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COMMISSION REGULATION (EU) No …/..

of XXX

on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk.

(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 thereof, 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 Abtei Pharma Vertriebs GmbH., submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was asked to deliver an opinion on a health claim related to Calcium and vitamin D3 chewing tablets and bone loss. **(Question No EFSA-Q-2008-721)**[2]. The claim proposed by the applicant was worded as follows: "Chewing tablets with calcium and vitamin D improves bone density in women 50 years and older".

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1 OJ L 404, 30.12.2006, p. 9.

2 The EFSA Journal (2009) 1180, 1-13.

(6) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 7 August 2009 that a cause and effect relationship had been established between the intake of calcium, either alone or in combination with vitamin D, and reducing the loss of bone mineral density (BMD) in postmenopausal women. Reducing the loss of BMD may contribute to a reduction in the risk of bone fractures. Accordingly, two health claims 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.

(7) However, the Authority concluded that the information provided was insufficient to establish conditions of use for the claims. Subsequently, the Commission went back to the Authority to seek further advice to enable the regulators to set appropriate conditions of use for the relevant health claims. The Authority concluded in its opinion received by the Commission and the Member States on 17 May 2010 **(Question No EFSA-Q-2009-00940)**[3] that at least 1200 mg of calcium from all sources or at least 1200 mg of calcium and 800 I.U. (20 µg) of vitamin D from all sources should be consumed daily in order to obtain the claimed effect.

(8) Following an application from DSM Nutritional Products Europe AG, 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 vitamin D and risk of falling for men and women 60 years of age and older **(Question No EFSA-Q-2010-01233)**[4]. The claim proposed by the applicant was worded as follows: "Vitamin D reduces the risk of falling. Falling is a risk factor for fractures".

(9) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 30 September 2011 that a cause and effect relationship had been established between the intake of vitamin D and a reduction in the risk of falling. Falling is a risk factor for bone fractures. 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.

(10) Following discussions with the Member States related, *inter alia*, to the authorisation of the two health claims for calcium and vitamin D, the Commission asked the Authority to re-evaluate the safety in use of calcium and vitamin D. The Authority proposed in its opinion received by the Commission and the Member States on 27 July 2012 (**Question No EFSA-Q-2011-00956**)[5] a tolerable upper level of 2500 mg of calcium for adults, including pregnant and lactating women. In addition, the Authority proposed in its opinion received by the Commission and the Member States on 27 July 2012 (**Question No EFSA-Q-2011-00955**)[6] a tolerable upper level of 100 µg of vitamin D for adults, including pregnant and lactating women.

(11) 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 this Regulation as regards the authorised

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3 The EFSA Journal (2010); 8(5):1609.
4 The EFSA Journal (2011); 9(9):2382.
5 The EFSA Journal 2012; 10(7):2814.
6 The EFSA Journal 2012; 10(7):2813.

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.

(12) 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.

(13) Following an application from GP International Holding B.V., 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 glucosamine hydrochloride and reduced rate of cartilage degeneration **(Question No EFSA-Q-2009-00412)**[7]. The claim proposed by the applicant was worded as follows: "Slowing down/reduce the destruction process of cartilage of the musculoskeletal system and consequently reduce the risk of osteoarthritis".

(14) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 29 October 2009 that a cause and effect relationship had not been established between the consumption of glucosamine hydrochloride 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.

(15) Following an application from the European Natural Soyfood Manufacturers Association (ENSA), 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 isolated soy protein on reduction of blood LDL-cholesterol concentrations **(Question No EFSA-Q-2011-00784)**[8]. The claim proposed by the applicant was worded as follows: "Protein-rich soybean component has been shown to lower/reduce blood cholesterol; blood cholesterol lowering may reduce the risk of (coronary) heart disease".

(16) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 2 February 2012 that a cause and effect relationship had not been established between the consumption of isolated soy protein (as defined by the applicant) 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.

(17) Following an application from Health Concern B.V., 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 a combination of plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations

[7] The EFSA Journal 2009; 7(10):1358.
[8] The EFSA Journal 2012; 10(2):2555.

