Commission Regulation (EC) No 1024/2009 of 29 October 2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1024/2009

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on the authorisation and refusal of authorisation of certain health claims made on food and 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 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 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) On 14 November 2008 the Commission and the Member States received two opinions on applications for health claim authorisation from the Authority. On 10 December 2008, the Commission and the Member States received five opinions on applications for health claim authorisation from the Authority. On 19 December 2008, the Commission and the Member States received nine opinions on applications for health claim authorisation from the Authority. On 15 January 2009, the Commission and the Member States received one opinion on an application for health claim authorisation from the Authority. Meanwhile one application for health claim authorisation was subject to a previous decision.

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 1024/2009. 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*

(6) One opinion was related to an application for reduction of disease risk claim, as referred to in Article 14(1)(a) of Regulation (EC) No 1924/2006, and 15 opinions were 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.

(7) Following an application from Leaf Int and Leaf Holland and Leaf Suomi Oy submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of xylitol chewing gum/pastilles on the risk of tooth decay (Question No EFSA-Q-2008-321)[(2)]. The claim proposed by the applicant was worded as follows: 'Xylitol chewing gum/pastilles reduces the risk of caries'.

(8) On the basis of the data presented, the Authority concluded that a cause and effect relationship was established between the consumption of chewing gum sweetened with 100 % xylitol and the claimed effect. However, it concluded that a cause and effect relationship had not been established between the consumption of pastilles sweetened with at least 56 % xylitol and the claimed effect. Subject to a revised wording, the claim should be considered as complying with the requirements of Regulation (EC) No 1924/2006 and in particular Article 14(1)(a) thereof, and it should be included in the Community list of permitted claims.

(9) Following an application from Danone SA 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 dairy fresh cheese with significant amounts of calcium, vitamin D, phosphorus and protein on bone growth (Question No EFSA-Q-2008-217)[(3)]. The claim proposed by the applicant was worded as follows: 'Dairy fresh cheese contains calcium, vitamin D, phosphorus and protein, nutrients that contribute to healthy bone growth'.

(10) On the basis of the data presented, the Authority concluded that a cause and effect relationship was established between the consumption of calcium, vitamin D, phosphorus and protein and the claimed effect. Subject to a revised wording and taking into account that health claims for the same claimed effect are authorised for calcium, vitamin D and protein, the claim for phosphorus should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and it should be included in the Community list of permitted claims.

(11) Article 16(4) of Regulation (EC) No 1924/2006 provides that an opinion in favour of authorising a health claim should include certain particulars. Accordingly, those particulars should be set out in the Annex I to the present Regulation as regards the two authorised claims and include, as the case may be, the revised wording of the claim, specific conditions of use of the claim, and, where applicable, conditions or restrictions of use of the food and/or an additional statement or warning, in accordance with the rules laid down in Regulation (EC) No 1924/2006 and in line with the opinions of the Authority.

(12) One of the objectives of the Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that wording

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and presentation have to be taken into account in that respect; that therefore where the wording of claims has the same meaning for consumers as that of an authorised health claim as they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, included in Annex I to the present Regulation, they should be subject to the same conditions of use indicated therein.

(13) Following an application from the Institute of Biotechnology, Sera and Vaccines Biomed SA, 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 Lactoral on the normal functioning of the alimentary tract (Question No EFSA-Q-2008-269)[(4)]. The claim proposed by the applicant was worded as follows: 'Lactoral helps to bring back the normal functioning of the alimentary tract during its microflora disturbances (for example, in case of loose stools, after taking antibiotics, in case of intestinal disorders caused by enteric pathogens)'.

(14) On the basis of the data presented, the Authority concluded that the constituents of Lactoral are insufficiently characterised, and that a cause and effect relationship had not been established between the consumption of Lactoral 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) Following an application from the Institute of Biotechnology, Sera and Vaccines Biomed SA, 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 Lactoral on the improvement of the general immunity (Question No EFSA-Q-2008-477)[(5)]. The claim proposed by the applicant was worded as follows: 'Lactoral is recommended in order to improve the general immunity by maintaining the microbiological balance'.

(16) On the basis of the data presented, the Authority concluded that the constituents of Lactoral are insufficiently characterised, and that a cause and effect relationship had not been established between the consumption of Lactoral 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.

(17) Following an application from the Institute of Biotechnology, Sera and Vaccines Biomed SA, 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 Lactoral on the building of the natural intestinal barrier (Question No EFSA-Q-2008-478)[(6)]. The claim proposed by the applicant was worded as follows: 'Lactoral helps to protect the alimentary system against enteric pathogens because of strong antagonistic properties and helps to build the natural intestinal barrier'.

(18) On the basis of the data presented, the Authority concluded that the constituents of Lactoral are insufficiently characterised, and that a cause and effect relationship had not been established between the consumption of Lactoral 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.

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(19) Following an application from the Institute of Biotechnology, Sera and Vaccines Biomed SA, 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 Lactoral on the maintenance of natural intestinal microflora during travel (Question No EFSA-Q-2008-479)[7]. The claim proposed by the applicant was worded as follows: 'Lactoral helps to maintain natural intestinal microflora during travel, changing the climatic zone or a diet, especially in poor hygiene conditions'.

(20) On the basis of the data presented, the Authority concluded that the constituents of Lactoral are insufficiently characterised, and that a cause and effect relationship had not been established between the consumption of Lactoral 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.

(21) Following an application from the Institute of Biotechnology, Sera and Vaccines Biomed SA, 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 Lactoral on the living probiotic bacteria (Question No EFSA-Q-2008-480)[8]. The claim proposed by the applicant was worded as follows: 'Lactoral contains living probiotic bacteria with strong ability to intestinal tract colonisation, isolated from healthy, naturally fed infants'.

(22) On the basis of the data presented, the Authority concluded that the constituents of Lactoral are insufficiently characterised, and that the claimed effect had not been shown. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(23) Following an application from Potters Ltd, 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 Mumomega® on central nervous system development (Question No EFSA-Q-2008-328)[9]. The claim proposed by the applicant was worded as follows: 'Mumomega® provides the nourishments that support healthy central nervous system development'.

(24) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of the food 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.

(25) Following an application from Efamol Ltd, 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 Efalex® on coordination (Question No EFSA-Q-2008-121)[10]. The claim proposed by the applicant was worded as follows: 'Efalex® may help maintain coordination'.

(26) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of Efalex® 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.

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(27) Following an application from Efamol Ltd, 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 Efalex® on concentration (Question No EFSA-Q-2008-317)[(11)]. The claim proposed by the applicant was worded as follows: 'Efalex® may help maintain concentration'.

(28) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of Efalex® 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.

(29) Following an application from Efamol Ltd, 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 Efalex® on brain development and function (Question No EFSA-Q-2008-318)[(12)]. The claim proposed by the applicant was worded as follows: 'Efalex® may help maintain and support brain development and function'.

(30) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of Efalex® 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.

(31) Following an application from Efamol Ltd, 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 Efalex® on learning ability (Question No EFSA-Q-2008-319)[(13)]. The claim proposed by the applicant was worded as follows: 'Efalex® may help maintain learning ability'.

(32) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of Efalex® 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.

(33) Following an application from Efamol Ltd, 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 Efalex® on eye development and function (Question No EFSA-Q-2008-320)[(14)]. The claim proposed by the applicant was worded as follows: 'Efalex® may help maintain and support eye development and function'.

(34) On the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of Efalex® 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.

(35) Following an application from Potters Ltd, 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 baby® on the central nervous system development (Question No EFSA-Q-2008-119)[(15)]. The claim proposed by the applicant