



Plenary sitting

B10-0466/2026

5.9.2026

MOTION FOR A RESOLUTION

pursuant to Rule 115(2) and (3), and (4)(c) of the Rules of Procedure

on the draft Commission regulation amending Annex III to Regulation (EC)
No 1925/2006 of the European Parliament and of the Council as regards
monacolins from red yeast rice
(D113902/02 – 2026/2821((RPS))

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European Parliament resolution on the draft Commission regulation amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards monacolins from red yeast rice (D113902/02 – 2026/2821(RPS))

The European Parliament,

- having regard to the draft Commission regulation amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards monacolins from red yeast rice (D113902/02),
- 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 foods¹, and in particular Article 8(5), first subparagraph, thereof,
- having regard to the opinion delivered on 13 May 2026 by the committee referred to in Article 14 of the above Regulation,
- having regard to Article 5a(3)(b) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission²,
- having regard to Rule 115(2) and (3), and (4)(c) of its Rules of Procedure,
- A. whereas red yeast rice (RYR) is produced by the fermentation of rice with *Monascus* species, resulting in the production of substances known as monacolins, of which monacolin K is the most abundant;
- B. whereas monacolin K from RYR has established cholesterol-lowering properties, and European Food Safety Authority (EFSA) has concluded that a cause-and-effect relationship exists between the consumption of monacolin K from RYR and the maintenance of normal blood low-density lipoprotein (LDL) cholesterol levels;
- C. whereas, on the basis of that assessment and in accordance with Articles 14, 15 and 18 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods³, a health claim relating to the contribution of monacolin K from RYR to the maintenance of normal blood cholesterol levels was authorised and included in the Union list of permitted health claims established by Commission Regulation (EU) No 432/2012⁴, before being subsequently revoked by Commission Regulation (EU) 2024/2041⁵;
- D. whereas Commission Regulation (EU) 2022/860⁶ already restricted the use of

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

² OJ L 184, 17.7.1999, p. 23, ELI: <http://data.europa.eu/eli/dec/1999/468/oj>.

³ OJ L 404, 30.12.2006, p. 9, ELI: <http://data.europa.eu/eli/reg/2006/1924/oj>.

⁴ OJ L 136, 25.5.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/432/oj>.

⁵ OJ L, 2024/2041, 30.7.2024, ELI: <http://data.europa.eu/eli/reg/2024/2041/oj>.

⁶ OJ L 151, 2.6.2022, p. 37, ELI: <http://data.europa.eu/eli/reg/2022/860/oj>.

monacolins from RYR in foods by listing them in Part B of Annex III to Regulation (EC) No 1925/2006 and requiring that an individual portion of a product for daily consumption provide less than 3 mg of monacolins from RYR, and the draft Commission regulation now proposes to move monacolins from RYR to Part A of Annex III, thereby imposing a prohibition on their use in foods, including food supplements;

- E. whereas, in its scientific opinion of 29 January 2025 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 concluded that the additional data submitted did not allow for the establishment of an intake threshold for monacolins from RYR that does not give rise to concerns about harmful effects to health for the general population; whereas, in reaching this conclusion, EFSA confirmed the concerns identified by the former EFSA Panel on Food Additives and Nutrient Sources added to Food, which had been unable to identify a level of intake of monacolins from RYR in food supplements that did not give rise to such concerns and had noted reports of severe adverse reactions requiring hospitalisation at intakes as low as 3 mg per day;
- F. whereas EFSA's scientific opinion did not assess or recommend any specific risk-management measure, nor did it address the relative effectiveness or appropriateness of different regulatory responses; whereas EFSA's scientific opinion also did not examine whether the identified risks could be adequately addressed through measures less restrictive than a prohibition;
- G. whereas on 13 May 2026 the draft Commission regulation received a favourable opinion from the Standing Committee on Plants, Animals, Food and Feed, Section General Food Law⁷, notwithstanding that the Commission had been informed that new data were imminently expected to become available, before those data could be taken into consideration;
- H. whereas available evidence indicates that monacolins from RYR can significantly reduce LDL-cholesterol, including at intake levels below the current regulatory threshold of 3 mg per day, and that such reductions can, on the basis of the established relationship between cholesterol levels and cardiovascular risk, contribute to a meaningful reduction in the risk of major adverse cardiovascular events;
- I. whereas cardiovascular disease remains the leading cause of mortality in the European Union, accounting for approximately 1,7 million deaths each year⁸ and affecting an estimated 62 million people, with an estimated total societal cost of more than EUR 282 billion annually across the Union⁹; whereas elevated cholesterol is a major modifiable risk factor for cardiovascular disease, yet a substantial proportion of people at increased cardiovascular risk remain untreated or do not achieve recommended cholesterol levels despite the availability of statins and other lipid-lowering therapies;

⁷ <https://ec.europa.eu/transparency/comitology-register/core/api/integration/ers/538068/117025/1/attachment>.

