

# REGULATIONS

시행 규칙 (EU) 2018/460

2018년 3월 20일

유럽 의회와 이사회 의 규정 (EU) 2015/2283에 따라  
신규 식품 Ecklonia cava phlorotannins의 판매를 허가하고  
시행 규칙 2017/2470을 개정함

- (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’<sup>(1)</sup>. 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<sup>(2)</sup>. 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<sup>(3)</sup> 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*.

<sup>(1)</sup> EFSA Journal 2017;15(10):5003.

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

<sup>(3)</sup> 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

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## 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 |
|-------------------------------------|---|---|---|--------------------|
| <b>'Ecklonia cava phlorotannins</b> | <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;<br>230 mg/day for adolescents above 14 years of age;<br>263 mg/day for adults. | Food supplements containing <i>Ecklonia cava</i> phlorotannins shall bear the following statement:<br>(a) This food supplement should not be consumed by children/adolescents under the age of twelve/fourteen/eighteen (*) years.<br>(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.<br>(c) This food supplement should not be consumed if other food supplements containing iodine are also consumed.<br>(*) Depending on the age group the food supplement is intended for. |                    |

