Commission Regulation (EU) No 1162/2010 of 9 December 2010 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)

COMMISSION REGULATION (EU) No 1162/2010

of 9 December 2010

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 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 of the application, 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) The two opinions referred to in this Regulation are related to applications for health claims referring to children's development and health, as referred to in Article 14(1)(b) of Regulation (EC) No 1924/2006.

(6) Following an application from Danone Baby Nutrition, 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 Immunofortis® on the infant's immune system (Question No EFSA-Q-2008-106)[(2)]. The claim proposed by the applicant was worded as follows: 'Immunofortis® to naturally strengthen your baby's immune system'.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) No 1162/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(7) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 4 February 2010 that the information provided is insufficient to establish a cause and effect relationship between the consumption of Immunofortis® 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.

(8) Following an application from Vifor Pharma (Potters), 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 Eye q™ on working memory (Question No EFSA-Q-2009-00485)[3]. The claim proposed by the applicant was worded as follows: 'Eye q ™ (a unique combination of High-EPA/DHA/GLA omega-3, 6 PUFA) provides the essential nutrients that helps improve working memory in children'. The abbreviations used by the applicant refer respectively to eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), gamma-linolenic acid (GLA) and polyunsaturated fatty acids (PUFA).

(9) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 4 March 2010 that the information provided is insufficient to establish a cause and effect relationship between the intake of Eye q ™ 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.

(10) 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 6 months after the adoption of this Regulation, provided an application was made before 19 January 2008. However, as the health claim application relevant to Eye q™ 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 6 months should be provided for, to enable food business operators to adapt to the requirements laid down in this Regulation.

(11) 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.

(12) 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 claims set out 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.

However, they may continue to be used for 6 months after the entry into force of this Regulation.

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) No 1162/2010. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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.

Done at Brussels, 9 December 2010.

For the Commission

The President

José Manuel BARROSO