Official Journal
of the European Union

EN
L series

2024/2063

31.7.2024

COMMISSION REGULATION (EU) 2024/2063

of 30 July 2024

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

(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 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 the Union list of permitted health claims.

(2) Pursuant to Regulation (EC) No 1924/2006, scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and food business operators using those claims should justify them. A claim should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence.

(3) Article 18 of Regulation (EC) No 1924/2006 provides that applications for the inclusion of health claims in the list of permitted claims must 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') for a scientific assessment, as well as to the Commission and the Member States for information.

(4) The Authority is to deliver an opinion on the health claim concerned within 5 months from the receipt of a request.

(5) The Commission is to decide on the authorisation of the health claims taking into account the opinion delivered by the Authority. However, in accordance with Article 17 of the Regulation (EC) No 1924/2006, in that consideration the Commission must take into account also any relevant provisions of Union law and other legitimate factors relevant to the matter.

(6) Following an application from Sylvan Bio Europe BV ('the applicant'), submitted pursuant to Article 18(1) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to monacolin K in SYLVAN BIO red yeast rice and the maintenance of normal blood LDL-cholesterol concentrations (Question No EFSA-Q-2012-00736). The claim proposed by the applicant was worded as follows: 'A daily intake of at least 2,4 g of SYLVAN BIO red yeast rice, corresponding to 4,08 mg of monacolin K, contributes to the maintenance of normal blood LDL-cholesterol.'.

(7) On 24 January 2013, the Authority adopted the Scientific Opinion ([2]) on the substantiation of a health claim related to monacolin K in SYLVAN BIO red yeast rice and maintenance of normal blood LDL-cholesterol concentrations pursuant to Article 13(5) of Regulation (EC) No 1924/2006. On 13 February 2013, the Commission and the Member States received the scientific opinion from the Authority.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) *EFSA Journal* 2013;11(2):3084.

(8) The Authority noted in its scientific opinion that according to the study of Myers *et al.,* 2006 ([3]), the content of monacolin K in 2,4 g of SYLVAN BIO red yeast rice should have been higher than 4,08 mg. Upon a request from the Authority, the applicant clarified that the red yeast rice preparation used in that study complied with the specifications provided for SYLVAN BIO red yeast rice, and that, taking into account all the active forms, 2,4 g of SYLVAN BIO red yeast rice contained 8,96 mg of monacolin K. The Authority considered that this study, with some methodological limitations, showed an effect of monacolin K in SYLVAN BIO red yeast rice on blood LDL-cholesterol concentrations, at doses of about 9 mg per day.

(9) With regard to the studies of Becker *et al.*, 2009 ([4]) and Halbert *et al.*, 2010 ([5]), the Authority noted that those studies showed an effect of monacolin K in SYLVAN BIO red yeast rice at doses of about 10 mg and 14 mg per day, respectively.

(10) In its opinion, the Authority also considered that the evidence provided by the applicant does not establish that monacolin K in SYLVAN BIO red yeast rice is different from that in other red yeast rice preparations with respect to its effect on blood LDL-cholesterol concentrations.

(11) The Authority concluded that a cause-and-effect relationship had been established between the consumption of monacolin K in red yeast rice preparations, which include SYLVAN BIO red yeast rice, and the maintenance of normal blood LDL-cholesterol concentrations. In order to obtain the claimed effect, 10 mg of monacolin K from fermented red yeast rice preparations should be consumed daily.

(12) The Authority found that it could have reached this conclusion without the human intervention study by Myers *et al.,* 2006, claimed as proprietary by the applicant.

(13) The Authority noted in its opinion that a claim on monacolin K from red yeast rice and the maintenance of normal blood LDL-cholesterol concentrations had already been assessed with a favourable outcome by the EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), in 2011 ([6]). The conditions of use for the claim subject to that opinion also provided for a daily intake of 10 mg monacolin K from any red yeast rice preparation (which would include SYLVAN BIO red yeast rice) in order to obtain the claimed effect.

