Commission Regulation (EC) No 983/2009 of 21 October 2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health (Text with EEA relevance)

COMMISSION REGULATION (EC) No 983/2009

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(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 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 19 August 2008, the Commission and the Member States received seven opinions on applications for health claim authorisation from the Authority. On 22 September 2008, the Commission and the Member States received one opinion on an application for health claim authorisation from the Authority. On 22 October 2008, the Commission and the Member States received eight opinions on applications for health claim authorisation from the Authority. On 31 October 2008, the Commission and the Member States received five opinions on applications for health claim authorisation from the Authority. On 14 November 2008, the Commission and the Member States received two opinions on applications for health claim authorisation from the Authority.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 983/2009. 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*

(6) Six opinions were related to applications for reduction of disease risk claims, as referred to in Article 14(1)(a) of Regulation (EC) No 1924/2006, and seventeen 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 was withdrawn by the applicant and one application for health claim authorisation will be subject to a further decision.

(7) Following an application from Unilever PLC (United Kingdom) and Unilever NV (Netherlands), 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 Plant sterols on blood cholesterol and the risk of coronary heart disease (Question No EFSA-Q-2008-085)[(2)]. The claim proposed by the applicant was worded as follows: 'Plant sterols have been proven to lower/reduce blood cholesterol significantly. Blood cholesterol lowering has been proven to reduce the risk of (coronary) heart disease'.

(8) On the basis of the data presented, the Authority concluded that a cause and effect relationship was established between the consumption of plant sterols and the claimed effect. Subject to a revised wording the claim should be considered as complying with the requirements of Regulation (EC) No 1924/2006 and in particular Article 14(1)(a) thereof, and it should be included in the Community list of permitted claims.

(9) Following an application from McNeil Nutritionals, 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 plant stanol esters on blood cholesterol and the risk of coronary heart disease (Question No EFSA-Q-2008-118)[(3)]. The claim proposed by the applicant was worded as follows: 'By actively lowering/reducing LDL-cholesterol (by up to 14 % within 2 weeks, by blocking cholesterol absorption,) plant stanol esters reduce the risk of (coronary) heart disease'.

(10) On the basis of the data presented, the Authority concluded that a cause and effect relationship was established between the intake of plant stanol esters and the claimed effect. Subject to a revised wording the claim should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and in particular Article 14(1)(a) thereof, and it should be included in the Community list of permitted claims.

(11) Following an application from Unilever PLC/NV 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 α-linolenic acid (ALA) and linoleic acid (LA) on growth and development of children (Question No EFSA-Q-2008-079)[(4)]. The claim proposed by the applicant was worded as follows: 'Regular consumption of essential fatty acids is important for proper growth and development of children'.

(12) On the basis of the data presented, the Authority concluded that a cause and effect relationship was established between the intake of ALA and LA and the claimed effect. A health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and it should be included in the Community list of permitted claims.

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(13) Following an application from the Association de la Transformation Laitière Française (ATLA) 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 vitamin D on bone growth (Question No EFSA-Q-2008-323)[(5)]. The claim proposed by the applicant was worded as follows: 'Vitamin D is essential for the bone growth of children'.

(14) On the basis of the data presented, the Authority concluded that a cause and effect relationship was established between the intake of vitamin D and the claimed effect. A health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and it should be included in the Community list of permitted claims.

(15) Following an application from Yoplait Dairy Crest Ltd 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 calcium and vitamin D on bone strength (Question No EFSA-Q-2008-116)[(6)]. The claim proposed by the applicant was worded as follows: 'Calcium and vitamin D, as part of a healthy diet and lifestyle, build stronger bones in children and adolescents'.

(16) On the basis of the data presented, the Authority concluded that a cause and effect relationship was established between the intake of calcium and vitamin D and the claimed effect. A health claim reflecting this conclusion should be considered as complying with the requirements set out in Regulation (EC) No 1924/2006, and it should be included in the Community list of permitted claims.

(17) Following an application from the Association de la Transformation Laitière Française (ATLA) 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 calcium on bone growth (Question No EFSA-Q-2008-322)[(7)]. The claim proposed by the applicant was worded as follows: 'Calcium is needed for the healthy bone growth of children'.

