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II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Notice concerning the entry into force of the Framework Agreement on Partnership and Cooperation between the European Union and its Member States, of the one part, and the Republic of the Philippines, of the other part

The Framework Agreement on Partnership and Cooperation between the European Union and its Member States, of the one part, and the Republic of the Philippines, of the other part ⁽¹⁾ entered into force on 1 March 2018, the procedure provided for in Article 57(1) of the Framework Agreement having been completed on 26 February 2018.

⁽¹⁾ OJ L 343, 22.12.2017, p. 3.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2018/460

of 20 March 2018

authorising the placing on the market of *Ecklonia cava* phlorotannins 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

(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⁾ was adopted, which establishes a Union list of authorised novel foods.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission shall submit a draft implementing act on the placing on the Union market of a novel food and on the updating of the Union list.
- (4) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽³⁾ and for which the final decision has not been taken before 1 January 2018, shall be treated as an application submitted under Regulation (EU) 2015/2283.
- (5) On 14 May 2015, the company Botamedi Inc. made a request to the competent authority of Ireland to place phlorotannins extracted from the edible marine alga *Ecklonia cava* ('*Ecklonia cava* phlorotannins') on the Union market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97. The application requests for *Ecklonia cava* phlorotannins to be used in food supplements for the general population, excluding children below 12 years of age.
- (6) While the request for placing *Ecklonia cava* phlorotannins as a novel food on the Union market was submitted in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.
- (7) On 29 March 2016, the competent authority of Ireland issued its initial assessment report. In that report it came to the conclusion that an additional assessment is required for *Ecklonia cava* phlorotannins in accordance with Article 6(3) of Regulation (EC) No 258/97.
- (8) On 10 May 2016, the Commission forwarded the initial assessment report to the other Member States. The Member States, within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97, agreed with the initial assessment report of Ireland.

⁽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⁾ 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).

- (9) In view of the initial assessment report issued by Ireland, to which the other Member States agreed, on 22 July 2016, the Commission consulted the European Food Safety Authority (EFSA), asking it to carry out an additional assessment for *Ecklonia cava* phlorotannins as a novel food ingredient in accordance with Regulation (EC) No 258/97.
- (10) On 20 September 2017, EFSA adopted ‘Scientific Opinion on the safety of *Ecklonia cava* phlorotannins as a novel food pursuant to Regulation (EC) No 258/97’ ⁽¹⁾. This opinion, although elaborated and adopted by EFSA under Regulation (EC) No 258/97, is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (11) The EFSA opinion underlined that iodine intake from food supplements containing *Ecklonia cava* phlorotannins may be of concern for people at risk of thyroid disease, and that, if people who are not at risk of thyroid disease take food supplements containing *Ecklonia cava* phlorotannins in addition to other food supplements containing iodine, their overall iodine intake may exceed the upper limit established for iodine ⁽²⁾. Food supplements containing *Ecklonia cava* phlorotannins should therefore be appropriately labelled.
- (12) Moreover, taking into account the intended use and the fact that the request for authorisation excludes children under the age of 12 years, food supplements containing *Ecklonia cava* phlorotannins should also be appropriately labelled in this regard.
- (13) It follows, that the EFSA opinion gives sufficient grounds to establish that *Ecklonia cava* phlorotannins in the proposed uses and use levels when used as an ingredient in food supplements, complies with the criteria laid down in Article 12(1) of Regulation (EU) 2015/2283
- (14) Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾ lays down requirements on food supplements. The use of *Ecklonia cava* phlorotannins should be authorised without prejudice to that Directive.
- (15) 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

1. *Ecklonia cava* phlorotannins as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods as provided for in Article 8 of Regulation (EU) 2015/2283.
2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.
3. The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

Article 2

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

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*.

⁽¹⁾ EFSA Journal 2017;15(10):5003.

⁽²⁾ Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Iodine, 7.10.2002.

⁽³⁾ 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).

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

Done at Brussels, 20 March 2018.