(14) In relation to the restrictions of use of both of the above-mentioned health claims, the Authority in its scientific opinions referred to the Summary of Product Characteristics (SmPC) of lovastatin-containing medicinal products available on the Union market. The SmPC provides information to healthcare professionals on the safe and effective use of medicinal products and specifically of lovastatin-containing medicinal products. It describes the properties and officially approved conditions for their use which includes special warnings and precautions that refer to the risk of myopathy/rhabdomyolysis, which is increased by the concomitant use of lovastatin with certain other medicinal products and discourages the use of lovastatin by pregnant and lactating women. The Authority considered that the monacolin K in lactone form was identical to lovastatin.

(15) Following the discussion of those restrictions of use, Member States raised potential safety concerns associated with the consumption of foods containing monacolins from red yeast rice.

([3]) Myers SP, Cheras PA, Brooks L and O'Connor J, 2006, unpublished. Study on the Safety and Efficacy of Sylvan Red Yeast Rice in Adults with Primary Hypercholesteremia.

([4]) Becker DJ, Gordon RY, Halbert SC, French B, Morris PB and Rader DJ, 2009. Red yeast rice for dyslipidemia in statin-intolerant patients: a randomized trial. *Annals of Internal Medicine*, 150, 830-839, W147-839.

([5]) Halbert SC, French B, Gordon RY, Farrar JT, Schmitz K, Morris PB, Thompson PD, Rader DJ and Becker DJ, 2010. Tolerability of red yeast rice (2,400 mg twice daily) versus pravastatin (20 mg twice daily) in patients with previous statin intolerance. *American Journal of Cardiology*, 105, 198-204.

([6]) *EFSA Journal* 2011;9(7):2304.

(16) The Commission considered that on the basis of the information provided by the Member States, the necessary conditions and requirements laid down in Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council ([7]) and Articles 3 and 4 of Commission Implementing Regulation (EU) No 307/2012 ([8]) were fulfilled. Therefore, the Commission, launched the procedure under Article 8 of Regulation (EC) No 1925/2006 for monacolins in red yeast rice.

(17) In that context, the Commission, in accordance with Article 8(2) of Regulation (EC) No 1925/2006, requested the Authority to deliver a scientific opinion on the evaluation of the safety of monacolins in red yeast rice.

(18) On 25 June 2018, the Authority adopted a scientific opinion ([9]) on the safety of monacolins in red yeast rice. The Authority reiterated that monacolin K in lactone form was identical to lovastatin, the active ingredient of several medicinal products authorised for the treatment of hypercholesterolemia in the Union. At the time, monacolin K from red yeast rice was available in food supplements at varying recommended daily intake levels for its effect on the maintenance of normal blood LDL-cholesterol levels. On the basis of the information available, the Authority concluded that the intake of monacolins from red yeast rice through food supplements could lead to estimated exposure to monacolin K within the range of the therapeutic doses of lovastatin. The Authority noted that the profile of adverse effects to red yeast rice was similar to that of lovastatin ([10]).

(19) In its scientific opinion, the Authority considered that the available information on the adverse effects reported in humans were judged to be sufficient to conclude that monacolins from red yeast rice when used as food supplements were of significant safety concern at the use level of 10 mg/day and that individual cases of severe adverse reactions had been reported for monacolins from red yeast rice at intake levels as low as 3 mg/day. On the basis of the information available and several uncertainties highlighted in its opinion, the Authority was unable to provide advice on a daily intake of monacolins from red yeast rice that does not give rise to concerns about harmful effects to health, for the general population, and as appropriate, for vulnerable subgroups of the population, as requested by the Commission. The Authority explained that there are uncertainties as to the composition and content of monacolins in food supplements containing red yeast rice and that monacolins in red yeast rice are used in multi-ingredient products, the components of which have not been fully evaluated individually or in combination. Furthermore, due to the lack of data, the safe use of monacolins in certain vulnerable groups of consumers cannot be evaluated and there is uncertainty as to the effects of concomitant consumption of red yeast rice-based food supplements with foods or drugs that inhibit the enzyme (CYP3A4) that is involved in the metabolism of monacolins.

