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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)

(OJ L 277, 22.10.2009, p. 3)

Amended by:

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► <u>M1</u>	Commission Regulation (EU) No 376/2010 of 3 May 2010	L 111	3	4.5.2010
► <u>M2</u>	Commission Regulation (EU) No 686/2014 of 20 June 2014	L 182	27	21.6.2014

**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)**

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.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.

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- (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) ⁽¹⁾. 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) ⁽²⁾. 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

⁽¹⁾ The EFSA Journal (2008) 781, 1-2.

⁽²⁾ The EFSA Journal (2008) 825, 1-13.

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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) ⁽¹⁾. 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.
- (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) ⁽²⁾. 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) ⁽³⁾. 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

⁽¹⁾ The EFSA Journal (2008) 783, 1-10.

⁽²⁾ The EFSA Journal (2008) 827, 1-2.

⁽³⁾ The EFSA Journal (2008) 828, 1-13.

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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) ⁽¹⁾. 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) ⁽²⁾. 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 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

⁽¹⁾ The EFSA Journal (2008) 826, 1-11.

⁽²⁾ The EFSA Journal (2008) 858, 1-2.

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related to the effects of NeOpuntia® on blood lipid parameters associated with cardiovascular risks, especially HDL-cholesterol (Question No EFSA-Q-2008-214) ⁽¹⁾. 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) ⁽²⁾. 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 (Question No EFSA-Q-2008-120) ⁽³⁾. 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

⁽¹⁾ The EFSA Journal (2008) 788, 1-2.

⁽²⁾ The EFSA Journal (2008) 824, 1-2.

⁽³⁾ The EFSA Journal (2008) 794, 1-2.

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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) ⁽¹⁾. 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) ⁽²⁾. 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) ⁽³⁾. The claim proposed by the applicant was worded as follows: ‘regulat[®].pro.kid IMMUN supports, stimulates and modulates the immune system of children during growth’.

⁽¹⁾ The EFSA Journal (2008) 787, 1-2.

⁽²⁾ The EFSA Journal (2008) 786, 1-10.

⁽³⁾ The EFSA Journal (2008) 782, 1-2.

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- (34) On the basis of the data presented, the Authority concluded that the food for which the claim is made, 'regulat[®].pro.kid IMMUN', has not been sufficiently characterised, and that a cause and effect relationship had not been established between the consumption of regulat[®].pro.kid IMMUN 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.
- (35) 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 BRAIN on the mental and cognitive development of children (Question No EFSA-Q-2008-083) ⁽¹⁾. The claim proposed by the applicant was worded as follows: 'regulat[®].pro.kid BRAIN contributes to mental and cognitive development of children'.
- (36) On the basis of the data presented, the Authority concluded that the food for which the claim is made 'regulat[®].pro.kid BRAIN', has not been sufficiently characterised, and that a cause and effect relationship had not been established between the consumption of regulat[®].pro.kid BRAIN 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.
- (37) Following two applications from Pharma Consulting & Industries 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 calming effect of I omega kids[®]/Pufan 3 kids[®] (Question No EFSA-Q-2008-091 and – Question No EFSA-Q-2008-096) ⁽²⁾. The claim proposed by the applicant was worded as follows: 'calming'.
- (38) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of DHA and eicosapentaenoic acid (EPA) 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.
- (39) Following two applications from Pharma Consulting & Industries 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 I omega kids[®]/Pufan 3 kids[®] on serenity (Question No EFSA-Q-2008-092 and Question No EFSA-Q-2008-097) ⁽³⁾. The claim proposed by the applicant was worded as follows: 'provide serenity and room for a beneficial development of the child'.
- (40) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of DHA and EPA 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.

⁽¹⁾ The EFSA Journal (2008) 829, 1-10.

⁽²⁾ The EFSA Journal (2008) 830, 1-2.

⁽³⁾ The EFSA Journal (2008) 831, 1-2.

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- (41) Following two applications from Pharma Consulting & Industries 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 I omega kids[®]/Pufan 3 kids[®] on vision (Question No EFSA-Q-2008-095 and Question No EFSA-Q-2008-100) ⁽¹⁾. The claim proposed by the applicant was worded as follows: ‘help to support vision’.
- (42) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of DHA and EPA 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.
- (43) Following two applications from Pharma Consulting & Industries 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 I omega kids[®]/Pufan 3 kids[®] on mental development (Question No EFSA-Q-2008-098 and Question No EFSA-Q-2008-104) ⁽²⁾. The claim proposed by the applicant was worded as follows: ‘help to support mental development’.
- (44) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of DHA and EPA 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.
- (45) Following two applications from Pharma Consulting & Industries 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 I omega kids[®]/Pufan 3 kids[®] on concentration (Question No EFSA-Q-2008-094 and Question No EFSA-Q-2008-099) ⁽³⁾. The claim proposed by the applicant was worded as follows: ‘help to promote concentration’.
- (46) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of DHA and EPA 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.
- (47) Following two applications from Pharma Consulting & Industries 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 I omega kids[®]/Pufan 3 kids[®] on thinking capacity (Question No EFSA-Q-2008-093 and Question No EFSA-Q-2008-101) ⁽⁴⁾. The claim proposed by the applicant was worded as follows: ‘helps to promote the thinking capacity’.

⁽¹⁾ The EFSA Journal (2008) 832, 1-8.

⁽²⁾ The EFSA Journal (2008) 847, 1-10.

⁽³⁾ The EFSA Journal (2008) 846, 1-10.

⁽⁴⁾ The EFSA Journal (2008) 845, 1-2.

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- (48) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of DHA and EPA 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.
- (49) Following two applications from Pharma Consulting & Industries 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 I omega kids[®]/Pufan 3 kids[®] on learning ability (Question No EFSA-Q-2008-102 and Question No EFSA-Q-2008-103) ⁽¹⁾. The claim proposed by the applicant was worded as follows: ‘help to support the learning ability’.
- (50) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of DHA and EPA 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.
- (51) 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.
- (52) In accordance with Article 28(6) of Regulation (EC) No 1924/2006 health claims as referred to in Article 14(1)(b) of that Regulation and not authorised by this Regulation may continue to be used for six months after the adoption of a decision pursuant to Article 17(3) of Regulation (EC) No 1924/2006. However, for applications which 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.
- (53) 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 Annex I to this Regulation may be made on food on the Community market in compliance with the conditions set out in that Annex.

⁽¹⁾ The EFSA Journal (2008) 848, 1-10.

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Those health claims shall be included in a list of permitted claims referred to in Article 14(1) of Regulation (EC) No 1924/2006.

Article 2

The health claims set out in Annex II to this Regulation are rejected.

Article 3

Health claims as referred to in Article 14(1)(b) of Regulation (EC) No 1924/2006 and set out in Annex II to this Regulation may continue to be used for six months after the entry into force of this Regulation.

Article 4

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.

ANNEX I

PERMITTED HEALTH CLAIMS

Application – Relevant provisions of Regulation (EC) No 1924/2006	Applicant – Address	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference
Article 14(1)(a) health claim referring to reduction of disease risk	Unilever PLC; Port Sunlight, Wirral, Merseyside, CH62 4ZD, UK and Unilever NV, Weena 455, Rotterdam, 3013 AL, Nederland	Plant sterols: Sterols extracted from plants, free or esterified with food grade fatty acids	Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease	► M2 Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant sterols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range '7 % to 10 %' for foods that provide a daily intake of 1,5-2,4 g plant sterols or the range '10 % to 12,5 %' for foods that provide a daily intake of 2,5-3 g plant sterols and the duration to obtain the effect 'in 2 to 3 weeks' must be communicated to the consumer. ◀		► M2 Q-2008-085 Q-2009-00530 and Q-2009-00718 Q-2011-01241 ◀
Article 14(1)(a) health claim referring to reduction of disease risk	McNeil Nutritionals, 1 Landis und Gyr Strasse, 6300 Zug; Switzerland	Plant stanol esters	Plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease	► M2 Information to the consumer that the beneficial effect is obtained with a daily intake of 1,5-3 g plant sterols/stanols. Reference to the magnitude of the effect may only be made for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the range '7 % to 10 %' for foods that provide a daily intake of 1,5-2,4 g plant sterols/stanols or the range '10 % to 12,5 %' for foods that provide a daily intake of 2,5-3 g plant sterols/stanols and the duration to obtain the effect 'in 2 to 3 weeks' must be communicated to the consumer. ◀		► M2 Q-2008-118 Q-2009-00530 and Q-2009-00718 Q-2011-00851 Q-2011-01241 ◀

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Application – Relevant provisions of Regulation (EC) No 1924/2006	Applicant – Address	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference
Article 14(1)(b) health claim referring to children's development and health	Unilever PLC; Port Sunlight, Wirral, Merseyside, CH62 4ZD, UK and Unilever NV, Weena 455, Rotterdam, 3013 AL, Nederland	α -linolenic acid & linoleic acid	Essential fatty acids are needed for normal growth and development of children	► MI Information to the consumer that the beneficial effect is obtained with a daily intake of 2 g of α -linolenic acid (ALA) and a daily intake of 10 g of linoleic acid (LA) ◀		Q-2008-079
Article 14(1)(b) health claim referring to children's development and health	Association de la Transformation Laitière Française (ATLA), 42, rue du Châteaudun, 75314 Paris Cedex 09, FRANCE	Calcium	Calcium is needed for normal growth and development of bone in children	The claim can be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006		Q-2008-322
Article 14(1)(b) health claim referring to children's development and health	Association de la Transformation Laitière Française (ATLA), 42, rue du Châteaudun, 75314 Paris Cedex 09, FRANCE	Protein	Protein is needed for normal growth and development of bone in children	The claim can be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN as listed in the Annex to Regulation (EC) No 1924/2006		Q-2008-326
Article 14(1)(b) health claim referring to children's development and health	Yoplait Dairy Crest Ltd, Claygate House, Claygate, Surrey, KT10 9PN, UK	Calcium and vitamin D	Calcium and vitamin D are needed for normal growth and development of bone in children	The claim can be used only for food which is at least a source of calcium and vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006		Q-2008-116

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Application – Relevant provisions of Regulation (EC) No 1924/2006	Applicant – Address	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference
Article 14(1)(b) health claim referring to children’s development and health	Association de la Transformation Laitière Française (ATLA), 42, rue du Châteaudun, 75314 Paris Cedex 09, FRANCE	Vitamin D	Vitamin D is needed for normal growth and development of bone in children	The claim can be used only for food which is at least a source of Vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006		Q-2008-323

ANNEX II

REJECTED HEALTH CLAIMS

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 14(1)(a) health claim referring to reduction of disease risk	NeOpuntia®	NeOpuntia® helps to improve blood lipid parameters associated with cardiovascular risks, especially the HDL-cholesterol	EFSA-Q-2008-214
Article 14(1)(a) health claim referring to reduction of disease risk	<i>Lactobacillus helveticus</i> fermented Evolus® low-fat milk products	Evolus® reduces arterial stiffness	EFSA-Q-2008-218
Article 14(1)(b) health claim referring to children's development and health	regulat®.pro.kid IMMUN	regulat®.pro.kid IMMUN supports, stimulates and modulates the immune system of children during growth	EFSA-Q-2008-082
Article 14(1)(b) health claim referring to children's development and health	Dairy products	Three portions of dairy food everyday, as part of a balanced diet, may help promote a healthy body weight during childhood and adolescence	EFSA-Q-2008-110
Article 14(1)(b) health claim referring to children's development and health	Dairy products	Dairy foods (milk & cheese) promote dental health in children	EFSA-Q-2008-112
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and Arachidonic Acid (ARA)	DHA and ARA support neural development of the brain and eyes	EFSA-Q-2008-120
Article 14(1)(b) health claim referring to children's development and health	regulat®.pro.kid BRAIN	regulat®.pro.kid BRAIN contributes to mental and cognitive development of children	EFSA-Q-2008-083
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and eicosapentaenoic acid (EPA)	Calming	EFSA-Q-2008-091 and EFSA-Q-2008-096
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and eicosapentaenoic acid (EPA)	Provide serenity and room for a beneficial development of the child	EFSA-Q-2008-092 and EFSA-Q-2008-097
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and eicosapentaenoic acid (EPA)	Help to support vision	EFSA-Q-2008-095 and EFSA-Q-2008-100

▼**B**

Application – Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and eicosapentaenoic acid (EPA)	Help to support mental development	EFSA-Q-2008-098 and EFSA-Q-2008-104
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and eicosapentaenoic acid (EPA)	Help to promote concentration	EFSA-Q-2008-094 and EFSA-Q-2008-099
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and eicosapentaenoic acid (EPA)	Helps to promote the thinking capacity	EFSA-Q-2008-093 and EFSA-Q-2008-101
Article 14(1)(b) health claim referring to children's development and health	Docosahexaenoic Acid (DHA) and eicosapentaenoic acid (EPA)	Help to support the learning ability	EFSA-Q-2008-102 and EFSA-Q-2008-103