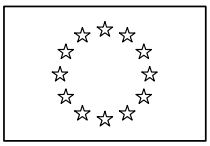

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2009) final

Draft

COMMISSION REGULATION

of

on the authorisation of 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)

Draft

COMMISSION REGULATION

of

on the authorisation of 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 and are forwarded by that authority to the European Food Safety Authority, 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 taking into account the opinion delivered by the Authority.

(5) Following an application from Pierre Fabre Dermo Cosmetique submitted 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)**. 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 the basis of the data submitted the Authority concluded that a cause and effect relationship is not established between the consumption of Elancyl Global Silhouette® in the quantities and duration proposed by the applicant and the claimed effect. On 12 August 2008, the Commission and the Member States received the opinion and

[1] OJ L 404, 30.12.2006, p. 9–25 [corrigendum: OJ L 12, 18.1.2007, p. 3–18].

since the claim does not comply with the conditions set out in Regulation (EC) No 1924/2006, it should not be authorised.

(7) Following an application from Valio Ltd submitted 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)**. The claim proposed by the applicant was worded as follows: "LGG® MAX helps to reduce gastro-intestinal discomfort".

(8) On the basis of the data submitted, the Authority concluded that a cause and effect relationship is not established between the consumption of LGG® MAX (Mixture A or Mixture B) and the claimed effect. On 30 August 2008 the Commission and the Member States received the opinion and since the claim does not comply with the conditions set out in 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 is provided by the Commission only 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 Article 28(6) of that Regulation. As the application was submitted later than 19 January 2008 the requirement provided under letter b) of Article 28(6) is not fulfilled, and therefore the transition period foreseen in Article 28(6) is not applicable. A transition period of six months is provided by the Commission only 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 listed in the Annex may not be made on food on the Community market.

Article 1 a

Health claims listed in the Annex may continue to be used for 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,

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

Application – Legal basis	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