For the Commission

The President

Jean-Claude JUNKER

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

(1) The following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'Ecklonia cava phlorotannins	<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 ' <i>Ecklonia cava</i> Phlorotannins'.	
	Food Supplements as defined in Directive 2002/46/EC intended for the general population, excluding children under the age of 12 years	163 mg/day for adolescents from 12 to 14 years of age; 230 mg/day for adolescents above 14 years of age; 263 mg/day for adults.	Food supplements containing <i>Ecklonia cava</i> phlorotannins shall bear the following statement: (a) This food supplement should not be consumed by children/adolescents under the age of twelve/fourteen/eighteen (*) years. (b) This food supplement should not be consumed by persons with thyroid disease or by persons who are aware of or have been identified as being at risk of developing thyroid disease. (c) This food supplement should not be consumed if other food supplements containing iodine are also consumed. (*) Depending on the age group the food supplement is intended for.'	

(2) The following entry is inserted in Table 2 (Specifications) in alphabetical order:

Authorised Novel Food	Specification
'Ecklonia cava phlorotannins	Description/Definition: <i>Ecklonia cava</i> phlorotannins are obtained via alcohol extraction from the edible marine alga <i>Ecklonia cava</i>. The extract is a dark brown powder, rich in phlorotannins, polyphenolic compounds found as secondary metabolites in certain brown algae species. Characteristics/Composition Phlorotannin content: 90 ± 5 % Antioxidant activity: > 85 % Moisture: < 5 % Ash: < 5 % Microbiological criteria: Total viable cell count: < 3 000 CFU/g

Authorised Novel Food	Specification
	Mould/yeast: < 300 CFU/g Coliforms: Negative to test <i>Salmonella</i> spp.: Negative to test <i>Staphylococcus aureus</i>: Negative to test Heavy metals and Halogens: Lead: < 3,0 mg/kg Mercury: < 0,1 mg/kg Cadmium: < 3,0 mg/kg Arsenic: < 25,0 mg/kg Inorganic Arsenic: < 0,5 mg/kg Iodine: 150,0-650,0 mg/kg CFU: Colony Forming Units'

COMMISSION IMPLEMENTING REGULATION (EU) 2018/461**of 20 March 2018****authorising an extension of use of taxifolin-rich extract 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****(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⁾ was adopted, which establishes a Union list of authorised novel foods.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission shall submit a draft implementing act on the placing on the Union market of a novel food and on the updating of the Union list.
- (4) On 23 August 2010, the company Ametis JSC made a request to the competent authority of the United Kingdom to place taxifolin-rich extract from the wood of Dahurian larch (*Larix gmelinii* (Rupr.) Rupr) on the Union market as a novel food ingredient within the meaning of point (e) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽³⁾. The application requested for taxifolin-rich extract to be used in food supplements for a population older than fourteen years, and in non-alcoholic beverages, yogurt and chocolate confectionery for the general population excluding infants, young children and children up to 9 years.
- (5) On 13 December 2016, EFSA adopted a ‘Scientific Opinion on the safety of taxifolin-rich extract as a novel food pursuant to Regulation (EC) No 258/97’ ⁽⁴⁾. In its opinion it concluded that taxifolin-rich extract is safe for the proposed uses and use levels.
- (6) Commission Implementing Decision (EU) 2017/2079 ⁽⁵⁾ authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of taxifolin-rich extract from the wood of Dahurian larch (*Larix gmelinii* (Rupr.) Rupr) as a novel food to be used in food supplements intended for the general population, excluding infants, young children, children and adolescents younger than 14 years.
- (7) This Implementing Regulation addresses the remainder of the uses and use levels for which authorisation was sought by the applicant. The Commission initiated a further evaluation before taking a final decision on the full scope of the application, in order to ensure, that taxifolin-rich extract is also safe when consumed in other forms than in food supplements by infants, young children and children younger than 9 years of age.

⁽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⁾ 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).

