COMMISSION IMPLEMENTING REGULATION (EU) 2023/463

of 3 March 2023

authorising the placing on the market of bovine milk osteopontin as a novel food and amending Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ([1]), and in particular Article 12(1) thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ([2]) has established a Union list of novel foods.

(3) On 27 March 2020, the company Arla Foods Ingredients Group P/S ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place bovine milk osteopontin ('bmOPN') on the Union market as a novel food. The applicant requested for bovine milk osteopontin to be used in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([3]) and in milk-based drinks intended for young children, at levels not exceeding 151 mg/L in the final product.

(4) On 27 March 2020, the applicant also made a request to the Commission for the protection of proprietary data for certificates of analyses and batch testing, stability reports and unpublished study ([4]) reports.

(5) On 9 October 2020, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of bovine milk osteopontin as a novel food.

(6) On 26 January 2022, the Authority adopted its scientific opinion on Safety of bovine milk osteopontin as a Novel food ([5]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that bovine milk osteopontin is safe under the proposed conditions of use for infants and young children up to 35 months of age at levels not exceeding 151 mg/L. Therefore, that scientific opinion gives sufficient grounds to establish that bovine milk osteopontin, when used at levels not exceeding 151 mg/L, intended for use in infant formula (IF), follow-on formula and milk-based drinks intended for young children, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

([1]) OJ L 327, 11.12.2015, p. 1.

([2]) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

([3]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

([4]) Bacterial reverse mutation assay (Kvistgaard et al., 2012), In vitro mammalian chromosome aberration test (Kvistgaard et al., 2013a), In vivo micronucleus test (Kvistgaard et al., 2013b), Subchronic oral toxicity study in rats (Lina, 2007) and Study in infants (Peng and Lonnerdal, 2013)

([5]) EFSA Journal 2022;20(5):7137.

(8) The opinion of the Authority follows the assessment of the safety of novel foods, in accordance with Regulation (EU) 2015/2283, and does not consider whether all other Union requirements for the placement of a food in the EU market are met. Therefore, infant formula and follow-on formula containing bovine milk osteopontin on the EU market must comply with the requirements of Regulation (EU) No 609/2013 and Commission Delegated Regulation (EU) 2016/127 ([6]).

(9) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the scientific data from the certificates of analyses and batch testing, stability reports and unpublished study reports without which it could not have assessed the novel food and reached its conclusion.

(10) The applicant declared that they held proprietary and exclusive rights of reference to the scientific data from the certificates of analyses and batch testing, stability reports and unpublished study reports at the time they submitted the application and that the third parties cannot lawfully use or refer to those data

(11) The Commission assessed all the information provided by the applicant and considered that it has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the previously mentioned scientific data should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place bovine milk osteopontin on the market within the Union during a period of five years from the entry into force of this Regulation.

(12) However, restricting the authorisation of bovine milk osteopontin and the reference to the scientific data contained in the applicant's file for the sole use by it does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.

(13) As the source of the novel food comes from bovine milk, which is listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council ([7]) as one of a number of substances or products which may cause allergies or intolerances, foods containing bovine milk basic protein isolate, such as bovine milk osteopontin, should be appropriately labelled following the requirements laid down in Article 21 of that Regulation.

(14) It is appropriate that the inclusion of bovine milk osteopontin as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.

(15) Bovine milk osteopontin should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

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

HAS ADOPTED THIS REGULATION:

Article 1

1. Bovine milk osteopontin is authorised to be placed on the market within the Union.

([6]) Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (OJ L 25, 2.2.2016, p. 1).

([7]) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

Bovine milk osteopontin shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

Only the company Arla Foods Ingredients Group P/S ([8]) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from 26 March 2023, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Arla Foods Ingredients Group P/S.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Arla Foods Ingredients Group P/S.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

([8]) Address: Sønderhøj 10-12 8260 Viby J Denmark.

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) In Table 1 (Authorised novel foods), the entry on 'Bovine milk Osteopontin' is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
'Bovine milk osteopontin	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Bovine milk Osteopontin'.		Authorised on 26 March 2023. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Arla Foods Ingredients Group P/S., Sønderhøj 10-12 8260 Viby J Denmark. During the period of data protection, the novel food Bovine milk osteopontin is authorised for placing on the market within the Union only by Arla Foods Ingredients Group P/S., unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Arla Foods Ingredients Group P/S. End date of the data protection: 26 March 2028.
	Infant formula as defined in Regulation (EU) No 609/2013 (*)	151 mg/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined in Regulation (EU) No 609/2013 (*)	151 mg/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Milk-based drinks intended for young children	151 mg/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			

(*) Without prejudice to the requirements of Regulation (EU) No 609/2013 and Regulation (EU) 2016/127.'

(2) in Table 2 (Specifications), the following entry 'Bovine milk osteopontin' is inserted:

Authorised Novel Food	Specification
'**Bovine milk osteopontin**	**Description** Bovine milk osteopontin is isolated from pasteurised or microfiltered bovine whey or milk by ion exchange chromatography, ultrafiltration to remove low molecular weight components and spray drying. During this filtration steps lactose and whey proteins predominantly alpha-lactalbumin and beta lactoglobulin are removed. **Characteristics/Composition** Protein % as is (N × 6,38): 76,5–80,5 Bovine milk osteopontin (bmOPN) (% of protein): ≥ 84,5 Full-length bmOPN (MW 33,9 kDa) (% of bmOPN): ≥ 15 N-terminal fragment bmOPN (MW 19,8 kDa) (% of bmOPN): ≥ 70 Other milk protein (% of protein): ≤ 14,5 Moisture: < 9,5 % Lactose: ≤ 1,0 % Fat: ≤ 1,0 % Ash: ≤ 11 % Insolubility index (mL) ≤ 1,0 **Heavy metals** Lead: < 0,05 mg/kg Cadmium: < 0,05 mg/kg Mercury: < 0,05 mg/kg Arsenic: < 0,5 mg/kg Aflatoxin M1 < 0,1 µg/kg **Microbiological criteria** Total plate count (30 °C) (CFU/g): ≤ 5 000 Mould/yeast (CFU/g): ≤ 100 *Bacillus cereus* (CFU/g): < 50 Sulfur-reducing Clostridia (CFU/g): < 10 *Staphylococcus aureus*: Not detected in 1 g Enterobacteriaceae (CFU/g): < 10 *Salmonella* spp.: Not detected in 25 g CFU: Colony Forming Units'