COUNCIL OF THE EUROPEAN UNION

Brussels, 25 January 2011

5610/11

DENLEG 7

COVER NOTE

from:	European Commission
date of receipt:	21 January 2011
to:	General Secretariat of the Council
Subject:	Draft COMMISSION REGULATION on the authorisation and refusal of authorisation of certain health claims made on foods and referring to children's development and health

Delegations will find attached Commission document D012200/02.

Encl.: D012200/02

EUROPEAN COMMISSION

Brussels,
C(2010) final
D012200/02

Draft

COMMISSION REGULATION

of

on the authorisation and refusal of authorisation of 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[1], 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 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. Any decision to amend the lists of permitted health claims shall include the particulars referred to in Article 16(4) of Regulation (EC) No 1924/2006 including, *inter alia* and as the case may be, specific conditions of use.

(5) The eight opinions referred to in this Regulation are related to applications for health claims referring to the effects of essential fatty acids on children's development and health, as referred to in Article 14(1)(b) of Regulation (EC) No 1924/2006.

[1] OJ L 404, 30.12.2006, p. 9.

(6) Following three applications from Mead Johnson & Company, submitted on 19 January 2008 pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006 and requesting the protection of proprietary data for nineteen studies, the Authority was required to deliver three opinions on health claims related to the effects of docosahexaenoic acid (DHA) and arachidonic acid (ARA) on visual development **(Question No EFSA-Q-2008-211**[2]**, EFSA-Q-2008-688**[3] and **EFSA-Q-2008-689**[4]**)**. The claims proposed by the applicant were worded, respectively, as follows: "DHA and ARA contribute to the optimal visual development of infants and young children", "Lipil® contributes to optimal visual development of infants and young children" and "Enfamil® Premium contributes to optimal visual development of infants". Lipil® and Enfamil® Premium, as stated by the applicant, contain DHA and ARA at specific levels and ratio.

(7) On the basis of the data submitted, the Authority concluded in its opinions received by the Commission on 13 February 2009 and on 23 March 2009 respectively that a cause and effect relationship had been established between the intake of infant and follow-on formulae supplemented with DHA and the visual development in infants either breastfed until weaning or having received a DHA-enriched formula containing 0.3% of fatty acids as DHA from birth until weaning. The Authority noted that it could not have reached this conclusion without considering seven studies claimed by the applicant as proprietary. Further, the Authority concluded that a cause and effect relationship had not been established between the intake of ARA and the claimed effect.

(8) In the Authority's responses of 3 September 2009 to comments received pursuant to Article 16(6) of Regulation (EC) No 1924/2006 and of 3 December 2009 to the request of the Commission for advice relating *inter alia* to the applications referred to in Question No EFSA-Q-2008-211, EFSA-Q-2008-688 and EFSA-Q-2008-689, it was concluded that the claimed effect could be extended to foods intended to infants while they are being weaned, as defined in Directive 2006/125/EC. Accordingly and without prejudice to Directive 2009/39/EC and specific Directives applicable to certain groups of foodstuffs for particular nutritional uses, a health claim reflecting this conclusion and accompanied by specific conditions of use should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and it should be included in the Union list of permitted claims.

(9) Following the receipt of the Authority's opinions in relation to the applications referred to in Question No EFSA-Q-2008-211, EFSA-Q-2008-688 and EFSA-Q-2008-689, the Commission went back to the applicant for further clarification on the justification provided regarding the seven studies claimed as proprietary and in particular regarding the *"exclusive right of reference"* as referred to in Article 21(1)(b) of Regulation (EC) No 1924/2006. All the justifiable information provided by the applicant has been assessed. As all seven studies had been published prior to the submission of the applications for authorisation of the health claims and in the light of the objectives of Regulation (EC) No 1924/2006 among which is the protection of the investment made by innovators in gathering the information and data supporting an application under

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2 The EFSA Journal (2009), 1003, 1-8.
3 The EFSA Journal (2009), 941, 1-14.
4 The EFSA Journal (2009), 1004, 1-8.

that Regulation, their protection is not justified and accordingly it should not be granted.

