COMMISSION REGULATION (EC) No 984/2009

of 21 October 2009

refusing to authorise certain health claims made on food, other than those referring to the reduction of disease risk and to children's development and health

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 18(5) 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 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 and to deliver an opinion on a health claim concerned.

(4) The Commission is to decide on the authorisaton of health claims taking into account the opinion delivered by the Authority.

(5) Following an application from Pierre Fabre Dermo Cosmétique submitted on 14 April 2008 pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Elancyl Global Silhouette® on the regulation of body composition in people with light to moderate overweight (Question No EFSA-Q-2008-285) [2]. The claim proposed by the applicant was worded as follows: 'Clinically tested as of 14 days. Your silhouette is apparently and globally redrawn, resculpted and refined at 28 days'.

(6) On 12 August 2008, the Commission and the Member States received the scientific opinion from the Authority which concluded that on the basis of the data presented, a cause and effect relationship was not established between the consumption of Elancyl Global Silhouette® in the quantities and duration proposed 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.

(7) Following an application from Valio Ltd submitted on 8 July 2008, pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of LGG® MAX on gastro-intestinal discomfort (Question No EFSA-Q-2008-444) [3]. The claim proposed by the applicant was worded as follows: 'LGG® MAX helps to reduce gastro-intestinal discomfort'.

(8) On 30 August 2008 the Commission and the Member States received the scientific opinion from the Authority which concluded that on the basis of the data presented, a cause and effect relationship was not established between the consumption of LGG® MAX (Mixture A or Mixture B) 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.

(9) 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.

(10) The health claim 'LGG® MAX helps to reduce gastro-intestinal discomfort' is a health claim as referred to Article 13(1)(a) of Regulation (EC) No 1924/2006 and therefore subject to the transition measure laid down in Article 28(5) of that Regulation. As the Authority concluded that a cause and effect relationship is not established between the consumption of LGG® MAX and the claimed effect the claim does not comply with Regulation (EC) No 1924/2006, and therefore the transition period foreseen in Article 28(5) is not applicable. A transition period of six months should be provided for, to enable food business operators to adapt to the requirements of Regulation (EC) No 1924/2006. The health claim 'Clinically tested as of 14 days. Your silhouette is apparently and globally redrawn, resculpted and refined at 28 days' is a health claim as referred to Article 13(1)(c) of Regulation (EC) No 1924/2006 and therefore subject to the transition measure laid down in

[1] OJ L 404, 30.12.2006, p. 9.
[2] *The EFSA Journal* (2008) 789, pp. 1-2.
[3] *The EFSA Journal* (2008) 853, pp. 1-2.

Article 28(6) of that Regulation. However, as the application 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. Accordingly, a transition period of six months should be provided for, to enable food business operators to adapt to the requirements of this Commission Regulation.

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

HAS ADOPTED THIS REGULATION:

Article 1

Health claims set out in the Annex to this Regulation may not be made on food on the Community market.

Article 2

Health claims set out in the Annex 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, 21 October 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

REJECTED HEALTH CLAIMS

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Elancyl Global Silhouette®	Clinically tested as of 14 days. Your silhouette is apparently and globally redrawn, resculpted and refined at 28 days	EFSA-Q-2008-285
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	LGG® MAX multispecies probiotic	LGG® MAX helps to reduce gastro-intestinal discomfort	EFSA-Q-2008-444