



EUROPEAN COMMISSION

Brussels, **XXX**
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[...] (2012) **XXX** draft

COMMISSION REGULATION (EU) No .../..

of **XXX**

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

(Text with EEA relevance)

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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 foods¹, and in particular Article 18(5) 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 Tchibo GmbH, submitted 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 consumption of coffee C21 and reduction of spontaneous DNA strand breaks (**Question No EFSA-Q-2011-00783**)². The claim proposed by the applicant was worded as follows: "Regular consumption of Coffee C21 contributes to the maintenance of DNA integrity in cells of the body"

¹ OJ L 404, 30.12.2006, p. 9.

² The EFSA Journal 2011; 9(12):2465.

- (6) On 6 December 2011, 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 had not been established between the consumption of coffee C21 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 Kao Corporation, submitted 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 diacylglycerol (DAG) oil and reduction of body weight (**Question No EFSA-Q-2011-00751**)³. The claim proposed by the applicant was worded as follows: "Substituting your usual vegetable oil with DAG oil helps in the management of body weight through weight loss"
- (8) On 6 December 2011, 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 had not been established between the consumption of DAG oil (as a replacement of triacylglycerol oils) 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) Following an application from Giuliani S.p.A., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was required to deliver an opinion on a health claim related to the effects of spermidine and prolongation of the growing phase (anagen) of the hair cycle (**Question No EFSA-Q-2011-00896**)⁴. The claim proposed by the applicant was worded as follows: "Spermidine prolongs the growing phase (anagen) of the hair cycle".
- (10) On 7 December 2011, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, the claimed effect is related to pathological conditions leading to the shortening of the anagen phase of hair growth and relates thus to the treatment of a disease. Pursuant to Directive (EC) No 2000/13⁵ and in particular its Article 7(3), it is a fundamental requirement that food information shall not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties. Accordingly, the claim should not be authorised.
- (11) Following an application from Clasado Ltd., submitted 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 Bimuno® (Bimuno® GOS) and reducing gastrointestinal discomfort (**Question No EFSA-Q-2011-00401**)⁶. The claim proposed by the applicant was worded as follows: "Regular daily consumption of 1.37 g galactooligosaccharides from Bimuno® may reduce intestinal discomfort".

³ The EFSA Journal 2011; 9(12):2469.

⁴ The EFSA Journal 2011; 9(12):2466.

⁵ Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, OJ L 109, 6.5.2000, p. 29.

⁶ The EFSA Journal 2011; 9(12):2472.

- (12) On 8 December 2011, 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 had not been established between the consumption of Bimuno® GOS 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) Following an application from Nordic Sugar A/S., submitted 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 sugar beet fibre and decreasing intestinal transit time (**Question No EFSA-Q-2011-00971**)⁷. The claim proposed by the applicant was worded as follows: "Sugar beet fibre decreases intestinal transit time".
- (14) On 8 December 2011, 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 had not been established between the consumption of sugar beet fibre 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.
- (15) Four health claims subject to this Regulation are health claims as referred to in point (a) of Article 13(1) of Regulation (EC) No 1924/2006 and may, in principle, benefit from the transitional period laid down in Article 28(5) of that Regulation. However, as the Authority concluded that cause and effect relationships have not been established between the foods and the claimed effects, the claims do not comply with Regulation (EC) No 1924/2006, and therefore they may not benefit from the transitional period provided for in that Article.
- (16) The health claim related to diacylglycerol (DAG) oil is a health claim as referred to in point (c) of Article 13(1) of Regulation (EC) No 1924/2006 and may, in principle, benefit from the transitional period laid down in Article 28(6) of that Regulation. However, as the application was not made before 19 January 2008, the requirement provided for in point (b) of Article 28(6) of that Regulation is not fulfilled, and the transitional period laid down in that Article is not applicable.
- (17) 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 are no longer used.
- (18) 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.
- (19) 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,

⁷ The EFSA Journal 2011; 9(12):2467.

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 13(3) of Regulation (EC) No 1924/2006.
2. However, the health claims 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,

For the Commission
The President
José Manuel BARROSO

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	Coffee C21	Regular consumption of Coffee C21 contributes to the maintenance of DNA integrity in cells of the body	Q-2011-00783
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Diacylglycerol (DAG) oil	Substituting your usual vegetable oil with DAG oil helps in the management of body weight through weight loss	Q-2011-00751
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Spermidine	Spermidine prolongs the growing phase (anagen) of the hair cycle	Q-2011-00896
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Bimuno® (Bimuno® GOS)	Regular daily consumption of 1.37 g galacto-oligosaccharides from Bimuno® may reduce intestinal discomfort	Q-2011-00401
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Sugar beet fibre	Sugar beet fibre decreases intestinal transit time	Q-2011-00971