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

(notified under document C(2017) 1576)

(Only the English text is authentic)

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 16 March 2015, the company DuPont Nutrition Biosciences ApS made a request to the competent authorities of Denmark to place lactitol on the Union market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97. In its request, the company proposes lactitol to be used in the same food categories and in the same use levels that are currently being used, when lactitol is added as a food additive under Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([2]).

(2) On 1 July 2015, the competent food assessment body of Denmark issued its initial assessment report. In that report it came to the conclusion that lactitol under the conditions of use proposed by the applicant meets the criteria for novel food ingredients set out in Article 3(1) of Regulation (EC) No 258/97.

(3) On 13 July 2015, the Commission forwarded the initial assessment report to the other Member States.

(4) Some Member States made comments within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97. Concerns were raised regarding the excess of lactitol intake and the possibility of misleading the consumer as the same uses and use levels are already authorised for lactitol as a food additive.

(5) In the light of the Member States' comments, the competent authorities of Denmark reviewed the initial assessment report and concluded that an additional assessment was required in accordance with Article 7 of Regulation (EC) No 258/97.

(6) That report takes into account the concerns regarding the excess of lactitol intake and the possibility of misleading the consumer and therefore gives sufficient grounds to restrict the use of lactitol to food supplements only and to establish that lactitol used in food supplements intended for adults is safe under the proposed conditions of use.

(7) Directive 2002/46/EC of the European Parliament and of the Council ([3]) lays down requirements for food supplements. The use of lactitol should be authorised without prejudice to the provisions of that Directive.

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

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).
([3]) 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).

HAS ADOPTED THIS DECISION:

Article 1

Without prejudice to Directive 2002/46/EC, lactitol as specified in the Annex to this Decision may be placed on the market in the Union as a novel food ingredient to be used in food supplements in capsule or tablet form intended for the adult population with a maximum dose of 20 g lactitol per day as recommended by the manufacturer.

Article 2

The designation of lactitol authorised by this Decision on the labelling of the foodstuffs containing it shall be 'lactitol'.

Article 3

This Decision is addressed to DuPont Nutrition Biosciences ApS, Langebrogade 1, PO Box 17, DK-1001, Copenhagen, Denmark.

Done at Brussels, 13 March 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

SPECIFICATION OF LACTITOL

Identity of lactitol

Chemical name	4-O-β-D-Galactopyranosyl-D-glucitol
Chemical formula	$C_{12}H_{24}O_{11}$
Molecular weight	344,31 g/mol
CAS No	585-86-4

Description: Crystalline powder or colourless solution manufactured via catalytic hydrogenation of lactose. Crystalline products occur in anhydrous, monohydrate and dihydrate forms. Nickel is used as a catalyst.

Parameters	Specification value
Solubility (in water)	Very soluble in water
Specific rotation	[α] D^{20} = + 13° to + 16°
Assay	Not less than 95 % d.b [1]
Water content	Not more than 10,5 %
Other polyols	Not more than 2,5 % d.b
Reducing sugars	Not more than 0,2 % d.b
Chlorides	Not more than 100 mg/kg d.b
Sulphates	Not more than 200 mg/kg d.b
Sulphated ash	Not more than 0,1 % d.b
Nickel	Not more than 2 mg/kg d.b
Arsenic	Not more than 3 mg/kg d.b
Lead	Not more than 1 mg/kg d.b

[1] d.b — expressed on the dry weight basis