**COMMISSION IMPLEMENTING REGULATION**

**of XXX**

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 and Commission Regulation (EC) No 1852/2001[[1]](#footnote-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]](#footnote-2) establishes a Union list of authorised novel foods.
3. 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 foods ingredients[[3]](#footnote-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.
4. Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on authorisation and on the placing on the Union market of a novel food and updating the Union list.
5. 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. 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.
6. Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97. On 5 December 2012, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for taxifolin-rich extract as novel food ingredient in accordance with Regulation (EC) No 258/97.
7. On 14 February 2017, EFSA in its "Scientific Opinion on the safety of taxifolin-rich extract as a novel food pursuant to Regulation (EC) No 258/97[[4]](#footnote-4)" concluded that taxifolin-rich extract was safe for the proposed uses and use levels.
8. Commission Implementing Decision (EU) 2017/2079[[5]](#footnote-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.
9. Experience has shown that in certain cases, when a novel food is intended for a particular group of the population but it is used in foods which may also reasonably be expected to be consumed by other groups of the population, it is necessary that sufficient information should be provided in the application to enable the assessment of potential risks to those other population groups which are excluded from the scope of the intended uses of the novel food.
10. On that basis, the Commission, informed the applicant that while taxifolin-rich extract can be authorised as a novel food to be used in food supplements for which experience has shown that they are consumed only by the intended groups of the population, additional information should be provided to enable the assessment of risks of taxifolin-rich extract for infants, young children and children up to 9 years of age when taxifolin-rich extract are used as a novel food in non-alcoholic beverages, yogurt and chocolate confectionery.
11. On 3 May 2017, the company Ametis JSC agreed with the Commission's request to include in the intended uses of taxifolin-rich extract in non-alcoholic beverages, yogurt and chocolate confectionery infants, young children and children up to 9 years. In addition, the company requested an extension of the intended uses of the novel food to dairy products for the general population and the inclusion in the specifications information of the novel food of a chemical name that was not included in the original application but was included in the EFSA opinion.
12. 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, yogurt and chocolate confectionery for infants, young children and children up to 9 years and in dairy products for all groups of population.
13. On 25 October 2017, EFSA in its "Scientific Opinion on the safety of taxifolin-rich extract"[[6]](#footnote-6) concluded that taxifolin-rich extract is safe for the proposed uses and use levels.
14. The opinion gives sufficient grounds to establish that taxifolin-rich extract at the proposed uses and use levels when used as an ingredient complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
15. The application was submitted in accordance with article 4 of Regulation (EC) 258/97 and a final decision has not been taken before 1 January 2018. It is therefore appropriate that it is treated as an application under Regulation (EU) 2015/2283 in accordance with the transitional measures set out in Article 35 of that Regulation.
16. Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to adopt an implementing act authorising an extension of use of taxifolin-rich extract as a novel food and to update the Union list of authorised novel foods.
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 DECISION:

*Article 1*

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

*Article 2*

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,

For the Commission

The President

Jean-Claude JUNCKER

1. OJ L 327, 11.12.2015, p. 1. [↑](#footnote-ref-1)
2. OJ L 351, 30.12.2017, p. 72 [↑](#footnote-ref-2)
3. OJ L 43, 14.2.1997, p. 1. [↑](#footnote-ref-3)
4. EFSA Journal 2017; 15(2):4682 [↑](#footnote-ref-4)
5. OJ L 295, 14.11.2017, p. 81 [↑](#footnote-ref-5)
6. EFSA Journal 2017; 15(11):5059 [↑](#footnote-ref-6)