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Delegations will find attached document D034098/02.

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COMMISSION REGULATION (EU) No …/..

of XXX

on the authorisation of a health claim made on foods and referring to the reduction of disease risk

(Text with EEA relevance)

COMMISSION REGULATION (EU) No …/..

of XXX

on the authorisation of a health claim made on foods and referring to the reduction of disease risk

(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 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 Lactalis B&C, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006, the Authority was asked to deliver an opinion on a health claim related to “Low fat and low trans spreadable fat rich in unsaturated and omega-3 fatty acids” and reduction of LDL-cholesterol concentrations **(Question No EFSA-Q-2009-00458)**[2]. The claim proposed by the applicant was worded as

1 OJ L 404, 30.12.2006, p. 9.
2 EFSA Journal 2011; 9(5):2168.

follows: “Replacing a fat rich in saturated/trans fatty acids by a fat rich in unsaturated fatty acids helps to reduce LDL cholesterol. LDL cholesterol is a cardiovascular risk factor”.

(6) On the basis of the data presented, the Authority concluded in its opinion received by the Commission and the Member States on 25 May 2011 that a cause and effect relationship had been established between the consumption of mixtures of dietary saturated fatty acids (SFAs) and an increase in blood LDL-cholesterol concentrations, and that replacement of a mixture of SFAs with cis-monounsaturated fatty acids and/or cis-polyunsaturated fatty acids in foods or diets on a gram-per-gram basis reduces LDL-cholesterol concentrations. Accordingly, a health claim reflecting this conclusion should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union list of permitted claims. The clinical intervention study claimed by the applicant as proprietary, was not considered necessary by the Authority for reaching its conclusion. It is therefore considered that the requirement laid down in Article 21(1)(c) of Regulation (EC) No 1924/2006 is not fulfilled and accordingly, protection of proprietary data should not be granted.

(7) In its opinion, the Authority concludes that in order to bear the claim, significant amounts of saturated fatty acids should be replaced by monounsaturated and/or polyunsaturated fatty acids in foods or diets on a gram-per-gram basis. Therefore, in order to ensure that a food provides significant amounts of monounsaturated and/or polyunsaturated fatty acids, it is appropriate to limit the use of the claim to fats and oils and to set conditions of use as those referred to in the nutrition claim "HIGH UNSATURATED FAT" as laid down in the Annex to Regulation (EC) No 1924/2006.

(8) Article 16(4) of Regulation (EC) No 1924/2006 provides that an opinion in favour of authorising a health claim is to include certain particulars. Accordingly, those particulars should be set out in the Annex to this Regulation as regards the authorised claim 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.

(9) One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that wording and presentation are taken into account in that respect. Therefore where the wording of claims has the same meaning for consumers as that of an authorised health claim, because they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, they should be subject to the same conditions of use indicated in the Annex to this Regulation.

(10) 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.

(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

1. The health claim listed in the Annex to this Regulation may be made on foods placed on the Union market in compliance with the conditions laid down in that Annex.

2. The health claim referred to paragraph 1 shall be included in the Union list of permitted claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006.

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