⁹⁾	0,010
3.1.3	Processed cereal-based foods and baby foods for infants and young children ⁽³⁾ ⁽²⁹⁾ other than those listed under point 3.1.5.	0,020
3.1.4	Foods for special medical purposes intended for infants and young children	
	marketed as powder ⁽³⁾ ⁽²⁹⁾	0,020
	marketed as liquid ⁽³⁾ ⁽²⁹⁾	0,010
3.1.5	Drinks for infants and young children labelled and sold as such, other than those mentioned under points 3.1.2 and 3.1.4	
	marketed as liquids or to be reconstituted following instructions of the manufacturer including fruit juices ⁽⁴⁾	0,020
	to be prepared by infusion or decoction ⁽²⁹⁾	0,50
3.1.6	Meat (excluding offal) of bovine animals, sheep, pig and poultry ⁽⁶⁾	0,10
3.1.7	Offal ⁽⁶⁾	
	of bovine animals and sheep	0,20
	of pig	0,15
	of poultry	0,10
3.1.8	Muscle meat of fish ⁽²⁴⁾ ⁽²⁵⁾	0,30
3.1.9	Cephalopods ⁽⁵²⁾	0,30
3.1.10	Crustaceans ⁽²⁶⁾ ⁽⁴⁴⁾	0,50
3.1.11	Bivalve molluscs ⁽²⁶⁾	1,50
3.1.12	Cereals and pulses	0,20
3.1.13	Root and tuber vegetables (excluding salsifies, fresh ginger and fresh turmeric), bulb vegetables, flowering brassica, head brassica, kohlrabies, legume vegetables and stem vegetables ⁽²⁷⁾ ⁽⁵³⁾	0,10
3.1.14	Leafy brassica, salsify, the following fungi <i>Agaricus bisporus</i> (common mushroom), <i>Pleurotus ostreatus</i> (Oyster mushroom), <i>Lentinula edodes</i> (Shiitake mushroom) and leafy vegetables (excluding fresh herbs) ⁽²⁷⁾	0,30
3.1.15	Wild fungi, fresh turmeric and fresh ginger	0,80

3.1.16	Fruiting vegetables	
	sweetcorn ⁽²⁷⁾	0,10
	other than sweetcorn ⁽²⁷⁾	0,05
3.1.17	Fruit, excluding cranberries, currants, elderberries and strawberry tree fruit ⁽²⁷⁾	0,10
3.1.18	Cranberries, currants, elderberries and strawberry tree fruit ⁽²⁷⁾	0,20
3.1.19	Fats and oils, including milk fat	0,10
3.1.20	Fruit juices, concentrated fruit juices as reconstituted and fruit nectars	
	exclusively from berries and other small fruits ⁽¹⁴⁾	0,05
	from fruits other than berries and other small fruits ⁽¹⁴⁾	0,03
3.1.21	Wine (including sparkling wine, excluding liqueur wine), cider, perry and fruit wine ⁽¹¹⁾	
	products produced from the 2001 fruit harvest to the 2015 fruit harvest	0,20
	products produced from the 2016 fruit harvest to the 2021 fruit harvest	0,15
	products produced from the 2022 fruit harvest onwards	0,10
3.1.22	Aromatised wine, aromatised wine-based drinks and aromatised wine-product cocktails ⁽¹³⁾	
	products produced from the 2001 fruit harvest to the 2015 fruit harvest	0,20
	products produced from the 2016 fruit harvest to the 2021 fruit harvest	0,15
	products produced from the 2022 fruit harvest onwards	0,10
3.1.23	Liqueur wine made from grapes (*)	
	products produced from the 2022 fruit harvest onwards	0,15
3.1.24	Food supplements ⁽³⁹⁾	3,0
3.1.25	Honey	0,10
3.1.26	Dried spices ⁽²⁹⁾	
	Fruit spices	0,60
	Root and rhizome spices	1,50
	Bark spices	2,0
	Bud spices and flower pistil spices	1,0
	Seed spices	0,90
3.1.27	Salt, except the following unrefined salts: 'fleur de sel' and 'grey salt' which are manually harvested from salt marshes with a clay bottom	1,0
	The following unrefined salts: 'fleur de sel' and 'grey salt' which are manually harvested from salt marshes with a clay bottom	2,0

(*) As defined in Part II of Annex VII to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).'