⁽⁴⁾ EFSA Journal 2017; 15(2):4682

⁽⁵⁾ Commission Implementing Decision (EU) 2017/2079 of 10 November 2017 authorising the placing on the market of taxifolin-rich extract as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 295, 14.11.2017, p. 81).

- (8) On 3 May 2017, the applicant was informed of and agreed with the Commission's additional request to EFSA. With this occasion, the applicant also sought a further extension of the use and use conditions for taxifolin-rich extract to a use as a novel food in milk products for the general population and the inclusion in the specifications information of the novel food of a chemical name that was not contained in the original application but was included in the EFSA opinion of 2016. For these extensions of use the applicant provided additional information to EFSA.
- (9) On 28 June 2017, the Commission consulted EFSA asking it to carry out a supplementary safety assessment for taxifolin-rich extract in non-alcoholic beverages, chocolate confectionery and milk products for all groups of population.
- (10) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018, shall be treated as an application submitted under Regulation (EU) 2015/2283.
- (11) On 25 October 2017, EFSA adopted 'Scientific Opinion on the safety of taxifolin-rich extract' ⁽¹⁾. This opinion, although elaborated and adopted by EFSA under Regulation (EC) No 258/97, is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (12) The opinion gives sufficient grounds to establish that taxifolin-rich extract when used as an ingredient in non-alcoholic beverages, milk products and chocolate confectionery taking into account all population groups, complies with Article 12(1) of Regulation (EU) 2015/2283.
- (13) Regulation (EU) No 1308/2013 of the European Parliament and of the Council ⁽²⁾ lays down requirements for milk and milk products which apply to taxifolin-rich extract when used as an ingredient in milk products. Pursuant to its point 2 of Part III of Annex VII taxifolin-rich extract cannot be used in milk products to replace, in whole or in part, any milk constituent. The use of taxifolin-rich extract as a novel food in milk products therefore has to be limited accordingly.
- (14) 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

1. The entry in the Union list of authorised novel foods as provided for in Article 8 of Regulation (EU) 2015/2283 referring to the substance taxifolin-rich extract shall be amended as specified in the Annex to this Regulation.
2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

Article 2

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

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*.

⁽¹⁾ EFSA Journal 2017; 15(11):5059.

⁽²⁾ 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).

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

Done at Brussels, 20 March 2018.

For the Commission

The President

Jean-Claude JUNKER

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

(1) The entry for ‘Taxifolin-rich extract’ 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
“Taxifolin-rich extract	Specified food category	Maximum levels	The designation of the novel food on the labelling of the foodstuffs containing it shall be “taxifolin-rich extract”	
	Yogurt plain/Yogurt with fruits (*)	0,020 g/kg		
	Kephir (*)	0,008 g/kg		
	Buttermilk (*)	0,005 g/kg		
	Milk powder (*)	0,052 g/kg		
	Cream (*)	0,070 g/kg		
	Sour cream (*)	0,050 g/kg		
	Cheese (*)	0,090 g/kg		
	Butter (*)	0,164 g/kg		
	Chocolate confectionery	0,070 g/kg		
	Non-alcoholic beverages	0,020 g/l		
	Food supplements as defined in Directive 2002/46/EC intended for the general population, excluding infants, young children, children and adolescents younger than 14 years	100 mg/day		
	(*) When used in milk products Taxifolin-rich extract may not replace in whole or in part, any milk constituent			

(2) The entry for ‘Definition’ for ‘Taxifolin-rich extract’ in in Table 2 (Specifications) is replaced by the following:

Authorised Novel Food	Specification
‘Taxifolin-rich extract’	Definition: Chemical name: [(2R,3R)-2-(3,4 dihydroxyphenyl)-3,5,7-trihydroxy-2,3-dihydrochromen-4-one, also called (+) trans (2R,3R)- dihydroquercetin] and with no more than 2 % of the cis-form’

**COMMISSION IMPLEMENTING REGULATION (EU) 2018/462
of 20 March 2018**

authorising an extension of use of L-ergothioneine 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