(18) On the basis of the data presented, the Authority concluded that a cause and effect relationship was established between the intake of calcium and the claimed effect. A health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and it should be included in the Community list of permitted claims.

(19) Following an application from the Association de la Transformation Laitière Française (ATLA) 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 proteins of animal origin on bone growth (Question No EFSA-Q-2008-326)[(8)]. The claim proposed by the applicant was worded as follows: 'Proteins of animal origin contribute to children's bone growth'.

(20) On the basis of the data presented, the Authority concluded that a cause and effect relationship was established between the intake of total protein and the claimed effect. A health claim reflecting this conclusion should be considered as complying with

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the requirements of Regulation (EC) No 1924/2006, and it should be included in the Community list of permitted claims.

(21) Article 16(4) of Regulation (EC) No 1924/2006 provides that an opinion in favour of authorising a health claim should include certain particulars. Accordingly, those particulars should be set out in the Annex I to the present Regulation as regards the seven authorised claims and include, as the case may be, the revised wording of the claim, specific conditions of use of the claim, and, where applicable, conditions or restrictions of use of the food 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.

(22) 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 wording and presentation have to be taken into account in that respect; therefore where the wording of claims has the same meaning for consumers as that of an authorised health claim as they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, included in Annex I they should be subject to the same conditions of use indicated therein.

(23) Following an application from BIO SERAE 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 NeOpuntia® on blood lipid parameters associated with cardiovascular risks, especially HDL-cholesterol (Question No EFSA-Q-2008-214)[(9)]. The claim proposed by the applicant was worded as follows: 'NeOpuntia® helps to improve blood lipid parameters associated with cardiovascular risks, especially the HDL-cholesterol'.

(24) On the basis of the data presented, the Authority concluded that a cause and effect relationship could not be established between the consumption of NeOpuntia® 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.

(25) Following an application from Valio 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 *Lactobacillus helveticus* fermented Evolus® low-fat milk products on arterial stiffness (Question No EFSA-Q-2008-218)[(10)]. The claim proposed by the applicant was worded as follows: 'Evolus® reduces arterial stiffness'.

(26) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of *Lactobacillus helveticus* fermented Evolus® low-fat milk 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.

(27) Following an application from Martek Biosciences Corporation 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 docosahexaenoic acid (DHA) and arachidonic acid (ARA) on neural development of the brain and eyes

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(Question No EFSA-Q-2008-120)[11]. The claim proposed by the applicant was worded as follows: 'DHA and ARA support neural development of the brain and eyes'.

(28) 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/constituent (DHA and ARA) starting at six months of age 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. In addition, the Authority concluded that the consumption of baby foods/formula supplemented with DHA and ARA from six months to one year of age might have a beneficial effect on visual acuity maturation in infants breast-fed until the age of 4-6 months. The Authority concluded also that no evidence had been presented on the effects of DHA and ARA supplementation starting at six months of age on visual maturation in healthy infants that had not been breastfed but fed unenriched formula during the first months of life. A health claim reflecting this conclusion could not comply with the general principles and requirements of Regulation (EC) No 1924/2006, and especially Articles 3, 5 and 6, and should not be authorised.

(29) Following an application from the National Dairy Council 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 dairy foods (milk and cheese) on dental health (Question No EFSA-Q-2008-112)[12]. The claim proposed by the applicant was worded as follows: 'Dairy foods (milk & cheese) promote dental health in children'.

(30) On the basis of the data presented, the Authority concluded that the food category dairy foods (milk and cheese) subject of the health claim has not been sufficiently characterised, and a cause and effect relationship had not been established between the consumption of milk or cheese 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.

(31) Following an application from the National Dairy Council 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 dairy foods on healthy body weight (Question No EFSA-Q-2008-110)[13]. The claim proposed by the applicant was worded as follows: 'Three portions of dairy food everyday, as part of a balanced diet, may help promote a healthy body weight during childhood and adolescence'.

(32) On the basis of the data presented, the Authority concluded that the food category dairy foods (milk and cheese) subject of the health claim has not been sufficiently characterised and that a cause and effect relationship had not been established between the daily consumption of dairy foods (milk, cheese and yogurt) 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.

(33) Following an application from enzyme.pro.ag, 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 regulat® .pro.kid IMMUN on the immune system of children during growth (Question No EFSA-Q-2008-082)[14]. The claim proposed by