

COMMISSION IMPLEMENTING DECISION (EU) 2015/1290**of 23 July 2015****authorising the placing on the market of refined oil from the seeds of *Buglossoides arvensis* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council***(notified under document C(2015) 4961)***(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 25 June 2013, the company Technology Crops International made a request to the competent authorities of the United Kingdom to place refined oil from the seeds of *Buglossoides arvensis* on the market as a novel food ingredient.
- (2) On 6 January 2014, the competent food assessment body of the United Kingdom issued its initial assessment report. In that report, it came to the conclusion that refined oil from the seeds of *Buglossoides arvensis* meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.
- (3) On 21 January 2014, the Commission forwarded the initial assessment report to the other Member States.
- (4) 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.
- (5) On 11 June 2014, the Commission consulted the European Food Safety Authority (EFSA), asking it to carry out an assessment for refined oil from the seeds of *Buglossoides arvensis* as a novel food ingredient in accordance with Regulation (EC) No 258/97.
- (6) On 5 February 2015, EFSA in its 'Scientific Opinion on the safety of refined *Buglossoides* oil as a novel food ingredient' ⁽²⁾, concluded that refined oil from the seeds of *Buglossoides arvensis* is safe for the proposed uses and use levels.
- (7) Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾ lays down requirements on food supplements. Regulation (EC) No 1925/2006 of the European Parliament and of the Council ⁽⁴⁾ lays down requirements on the addition of vitamins and minerals and of certain other substances to foods. Commission Directive 1999/21/EC ⁽⁵⁾ lays down requirements for dietary foods for special medical purposes. Commission Directive 96/8/EC ⁽⁶⁾ lays down requirements on foods intended for use in energy-restricted diets for weight reduction. The use of refined oil from the seeds of *Buglossoides arvensis* should be authorised without prejudice to the requirements of those legislations.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.⁽²⁾ EFSA Journal 2015; 13(2):4029.⁽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).⁽⁴⁾ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).⁽⁵⁾ Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).⁽⁶⁾ 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).

- (8) 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

Refined oil from the seeds of *Buglossoides arvensis* as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses defined and at the maximum levels established in Annex II without prejudice to the specific provisions of Directive 2002/46/EC, Regulation (EC) No 1925/2006, Directive 1999/21/EC and Directive 96/8/EC.

Article 2

The designation of refined oil from the seeds of *Buglossoides arvensis* authorised by this Decision on the labelling of the foodstuffs containing it shall be 'refined Buglossoides oil'.

Article 3

This Decision is addressed to Technology Crops International, 7996 North Point Blvd Winston Salem, NC 27106, USA.

Done at Brussels, 23 July 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX I

SPECIFICATION OF REFINED OIL FROM THE SEEDS OF *BUGLOSSOIDES ARVENSIS*

Description: Refined *Buglossoides* oil is extracted from the seeds of *Buglossoides arvensis* (L.) I.M.Johnst.

Test	Specification
Alpha-linolenic acid	Not less than 35 % w/w of total fatty acids
Stearidonic acid	Not less than 15 % w/w of total fatty acids
Linoleic acid	Not less than 8 % w/w of total fatty acids
Trans fatty acids	Not more than 2 % w/w of total fatty acids
Acid value	Not more than 0,6 mg KOH/g
Peroxide value	Not more than 5 meq O ₂ /kg
Unsaponifiable content	Not more than 2 %
Protein content (total nitrogen)	Not more than 10 µg/ml
Pyrrolizidine alkaloids	Not detectable with a detection limit of 4 µg/kg

ANNEX II

AUTHORISED USES OF REFINED OIL FROM THE SEEDS OF *BUGLOSSOIDES ARVENSIS*

Food category	Maximum level of stearidonic acid
Dairy products and analogues	250 mg/100 g; 75 mg/100 g for drinks
Cheese and cheese products	750 mg/100 g
Butter and other fat and oil emulsions including spreads (not for cooking or frying purposes)	750 mg/100 g
Breakfast cereals	625 mg/100 g
Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	500 mg/daily dose as recommended by the manufacturer
Dietary foods for special medical purposes as defined in Directive 1999/21/EC, excluding dietary foods for infants and young children	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Foods intended for use in energy-restricted diets for weight reduction as defined in Directive 96/8/EC	250 mg/meal replacement