Commission Implementing Regulation (EU) 2018/469 of 21 March 2018 authorising the placing on the market of an extract of three herbal roots (Cynanchum wilfordii Hemsley, Phlomis umbrosa Turcz. and Angelica gigas Nakai) 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/469

of 21 March 2018

authorising the placing on the market of an extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) 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 13 March 2014, the company Naturalendo Tech Co., Ltd made a request to the competent authority of Ireland to place an extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) on the market

as a novel food ingredient within the meaning of point (e) of Article 1(2) of Regulation (EC) No 258/97. The application requests for the novel food to be used in food supplements intended for post-menopausal women.

(6) While the request for placing an extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) on the market as a novel food within the Union was submitted to a Member State 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 July 2014, the competent authority of Ireland issued its initial assessment report. In that report it came to the conclusion that an extract of mixture of the three herbal roots meets the criteria for novel food ingredients set out in Article 3(1) of Regulation (EC) No 258/97.

(8) On 15 September 2014, the Commission forwarded the initial assessment report to the other Member States. Reasoned objections were raised by the other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97.

(9) In view of the objections raised by the other Member States, the Commission consulted the European Food Safety Authority (EFSA) on 20 April 2015, asking it to carry out an additional assessment for an extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) as novel food ingredient in accordance with Regulation (EC) No 258/97.

(10) On 21 September 2016, EFSA adopted 'Scientific opinion on the safety of an extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) as a novel food'[(4)]. 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) In its opinion, EFSA did not establish the safety of the extract of mixture of the three herbal roots used in food supplements intended for adults at the maximum intake level of 514 mg/day as proposed by the applicant because the intake would exceed the level which is considered safe (2,5 mg/kg bw). However, EFSA concluded that the extract of mixture of the three herbal roots is safe for adults when added to food supplements at a maximum daily dose of 175 mg which corresponds to the safe level of intake for an adult person with a default body weight of 70 kg.

(12) In view of the EFSA opinion, the applicant provided additional information to alleviate the safety concerns. On 12 January 2017, the Commission consulted EFSA to review the additional information in relation to the scientific opinion on the safety of the extract of mixture of the three herbal roots. On 4 April 2017, EFSA in its reviewed opinion on the safety of the extract of mixture of the three herbal roots[(5)], concluded that the scientific opinion initially adopted on 21 September 2016 did not need to be revised and thus, EFSA reconfirmed that the extract of mixture of the three herbal roots is safe for adults when added to food supplements at a maximum daily dose of 175 mg.

(13) In its initial opinion, EFSA considers that the risk of allergic reaction to *Angelica gigas* Nakai is not dissimilar to that associated with celery as both plants belong to the same botanical family (i.e. *Apiaceae*). As celery is a food required to be labelled as an allergen under Regulation (EU) No 1169/2011 of the European Parliament and of the Council[6], it is necessary that the novel food ingredient should be appropriately labelled.

(14) Both opinions give sufficient grounds to establish that the extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) at the proposed uses and use levels when used as an ingredient in food supplements, complies with Article 12(1) of Regulation (EU) 2015/2283.

(15) Taking into account the intended use and the fact that the request for authorisation is only intended for adults, food supplements containing an extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) should be appropriately labelled.

(16) Directive 2002/46/EC of the European Parliament and of the Council[7] lays down requirements on food supplements. The use of the extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) should be authorised without prejudice to that Directive.

(17) 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 An extract of three herbal roots (*Cynanchum wilfordii* Hemsley, *Phlomis umbrosa* Turcz. and *Angelica gigas* Nakai) 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*.

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

Done at Brussels, 21 March 2018.

For the Commission

The President

Jean-Claude JUNCKER