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COMMISSION IMPLEMENTING DECISION

of 22 November 2012

authorising the placing on the market of bovine lactoferrin as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (Morinaga)

(notified under document C(2012) 8390)

(Only the English text is authentic)

(2012/725/EU)

(OJ L 327, 27.11.2012, p. 46)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Implementing Decision (EU) 2015/568 of 7 April 2015	L 93	71	9.4.2015

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(2012/725/EU)

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 2 March 2011 the company Morinaga Milk Industry Co. Ltd made a request to the competent authorities of Ireland to place bovine lactoferrin on the market as novel food ingredient. Bovine lactoferrin is an iron binding protein from milk to be added to foods.

(2) On 22 June 2011 the competent food assessment body of Ireland issued its initial assessment report. In this report they recommended that instead of carrying out an initial assessment an additional assessment was required, because another application concerning bovine lactoferrin was already referred to EFSA.

(3) The Commission forwarded the initial assessment report to all Member States on 20 July 2011.

(4) The European Food Safety Authority (EFSA) was consulted on 22 August 2011.

(5) On 28 June 2012 in their 'Scientific opinion on bovine lactoferrin' ([2]) EFSA came to the conclusion that bovine lactoferrin is safe under the proposed uses and use levels.

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) *EFSA Journal* 2012; 10(7): 2811.

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(6) On 27 April 2012 in another ‘Scientific opinion on bovine lactoferrin’ ([1]) EFSA already came to the conclusion that lactoferrin was safe under the proposed uses and use levels. Therefore it appears appropriate to authorise the same uses for both applications.

(7) Bovine lactoferrin complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Bovine lactoferrin as specified in Annex I may be placed on the market as a novel food ingredient for the uses defined and at the maximum levels established in Annex II, and without prejudice to the provisions of Regulation (EC) No 1925/2006 of the European Parliament and of the Council ([2]) and Directive 2009/39/EC of the European Parliament and of the Council ([3]).

Article 2

The designation of bovine lactoferrin authorised by this Decision on the labelling of the foodstuffs containing it shall be ‘Lactoferrin from cow’s milk’.

Article 3

This Decision is addressed to Morinaga Milk Industry Co., Ltd, 33-1, Shiba 3-chome, Minato-ku, Tokyo 108-8384, Japan.

([1]) *EFSA Journal* 2012; 10(5): 2701.
([2]) OJ L 404, 30.12.2006, p. 26.
([3]) OJ L 124, 20.5.2009, p. 21.

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ANNEX I

SPECIFICATIONS OF BOVINE LACTOFERRIN

Definition

▼M1

Bovine lactoferrin (bLF) is a protein that occurs naturally in cow's milk. It is an iron-binding glycoprotein of approximately 77 kDa and consists of a single polypeptide chain of 689 amino acids.

bLF is isolated from skimmed milk or cheese whey via ion exchange and subsequent ultra-filtration steps. Finally it is dried by freeze drying or spraying and the large particles are sieved out.

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Description: Virtually odorless, light pinkish powder

Physical-chemical properties of bovine lactoferrin

Moisture	less than 4,5 %
Ash	less than 1,5 %
Arsenic	less than 2 mg/kg
Iron	less than 350 mg/kg
Protein	more than 93,0 %
of which bovine lactoferrin	more than 95,0 %
of which other proteins	less than 5,0 %
pH (2 % solution, 20 °C)	5,2 to 7,2
Solubility (2 % solution, 20 °C)	complete

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ANNEX II

USES OF BOVINE LACTOFERRIN (bLF)

Food category	Maximum use levels of bLF
Infant formulae and follow on formulae (ready to drink)	100 mg/100 ml
Foods on dairy basis intended for young children (ready to eat/drink)	200 mg/100 g
Processed cereal food (solid)	670 mg/100 g
Foods for special medical purposes	Depending on the needs of the individual up to 3 g/day
Beverages based on milk	200 mg/100 g
Powdered drink mixes based on milk (ready to drink)	330 mg/100 g
Beverages based on fermented milk (including yoghurt drinks)	50 mg/100 g
Non-alcoholic drinks	120 mg/100 g
Products based on yoghurt	80 mg/100 g
Products based on cheese	2 000 mg/100 g
Ice cream	130 mg/100 g
Cakes and pastries	1 000 mg/100 g
Candies	750 mg/100 g
Chewing gum	3 000 mg/100 g