COMMISSION IMPLEMENTING DECISION (EU) 2017/2079

of 10 November 2017

authorising the placing on the market of taxifolin-rich extract as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2017) 7418)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ([1]), and in particular Article 7 thereof,

Whereas:

(1) 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 requests for taxifolin-rich extract to be used in food supplements for the general population, excluding infants, young children, children and adolescents younger than fourteen years.

(2) On 2 September 2011, the competent authority of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that taxifolin-rich extract meets the criteria for novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.

(3) On 20 September 2011, the Commission forwarded the initial assessment report to the other Member States.

(4) 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.

(5) 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.

(6) 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' ([2]) concluded that taxifolin-rich extract is safe for the proposed uses and use levels.

(7) That opinion gives sufficient grounds to establish that taxifolin-rich extract in the proposed uses and use levels complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(8) Directive 2002/46/EC of the European Parliament and of the Council ([3]) lays down requirements on food supplements. The use of taxifolin-rich extract should be authorised without prejudice to that Directive.

(9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) EFSA Journal 2017;15(2):4682.
([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).

HAS ADOPTED THIS DECISION:

Article 1

Without prejudice to Directive 2002/46/EC, taxifolin-rich extract as specified in Annex I to this Decision may be placed on the Union market as a novel food ingredient to be used in food supplements for the general population, excluding infants, young children, children and adolescents younger than 14 years at the maximum levels established in Annex II to this Decision.

Article 2

The designation of taxifolin-rich extract authorised by this Decision for the labelling of the foodstuffs shall be 'taxifolin-rich extract'.

Article 3

This Decision is addressed to Ametis JSC, 68, Naberezhnaya St., Blagoveshchensk, Amur District, Russia 675000.

Done at Brussels, 10 November 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX I

SPECIFICATIONS OF TAXIFOLIN-RICH EXTRACT

Definition:

Chemical name	[(2R,3R)-2-(3,4 dihydroxyphenyl)-3,5,7-trihydroxy-2,3-dihydrochromen-4-one, also called (+) trans (2R,3R)- dihydroquercetin]
Chemical formula	$C_{15}H_{12}O_7$
Molecular mass	304,25 Da
CAS No.	480-18-2

Description: Taxifolin-rich extract from the wood of Dahurian Larch (*Larix gmelinii* (Rupr.) Rupr) is a white to pale-yellow powder that crystallizes from hot aqueous solutions.

Specifications:

Specification Parameter		Limits
Physical parameter	Moisture	≤ 10 %
Compound analysis	Taxifolin (m/m)	≥ 90,0 % of the dry weight
Heavy Metals, Pesticide	Lead	≤ 0,5 mg/kg
	Arsenic	≤ 0,02 mg/kg
	Cadmium	≤ 0,5 mg/kg
	Mercury	≤ 0,1 mg/kg
	Dichlorodiphenyltrichloroethane (DDT)	≤ 0,05 mg/kg
Residual solvents	Ethanol	< 5 000 mg/kg
Microbial Parameters	Total Plate Count (TPC)	≤ 10^4 CFU ([1])/g
	Enterobacteria	≤ 100/g
	Yeast and Mould	≤ 100 CFU/g
	Escherichia coli	Negative/1 g
	Salmonella spp.	Negative/10 g
	Staphylococcus aureus	Negative/1 g
	Pseudomonas spp.	Negative/1 g

([1]) CFU: Colony forming unit.

Usual range of components of the Taxifolin-rich extract (as per dry substance)

Extract component	Content, usual observed range (%)
Taxifolin	90 – 93
Aromadendrin	2,5 – 3,5

Extract component	Content, usual observed range (%)
Eriodictyol	0,1 – 0,3
Quercetin	0,3 – 0,5
Naringenin	0,2 – 0,3
Kaempferol	0,01 – 0,1
Pinocembrin	0,05 – 0,12
Unidentified flavonoids	1 – 3
Water ([1])	1,5

([1]) Taxifolin in its hydrated form and during the drying process is a crystal. This results on the inclusion of water of crystallisation in a quantity of 1,5 %.

ANNEX II

AUTHORISED USES OF TAXIFOLIN-RICH EXTRACT

Food category	Maximum levels
Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants, young children, children and adolescents younger than 14 years	100 mg/day