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COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

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)

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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 Granarolo S.p.A., 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 a low-fat fermented milk with a combination of fructooligosaccharides and live *Lactobacillus rhamnosus* GG (ATCC 53103), Streptococcus thermophilus (Z57) and *Lactobacillus bulgaricus* (LB2), and defence against reactivation of Herpes simplex virus in the orolabial epithelia (Question No EFSA-Q-2015-00488[2]). The claim proposed by the applicant was worded as follows: “Consumption of low-fat fermented milk with a combination of fructo-oligosaccharides (FOS) and live *Lactobacillus rhamnosus* GG (ATCC 53103), Streptococcus thermophilus (Z57) and *Lactobacillus delbrueckii* subsp. *bulgaricus* (LB2) helps to reduce recurrence of lip cold sores caused by Herpes simplex virus infection in healthy susceptible individuals”.

1 OJ L 404, 30.12.2006, p. 9.

2 EFSA Journal 2016;14(7):4538

(6) On 19 July 2016, 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 the low-fat fermented milk, which was the subject of the health claim, and defence against reactivation of Herpes simplex virus in the orolabial epithelia. 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 Food for Health Ireland, 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 FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of post-prandial blood glucose responses (Question No EFSA- Q-2015-00755[3]). The claim proposed by the applicant was worded as follows: "FHI LFC24 helps to regulate blood glucose levels following food consumption".

(8) On 22 July 2016, the Commission and the Member States received the scientific opinion from the Authority, which noted that the evidence provided by the applicant does not establish that a reduction in post-prandial glycaemic responses achieved by an increase in insulin secretion is a beneficial physiological effect for the target population. Therefore, on the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of the food subject to the claim and a beneficial physiological effect for the target population. 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 Pierre Fabre Medicament, 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 V0137, a 'DHA-enriched fish oil', and 'helps to slow the age-related cognitive decline in domains such as memory and executive function' (Question No EFSA- Q- 2016-00071[4]). The claim proposed by the applicant was worded as follows: "V0137, in association with physical and intellectual training, helps to slow the age-related cognitive decline in domains such as memory and executive function".

(10) On 5 August 2016, 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 V0137, which was the subject of the health claim, and a reduced loss of cognitive function. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(11) 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.

[3] EFSA Journal 2016;14(7):4540

[4] EFSA Journal 2016;14(8):4539

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,

For the Commission
The President
Jean-Claude JUNCKER