COMMISSION IMPLEMENTING DECISION (EU) 2015/1213

of 22 July 2015

authorising extension of uses of flavonoids from *Glycyrrhiza glabra* L. as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2015) 4968)

(Only the Dutch and the French texts are 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) The specification of flavonoids from *Glycyrrhiza glabra* L. has been laid down and its placing on the market has been authorised in several foods at certain maximum use levels by Commission Implementing Decision 2011/761/EU ([2]).

(2) On 19 March 2014, the company Kaneka Pharma Europe NV made a request to the competent authorities of Belgium for extension of uses of flavonoids from *Glycyrrhiza glabra* L. as a novel food ingredient.

(3) On 6 August 2014, the competent food assessment body of Belgium issued its initial assessment report. In that report it came to the conclusion that the extension of uses of flavonoids from *Glycyrrhiza glabra* L. meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(4) On 22 September 2014, the Commission forwarded the initial assessment report to the other Member States.

(5) Reasoned objections were raised within the 60 day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97. Additional explanations by the applicant alleviated the concerns to the satisfaction of Member States and the Commission.

(6) Commission Directive 1999/21/EC ([3]) lays down requirements for dietary foods for special medical purposes. Commission Directive 96/8/EC ([4]) lays down requirements on foods intended for use in energy-restricted diets for weight reduction. The use of flavonoids from *Glycyrrhiza glabra* L should be authorised without prejudice to the requirements of those legislations.

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

HAS ADOPTED THIS DECISION:

Article 1

Flavonoids from *Glycyrrhiza glabra* L. (hereinafter referred to as 'Glavonoid'), as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses specified in Annex II without prejudice to the provisions of Directive 96/8/EC and Directive 1999/21/EC.

Glavonoid shall not be sold to the final consumer as such.

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) Commission Implementing Decision 2011/761/EU of 24 November 2011 authorising the placing on the market of flavonoids from Glycyrrhiza glabra L. as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 313, 26.11.2011, p. 37).
([3]) Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).
([4]) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22).

Article 2

1. The designation of Glavonoid authorised by this Decision on the labelling of the foodstuffs containing it shall be 'flavonoids from *Glycyrrhiza glabra* L.'.

2. There shall be a statement on the labelling of the foods where the product was added as a novel food ingredient indicating that:

(a) the product should not be consumed by pregnant and breast feeding women, children and young adolescents; and

(b) people taking prescription drugs should only consume the product under medical supervision;

(c) a maximum of 120 mg of Glavonoid per day should be consumed.

3. The amount of Glavonoid in the final food shall be indicated on the labelling of the food containing it.

4. Beverages containing Glavonoid shall be presented to the final consumer as single portions.

Article 3

This Decision is addressed to Kaneka Pharma Europe NV Triomflaan 173, 1160 Brussels, Belgium.

Done at Brussels, 22 July 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX I

SPECIFICATIONS OF GLAVONOID

Description

Glavonoid is an extract derived from the roots or rootstock of *Glycyrrhiza glabra* by extraction with ethanol followed by further extraction of this ethanolic extract with medium-chain triglycerides. It is a dark-brown coloured liquid, containing 2,5 % to 3,5 % of glabridin.

Specifications

Parameter	
Moisture	less than 0,5 %
Ash	less than 0,1 %
Peroxide value	less than 0,5 meq/kg
Glabridin	2,5 to 3,5 % of fat
Glycyrrhizinic acid	less than 0,005 %
Fat including polyphenol-type substances	not less than 99 %
Protein	less than 0,1 %
Carbohydrates	not detectable

ANNEX II

AUTHORISED USES OF GLAVONOID

Food category	Maximum content of Glavonoid
Foods intended for use in energy-restricted diets for weight reduction (only for products presented as a replacement for the whole of the daily diet)	120 mg of daily consumption
Dietary foods for special medical purposes	120 mg of daily consumption