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)

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.

(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'[(6)]. 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[(7)] 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,

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/461. (See end of Document for details)*

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*.

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