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COMMISSION IMPLEMENTING REGULATION (EU) 2024/1023

of 8 April 2024

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food lactitol

(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 and Commission Regulation (EC) No 1852/2001 ([1]), and in particular Article 12 thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list 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) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes lactitol as an authorised novel food.

(4) Commission Implementing Decision (EU) 2017/450 ([3]) authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council ([4]), the placing on the market of lactitol as a novel food to be used in capsule or tablet form in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([5]) and intended for the adult population.

(5) Commission Implementing Regulation (EU) 2018/1293 ([6]) authorised an extension of the use of the novel food lactitol in powder form at the existing maximum authorised level in accordance with Regulation (EU) 2015/2283.

(6) On 31 October 2023, the company H.C. Clover Productos y Servicios, S.L., submitted an application to the Commission to change the conditions of use of the novel food lactitol in accordance with Article 10(1) of Regulation (EU) 2015/2283. The applicant requested to include ampoules of liquids, drop dispensing bottles and other similar forms of liquids, as allowed forms of lactitol, to be used in food supplements.

(7) The Commission considers that the requested update of the Union list is not liable to have an effect on human health and that a safety evaluation by the European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The safety assessment underpinning the authorisation of lactitol at a

([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, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj
([3]) Commission Implementing Decision (EU) 2017/450 of 13 March 2017 authorising the placing on the market of lactitol as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 69, 15.3.2017, p. 31, ELI: http://data.europa.eu/eli/dec_impl/2017/450/oj).
([4]) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1, ELI: http://data.europa.eu/eli/reg/1997/258/oj).
([5]) 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, ELI: http://data.europa.eu/eli/dir/2002/46/oj).
([6]) Commission Implementing Regulation (EU) 2018/1293 of 26 September 2018 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food lactitol (OJ L 243, 27.9.2018, p. 2, ELI: http://data.europa.eu/eli/reg_impl/2018/1293/oj).

maximum level of 20 g/day in food supplements is not linked to a specific form in which the food supplements are made available to the consumer and therefore, the form does not affect the safety profile of the novel food. At the time of the authorisation, the forms of this novel food were limited to capsules, tablets or powders simply because these were the forms proposed by the respective applicant. As the proposed uses in this application concern only forms in ampoules of liquids, drop dispensing bottles, and other similar forms of liquids, while maintaining the authorised maximum levels of lactitol in food supplements, the Commission considers that the conditions of use of lactitol should be limited to the generic reference to food supplements and their forms defined in Article 2 of Directive 2002/46/EC. This will be consistent with the other authorisations of novel foods used in food supplements for which the form of the food supplement is not of relevance for the safety of the novel food.

(8) The information provided in the application gives sufficient grounds to establish that the requested changes to the conditions of use of the novel food lactitol by including any allowed form of lactitol to be used in food supplements are in accordance with Article 12 of Regulation (EU) 2015/2283 and should be approved.

(9) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(10) 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

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

Article 2

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, 8 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for 'Lactitol' is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'Lactitol	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the food supplements containing it shall be "Lactitol"'	
	Food supplements as defined in Directive 2002/46/EC intended for the adult population	20 g/day		