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EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

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

(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 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 Laboratoire Lescuyer, submitted pursuant to Article 14(1)(a) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was asked to deliver an opinion on a health claim related to the combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, OPC from French maritime pine bark, garlic dry extract standardised in allicin, d-α-tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate in Limicol® and reduction of blood LDL-cholesterol concentrations (Question No EFSA-Q-2012-00968[2]). The claim proposed by the applicant was worded as follows "Limicol® has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease."

[1] OJ L 404, 30.12.2006, p. 9.
[2] EFSA Journal 2013;11(7):3327

(6) On 26 July 2013, the Commission and the Member States received the scientific opinion from the Authority which concluded that a cause and effect relationship has been established between the consumption of the combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, OPC from French maritime pine bark, garlic dry extract standardised in allicin, d-α-tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate in the food subject to the claim and a reduction in blood 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, established by Regulation (EU) No 432/2012.

(7) The Authority indicated in its opinion that it could not have reached its conclusions without the human intervention studies claimed as proprietary by the applicant. These studies are the following:

– Barrat E, Zaïr Y, Chauveau P, Maudet C, Housez B, Derbord E, Lescuyer JF, Bard JM, Cazaubiel M and Peltier SL, 2012, unpublished-a. Effect on LDL-cholesterol of a large dose of a dietary portfolio supplement in subjects with untreated moderate hypercholesterolaemia: a double-blind, placebo-controlled study.

– Barrat E, Zair Y, Ogier N, Housez B, Vergara C, Maudet C, Lescuyer JF, Bard JM, Carpentier YA, Cazaubiel M and Peltier SL, 2013. A combined natural supplement lowers LDL cholesterol in subjects with moderate untreated hypercholesterolemia: a randomized placebo-controlled trial. International Journal of Food Sciences and Nutrition, Jul 2. [Epub ahead of print].

– Ogier N, Amiot MJ, Georgé S, Maillot M, Mallmann C, Maraninchi M, Morange S, Lescuyer JF, Peltier SL and Cardinault N, 2013. LDL-cholesterol-lowering effect of a dietary supplement with plant extracts in subjects with moderate hypercholesterolemia. European Journal of Nutrition, 52, 547-557.

(8) Article 16(4) of Regulation (EC) No 1924/2006 provides that in the event of an opinion in favour of authorising the health claim, the opinion should include certain particulars. Accordingly, those particulars should be set out in Annex I to this Regulation as regards the authorised claim and include, inter alia, the 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 that should accompany the health claim on the label and in advertising, in accordance with the rules laid down in Regulation (EC) No 1924/2006 and in line with the opinions of the Authority. In its opinion, in relation to restrictions of use, the Authority referred to the Summary of Product Characteristics of lovastatin-containing medicinal products available on the EU market. Therefore, it is necessary to provide for certain warning statements to accompany the health claim on monacolin K in question.

(9) All the justifiable information provided by the applicant has been assessed by the Commission and it is considered that the requirements laid down in Article 21(1) of Regulation (EC) No 1924/2006 are fulfilled for all three studies claimed as proprietary. Accordingly, the scientific data and other information included in those studies may not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation, under the conditions laid down in Article 21(1) of Regulation (EC) No 1924/2006.

(10) 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 the wording and the presentation are taken into account in that respect. Therefore, where the wording of claims used by the applicant 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 as those listed in the Annex to this Regulation.

(11) In accordance with Article 20 of Regulation (EC) No 1924/2006, the Register of nutrition and health claims containing all authorised health claims should be updated in order to take into account this Regulation.

(12) Since the applicant claims protection of proprietary data, it is considered appropriate to restrict the use of this claim in favour of the applicant for a period of five years. However, the authorisation of this claim restricted for the use of an individual operator should not prevent other applicants from applying for authorisation to use the same claim in case the application is based on data and studies other than those protected under Article 21 of Regulation (EC) No 1924/2006.

(13) The comments from the applicant 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.

(14) The addition of substances to or the use of substances in foodstuffs is governed by specific Union and national legislation, as is the classification of products as foodstuffs or medicinal products. Any decision on a health claim in accordance with Regulation (EC) No 1924/2006 such as inclusion in the list of permitted claims referred to in Article 14(1) thereof does not constitute an authorisation to the marketing of the substance on which the claim is made, a decision on whether the substance can be used in foodstuffs, or a classification of a certain product as a foodstuff.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. The health claim listed in the Annex to this Regulation may be made on foods on the European 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
Jean-Claude JUNCKER