COMMISSION REGULATION (EU) No 378/2012

of 3 May 2012

refusing to authorise 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)

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 SVUS Pharma a.s, 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 ProteQuine®, a mixture of free amino acids, oligopeptides and nucleotides on increase of suppressed concentrations of secretory immunoglobulin A (ScIgA) and reduction of the risk of influenza and common cold (Question No EFSA-Q-2008-397) [2]. The claim proposed by the applicant was worded as follows: "ProteQuine® elevates/maintains the level of ScIgA on mucous membranes. Decreased or insufficient level of ScIgA is a risk factor in the development of common cold or influenza".

(6) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 13 April 2011 that a cause and effect relationship had not been established between the consumption of ProteQuine® and increasing suppressed concentrations of ScIgA and reducing the risk of common cold and influenza. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) Following an application from SVUS Pharma a.s, 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 ProteQuine®, a mixture of free amino acids, oligopeptides and nucleotides, and bovine lactoferrin on increase of suppressed concentrations of secretory immunoglobulin A (ScIgA) and reduction of the risk of common cold with sore throat (Question No EFSA-Q-2008-398) [3]. The claim proposed by the applicant was worded as follows: "ProteQuine® in combination with bovine lactoferrin elevates/maintains the level of ScIgA on mucous membranes. Decreased or insufficient level of ScIgA is a risk factor in the development of common cold with sore throat and combination of ProteQuine® with bovine lactoferrin reduces the risk of the development of sore throat".

(8) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 13 April 2011 that a cause and effect relationship had not been established between the consumption of ProteQuine® and bovine lactoferrin and increasing suppressed concentrations of ScIgA and reduction of the risk of common cold with sore throat. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(9) Following an application from CSL - Centro Sperimentale del Latte S.p.A., 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 *Lactobacillus delbrueckii* subsp. *bulgaricus* strain AY/CSL (LMG P-17224) and *Streptococcus thermophilus* strain 9Y/CSL (LMG P-17225) on beneficial modulation of intestinal microflora (Question No EFSA-Q-2008-273) [4]. The claim proposed by the applicant was worded as follows: "Maintaining the gut health by normalizing the intestinal flora".

[1] OJ L 404, 30.12.2006, p. 9.
[2] The EFSA Journal 2011; 9(4):2128.
[3] The EFSA Journal 2011; 9(4):2129.
[4] The EFSA Journal 2011; 9(7):2288.

(10) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 20 July 2011 that a cause and effect relationship had not been established between the consumption of the combination of *L. delbrueckii* subsp. *bulgaricus strain* AY/CSL (LMG P-17224) and *S. thermophilus strain* 9Y/CSL (LMG P-17225) and a beneficial physiological effect related to 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 the European Dietetic Food Industry Association (IDACE), 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 beta-palmitate on increased calcium absorption (Question No EFSA-Q-2008-172) [1]. The claim proposed by the applicant was worded, *inter alia*, as follows: "Beta palmitate enrichment contributes to increase calcium absorption".

(12) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 28 July 2011 that the evidence provided was insufficient to establish a cause and effect relationship between the consumption of beta-palmitate 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.

(13) 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 the health claim relevant to beta-palmitate listed in the Annex of this Regulation.

(14) As the health claim application relevant to *Lactobacillus delbrueckii* subsp. *bulgaricus* strain AY/CSL (LMG P-17224) and *Streptococcus thermophilus* strain 9Y/CSL (LMG P-17225) was not made before 19 January 2008, the requirement provided for in Article 28(6)(b) is not fulfilled, and the transition period laid down in that Article is not applicable.

(15) However, in order to ensure that this Regulation is fully complied with, both food business operators and the national competent authorities should take the necessary actions to ensure that, at the latest six months following the entry into force of this Regulation, the health claims listed in its Annex that have been submitted pursuant to Article 14(1)(b) of Regulation (EC) No 1924/2006 are no longer used.

(16) 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.

(17) 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 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, health claims as referred to in Article 14(1)(b) of Regulation (EC) No 1924/2006 and referred to in paragraph 1 used prior to the entry into force of this Regulation, may continue to be used for a maximum period of six months after the entry into force of this Regulation.

Article 2

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, 3 May 2012.

For the Commission
The President
José Manuel BARROSO

[1] The EFSA Journal 2011; 9(7):2289.

ANNEX

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	ProteQuine®	ProteQuine® elevates/maintains the level of ScIgA on mucous membranes. Decreased or insufficient level of ScIgA is a risk factor in the development of common cold or influenza	Q-2008-397
Article 14(1)(a) health claim referring to a reduction of a disease risk	ProteQuine® in combination with bovine lactoferrin	ProteQuine® in combination with bovine lactoferrin elevates/maintains the level of ScIgA on mucous membranes. Decreased or insufficient level of ScIgA is a risk factor in the development of common cold with sore throat and combination of ProteQuine® with bovine lactoferrin reduces the risk of the development of sore throat	Q-2008-398
Article 14(1)(b) health claim referring to children's development and health	*Lactobacillus delbrueckii* subsp. *bulgaricus* strain AY/CSL (LMG P-17224) and *Streptococcus thermophilus* strain 9Y/CSL (LMG P-17225)	Maintaining the gut health by normalizing the intestinal flora	Q-2008-273
Article 14(1)(b) health claim referring to children's development and health	Beta palmitate	Beta palmitate enrichment contributes to increase calcium absorption	Q-2008-172