(Question No EFSA-Q-2009-00237, EFSA-Q-2011-01114)[9]. The claim proposed by the applicant was worded as follows: "Actively lowers cholesterol".

(18) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 17 July 2012 that a cause and effect relationship had not been established between the consumption of a combination of plant sterols and Cholesternorm®mix and the claimed effect at the proposed conditions of use. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(19) 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.

(20) The addition of substances to or the use of substances in foodstuffs is governed by specific Union and national legislation, as is the classification of products as foodstuffs or medicinal products. Any decision on a health claim in accordance with Regulation (EC) No 1924/2006 such as inclusion in the list of permitted claims referred to in Article 14(1) thereof does not constitute an authorisation to the marketing of the substance on which the claim is made, a decision on whether the substance can be used in foodstuffs, or a classification of a certain product as a foodstuff.

(21) 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 the 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 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

The health claims listed in the 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.

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*.

9 The EFSA Journal 2012; 10(7):2810.

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

Done at Brussels,

For the Commission
The President
José Manuel BARROSO

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 a reduction of a disease risk	Abtei Pharma Vertriebs GmbH, Abtei 1, 37696, Marienműnster, Germany.	Calcium	Calcium may reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor in the development of osteoporotic bone fractures	The claim may be used only for food which provides at least 360 mg of calcium per quantified portion. When the claim is used on food supplements at least 1200mg of calcium should be provided per daily portion. Information shall be given to the consumer that the target population is women 50 years and older and the beneficial effect is obtained with a daily intake of at least 1200 mg of calcium from all sources.	For foods with added calcium the claim may be used only for those targeting women 50 years and older	Q-2008-721 Q- 2009-940
Article 14(1)(a) health claim referring to a reduction of a disease risk	Abtei Pharma Vertriebs GmbH, Abtei 1, 37696, Marienműnster, Germany.	Calcium and vitamin D	Calcium and vitamin D may reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a	The claim may be used only for food supplements which provide at least 1200 mg of calcium and 20µg of vitamin D per daily portion Information shall be given to the consumer that the target population is women 50 years and older and the	[For foods with added calcium and/or vitamin D the claim may be used only for those targeting women 50 years	Q-2008-721 Q- 2009-940

			risk factor in the development of osteoporotic bone fractures	beneficial effect is obtained with a daily intake of at least 1200 mg of calcium and 20µg of vitamin D from all sources.	and older]	
Article 14(1)(a) health claim referring to a reduction of a disease risk	DSM Nutritional Products Europe AG, Peter Merian Haus, Peter Merian-Strasse 80, 4052 Basel, Switzerland.	Vitamin D	Vitamin D may reduce the risk of falling. Falling is a risk factor for bone fractures.	[The claim may be used only for food supplements which provide 20µg of vitamin D per daily portion] OR [The claim may be used only for food which **naturally** contains vitamin D and which provides at least 6µg of vitamin D per quantified portion. When the claim is used on food supplements at least 20µg of vitamin D should be provided per daily portion.] Information shall be given to the consumer that the target population is men and women 60 years and older and the beneficial effect is obtained with a daily intake of 20µg of vitamin D from all sources.	[For foods with added vitamin D the claim may be used only for those targeting men and women 60 years and older]	Q-2010-01233

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 a reduction of a disease risk	Glucosamine hydrocloride	Slowing down/reduce the destruction process of cartilage of the musculoskeletal system and consequently reduce the risk of osteoarthritis.	Q-2009-00412
Article 14(1)(a) health claim referring to a reduction of a disease risk	Isolated soy protein	Protein-rich soybean component has been shown to lower/reduce blood cholesterol; blood cholesterol lowering may reduce the risk of (coronary) heart disease.	Q-2011-00784
Article 14(1)(a) health claim referring to a reduction of a disease risk	Plant sterols in combination with Cholesternorm®mix	Actively lowers cholesterol.	Q-2009-00237 Q-2011-01114