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 $C_{26}H_{45}O_{21}$ instead of the correct $C_{26}H_{45}NO_{21}$. 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:

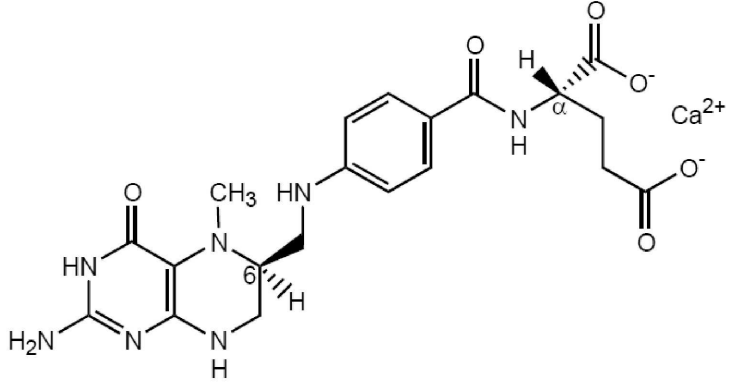
(a) the entry for ‘Arachidonic acid-rich oil from the fungus *Mortierella alpina*’ in Table 1 (Authorised novel foods) is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
“Arachidonic acid-rich oil from the fungus <i>Mortierella alpina</i>”	<i>Specified food category</i>	<i>Maximum levels</i>	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		

(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		

“Calcium L-Methylfolate	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. 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:  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: $\leq 2.5 \%$ Ethanol: $\leq 0.5 \%$ Lead: $\leq 1 \text{ mg/kg}$ Boron: $\leq 10 \text{ mg/kg}$ Cadmium $\leq 0.5 \text{ mg/kg}$ Mercury $\leq 1.0 \text{ mg/kg}$ Arsenic $\leq 1.5 \text{ mg/kg}$ Platinum $\leq 2 \text{ mg/kg}$ Microbiological criteria: Total viable aerobic counts: $\leq 1\,000 \text{ CFU/g}$ Total yeast and mould count: $\leq 100 \text{ CFU/g}$
--	--

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:

“Lacto-N-tetraose (‘LNT’) (microbial source)”	Definition: Chemical formula: $\text{C}_{26}\text{H}_{45}\text{NO}_{21}$ Chemical name: $\beta\text{-D-Galactopyranosyl-(1}\rightarrow\text{3)-2-acetamido-2-deoxy-}\beta\text{-D-glucopyranosyl-(1}\rightarrow\text{3)-}\beta\text{-D-galactopyranosyl-(1}\rightarrow\text{4)-D-glucopyranose}$ Molecular mass: 707.63 Da CAS No 14116-68-8 Description: Lacto-N-tetraose is a purified, white to off-white amorphous powder or agglomerates that is produced by a microbial process. Source: Genetically modified strain of <i>Escherichia coli</i> strain K-12 DH1 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): $\geq 90.0 \%$ (w/w) Lacto-N-tetraose (% of dry matter): $\geq 70.0 \%$ (w/w) D-Lactose: $\leq 12.0 \%$ (w/w)
---	---

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”

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1319**of 9 August 2021****authorising changes in the specifications of the novel food Coriander seed oil from *Coriandrum sativum* and amending Implementing Regulation (EU) 2017/2470****(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) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing the Union list of authorised novel foods was adopted.
- (3) Commission Implementing Decision 2014/155/EU ⁽³⁾ authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽⁴⁾, the placing on the market in the Union of coriander seed oil from *Coriandrum sativum* as a novel food ingredient to be used in food supplements.
- (4) In October 2017, the company Ovalie Innovation ('the applicant') informed the Commission of its intention to place on the market crude coriander seed oil from *Coriandrum sativum* as a novel food ingredient in accordance with Article 5 of Regulation (EC) No 258/97. Accordingly, the applicant submitted a report of the competent authority of Ireland pursuant to Article 3(4) of Regulation (EC) No 258/97, which, on the basis of the scientific evidence submitted by the applicant, had concluded that the coriander seed oil from *Coriandrum sativum* was substantially equivalent to the coriander seed oil authorised by Implementing Decision 2014/155/EU.
- (5) Commission Implementing Regulation (EU) 2019/456 ⁽⁵⁾ and Commission Implementing Regulation (EU) 2019/2165 ⁽⁶⁾ authorised changes in the specifications of the novel food coriander seed oil from *Coriandrum sativum* to decrease the lowest saponification value from 186 mg KOH/g to 179 mg KOH/g and the minimum level of oleic acid from 8,0 % to 7,0 %.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ 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).

⁽³⁾ Commission Implementing Decision 2014/155/EU of 19 March 2014 authorising the placing on the market of coriander seed oil as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 85, 21.3.2014, p. 13).

⁽⁴⁾ 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).

⁽⁵⁾ Commission Implementing Regulation (EU) 2019/456 of 20 March 2019 authorising the change of the specifications of the novel food coriander seed oil from *Coriandrum sativum* under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 79, 21.3.2019, p. 13).

⁽⁶⁾ Commission Implementing Regulation (EU) 2019/2165 of 17 December 2019 authorising the change of the specifications of the novel food coriander seed oil from *Coriandrum sativum* under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 328, 18.12.2019, p. 81).

