# Commission Regulation (EU) No 383/2010 of 5 May 2010 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health (Text with EEA relevance)

## COMMISSION REGULATION (EU) No 383/2010

## of 5 May 2010

## refusing to authorise a health claim made on foods, other than those 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 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 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 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) Following an application from ELVIR S.A.S., submitted on 5 June 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 a milk product, rich in fibre and protein, on the reduction of the sense of hunger (Question No EFSA-Q-2008-396)[(2)]. The claim proposed by the applicant was worded as follows: 'This product reduces the sense of hunger'.

(6) On 19 December 2008, the Commission and the Member States received the scientific opinion from the Authority. It followed from the opinion and subsequent clarification from the Authority that on the basis of the data presented, a cause and effect relationship

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had not been established between the consumption of the milk product, rich in fibre and protein, and a reduction of the sense of hunger that is nutritionally or physiologically beneficial in terms of effect on food energy intake. Considering this, the Standing Committee of the Food Chain and Animal Health, at its meeting of 27 April 2009 concluded that the health claim should be subject to further consideration and the Commission submitted on 24 June 2009 a request to the Authority for further advice on a number of elements in relation to the submitted application.

(7) On 22 July 2009 the Commission and the Member States received the response from the Authority where it is clarified that the effect observed could not be attributed solely to the food tested because of the lack of information on the dietary conditions of the studies. Accordingly, that health claim can not be considered as complying with the requirements of Regulation (EC) No 1924/2006, and it should not be authorised.

(8) 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.

(9) Health claims referred to in Article 13(1)(c) of Regulation (EC) No 1924/2006 are subject to the transition measures laid down in Article 28(6) of that Regulation only if they comply with the conditions therein mentioned, among which that the applications for health claims not subject of evaluation and authorisation in a Member State have to be made before 19 January 2008. As the application for the health claim subject to the present Regulation was not made before that date it can not benefit from the transition period foreseen in Article 28(6) of that Regulation.

(10) 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 claim set out in the Annex to this Regulation shall not be included in the Community list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

*Article 2*

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.

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Done at Brussels, 5 May 2010.

*For the Commission*

*The President*

José Manuel BARROSO