(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⁾ was adopted, which establishes a Union list of authorised novel foods.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission shall submit a draft implementing act on the placing on the Union market of a novel food and on the updating of the Union list.
- (4) On 25 July 2013, the company Tetrahedron made a request to the competent authority of France to place synthetic L-ergothioneine ('L-ergothioneine') on the Union market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97 ⁽³⁾. The application requested for L-ergothioneine to be used in food supplements for the general population excluding pregnant and lactating women and for children older than three years, and in non-alcoholic beverages, fresh milk products, milk based drinks, cereal bars and chocolate for the general population excluding pregnant and lactating women, infants and young children.
- (5) On 26 October 2016, EFSA adopted a 'Scientific Opinion on the safety of L-ergothioneine as a novel food pursuant to Regulation (EC) No 258/97' ⁽⁴⁾. In its opinion it concluded that L-ergothioneine is safe for the proposed uses and use levels.
- (6) Commission Implementing Decision (EU) 2017/1281 ⁽⁵⁾ authorised, in accordance with Regulation (EC) No 258/97, the placing on the market of L-ergothioneine as a novel food ingredient to be used in food supplements intended for the general population, excluding infants and young children, pregnant and lactating women.
- (7) This Implementing Regulation addresses the remainder of the uses and use levels for which authorisation was sought by the applicant. The Commission initiated a further evaluation before taking a final decision on the full scope of the application, in order to ensure that L-ergothioneine is also safe when consumed in other forms than in food supplements by infants, young children, pregnant and lactating women.
- (8) On 26 April 2017, the applicant was informed of and agreed with the Commission's additional request to EFSA.

⁽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⁾ 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).

⁽⁴⁾ EFSA Journal 2016; 14(11):4629

⁽⁵⁾ Commission Implementing Decision (EU) 2017/1281 of 13 July 2017 authorising the placing on the market of L-ergothioneine as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 184, 15.7.2017, p. 65).

- (9) On 19 May 2017, the Commission consulted EFSA asking it to carry out a supplementary safety assessment for L-ergothioneine in non-alcoholic beverages, fresh milk products, milk-based drinks, cereal bars and chocolate for pregnant and lactating women, infants and young children.
- (10) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients and for which the final decision has not been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283.
- (11) On 25 October 2017, EFSA adopted a 'Scientific Opinion on the safety of L-ergothioneine' ⁽¹⁾. This opinion, although elaborated and adopted by EFSA under Regulation (EC) No 258/97 is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (12) The opinion gives sufficient grounds to establish that L-ergothioneine when used as an ingredient in non-alcoholic beverages, fresh milk products, milk-based drinks, cereal bars and chocolate confectionery taking into account all population groups, complies with Article 12(1) of Regulation (EU) 2015/2283.
- (13) Regulation (EU) No 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products ⁽²⁾ lays down requirements for milk and milk products which apply to L-ergothioneine when used as an ingredient in milk products. Pursuant to its point 2 of Part III of Annex VII L-ergothioneine cannot be used in milk products to replace, in whole or in part, any milk constituent. The use of L-ergothioneine as a novel food in milk products therefore has to be limited accordingly.
- (14) 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

1. The entry in the Union list of authorised novel foods as provided for in Article 8 of Regulation (EU) 2015/2283 referring to the substance L-ergothioneine shall be amended as specified in the Annex to this Regulation
2. The entry in the Union list referred to in the first paragraph shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

Article 2

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

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*.

⁽¹⁾ EFSA Journal 2017; 15(11):5060.

⁽²⁾ 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).

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

Done at Brussels, 20 March 2018.

