EUROPEAN
COMMISSION

Brussels, XXX
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[…](2025) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending [Annex III to] Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards monacolins from red yeast rice

(Text with EEA relevance)

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(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 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[1], and in particular Article 8(5), first subparagraph, thereof,

Whereas:

(1) Commission Regulation (EU) 2022/860[2] prohibited the use of monacolins from red yeast rice at levels of 3 mg and more per portion of the product, recommended for daily consumption and included monacolins from red yeast rice in Part B of Annex III to Regulation (EC) No 1925/2006. Furthermore, it placed the use of that substance under Union scrutiny for four years, by listing it in Part C of Annex III to Regulation (EC) No 1925/2006. In its scientific opinion of 3 August 2018 on the safety of monacolins in red yeast rice[3], on which Regulation (EU) 2022/860 was based, the European Food Safety Authority('the Authority') had concluded that exposure to monacolins from red yeast rice at intake levels as low as 3 mg/day could lead to severe adverse effects on the musculoskeletal system, including rhabdomyolysis, and on the liver, and outlined several uncertainties.

(2) Four interested parties submitted files for evaluation to the Authority, within the period provided for in Article 5(2) of Commission Implementing Regulation (EU) No 307/2012[4]. All the documents submitted by each interested party are listed in Appendix A of the scientific opinion. The files submitted aimed at addressing the uncertainties outlined by the Authority in its scientific opinion on the safety of monacolins in red yeast rice.

(3) On the basis of those files, the Authority consulted stakeholders and the public, in accordance with Article 5c, point (b), of Implementing Regulation (EU) No 307/2012.

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1 OJ L 404, 30.12.2006, p. 26, ELI: http://data.europa.eu/eli/reg/2006/1925/oj.

2 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 in red yeast rice (OJ L 151, 2.6.2022, p. 37, ELI: http://data.europa.eu/eli/reg/2022/860/oj).

3 EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), Aggett, P., Aguilar, F., Crebelli, R., Dusemund, B. et al., Scientific opinion on the safety of monacolins in red yeast rice, EFSA Journal; 2018;16(8):5368.

4 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, ELI: http://data.europa.eu/eli/reg_impl/2012/307/oj).

During the public consultation, no comments were submitted to the Authority. In its assessment, the Authority considered the scientific data submitted within the period provided for in Article 5(2) of Regulation (EU) No 307/2012, which included analytical data on the composition of red yeast rice supplements, the intake of monacolins from other dietary sources, in vitro bioaccessibility and cytotoxicity data of monacolins versus other statins, nutrivigilance and post-marketing data, case reports and clinical studies.

(4) In its scientific opinion of 29 January 2025[5], the Authority concluded that the submitted additional data did not allow establishing the safety of monacolins in red yeast rice supplements below 3 mg/day or identifying a daily intake of monacolins from red yeast rice in food supplements that does not raise safety concerns for the general population or vulnerable subgroups thereof. The Authority reiterated the concerns raised in its opinion of 2018 that exposure to monacolins from red yeast rice at intake levels as low as 3 mg/day could lead to severe adverse effects on the musculoskeletal system, including rhabdomyolysis, and on the liver.

(5) Considering that the safety of monacolins from red yeast rice could not be established by the Authority based on the submitted scientific data, monacolins from red yeast rice should be included in Part A of Annex III to Regulation (EC) No 1925/2006 and be deleted from Part B and Part C of that Annex.

(6) In order to ensure a safe transition, while considering the Authority's conclusions in its opinions of 3 August 2018 and 29 January 2025 as regards the severe adverse effects, only products already lawfully placed on the market before the entry into force of this Regulation should continue to be marketed and for a limited period of time.

(7) Regulation (EC) No 1925/2006 should therefore be amended accordingly.

(8) 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

Annex III to Regulation (EC) No 1925/2006 is amended as follows:

(1) in Part A, the following entry is inserted after the entry 'Ephedra herb and its preparations originating from *Ephedra* species':

'monacolins from red yeast rice';

(2) in Part B, the entry for monacolins from red yeast rice is deleted;

(3) in Part C, the entry for monacolins from red yeast rice is deleted.'

Article 2

Foodstuffs containing monacolins from red yeast rice, which were lawfully placed on the market before the entry into force of this Regulation may remain on the market until [*entry into force + 12 months*].

[5] Scientific opinion on additional scientific data related to the safety of monacolins from red yeast rice submitted pursuant to Article 8(4) of Regulation (EC) No 1925/2006, EFSA Journal; 2025;23:e9276.

Article 3

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
Ursula VON DER LEYEN