Official Journal
of the European Union

EN
L series

2024/2041

30.7.2024

COMMISSION REGULATION (EU) 2024/2041

of 29 July 2024

amending Regulation (EU) No 432/2012 as regards the health claim on monacolin K from red yeast rice

(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 13(4) 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) Commission Regulation (EU) No 432/2012 ([2]) establishes a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.

(3) Pursuant to Regulation (EC) No 1924/2006, scientific substantiation should be the main consideration for the use of nutrition and health claims and food business operators using claims should justify those claims. A claim should be scientifically substantiated by taking into account the totality of the available relevant scientific data, and by weighing the evidence. Furthermore, in order to keep up with scientific and technological developments, the list of permitted health claims should be revised promptly whenever necessary.

(4) A health claim on monacolin K from red yeast rice was included in the list of health claims submitted to the Commission under Article 13(2) of Regulation (EC) No 1924/2006 and transmitted to the European Food Safety Authority ('the Authority') in accordance with Article 13(3) of that Regulation. On 28 July 2011, the Authority published a scientific opinion ([3]) on the substantiation of a health claim related to monacolin K from red yeast rice and the maintenance of normal blood LDL-cholesterol concentrations. The Authority concluded that a cause-and-effect relationship had been established between the consumption of monacolin K from red yeast rice and the maintenance of normal blood LDL-cholesterol concentrations, at a daily intake of 10 mg of monacolin K from red yeast rice.

(5) Based on the opinion of the Authority, the health claim on monacolin K from red yeast rice and its contribution to the maintenance of normal blood cholesterol levels was authorised and included in the list of permitted health claims contained in the Annex to Regulation (EU) No 432/2012. The accompanying conditions of use required a daily intake of 10 mg of monacolin K from red yeast rice preparations.

([1]) OJ L 404, 30.12.2006, p. 9.
([2]) Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ L 136, 25.5.2012, p. 1).
([3]) *EFSA Journal* 2011;9(7):2304.

(6) In relation to the restrictions of use of the health claim, the Authority 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.

(7) 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.

(8) 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 ([4]) and Articles 3 and 4 of Commission Implementing Regulation (EU) No 307/2012 ([5]) were fulfilled. Therefore, the Commission launched the procedure under Article 8 of Regulation (EC) No 1925/2006 for monacolins in red yeast rice.

(9) 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.

(10) On 25 June 2018, the Authority adopted a scientific opinion ([6]) 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 an 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. ([7])

(11) 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.

([4]) 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).

([5]) 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).

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

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

(12) 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 ([8]). 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.

(13) 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 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.

(14) In accordance with Article 1(2) of Regulation (EC) No 1925/2006, the provisions on the addition of certain other substances than vitamins and minerals to food are applicable to food supplements covered by Directive 2002/46/EC of the European Parliament and of the Council ([9]).

(15) Therefore, in view of the current prohibition of the use of monacolins from red yeast rice at levels of 3 mg and more per portion of the product recommended for daily consumption based on generally accepted scientific evidence and in view of legal certainty, the Commission must revoke the health claim on monacolin K from red yeast rice from the Union list of permitted health claims. Accordingly, the health claim on monacolin K from red yeast rice should no longer be used on foods.

(16) The Annex to Regulation (EU) No 432/2012 should therefore be amended accordingly.

(17) 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

In the Annex to Regulation (EU) No 432/2012, the entry for *Monascus purpureus* (red yeast rice) is deleted.

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*.

([8]) 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).

([9]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

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

Done at Brussels, 29 July 2024.

For the Commission
The President
Ursula VON DER LEYEN