

EN
E-002725/2026
Answer given by Mr Várhelyi
on behalf of the European Commission
(2.10.2026)

The draft Regulation¹ referred to in the question aims to prohibit the use of monacolins from red yeast rice following a period of Union scrutiny during which interested parties could submit scientific evidence to demonstrate their safety in accordance with Article 8(4) of Regulation (EC) No 1925/2006². It is based on the European Food Safety Authority's (EFSA) scientific opinion³ of 29 January 2025, which concluded that safety of monacolins could not be established based on the data submitted. The Commission is not aware of any new scientific evidence on the safety of monacolins to be expected shortly.

The Commission, in close consultation with the Member States, took into account EFSA's scientific opinions, other legitimate factors and the objective of the Article 8 procedure in deciding how to proceed. Given the severe adverse health effects, identified by EFSA in its opinion of 3 August 2018⁴ and reiterated in its opinion of 29 January 2025, namely that exposure to monacolins at intake levels as low as 3 mg/day could lead to severe adverse effects on the musculoskeletal system and the liver, less restrictive measures, such as continuing to allow monacolins under certain conditions of use, would not adequately protect consumers' health. This is consistent with the Safe Hearts Plan, which is built on evidence-based screening and access to properly authorised treatment pathways for cardiovascular risk factors, and considering the food supplements should not be relied upon to prevent or treat disease.

The ongoing court cases concern solely Commission Regulation (EU) 2021/468⁵. Under Article 8(5) of Regulation (EC) No 1925/2006, the Commission is legally obliged to act following the expiry of a scrutiny period related to the safety of a substance.

¹ PE-E1-PRAC-SANTE/1575/2025 - 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.

² 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, ELI: <http://data.europa.eu/eli/reg/2006/1925/oj>.

³ 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.

⁴ 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.

⁵ Commission Regulation (EU) 2021/468 of 18 March 2021 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards botanical species containing hydroxyanthracene derivatives, C/2021/1670, OJ L 96, 19.3.2021, p. 6., ELI: <http://data.europa.eu/eli/reg/2021/468/oj>.