REGULATIONS

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

(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]) was adopted, which establishes a Union list of authorised novel foods.

(3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on the updating of the Union list.

(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 in food supplements intended for the adult population.

(5) On 22 March 2018, the company DuPont Nutrition Biosciences ApS made a request to the Commission to change the conditions of use of the novel food lactitol within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to include powder as an allowed form of lactitol to be used in food supplements.

(6) The Commission did not request an opinion from the European Food Safety Authority in accordance with Article 10(3) as the amendment of the conditions of use of the novel food lactitol by including powder, as an allowed form of lactitol to be used in food supplements is not liable to have an effect on human health.

(7) The maximum level of lactitol authorised by Implementing Decision (EU) 2017/450 as a novel food to be used in capsule or tablet in food supplements is 20 g/day. The proposed use level of the novel food lactitol in powder form in the same food category corresponds to the maximum level that is currently authorized. Therefore, it is appropriate to amend the conditions of use of lactitol to authorise its use in powder form at the existing maximum authorised level.

(8) The information provided in the application gives sufficient grounds to establish that the application for changing of the conditions of use of the novel food lactitol by including powder, as an allowed form of lactitol to be used in food supplements, comply with Article 12(2) 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]) 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).
([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).

(9) Directive 2002/46/EC of the European Parliament and of the Council [1] lays down requirements on food supplements. The additional form of lactitol to be used in food supplements should be authorised without prejudice to that Directive.

(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

1. The entry in the Union list of authorised novel foods as provided for in Article 8 of Regulation (EU) 2015/2283 referring to the substance lactitol shall be amended as specified in the Annex to this Regulation.

2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

3. The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

Article 2

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

Article 3

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, 26 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

[1] 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).

ANNEX

The entry for 'Lactitol' in Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470 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 (capsules, tablets or powder) intended for the adult population	20 g/day		