Commission Regulation (EU) No 957/2010 of 22 October 2010 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk and to children's development and health (Text with EEA relevance)

COMMISSION REGULATION (EU) No 957/2010

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(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 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 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.

(5) Two opinions referred to in this Regulation are related to applications for reduction of disease risk claims, as referred to in Article 14(1)(a) of Regulation (EC) No 1924/2006 and three opinions are 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.

(6) Following an application from 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

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iodine on normal growth of children (Question No EFSA-Q-2008-324)[(2)]. The claim proposed by the applicant was worded as follows: 'Iodine is necessary for the growth of children'.

(7) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 20 November 2009 that a cause and effect relationship had been established between the intake of iodine and the claimed effect. Accordingly, 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 Union list of permitted claims.

(8) Following an application from 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 iron on cognitive development of children (Question No EFSA-Q-2008-325)[(3)]. The claim proposed by the applicant was worded as follows: 'Iron is necessary for the cognitive development of children'.

(9) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 20 November 2009 that a cause and effect relationship had been established between the intake of iron and the claimed effect. Accordingly, 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 Union list of permitted claims.

(10) 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 authorised claims and include, as the case may be, the revised wording of the claims, specific conditions of use of the claims, 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.

(11) 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, as indicated in Annex I.

(12) Following an application from GP International Holding BV, 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 OPC Premium™ on reduction of blood cholesterol (Question No EFSA-Q-2009-00454)[(4)]. The claim proposed by the applicant was worded as follows: 'OPC have been shown to reduce blood cholesterol levels and may therefore reduce the risk of cardiovascular disease'.

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(13) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 26 October 2009 that a cause and effect relationship had not been established between the intake of OPC Premium™ 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.

(14) Following an application from Valosun AS, 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 Uroval® on urinary tract infections (Question No EFSA-Q-2009-00600)[(5)]. The claim proposed by the applicant was worded as follows: 'Cranberry extract and D-mannose, the main active ingredients of the food supplement Uroval®, eliminate the adhesion of harmful bacteria to the bladder wall. The adhesion of harmful bacteria to the bladder wall is the main risk factor in the development of urinary tract infections'.

(15) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 22 December 2009 that a cause and effect relationship had not been established between the intake of Uroval® 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 Töpfer 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 the effects of a combination of bifidobacteria (*Bifidobacterium bifidum*, *Bifidobacterium breve*, *Bifidobacterium infantis*, *Bifidobacterium longum*) on decreasing potentially pathogenic intestinal micro-organisms (Question No EFSA-Q-2009-00224)[(6)]. The claim proposed by the applicant was worded as follows: 'Probiotic bifidobacteria lead to a healthy intestinal flora comparable to the composition of the intestinal flora of breast-fed infants' intestine'.

(17) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 22 December 2009 that a cause and effect relationship had not been established between the intake of the combination of bifidobacteria 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) 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.

(19) 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

The health claims set out in Annex I to this Regulation may be made on foods on the European Union market in compliance with the conditions set out in that Annex.

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Those health claims shall be included in the Union 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 shall not be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

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 3

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.

Done at Brussels, 22 October 2010.

For the Commission

The President

José Manuel BARROSO