(10) Following an application from Merck Selbstmedikation GmbH, submitted on 16 January 2008 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 DHA on visual development of the unborn child and breastfed infant **(Question No EFSA-Q-2008-675)**[5]. The claim proposed by the applicant was worded as follows: "DHA is important for early development of the eyes in the foetus (unborn child) and infant. Maternal DHA supply contributes to the child's visual development".

(11) On the basis of the data submitted, the Authority concluded in its opinion received by the Commission on 23 April 2009 that there was insufficient evidence to establish a cause and effect relationship between the consumption of supplementary DHA during pregnancy and lactation and visual development in unborn children or breastfed infants.

(12) Following an application from Merck Selbstmedikation GmbH, submitted on 16 January 2008 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 DHA on cognitive development **(Question No EFSA-Q-2008-773)**[6]. The claim proposed by the applicant was worded as follows: "DHA is important for early development of the brain in the foetus (unborn child) and infant. Maternal DHA supply contributes to the child's cognitive development".

(13) On the basis of the data submitted, the Authority concluded in its opinion received by the Commission on 23 April 2009 that there was insufficient evidence to establish a cause and effect relationship between the consumption of supplementary DHA during pregnancy and lactation and cognitive development in unborn children or breastfed infants.

(14) However, in the Authority's responses of 4 August 2009 to comments received pursuant to Article 16(6) of Regulation (EC) No 1924/2006 and of 3 December 2009 to a request from the Commission for advice related *inter alia* to the applications referred to in Question No EFSA-Q-2008-675 and EFSA-Q-2008-773, it was concluded that as DHA is a major structural and functional long chain polyunsaturated fatty acid, it can contribute to the normal brain development and to the normal development of the eye of the foetus and breastfed infants. Further, it was clarified that most DHA is provided to breastfed infants via breast milk in which the DHA concentration is dependent both on maternal DHA dietary intake and on maternal DHA stores. Accordingly, health claims reflecting these conclusions and accompanied by specific conditions of use should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and they should be included in the Union list of permitted claims.

(15) 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 to the present Regulation as regards the

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[5] The EFSA Journal (2009), 1006, 1-12.

[6] The EFSA Journal (2009), 1007, 1-14.

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.

(16) 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 to this Regulation.

(17) Following three applications from Mead Johnson & Company, submitted on 19 January 2008 pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006, the Authority was required to deliver three opinions on health claims related to the effects of DHA and ARA on brain development **(Question No EFSA-Q-2008-212**[7], **EFSA-Q-2008-690**[8] and **EFSA-Q-2008-691**[9]**).** The claims proposed by the applicant were worded, respectively, as follows: "DHA and ARA contribute to the optimal brain development of infants and young children", "Lipil® contributes to optimal brain development of infants and young children" and "Enfamil® Premium contributes to optimal brain development of infants and young children". Lipil® and Enfamil® Premium as stated by the applicant contain DHA and ARA at specific levels and ratio.

(18) On the basis of the data submitted, the Authority concluded in its opinions received by the Commission on 23 March 2009 that there was insufficient evidence to establish a cause and effect relationship between the consumption of DHA and ARA, Lipil® and Enfamil® Premium, respectively, and the claimed effect.

(19) In the Authority's responses of 3 September 2009 to comments received pursuant to Article 16(6) of Regulation (EC) No 1924/2006 and of 3 December 2009 to the request of the Commission for advice relating *inter alia* to the applications referred to in Question No EFSA-Q-2008-690, EFSA-Q-2008-691 and EFSA-Q-2008-212, it was concluded that as DHA is a major structural and functional long chain polyunsaturated fatty acid, it can contribute to the normal brain development of the foetus, infants and young children. Therefore, the Commission and the Member States considered whether a health claim reflecting this conclusion should be authorised. However, on the basis of the data submitted in the three applications and of the current scientific knowledge, the Authority could not provide specific advice on the appropriate conditions of use that should accompany this health claim. Accordingly, as risk managers could not establish specific conditions of use in accordance with Article 16(4) of the Regulation (EC) No 1924/2006, and given that the lack of such specific conditions of use means that the beneficial effect of the product could not be assured, which amounts to misleading the consumer, this health claim should not be included in the lists of permitted health claims.