- (6) On 12 January 2021, the applicant submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to change the specifications of the novel food 'coriander seed oil from *Coriandrum sativum*'. The applicant requested to increase the maximum level of acid value in the coriander seed oil from 2,5 mg KOH/g of oil as indicated in the Union list of novel foods to $\leq 3,5$ mg KOH/g of oil and to modify the colour description from 'slight yellow' to 'yellowish to brown' colour.
- (7) The applicant justified the request by indicating that the change is necessary in order to reflect the natural variation in the visual characteristics of coriander seed oil and in the levels of free fatty acids therein that are measured by titration with potassium hydroxide (KOH) of the seed oil obtained from the *Coriandrum sativum* plant.
- (8) The Commission considers that a safety evaluation by the European Food Safety Authority ('the Authority') of the proposed change of the specifications in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The increase in the acid value in coriander seed oil from 2,5 mg to $\leq 3,5$ mg KOH/g of oil is comparable to the acid values of other common edible oils with a long history of safe consumption, and is below the upper limit of 4,0 mg KOH/g for edible fats and oils set by the joint Food and Agriculture Organisation of the United Nations and World Health Organisation Food Standards Programme Codex Alimentarius ('FAO/WHO Codex Alimentarius') ⁽⁷⁾. On this basis, and for consistency with the FAO/WHO Codex Alimentarius standard, the Commission considers that the limit for the acid value of the coriander seed oil should also be set at 4,0 mg KOH/g. The proposed changes in the specification parameters reflecting the physical appearance of the oil are also comparable to the natural variations observed among practically all edible oils and do not affect its safety or nutritional value.
- (9) The proposed changes in the acid values and the physical appearance of coriander seed oil from *Coriandrum sativum* do not alter the conclusions of the safety assessment conducted by the Authority ⁽⁸⁾ that supported its initial authorisation. Therefore, it is appropriate to amend the specifications of the novel food coriander seed oil from *Coriandrum sativum* at the proposed acid level and as regards the physical appearance of the oil.
- (10) The information provided in the application gives sufficient grounds to establish that the proposed changes to the specifications of the novel food coriander seed oil from *Coriandrum sativum* comply with Article 12 of Regulation (EU) 2015/2283.
- (11) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (12) 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 Union list of authorised novel foods as provided for in Article 6 of Regulation (EU) 2015/2283 and included in the Annex to Implementing Regulation (EU) 2017/2470, referring to the novel food coriander seed oil from *Coriandrum sativum*, shall be amended as specified in 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*.

⁽⁷⁾ CODEX STAN 19-1981, Rev. 2 – 1999.

⁽⁸⁾ EFSA Journal 2013;11(10):3422.

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

ANNEX

In Table 2 (Specifications) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for 'coriander seed oil from *Coriandrum sativum*' is replaced by the following:

'Authorised Novel Food'	Specifications
Coriander seed oil from <i>Coriandrum sativum</i>	Description/Definition: Coriander seed oil is an oil containing glycerides of fatty acids that is produced from the seeds of the coriander plant <i>Coriandrum sativum</i> L. Yellowish to brown colour, bland taste CAS No.: 8008-52-4 Composition of fatty acids: Palmitic acid (C16:0): 2-5 % Stearic acid (C18:0): < 1,5 % Petroselinic acid (cis-C18:1(n-12)): 60-75 % Oleic acid (cis-C18:1 (n-9)): 7-15 % Linoleic acid (C18:2): 12-19 % α-Linolenic acid (C18:3): < 1,0 % Trans fatty acids: ≤ 1,0 % Purity: Refractive index (20 °C): 1.466-1.474 Acid value: ≤ 4 mg KOH/g Peroxide value (PV): ≤ 5,0 meq/kg Iodine value: 88-110 units Saponification value: 179-200 mg KOH/g Unsaponifiable matter: ≤ 15 g/kg'

DECISIONS

COUNCIL DECISION (EU) 2021/1320

of 30 July 2021

appointing an alternate member, proposed by the Hellenic Republic, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to Council Decision (EU) 2019/852 of 21 May 2019 determining the composition of the Committee of the Regions ⁽¹⁾,

Having regard to the proposal of the Greek Government,

Whereas:

- (1) Pursuant to Article 300(3) of the Treaty, the Committee of the Regions is to consist of representatives of regional and local bodies who either hold a regional or local authority electoral mandate or are politically accountable to an elected assembly.
- (2) On 20 January 2020, the Council adopted Decision (EU) 2020/102 ⁽²⁾, appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025.
- (3) An alternate member's seat on the Committee of the Regions has become vacant following the resignation of Mr Konstantinos TZIOUMIS.
- (4) The Greek Government has proposed Mr Dimitrios KAFANTARIS, representative of a local body who holds a local authority electoral mandate, Δημοτικός Σύμβουλος Δήμος Πύλου-Νέστορος (Municipal Councillor, Municipality of Pylou-Nestoros), as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025,

HAS ADOPTED THIS DECISION:

Article 1

Mr Dimitrios KAFANTARIS, representative of a local body who holds an electoral mandate, Δημοτικός Σύμβουλος Δήμος Πύλου-Νέστορος (Municipal Councillor, Municipality of Pylou-Nestoros), is hereby appointed as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 30 July 2021.

