Commission Regulation (EU) No 1160/2011 of 14 November 2011 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)

COMMISSION REGULATION (EU) No 1160/2011

of 14 November 2011

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)

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 CreaNutrition 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 oat beta-glucan on lowering blood cholesterol (Question No EFSA-Q-2008-681)[(2)]. The claim proposed by the applicant was worded as follows: 'The inclusion of oat beta-glucan as part of a balanced diet can actively lower/reduce blood LDL (low-density lipoprotein) and total cholesterol'.

(6) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 8 December 2010 that a cause and effect relationship had been established between the consumption of oat beta-glucan

and lowering of blood LDL-cholesterol concentrations. 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.

(7) 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 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.

(8) 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.

(9) Following an application from HarlandHall Ltd (on behalf of the Soya Protein Association, the European Vegetable Protein Federation and the European Natural Soyfood Manufacturers Association), 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 soy protein on the reduction of blood cholesterol concentrations (Question No EFSA-Q-2009-00672)[3]. The claim proposed by the applicants was worded as follows: 'Soy protein has been shown to lower/reduce blood cholesterol; blood cholesterol lowering may reduce the risk of (coronary) heart disease'.

(10) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 30 July 2010 that a cause and effect relationship had not been established between the consumption of soy protein 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.

(11) Following an application from Danone France, 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 Actimel®, a fermented milk product containing *Lactobacillus casei* DN-114 001 and yoghurt symbiosis on the reduction of the presence of *Clostridium difficile* toxins in the gut (Question No EFSA-Q-2009-00776)[4]. The claim proposed by the applicant was worded as follows: 'Fermented milk containing the probiotic *Lactobacillus casei* DN-114001 and yogurt symbiosis decreases presence of *Clostridium difficile* toxins in the gut (of susceptible ageing people). Presence of *Clostridium difficile* toxins is associated with the incidence of acute diarrhoea'.

(12) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 8 December 2010 that the evidence provided

is insufficient to establish a cause and effect relationship between the consumption of Actimel® and reduction of the risk of *C. difficile* diarrhoea by reducing the presence of *C. difficile* toxins. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(13) 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.

(14) 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 claim 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 claim 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 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 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, 14 November 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX I

PERMITTED HEALTH CLAIM

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	CreaNutrition AG, Business Park, 6301 Zug, Switzerland	Oat beta-glucan	Oat beta-glucan has been shown to lower/ reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of oat beta-glucan. The claim can be used for foods which provide at least 1 g of oat beta glucan per quantified portion.		Q-2008-681

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	Soy protein	Soy protein has been shown to lower/reduce blood	Q-2009-00672

to a reduction of a disease risk		cholesterol; blood cholesterol lowering may reduce the risk of (coronary) heart disease	
Article 14(1)(a) health claim referring to a reduction of a disease risk	Actimel® *Lactobacillus casei* DN-114 001 plus yoghurt symbiosis	Fermented milk containing the probiotic *Lactobacillus casei* DN-114 001 and yoghurt symbiosis decreases presence of *Clostridium difficile* toxins in the gut (of susceptible ageing people). Presence of *Clostridium difficile* toxins is associated with the incidence of acute diarrhoea.	Q-2009-00776

(**1**) OJ L 404, 30.12.2006, p. 9.

(**2**) *EFSA Journal* 2010; 8(12):1885.

(**3**) *EFSA Journal* 2010; 8(7):1688.

(**4**) *EFSA Journal* 2010; 8(12):1903.

Status:
Point in time view as at 14/11/2011.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EU) No 1160/2011. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.