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7 The EFSA Journal (2009), 1000, 1-13.
8 The EFSA Journal (2009) 1001, 1-8.
9 The EFSA Journal (2009) 1002, 1-8.

(20) 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. The Commission took also into account all relevant advice from the Authority, including opinions on labelling reference intake values for n-3 and n-6 polyunsaturated fatty acids (**Question No EFSA-Q-2009-00548**[10]) and on dietary reference values for fat including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, *trans* fatty acids, and cholesterol (**Question No EFSA-Q-2008-466**[11]).

(21) 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, provided an application was made before 19 January 2008. Accordingly, the transition period laid down in that Article is applicable to health claims listed in Annex II of this Regulation.

(22) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

1. The health claims listed in Annex I to this Regulation may be made on foods on the European 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 referred to in Article 14(1) of Regulation (EC) No 1924/2006.

Article 2

1. The health claims listed in Annex II to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

2. However, they may continue to be used for six months after the entry into force of this Regulation.

Article 3

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

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[10] The EFSA Journal (2009), 1176, 1-11.
[11] The EFSA Journal 2010; 8(3) 1461.

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

Done at Brussels,

For the Commission
José Manuel BARROSO
The President

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)(b) health claim referring to children's development and health	Mead Johnson & Company, 3 rue Joseph Monier-BP 325, 92506 Rueil-Malmaison Cedex, France	Docosahexaenoic acid (DHA)	Docosahexaenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age.	Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 100 mg of DHA. When the claim is used on follow-on formula, the food shall contain at least 0.3% of the total fatty acids as DHA.		Q-2008-211, Q-2008-688, Q-2008-689
Article 14(1)(b) health claim referring to children's development and health	Merck Selbstmedikation GmbH, Roesslerstrasse 96, 64293 Darmstadt, Germany	Docosahexaenoic acid (DHA)	Docosahexaenoic acid (DHA) maternal intake contributes to the normal development of the eye of the foetus and breastfed infants.	Information shall be given to pregnant and lactating women that the beneficial effect is obtained with a daily intake of 200 mg of DHA in addition to the recommended daily intake for omega-3 fatty acids for adults, i.e.: 250 mg DHA		Q-2008-675

				and eicosapentaenoic acid (EPA). The claim can be used only for food which provides a daily intake of at least 200 mg DHA.		
Article 14(1)(b) health claim referring to children's development and health	Merck Selbstmedikation GmbH, Roesslerstrasse 96, 64293 Darmstadt, Germany	Docosahexaenoic acid (DHA)	Docosahexaenoic acid (DHA) maternal intake contributes to the normal brain development of the foetus and breastfed infants.	Information shall be given to pregnant and lactating women that the beneficial effect is obtained with a daily intake of 200 mg of DHA in addition to the recommended daily intake for omega-3 fatty acids for adults, i.e.: 250 mg DHA and EPA. The claim can be used only for food which provides a daily intake of at least 200 mg DHA.		Q-2008-773

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)(b) health claim referring to children's development and health	Docosahexaenoic acid (DHA) and arachidonic acid (ARA)	Docosahexaenoic acid (DHA) and arachidonic acid (ARA) contribute to the optimal brain development of infants and young children	Q-2008-212
Article 14(1)(b) health claim referring to children's development and health	Lipil®	Lipil® contributes to optimal brain development of infants and young children	Q-2008-690
Article 14(1)(b) health claim referring to children's development and health	Enfamil® Premium	Enfamil® Premium contributes to optimal brain development of infants and young children	Q-2008-691