(20) Considering that no daily intake of monacolins from red yeast rice that does not give rise to concerns for human health could be set, and considering the significant harmful effect on health associated with the use of monacolins from red yeast rice at levels of 10 mg/day, as well as individual cases of severe adverse health reactions at levels as low as 3 mg/day, the use of monacolins from red yeast rice at levels of 3 mg and more per portion of the product recommended for daily consumption has been prohibited by Commission Regulation (EU) 2022/860 ([11]). By that Regulation the Commission amended Annex III to Regulation (EC) No 1925/2006 by placing monacolins from red yeast rice in Part B 'Restricted substances' of that Annex. Its addition to foods or its use in the manufacture of foods is therefore only allowed under the conditions specified in that Annex.

([7]) 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).

([8]) Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods (OJ L 102, 12.4.2012, p. 2).

([9]) *EFSA Journal* 2019;16(8):5368.

([10]) *EFSA Journal* 2018;16(8):5368, page 38

([11]) 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).

(21) As there is still a possibility of harmful effects on health associated with the use of monacolins from red yeast rice, but scientific uncertainty in this regard persists, and considering that monacolins from red yeast rice may only be used in food supplements and that the extent of use of those food supplements could not be determined by the Authority, the use of monacolins from red yeast rice in food supplements is placed under Union scrutiny and therefore included in Part C of Annex III to Regulation (EC) No 1925/2006. Interested parties have the possibility under Article 8(4) of Regulation (EC) No 1925/2006 to submit data demonstrating the safety of monacolins from red yeast rice to the Authority in accordance with Article 5 of Implementing Regulation (EU) No 307/2012. In accordance with Article 8(5) of Regulation (EC) No 1925/2006 the Commission should take a decision within four years from the entry into force of Commission Regulation (EU) 2022/860, whether to generally allow the use of monacolins from red yeast rice listed in Annex III, Part C or to list the substance in Annex III, Part A or Part B, as appropriate, taking into account the opinion of the Authority on any submitted data.

(22) Therefore, the proposed health claim should not be authorised and included in the Union list of permitted health claims.

(23) The comments of the applicant received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006, have been considered when adopting this Regulation.

(24) On 4 March 2013 the applicant submitted comments to the Commission indicating that the conditions of use for the claim set in the scientific opinion, did not take into account evidence of a potential effect on blood LDL-cholesterol of concentrations of monacolin K below a daily dose of 10 mg.

(25) Following a request from the Commission, the Authority was asked to review the scientific comments received and on 13 May 2013, the Authority published the technical report ([12]) as a response to the comments of the applicant.

(26) In its report, the Authority noted that the studies of Myers *et al.,* 2006 and Becker *et al.,* 2009 showed an effect of monacolin K in SYLVAN BIO red yeast rice on blood LDL-cholesterol concentrations at doses of about 9 and 10 mg per day respectively. As stated in the opinion, this is in the range of the doses used in the two human intervention studies (Heber *et al.,* 1999; Lin *et al.,* 2005) which were evaluated by the Authority to set conditions of use of 10 mg monacolin K per day for a claim on monacolin K from red yeast rice preparations in general and maintenance of normal blood LDL-cholesterol concentrations (EFSA NDA Panel, 2011). The Authority also noted that when setting conditions of use, it takes into account and weighs the totality of the available scientific evidence. In this specific case, the Authority took into account the evidence provided by two human intervention studies (Heber *et al.,* 1999; Lin *et al.,* 2005) at doses of around 7,5 and 11,5 mg/day monacolin K, as well as the lowest dose of lovastatin (pure monacolin K) which has been shown consistently to reduce LDL-cholesterol concentrations in the target population (i.e. 10 mg/day). The Authority concluded that the comments received did not change its conclusions and reconfirmed its opinion.

(27) 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 proposed health claim set out in the Annex to this Regulation shall not be included in the Union list of permitted health claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

([12]) Technical report from EFSA – Response to comments on the Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on the scientific substantiation of health claims related to monacolin K in SYLVAN BIO red yeast rice and maintenance of normal blood LDL-cholesterol concentrations pursuant to Article 13(5) 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, 30 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

REJECTED HEALTH CLAIM

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	Monacolin K in SYLVAN BIO red yeast rice	Monacolin K from red yeast rice contributes to the maintenance of normal blood LDL-cholesterol concentrations	Q-2012-00736