Commission Regulation (EC) No 1025/2009 of 29 October 2009 refusing to authorise certain health claims made on food, other than those referring to the reduction of disease risk and to children's development and health (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1025/2009

of 29 October 2009

refusing to authorise certain health claims made on food, other than those referring to the reduction of disease risk and to children's development and health

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 food 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.

(3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission and to deliver an opinion on a 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 Elvir SAS, submitted on 30 July 2008 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 the effects of a dairy product enriched with milk peptide and magnesium on the reduction of anxiety (Question No EFSA-Q-2008-476)[(2)]. The claim proposed by the applicant was worded as follows: 'This product helps moderate signs of anxiety in mildly stress-sensitive adults due to its milk peptide and magnesium content'.

(6) On 19 December 2008, the Commission and the Member States received the scientific opinion from the Authority which concluded that on the basis of the data presented,

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 1025/2009. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

a cause and effect relationship was not established between the consumption of the constituents proposed to exert the claimed effect and the claimed effect. 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 Unilever plc (UK) and Unilever NV (Netherlands) submitted on 7 July 2008, 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 the effects of black tea from *Camellia Sinensis* on help to focus attention (Question No EFSA-Q-2008-434)[(3)]. The claim proposed by the applicant was worded as follows: 'Black tea helps you to focus attention'.

(8) On the 22 December 2008 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 was not established between the consumption of black tea from *Camellia Sinensis* and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(9) The comments from the applicants and the members of the public received by the Commission, pursuant to article 16(6) of Regulation (EC) No 1924/2006, have been considered when setting the measures provided for in this Regulation.

(10) The health claims 'This product helps moderate signs of anxiety in mildly stress-sensitive adults due to its milk peptide and magnesium content', and 'Black tea helps you to focus attention' are health claims as referred to in Article 13(1)(b) of Regulation (EC) No 1924/2006. Therefore they are both subject to the transition measures laid down in Article 28(6) of Regulation (EC) No 1924/2006. However, as the applications were not made before 19 January 2008, the requirement provided for in Article 28(6)(b) is not fulfilled and the transition period laid down in that Article is not applicable. Accordingly, a transition period of 6 months should be provided for, to enable food business operators to adapt to the requirements laid down in this Regulation.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Health claims set out in the Annex to this Regulation shall not be included in the Community list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

However, the health claims set out in the Annex to this Regulation may continue to be used for 6 months after the entry into force of this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

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This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 29 October 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission