Commission Regulation (EU) 2015/1041 of 30 June 2015 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (Text with EEA relevance)

COMMISSION REGULATION (EU) 2015/1041

of 30 June 2015

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(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(5) thereof,

Whereas:

(1) Pursuant to Regulation (EC) No 1924/2006 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) 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.

(3) The Authority is to deliver an opinion on the health claim concerned.

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

(5) Following an application from Biocodex, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was required to deliver an opinion on a health claim related to the effect of citrulline-malate and faster recovery from muscle fatigue after exercise (Question No EFSA-Q-2013-00659[(2)]). The claim proposed by the applicant was worded as follows: ‘Maintenance of ATP levels through reduction of lactates in excess for an improved recovery from muscle fatigue’.

(6) On 5 May 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that a health claim on citrulline-malate and faster recovery from muscle fatigue after exercise pursuant to Article 13(5) of Regulation

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(EC) No 1924/2006 had already been assessed by the Authority with an unfavourable outcome (Question No EFSA-Q-2011-00931[(3)]). The additional information submitted by the applicant, in the context of Question No EFSA-Q-2013-00659, did not provide evidence that could be used for the scientific substantiation of the claim. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) Following an application from Comvita New Zealand Limited, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was required to deliver an opinion on a health claim related to the effect of olive (*Olea europaea* L.) leaf water extract and increase in glucose tolerance (Question No EFSA-Q-2013-00783[(4)]). The claim proposed by the applicant was worded as follows: 'Daily intake of supplemental olive leaf extract polyphenols contributes to the reduction of the blood glucose rise after meals'.

(8) On 5 May 2014, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, the scientific evidence is insufficient to establish a cause and effect relationship between the consumption of olive leaf water extract and increase in glucose tolerance. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(9) Following an application from Naturex SA, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was required to deliver an opinion on a health claim related to the effect of Pacran® and defence against bacterial pathogens in the lower urinary tract (Question No EFSA-Q-2013-00889[(5)]). The claim proposed by the applicant was worded as follows: 'Pacran® helps to inhibit the adhesion of P-fimbriated E. coli to the urinary tract cells'.

(10) On 5 May 2014, 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 not been established between the consumption of Pacran® and defence against bacterial pathogens in the lower urinary tract. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(11) Following an application from PiLeJe, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was required to deliver an opinion on a health claim related to the effect of a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 and reducing intestinal discomfort (Question No EFSA-Q-2013-00892[(6)]). The claim proposed by the applicant was worded, inter alia, as follows: 'improves intestinal comfort'.

(12) On 5 May 2014, 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 not been established between the consumption of a combination

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of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 and reducing gastro-intestinal discomfort. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(13) Following an application from PiLeJe, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was required to deliver an opinion on a health claim related to the effect of a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 and improvement of bowel function by increasing stool frequency (Question No EFSA-Q-2013-00893[7]). The claim proposed by the applicant was worded, inter alia, as follows: 'regulates your (intestinal) transit'.

(14) On 5 May 2014, 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 not been established between the consumption of a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103 and *Streptococcus thermophilus* LA 104 and improvement of bowel function by increasing stool frequency. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(15) Following an application from DoubleGood AB, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was required to deliver an opinion on a health claim related to the effect of a combination of L-threonine, L-valine, L-leucine, L-isoleucine, L-lysine plus chromium picolinate and reduction of post-prandial glycaemic responses (Question No EFSA-Q-2013-00756[8]). The claim proposed by the applicant was worded as follows: 'Contributes to the reduction of the blood glucose rise when consumed together with a carbohydrate rich meal'.

(16) On 16 July 2014, the Commission and the Member States received the scientific opinion from the Authority, in which it was stated that the applicant did not provide any evidence that a reduction in post-prandial blood glucose responses achieved by an increase in insulin secretion is a beneficial physiological effect. Consequently, the Authority concluded that, on the basis of the data presented, a cause and effect relationship had not been established between the consumption of the food, a combination of L-threonine, L-valine, L-leucine, L-isoleucine, L-lysine plus chromium picolinate, which is the subject of the health claim, and a beneficial physiological effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(17) Following an application from DSM Nutritional Products and Kemin Foods, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was required to deliver an opinion on a health claim related to the effect of a combination of lutein and zeaxanthin and improved vision under bright light conditions (Question No EFSA-Q-2013-00875[9]). The claim

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proposed by the applicants was worded as follows: 'Lutein together with zeaxanthin helps maintain clarity and contrast of sight in bright light conditions'.

(18) On 16 July 2014, 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 not been established between the consumption of a combination of lutein and zeaxanthin and improved vision under bright light conditions. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(19) 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 health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

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, 30 June 2015.

For the Commission

The President

Jean-Claude JUNCKER