For the Commission

The President

Jean-Claude JUNKER

ANNEX

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

The entry for 'L-ergothioneine' 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
L-ergothioneine	<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 “L-ergothioneine”	
	Alcohol-free beverages	0,025 g/kg		
	Milk-based drinks	0,025 g/kg		
	‘Fresh’ milk products (*)	0,040 g/kg		
	Cereal bars	0,2 g/kg		
	Chocolate confectionery	0,25 g/kg		
	Food supplements as defined in Directive 2002/46/EC	30 mg/day for general population (excluding pregnant and lactating women) 20 mg/day for children older than 3 years		
	(*) When used in milk products L-ergothioneine may not replace in whole or in part, any milk constituent			

DECISIONS

COUNCIL IMPLEMENTING DECISION (EU) 2018/463 of 19 March 2018 on the appointment of a member of the Single Resolution Board

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Regulation (EU) No 806/2014 of the European Parliament and of the Council of 15 July 2014 establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Resolution Fund and amending Regulation (EU) No 1093/2010 ⁽¹⁾, and in particular Article 56(6) thereof,

Having regard to the proposal from the European Commission,

Having regard to the approval by the European Parliament ⁽²⁾,

Whereas:

- (1) On 20 December 2017 the Commission, after hearing the Single Resolution Board ('the Board'), in its plenary session, adopted a shortlist of candidates for the position of a member of the Board and provided it to the European Parliament.
- (2) The Council was informed of the shortlist on the same day.
- (3) Pursuant to Article 56(5) of Regulation (EU) No 806/2014, the term of office of full time members of the Board is 5 years.
- (4) On 14 February 2018, the Commission adopted a proposal for the appointment of Boštjan JAZBEC as a member of the Board and submitted it to the European Parliament for approval,

HAS ADOPTED THIS DECISION:

Article 1

Mr Boštjan JAZBEC is hereby appointed as a full-time member of the Single Resolution Board for a term of office of 5 years as from the entry into force of this Decision.

Article 2

This Decision shall enter into force on the date of its publication in the *Official Journal of the European Union*.

Done at Brussels, 19 March 2018.

For the Council
The President
R. PORODZANOV

⁽¹⁾ OJ L 225, 30.7.2014, p. 1.
⁽²⁾ Approval of 1 March 2018.

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2018/464

of 19 March 2018

on the monitoring of metals and iodine in seaweed, halophytes and products based on seaweed

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) For arsenic, cadmium and lead, maximum levels (MLs) for various foodstuffs are established under Commission Regulation (EC) No 1881/2006 ⁽¹⁾. However, currently no MLs are established for these substances in seaweed and halophytes, except for the MLs established under this Regulation for food supplements consisting exclusively or mainly of seaweed or products derived from seaweed.
- (2) For mercury, currently under Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽²⁾ a maximum residue level (MRL) for algae and prokaryotic organisms is established at the default level of 0,01 mg/kg.
- (3) In 2006 the Scientific Committee for food established an upper limit for iodine intake of 600 µg/day for adults and of 200 µg a day for children of 1-3 years ⁽³⁾. It indicated that the ingestion of iodine-rich algal products, particularly dried products, can lead to dangerously excessive iodine intakes, if such products contain more than 20 mg iodine/kg dry matter and the exposed population lives in an area of endemic iodine deficiency.
- (4) Available occurrence data show that seaweeds contain significant concentrations of arsenic, cadmium, iodine, lead and mercury. As halophytes also grow in a marine environment, it can reasonably be assumed that they will show a similar uptake pattern of these substances and by consequence a similar contamination pattern.
- (5) Seaweed and halophytes form an increasingly important contribution to the consumption patterns of certain EU consumers. Therefore it is necessary to assess whether the contribution of arsenic, cadmium, iodine, lead and mercury from seaweed and halophytes to the total exposure of these substances, would necessitate the establishment of MLs for arsenic, cadmium and lead for these commodities or the amendment of the MRL for mercury for algae and prokaryotic organisms or any action to be taken related to the exposure to iodine from these products.
- (6) For food additives based on seaweed, specifications are laid down in the annexes to Commission Regulation (EU) No 231/2012 ⁽⁴⁾. For certain of these additives, EFSA recommended that the limits for the impurities of toxic elements should be revised in order to ensure that the use of these additives will not form a significant source of exposure to those toxic elements in particular for infants and young children ⁽⁵⁾. Therefore the exposure to arsenic, cadmium, iodine, lead and mercury in food additives based on seaweed and algae should be assessed.

⁽¹⁾ 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).

⁽²⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

⁽³⁾ Tolerable upper intake levels for vitamins and minerals — Scientific Committee on Food — Scientific Panel on Dietetic Products, Nutrition and Allergies. February, 2006 http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf

⁽⁴⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽⁵⁾ Re-evaluation of agar (E406) as a food additive. *EFSA Journal* 2016; 14(12): 4645.

- (7) For arsenic, lead, cadmium and mercury, maximum levels in feed are established under Directive 2002/32/EC of the European Parliament and of the Council ⁽¹⁾. As certain seaweed species are used as feed, the metal content of these species should also be investigated, both for animal health reasons and in view of the transfer of these metals to food products of animal origin.
- (8) Occurrence data for arsenic, cadmium, iodine, lead and mercury in different seaweed species, halophytes and products based on seaweed should be gathered to support a dietary exposure assessment,

HAS ADOPTED THIS RECOMMENDATION:

1. That Member States, in collaboration with food and feed business operators, perform during the years 2018, 2019 and 2020 monitoring on the presence of arsenic, cadmium, iodine, lead and mercury in seaweed, halophytes and products based on seaweed. The monitoring should include edible halophytes including *Salicornia europaea* and *Tetragonia tetragonoides* and a wide variety of seaweed species, reflecting consumption habits and feed uses, including Arame (*Ecklonia bicyclis*), Bladderwrack (*Fucus vesiculosus*), Dulse (*Palmaria palmata*), Hiziki (*Hizikia fusiforme*), Irish moss (*Chondrus crispus*), Oarweed (*Laminaria digitata*), Kombu (*Laminaria japonica*, *Saccharina japonica*), Nori or Purple laver (*Porphyra* and *Pyropia* spp.), Rockweed (*Ascophyllum nodosum*), Sea lettuce (*Ulva* sp.), Sea spaghetti (*Himanthalia elongata*), Serrated wrack (*Fucus serratus*), Sponge seaweed (*Codium* sp.) Sugar kelp (*Saccharina latissima*) Wakame (*Undaria pinnatifida*) and Winged kelp (*Alaria esculenta*), in order to enable an accurate estimation of exposure. Also occurrence data should be gathered for food additives based on seaweed, including E400, E401, E403, E404, E405, E406, E407, E407a and E160a(iv).
2. For the monitoring of food, the sampling procedures as laid down in Commission Regulation (EC) No 333/2007 ⁽²⁾ should be followed, in order to ensure that the samples are representative for the sampled lot.
3. For the monitoring of feed, the provisions provided for in Commission Regulation (EC) No 152/2009 ⁽³⁾ should be followed.
4. The analyses should be carried out in accordance with Annex III to Regulation (EC) No 882/2004 of the European Parliament and of the Council ⁽⁴⁾ by making use of a method of analysis that has been proven to generate reliable results.
5. The analysis of mercury should preferably be carried out by determining the content of methylmercury and total mercury and the analysis of arsenic should be carried out by determining the content of inorganic and total arsenic and, if possible, other relevant arsenic species.
6. The species or additive numbers should be reported and whether fresh, dried or processed products were analysed. Where possible also the origin of the products (wild or cultivated), the date and location of harvest, the part of the seaweed which was analysed, and possible information on the label of the end products should be reported.

⁽¹⁾ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).

⁽²⁾ Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs (OJ L 88, 29.3.2007, p. 29).

⁽³⁾ Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

⁽⁴⁾ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

7. The monitoring data should be provided to EFSA on a regular basis, with the information and in the electronic reporting format as set out by EFSA, for compilation into one database.

Done at Brussels, 19 March 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

