II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/676

of 10 April 2017

authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([1]), and in particular Article 18(4) thereof,

Whereas:

(1) Regulation (EC) No 1924/2006 provides that health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Pursuant to Article 13(3) of Regulation (EC) No 1924/2006, Commission Regulation (EU) No 432/2012 ([2]) was adopted, which establishes a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children's development and health.

(3) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) In order to stimulate innovation, health claims which are based on newly developed scientific evidence and/or which include a request for the protection of proprietary data shall undergo an accelerated type of authorisation.

(6) Following an application from DuPont Nutrition BioSciences ApS, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to lactitol and the maintenance of normal defecation (Question No EFSA-Q-2015-00375 ([3])). The claim proposed by the applicant was worded as follows: 'lactitol contributes to normal bowel function'.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ L 136, 25.5.2012, p. 1.).
([3]) *EFSA Journal* 2015;13(10):4252

(7) On 13 October 2015, the Commission and the Member States received the scientific opinion from the Authority which concluded that, on the basis of the data presented, a cause and effect relationship had been established between the consumption of lactitol and the maintenance of normal defecation and that the target population is the general adult population. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006 and should be included in the Union list of permitted claims, established by Regulation (EU) No 432/2012.

(8) Article 13(3) of Regulation (EC) No 1924/2006 provides that permitted health claims must be accompanied with all necessary conditions (including restrictions) for their use. Accordingly, the list of permitted claims should include the wording of the claims and specific conditions of use of the claims, and where applicable, conditions or restrictions of use and/or an additional statement or warning, in accordance with the rules laid down in Regulation (EC) No 1924/2006 and in line with the opinions of the Authority.

(9) One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that the wording and the presentation are taken into account in that respect. Therefore, where the wording of a claim used by the applicant has the same meaning for consumers as that of an authorised health claim, because it demonstrates the same relationship that exists between a food category, a food or one of its constituents and health, that claim should be subject to the same conditions of use, as the one listed in the Annex to this Regulation.

(10) In accordance with Article 20 of Regulation (EC) No 1924/2006, the Register of nutrition and health claims containing all authorised health claims should be updated in order to take into account the present Regulation.

(11) Regulation (EU) No 432/2012 should therefore be amended accordingly.

(12) The Member States have been consulted,

HAS ADOPTED THIS REGULATION:

Article 1

The health claim set out in the Annex to this Regulation shall be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

Article 2

The Annex to Regulation (EU) No 432/2012 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, 10 April 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In the Annex to Regulation (EU) No 432/2012, the following entry is inserted in an alphabetical order:

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	*EFSA Journal* number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
'Lactitol	Lactitol contributes to normal bowel function by increasing stool frequency	The claim may be used only for food supplements which contain 10 g of lactitol in a single daily quantified portion. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained by consuming 10 g of lactitol in one daily dose	The claim shall not be used for foods targeting children.	2015;13(10):4252'	