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 (OL 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 foods 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 JUNCKER

ANNEX

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**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be '*Ecklonia cava* Phlorotannins'. Food supplements containing *Ecklonia cava* 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.'	
	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.		

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

Authorised Novel Food	Specification
'***Ecklonia cava* phlorotannins**	**Description/Definition:** *Ecklonia cava* phlorotannins are obtained via alcohol extraction from the edible marine alga *Ecklonia cava*. 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 *Salmonella* spp.: Negative to test *Staphylococcus aureus*: 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'