For the Council
The President
G. DOVŽAN

⁽¹⁾ OJ L 139, 27.5.2019, p. 13.

⁽²⁾ Council Decision (EU) 2020/102 of 20 January 2020 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 20, 24.1.2020, p. 2).

COMMISSION IMPLEMENTING DECISION (EU) 2021/1321**of 6 August 2021****amending the Annex to Decision 2007/453/EC as regards the BSE status of Canada and Ireland***(notified under document C(2021) 5789)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽¹⁾, and in particular Article 5(2), third subparagraph, thereof,

Whereas:

- (1) Regulation (EC) No 999/2001 provides that Member States or third countries or regions thereof (countries or regions) are to be classified according to their bovine spongiform encephalopathy (BSE) status into one of three categories: negligible BSE risk, controlled BSE risk and undetermined BSE risk.
- (2) Article 5(2), third subparagraph, of Regulation (EC) No 999/2001 provides that if the World Organisation for Animal Health (OIE) has placed an applicant country in one of the three BSE categories, a re-assessment of the BSE categorisation at Union level may be decided.
- (3) Commission Decision 2007/453/EC ⁽²⁾ lists the BSE status of countries or regions according to their BSE risk in Parts A, B or C of the Annex to that act. The countries or regions listed in Part A of that Annex are regarded as having a negligible BSE risk, those listed in Part B are regarded as having a controlled BSE risk, while Part C of that Annex provides that countries or regions not listed in Part A or B are to be regarded as having an undetermined BSE risk.
- (4) Canada and Ireland currently fall within Part B of the Annex to Decision 2007/453/EC as countries with a controlled BSE risk.
- (5) On 27 May 2021, the OIE World Assembly of Delegates adopted Resolution No 17, 'Recognition of the Bovine Spongiform Encephalopathy Risk Status of Members' ⁽³⁾, in view of an entry into force on 29 May 2021. That Resolution recognised Canada and Ireland as having a negligible BSE risk, in accordance with the Terrestrial Animal Health Code of the OIE. After reassessment of the situation at Union level, stemming from OIE Resolution No 17, the Commission has considered that the new OIE BSE status of both countries should be reflected in the Annex to Decision 2007/453/EC.
- (6) The list of countries or regions in the Annex to Decision 2007/453/EC should therefore be amended so that Canada and Ireland are listed in Part A of that Annex under countries or regions with a negligible BSE risk.
- (7) The Annex to Decision 2007/453/EC should therefore be amended accordingly.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

⁽²⁾ Commission Decision 2007/453/EC of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk (OJ L 172, 30.6.2007, p. 84).

⁽³⁾ <https://www.oie.int/app/uploads/2021/05/a-r17-2021-bse.pdf>

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2007/453/EC is replaced by the text set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 6 August 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

The Annex to Decision 2007/453/EC is replaced by the following:

'ANNEX

LIST OF COUNTRIES OR REGIONS

A. Countries or regions with a negligible BSE risk*Member States*

- Belgium
- Bulgaria
- Czechia
- Denmark
- Germany
- Estonia
- Ireland
- Spain
- Croatia
- Italy
- Cyprus
- Latvia
- Lithuania
- Luxembourg
- Hungary
- Malta
- Netherlands
- Austria
- Poland
- Portugal
- Romania
- Slovenia
- Slovakia
- Finland
- Sweden

Regions of Member States ()*

- Northern Ireland

European Free Trade Association countries

- Iceland
- Liechtenstein
- Norway
- Switzerland

Third countries

- Argentina

- Australia
- Brazil
- Canada
- Chile
- Colombia
- Costa Rica
- India
- Israel
- Japan
- Jersey
- Namibia
- New Zealand
- Panama
- Paraguay
- Peru
- Serbia (**)
- Singapore
- United States
- Uruguay

B. Countries or regions with a controlled BSE risk

Member States

- Greece
- France

Third countries

- Mexico
- Nicaragua
- South Korea
- Taiwan
- United Kingdom with the exception of Northern Ireland

C. Countries or regions with an undetermined BSE risk

- Countries or regions not listed in Parts A or B..

(*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to Member States include the United Kingdom in respect of Northern Ireland.

(**) As referred to in Article 135 of the Stabilisation and Association Agreement between the European Communities and their Member States of the one part, and the Republic of Serbia, of the other part (OJ L 278, 18.10.2013, p. 16).'

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN