EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

authorising certain health claims made on foods and referring 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 , and in particular Article 17(3) 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'.

(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 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 Specialised Nutrition Europe[1], 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 thiamine and carbohydrate and energy-yielding metabolism (Question No EFSA-Q-2008-183[2]). The claim proposed by the applicant was worded, inter alia, as follows: "Vitamin B1 (thiamine) is necessary to release energy from carbohydrates".

(6) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 22 July 2010 that a cause and effect relationship had been established between the intake of thiamine and carbohydrate and energy-yielding metabolism. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

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1 Formerly IDACE (Association of the Food Industries for Particular Nutritional Uses of the European Union)

2 EFSA Journal 2010;8(7):1690

(7) Following an application from HiPP GmbH, 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 thiamine and maintenance of normal neurological development and function (Question No EFSA-Q-2009-00455[3]). The claim proposed by the applicant was worded, inter alia, as follows: "Vitamin B1 for development of the nervous system".

(8) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 10 February 2011 that a cause and effect relationship had been established between dietary intake of thiamine and maintenance of normal neurological development and function. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(9) Following an application from HiPP GmbH & Co Vertrieb KG, 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 alpha-linolenic acid and contribution to brain and nerve tissue development (Question No EFSA- Q-2009-00197[4]) . The claim proposed by the applicant was worded, *inter alia*, as follows: "Alpha-linolenic acid is important for brain and nervous tissue development".

(10) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 7 April 2011 that a cause and effect relationship had been established between the dietary intake of ALA and contribution to brain and nerve tissue development. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(11) Following an application from Specialised Nutrition Europe, 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 magnesium and contribution to normal development of bone (Question No EFSA-Q-2008-150[5]). The claim proposed by the applicant was worded, *inter alia*, as follows: "magnesium supports the development of strong/healthy bones".

(12) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 26 July 2013 that a cause and effect relationship had been established between dietary intake of magnesium and contribution to normal development of bone. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(13) Following an application from Specialised Nutrition Europe, 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 vitamin A and contribution to normal development and function of the immune system (Question No EFSA-Q-2008-160[6]).

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3 EFSA Journal 2011;9(2):1980.
4 EFSA Journal 2011;9(4):2130
5 EFSA Journal 2013;11(7):3331
6 EFSA Journal 2013;11(7):3334

The claim proposed by the applicant was worded, *inter alia*, as follows: "Vitamin A helps support healthy immune function".

(14) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 26 July 2013 that a cause and effect relationship had been established between dietary intake of vitamin A and contribution to normal development and function of the immune system. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(15) Following an application from Specialised Nutrition Europe, 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 iron and contribution to normal cognitive development (Question No EFSA-Q-2008-199[7]). The claim proposed by the applicant was worded, *inter alia*, as follows: "with iron, important for cognitive development".

(16) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 26 July 2013 that a cause and effect relationship had been established between dietary intake of iron and contribution to normal cognitive development. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(17) Following an application from Specialised Nutrition Europe, 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 riboflavin (vitamin B2) and contribution to normal energy-yielding metabolism (Question No EFSA-Q-2008-184[8]). The claim proposed by the applicant was worded, *inter alia*, as follows: "vitamin B2 (riboflavin) is needed to release energy from foods".

(18) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 25 October 2013 that a cause and effect relationship had been established between the dietary intake of riboflavin and contribution to normal energy-yielding metabolism. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(19) Following an application from Specialised Nutrition Europe, 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 pantothenic acid and contribution to normal energy-yielding metabolism (Question No EFSA-Q-2008-186[9]). The claim proposed by the applicant was worded, *inter alia*, as follows: "vitamin B5 (pantothenic acid) is needed to release energy from food".

(20) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 25 October 2013 that a cause and effect relationship had been established between the dietary intake of pantothenic acid and

[7] EFSA Journal 2013;11(7):3335
[8] EFSA Journal 2013;11(10):3410
[9] EFSA Journal 2013;11(10):3411

contribution to normal energy-yielding metabolism. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(21) Following an application from Specialised Nutrition Europe, 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 vitamin C and increasing non-haem iron absorption (Question No EFSA-Q-2008-176[10]). The claim proposed by the applicant was worded, *inter alia*, as follows: "Vitamin C enhances iron absorption".

(22) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 10 January 2014 that a cause and effect relationship had been established between the dietary intake of vitamin C and increasing non-haem iron absorption. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(23) Following an application from Specialised Nutrition Europe, 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 iron and contribution to normal formation of haemoglobin and red blood cells (Question No EFSA-Q-2008-147[11]). The claim proposed by the applicant was worded, *inter alia*, as follows: "Iron is important for blood formation".

(24) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 10 January 2014 that a cause and effect relationship had been established between dietary intake of iron and contribution to normal formation of haemoglobin and red blood cells. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(25) Following an application from Specialised Nutrition Europe, 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 iodine and contribution to normal thyroid function (Question No EFSA-Q-2008-144[12]). The claim proposed by the applicant was worded, *inter alia*, as follows: "iodine is important for thyroid function".

(26) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 10 January 2014 that a cause and effect relationship had been established between the dietary intake of iodine and contribution to normal thyroid function. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(27) Following an application from Specialised Nutrition Europe, 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 iodine and contribution to normal

[10] EFSA Journal 2014;12(1):3514
[11] EFSA Journal 2014;12(1):3515
[12] EFSA Journal 2014;12(1):3516

cognitive development (Question No EFSA-Q-2008-145[13]). The claim proposed by the applicant was worded, *inter alia*, as follows: "iodine is important for cognitive development".

(28) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 10 January 2014 that a cause and effect relationship had been established between the dietary intake of iodine and contribution to normal cognitive development. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(29) Following an application from Specialised Nutrition Europe, 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 vitamin D and contribution to normal development of bones and teeth (Question No EFSA-Q-2008-178[14]). The claim proposed by the applicant was worded, *inter alia*, as follows: "vitamin D is essential for the absorption and utilization of calcium and phosphorus in building strong teeth and bones".

(30) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 24 February 2014 that a cause and effect relationship had been established between the dietary intake of vitamin D and contribution to normal development of bones and teeth. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(31) Following an application from Specialised Nutrition Europe, 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 zinc and normal function of the immune system (Question No EFSA-Q-2008-189[15]). The claim proposed by the applicant was worded, *inter alia*, as follows: "zinc helps to support a healthy immune system".

(32) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 5 May 2014 that a cause and effect relationship had been established between the dietary intake of zinc and normal function of the immune system. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(33) Following an application from DSM Nutritional Products, 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 docosahexaenoic acid (DHA) and contribution to normal brain development (Question No EFSA-Q-2014-00059[16]). The claim proposed by the applicant was worded as follows: "Pre-formed DHA contributes to brain development".

(34) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 8 October 2014 that a cause and effect

[13] EFSA Journal 2014;12(1):3517
[14] EFSA Journal 2014;12(2):3579
[15] EFSA Journal 2014;12(5):3653
[16] EFSA Journal 2014;12(10):3840

relationship had been established between the consumption of DHA and contribution to normal brain development. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(35) Following an application from Specialised Nutrition Europe, 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 selenium and protection of DNA, proteins and lipids from oxidative damage (Question No EFSA-Q-2008-159[17]). The claim proposed by the applicant was worded, *inter alia*, as follows: "Selenium has an antioxidant functionality that helps maintain and protect healthy cells".

(36) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 19 November 2014 that a cause and effect relationship had been established between the dietary intake of selenium and protection of DNA, proteins and lipids from oxidative damage. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(37) Following an application from Specialised Nutrition Europe, 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 zinc and normal growth (Question No EFSA-Q-2008-190[18]). The claim proposed by the applicant was worded, *inter alia*, as follows: "zinc is essential for growth".

(38) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 19 November 2014 that a cause and effect relationship had been established between the dietary intake of zinc and normal growth. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims.

(39) Article 7(1)(c) of Regulation (EU) No 1169/2011 on food information to consumers states that *"food information shall not be misleading, particularly by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics"*. For certain categories of foods, the mandatory addition of certain nutrients, for which health claims are authorised by this Regulation, is required by specific Union food legislation[19], under specific conditions. In order to appropriately inform the consumers about the effects of these nutrients, while ensuring that they are not misled by the way this information is conveyed, the wording for health claims on nutrients that are mandatorily added to certain categories of foods, in accordance with Union legislation, should take into account the relevant requirement of Article 7(1)(c) of Regulation (EU) No 1169/2011.

(40) 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

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17 EFSA Journal 2014;12(11):3890

18 EFSA Journal 2014;12(11):3891

19 Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae; Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children, Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes.

particulars should be set out in the Annex to the present Regulation as regards the authorised claim 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.

(41) 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 are 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, because they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, they should be subject to the same conditions of use indicated in the Annex I to this Regulation.

(42) 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.

(43) 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

1. The health claims listed in the Annex to this Regulation may be made on foods placed on the Union market in compliance with the conditions laid down in that Annex.

2. The health claims referred to in paragraph 1 shall be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

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