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Subject:	COMMISSION REGULATION (EU) No …/.. of XXX authorising and refusing to authorise certain health claims made on foods and referring to the reduction of disease risk

Delegations will find attached document D034099/02.

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COMMISSION REGULATION (EU) No …/..

of XXX

authorising and refusing to authorise certain health claims made on foods and referring to the reduction of disease risk

(Text with EEA relevance)

COMMISSION REGULATION (EU) No …/..

of XXX

authorising and refusing to authorise certain health claims made on foods and referring to the reduction of disease risk

(Text with EEA relevance)

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 required 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

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1 OJ L 404, 30.12.2006, p. 9.

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

applicant was worded as follows: "Chewing tablets with calcium and vitamin D improve bone density in women 50 years and older. Thus chewing tablets may reduce the risk of osteoporotic fractures".

(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. 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 risk managers 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.

(7) When the health claim is made only on calcium, in order to ensure that a food provides a significant quantity of calcium, it is appropriate to set conditions of use which allow the claim to be made only on foods which provide at least 400 mg of calcium per quantified portion.

(8) Taking into account the high level of vitamin D intake required to achieve the claimed effect (20 μg), when the health claim is made on the combination of calcium and vitamin D, it is appropriate to limit the use of the claim to food supplements. In order to ensure that a food supplement would provide a significant quantity of calcium and vitamin D in the context of this claim, it is appropriate to set conditions of use which allow the claim to be made only on food supplements which provide at least 400 mg of calcium and 15 μg of vitamin D per daily portion.

(9) 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”.

(10) 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, which is positevely associated with postural instability and muscle weakness. A reduction in the risk of falling among men and women 60 years of age

[3] EFSA Journal (2010);8(5):1609.
[4] EFSA Journal (2011);9(9):2382.

and older is beneficial to human health by reducing the risk of 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.

(11) In its opinion, the Authority also concluded that 800 I.U. (20 μg) of vitamin D, from all sources, should be consumed daily in order to obtain the claimed effect. Taking into account the high level of vitamin D intake required to achieve the claimed effect (20 μg), it is appropriate to limit the use of the claim to food supplements. In order to ensure that a food supplement would provide a significant quantity of vitamin D in the context of this claim, it is appropriate to set conditions of use which allow the claim to be made only on food supplements which provide at least 15 μg of vitamin D per daily portion.

(12) 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 Annex I to this Regulation as regards the 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.

(13) 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 Annex I to this Regulation.

(14) 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)**[5]. 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".

(15) 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.

(16) Following an application from the European Natural Soyfood Manufacturers Association (ENSA), the European Vegetable Protein Federation (EUVEPRO) and the Soya Protein Association (SPA), submitted pursuant to Article 14(1)(a) of Regulation

5 EFSA Journal 2009;7(10):1358.

(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)**[6]. 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".

(17) 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.

(18) 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 **(Question No EFSA-Q-2009-00237, EFSA-Q-2011-01114)**[7]. The claim proposed by the applicant was worded as follows: “Actively lowers cholesterol”.

(19) 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.

(20) Following an application from Minami Nutrition Health BVBA, 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 eicosapentaenoic acid (EPA) on a reduction of the Arachidonic Acid (AA)/EPA ratio in blood in children with attention deficit hyperactivity disorder (ADHD) **(Question No EFSA-Q-2012-00573)**[8]. The claim proposed by the applicant was worded as follows: “EPA has been shown to reduce the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms. These children are also characterised by less hyperactivity and/or coexisting oppositional behaviour”.

(21) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 8 April 2013 that the target population for the claim is a diseased population (i.e. children with ADHD) and that the claimed effect relates to the treatment of a disease.

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6 EFSA Journal 2012;10(2):2555.
7 EFSA Journal 2012;10(7):2810.
8 EFSA Journal 2013;11(4):3161.

(22) Regulation (EC) No 1924/2006 complements the general principles of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs[9]. Article 2(1)(b) of Directive 2000/13/EC provides that the labelling shall not attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties. Accordingly, as the attribution of medicinal properties to foods is prohibited, the claim related to the effects of eicosapentaenoic acid (EPA) on a reduction of the AA/EPA ratio in blood in children with ADHD should not be authorised.

(23) Following an application from McNeil Nutritionals and Raisio Nutrition 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 consumption of 2g/day of plant stanols (as plant stanol esters) as part of a diet low in saturated fat and a two-fold greater reduction in blood LDL-cholesterol concentrations compared to the consumption of a diet low in saturated fat alone **(Question No EFSA-Q-2012-00915)**[10]. The claim proposed by the applicant was worded as follows: "Consuming 2 g/day plant stanols (as plant stanol esters) as part of a diet low in saturated fat results in a 2-fold greater reduction in LDL-cholesterol than consuming a low saturated fat diet alone. High cholesterol is a risk factor in the development of coronary heart disease".

(24) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 8 April 2013 that the evidence provided by the applicant does not establish that the consumption of 2 g/day plant stanols (as plant stanol esters) as part of a diet low in saturated fat results in a two-fold greater reduction in LDL-cholesterol concentrations compared with consuming a diet low in saturated fat alone. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(25) 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.

(26) 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.

(27) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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9 OJ L 109, 6.5.2000, p. 29.

10 EFSA Journal 2013;11(4):3160.

HAS ADOPTED THIS REGULATION:

Article 1

1. The health claims listed in Annex I 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

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.

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*.

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