Commission Regulation (EC) No 1167/2009 of 30 November 2009 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk and to children's development and health (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1167/2009

of 30 November 2009

refusing to authorise certain health claims made on foods and 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 17(3) 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 of the application, 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) On 13 February 2009 the Commission and the Member States received four opinions on applications for health claim authorisation from the Authority. On 16 March 2009, the Commission and the Member States received one opinion on an application for health claim authorisation from the Authority.

(6) Two opinions were related to applications for reduction of disease risk claim, as referred to in Article 14(1)(a) of Regulation (EC) No 1924/2006, and three opinions were related to applications for health claims referring to children's development and health, as referred to in Article 14(1)(b) of Regulation (EC) No 1924/2006. Meanwhile one application for health claim authorisation will be subject to a further decision.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 1167/2009. 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*

(7) Following an application from the UNICER Bebidas de Portugal SGPS, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Melgaço® mineral water on the reduction of glycaemia (Question No EFSA-Q-2008-219)[(2)]. The claim proposed by the applicant was worded as follows: 'The regular consumption of Melgaço mineral water reduces body hyperglycaemic levels'.

(8) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of Melgaço® mineral water 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) Following an application from the Ocean Spray International Services (UK) Ltd, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Ocean Spray Cranberry Products® on urinary tract infection in women (Question No EFSA-Q-2008-117)[(3)]. The claim proposed by the applicant was worded as follows: 'Regular consumption of 2 servings per day of an Ocean Spray product each containing typically 80 mg cranberry proanthocyanidins helps reduce the risk of urinary tract infection in women by inhibiting the adhesion of certain bacteria in the urinary tract'.

(10) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of Ocean Spray Cranberry Products® 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.

(11) Following an application from Soremartec Italia SRL, submitted pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Kinder Chocolate® on growth (Question No EFSA-Q-2008-283)[(4)]. The claim proposed by the applicant was worded as follows: 'Kinder Chocolate, the chocolate that helps to grow'.

(12) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of Kinder Chocolate® 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.

(13) Following an application from the Plada Industriale SRL, submitted pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of follow-on formulae with bioactive constituents on intestinal ailments (Question No EFSA-Q-2008-270)[(5)]. The claim proposed by the applicant was worded as follows: 'Aids minor intestinal ailments (as colic, constipation, digestive symptoms)'.

(14) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of follow-on formulae with a fixed combination of short-chain galacto-oligosaccharides, acidified milk, nucleotides and beta-palmitate and the claimed effect. Accordingly, as the claim does

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not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(15) 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.

(16) In accordance with Article 28(6) of Regulation (EC) No 1924/2006 health claims referred to in its Article 14(1)(b) and not authorised by a decision pursuant to Article 17(3) of Regulation (EC) No 1924/2006 may continue to be used for six months after the adoption of this Regulation. However, as the concerned 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 six months should be provided for, to enable food business operators to adapt to the requirements laid down in this Regulation.

(17) 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

The 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 14(1) of Regulation (EC) No 1924/2006.

However, the health claims as referred to in Article 14(1)(b) of Regulation (EC) No 1924/2006 and set out in the Annex to this Regulation may continue to be used for six 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*.

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

Done at Brussels, 30 November 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission