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 (FrieslandCampina)

(notified under document C(2012) 8404)

(Only the Dutch text is authentic)

(2012/727/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 2009 the company FrieslandCampina (formerly DMV International) made a request to the competent authorities of the Netherlands to place lactoferrin on the market as novel food ingredient. Lactoferrin is an iron-binding protein from milk to be added to foods.

(2) On 31 March 2010 the competent food assessment body of the Netherlands issued its initial assessment report. In this report it came to the conclusion that there was no reason for concern thus lactoferrin may be placed on the market as a novel food ingredient.

(3) The Commission forwarded the initial assessment report to all Member States on 13 April 2010.

(4) Within the 60-day period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections were raised in accordance with that provision.

(5) Therefore the European Food Safety Authority (EFSA) was consulted on 9 November 2010.

(6) On 27 April 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.

(7) On 28 June 2012 in another 'Scientific opinion on bovine lactoferrin' ([3]) EFSA also came to the conclusion that bovine lactoferrin is safe under the proposed uses and use levels. Therefore it appears appropriate to authorise the same uses for both applications.

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

(9) 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 ([4]) and Directive 2009/39/EC of the European Parliament and of the Council ([5]).

Article 2

The designation of bovine lactoferrin authorised by this Decision on the labelling of the foodstuffs containing it shall be 'Lactoferrin from cows' milk'.

Article 3

This Decision is addressed to FrieslandCampina, Nieuwe Kanaal 7R, 6709 PA Wageningen, The Netherlands.

Done at Brussels, 22 November 2012.

For the Commission

Maroš ŠEFČOVIČ

Vice-President

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) *EFSA Journal* 2012;(5):2701.
([3]) *EFSA Journal* 2012;10(7):2811.
([4]) OJ L 404, 30.12.2006, p. 26.
([5]) OJ L 124, 20.5.2009, p. 21.

ANNEX I

SPECIFICATIONS OF BOVINE LACTOFERRIN

Definition

Bovine lactoferrin (bLF) is a protein that occurs naturally in cows' 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 via ion exchange and subsequent ultra-filtration steps. Finally it is dried by spraying and large particles are sieved out.

Description: Virtually odourless, 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 %
of which bovine lactoferrin	more than 95 %
of which other proteins	less than 5 %
pH (2 % solution, 20 °C)	5,2 to 7,2
Solubility (2 % solution, 20 °C)	complete

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