

COMMISSION REGULATION (EU) 2023/648**of 20 March 2023****authorising 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 are included in the list of permitted health claims.
- (2) Regulation (EC) No 1924/2006 provides that applications for authorisations of health claims are to 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 ('the Authority').
- (3) Following the receipt of an application, the Authority is to inform without delay the other Member States and the Commission, 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 ('the applicant'), submitted pursuant to Article 14(1), point (a), of Regulation (EC) No 1924/2006 and including a request for the protection of proprietary data, the Authority was required to deliver an opinion on the scientific substantiation of 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, procyanidolic oligomers from French maritime pine bark, garlic dry extract standardised in allicin, d- α -tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate (contained in applicant's product Limicol®) and the reduction of blood LDL-cholesterol concentrations ⁽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'.
- (6) On 26 July 2013, the Commission and the Member States received the scientific opinion ⁽³⁾ on that application from the Authority which concluded that on the basis of the data presented, a cause and effect relationship had 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, procyanidolic oligomers 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 health claims.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.

⁽²⁾ Question No EFSA-Q-2012-00968.

⁽³⁾ EFSA Journal 2013;11(7):3327.

- (7) The Authority indicated in its opinion that it could not have reached its conclusions without three human intervention studies ⁽⁴⁾, which are claimed as proprietary by the applicant.
- (8) Following the receipt of the Authority's opinion, the Commission requested the applicant to further clarify the justifications provided with regard to their proprietary claim over the three human intervention studies, and their claim to an exclusive right of reference to those studies in accordance with Article 21(1) of Regulation (EC) No 1924/2006.
- (9) The applicant has declared that, at the time the application was submitted, it held proprietary right as well as an exclusiveright of reference to those studies and that therefore third parties could not lawfully access or use those studies. The Commission assessed all the justifiable information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 21(1) of Regulation (EC) No 1924/2006 for the studies claimed as proprietary.
- (10) Accordingly, the scientific data and other information included in those three studies should not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation. As a consequence, the use of the health claim authorised by this Regulation should be restricted to the applicant for a period of 5 years.
- (11) However, restricting the authorisation of this claim and the reference to the studies contained in the applicant's file to the sole use by them, does not prevent other applicants from applying for an authorisation to use the same claim provided that their application is based on legally obtained information supporting the authorisation under this Regulation.
- (12) 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 their wording and the presentation are taken into account in that respect. Therefore, where the wording of a claim used by an applicant has the same meaning for consumers as that of this authorised health claim, because it demonstrates that the same relationship exists between a food category, a food or one of its constituents and health, that claim should be subject to the same conditions of use as those authorised by this Regulation.
- (13) In accordance with Article 20 of Regulation (EC) No 1924/2006, the Register of nutrition and health claims containing all authorised health claims should therefore be updated.

⁽⁴⁾ Barrat E, Zaïr Y, Chauveau P, Maudet C, Housez B, Derbord E, Lescuyer JF, Bard JM, Cazaubiel M and Peltier SL, 2012, unpublished; 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, *published as*: Barrat E, Zaïr Y, Sirvent P, Chauveau P, Maudet C, Housez B, Derbord E, Lescuyer JF, Bard JM, Cazaubiel M and Peltier SL, 2012; Effect on LDL-cholesterol of a large dose of a dietary supplement with plant extracts in subjects with untreated moderate hypercholesterolaemia: a randomised, double-blind, placebo-controlled study, *European Journal of Nutrition*, Dec 25. [Epub ahead of print]; Barrat E, Zaïr Y, Ogier N, Housez B, Vergara C, Maudet C, Lescuyer JF, Bard JM, Carpentier YA, Cazaubiel M and Peltier SL, 2012, unpublished; A dietary portfolio supplement substantially lowers LDL-cholesterol in subjects with moderate untreated hypercholesterolaemia: a randomised controlled study, *published as*: Barrat E, Zaïr 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, Georges 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, p. 547.

- (14) The Commission has considered the comments received from the applicant pursuant to Article 16(6) of Regulation (EC) No 1924/2006 when adopting this Regulation.
- (15) 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. Concerning specifically monacolins from red yeast rice, Commission Regulation (EU) 2022/860 ⁽⁵⁾ regulated its use by amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council ⁽⁶⁾ to add the substance to the list of 'Restricted substances' and thus to permit the use of monacolins from red yeast rice only under certain conditions. Regulation (EU) 2022/860 also provides for appropriate labelling requirements for all foods containing monacolins from red yeast rice.
- (16) 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

The health claim set out in the Annex to this Regulation shall be included in the Union list of permitted health claims as provided for in Article 14(1) of Regulation (EC) No 1924/2006 and may be made on foods in compliance with the conditions laid down in the Annex to this Regulation.

Article 2

Only Laboratoire Lescuyer ⁽⁷⁾ is authorised to use the health claim set out in the Annex, for a period of 5 years from the date into force of this Regulation in accordance with Article 4 of this Regulation, unless a subsequent applicant obtains an authorisation to use the same claim without reference to the scientific data protected pursuant to Article 3, or with the agreement of Laboratoire Lescuyer. After the expiry of that period, that health claim may be used, in conformity with the conditions applying to it, by any food business operator.

Article 3

The scientific data of the studies included in the application, on the basis of which the health claim referred to in Article 1 has been assessed by the Authority, and fulfilling the requirements laid down in Article 21(1) of Regulation (EC) No 1924/2006, shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the prior agreement of Laboratoire Lescuyer.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

⁽⁵⁾ Commission Regulation (EU) 2022/860 of 1 June 2022 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards monacolins from red yeast rice. OJ L 151, 2.6.2022, p. 37.

⁽⁶⁾ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26.

⁽⁷⁾ Address: ZAC de Belle Aire Nord, 15 rue le Corbusier, 17440 Aytré, France.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Permitted health claim

Application – Relevant provisions of Regulation (EC) No 1924/2006	Applicant – Address	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA opinion reference
Article 14(1)(a) health claim referring to a reduction of a disease risk	Laboratoire Lescuyer, ZAC de Belle Aire Nord, 15 rue le Corbusier, 17440 Aytré, France	A combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, procyanidolic oligomers from French maritime pine bark, garlic dry extract standardised in allicin, d- α -tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate	A combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, procyanidolic oligomers from French maritime pine bark, garlic dry extract standardised in allicin, d- α -tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate reduces blood LDL-cholesterol concentrations. High LDL-cholesterol is a risk factor in the development of coronary heart disease ⁽¹⁾ .	The claim may be used only for food supplements which provide 600 mg artichoke leaf dry extract with 30-36 mg caffeoylquinic acids, 500 mg red yeast rice with 2 mg monacolin K, 10 mg sugar-cane derived policosanols, 20 mg French maritime pine bark extract with 18 mg procyanidolic oligomers, 30 mg garlic dry extract with 0,25 mg allicin, 30 mg α -tocopherol equivalents, 5 mg riboflavin and 9 mg inositol hexanicotinate divided in three daily doses to be consumed with the major meals.		Q-2012-00968

⁽¹⁾ Authorised on 10 April 2023 and restricted to the use by Laboratoire Lescuyer, ZAC de Belle Aire Nord, 15 rue le Corbusier, 17440 Aytré, France, for a period of 5 years.