⁸ https://health.ec.europa.eu/non-communicable-diseases/cardiovascular-health_en.

⁹ [https://ec.europa.eu/commission/presscorner/api/files/attachment/882088/FACTSHEET%20Cardiovascular%20FINAL%20\(1\).pdf](https://ec.europa.eu/commission/presscorner/api/files/attachment/882088/FACTSHEET%20Cardiovascular%20FINAL%20(1).pdf).

- J. whereas monacolins from RYR are used by consumers seeking to manage elevated LDL-cholesterol through non-pharmacological means, including persons for whom pharmacological lipid-lowering treatment is not considered necessary or appropriate, and RYR supplements have been used alongside dietary and lifestyle measures as an option for managing cholesterol levels;
- K. whereas a prohibition would remove that option from the Union market and could lead some consumers to purchase RYR products from outside the Union, where equivalent regulatory safeguards may not apply;
- L. whereas monacolins from RYR have been used in food supplements for decades in the Union and internationally, and available post-marketing nutriviigilance data indicated an estimated reporting rate of 0,0007 % for suspected serious adverse events and 0,0002 % for serious adverse events assessed as potentially related to the consumption of RYR supplements¹⁰;
- M. whereas by its judgments of 13 November 2024 in Cases T-189/21, T-271/21, T-274/21 and T-302/21¹¹, the General Court annulled relevant provisions of Commission Regulation (EU) 2021/468 of 18 March 2021 amending Annex III to Regulation (EC) No 1925/2006 as regards botanical species containing hydroxyanthracene derivatives¹², and the Commission's appeals against those judgments are pending before the Court of Justice; whereas the findings of the General Court are relevant to the present draft Commission regulation insofar as they concern the adequacy of the scientific assessment and the proportionality of the risk-management response pursuant to Article 8 of Regulation (EC) No 1925/2006, including the imposition of a prohibition irrespective of the amount of the substance concerned;
- N. whereas the Court of Justice has not yet ruled on those appeals, and the adoption of the present draft Commission regulation before the Court of Justice of the European Union has clarified the conditions governing the application of Article 8 of Regulation (EC) No 1925/2006 risks disrupting an existing lawful market on the basis of a legal framework, the interpretation of which remains subject to pending judicial review;
- O. whereas the Treaty on the Functioning of the European Union, pursuant to Article 168(1), requires that a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities, and pursuant to Article 191(2), that Union policy on the environment is to aim at a high level of protection, and that those objectives are to be pursued in accordance with the principle of proportionality as set out in Article 5(4) of the Treaty on European Union;
- P. whereas less restrictive risk-management measures, such as labelling, consumer information and post-marketing surveillance, should be duly assessed in order to ensure that any measure adopted under Regulation (EC) No 1925/2006 meets the requirements

¹⁰ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2025.9276>.

¹¹ Judgements of the General Court of 13 November 2024, *Aloe Vera of Europe BV v European Commission*, T-189/21, ECLI:EU:T:2024:802; *Ortis v European Commission*, T-271/21, ECLI:EU:T:2024:804; *Synadiet and Others v Commission*, T-274/21, ECLI:EU:T:2024:806; and *Aboca and Others v European Commission*, T-302/21, ECLI:EU:T:2024:808.

¹² OJ L 96, 19.3.2021, p. 6, ELI: <http://data.europa.eu/eli/reg/2021/468/oj>.

of necessity and proportionality within the meaning of Article 5a(3)(b) of Council Decision 1999/468/EC and the case law of the Court of Justice of the European Union on the proportionality of risk-management measures adopted under the regulatory procedure with scrutiny;

1. Opposes adoption of the draft Commission regulation;
2. Considers that the draft Commission regulation exceeds the implementing powers provided for in Article 8 of Regulation (EC) No 1925/2006, insofar as it imposes a prohibition on listing monacolins from RYR in Part A of Annex III without having adequately assessed whether less restrictive risk-management measures could achieve the same level of consumer protection, as required by the proportionality principle;
3. Considers that the draft Commission regulation fails to respect the principle of proportionality, in that a prohibition has not been shown to be the least restrictive measure capable of achieving the objective of protecting consumer health, and that appropriately calibrated maximum daily intake levels, targeted labelling requirements product standardisation, quality-control requirements, including citrinin limits, and structured post-marketing surveillance could constitute less restrictive alternatives that should have been fully examined before resorting to a total prohibition;
4. Considers that the scientific assessment underpinning the draft Commission regulation, while noting that EFSA could not establish a safe daily intake threshold, does not in itself justify the most restrictive regulatory response available under the basic act, particularly where relevant post-marketing data are affected by product variability, and population heterogeneity, factors that may be addressed through regulatory intervention, including quality-control and labelling measures;
5. Calls on the Commission to withdraw the draft regulation and submit a new one to the committee;
6. Calls on the Commission, before proceeding with the adoption of the draft regulation, to take due account of the judgments to be delivered by the Court of Justice in the pending appeals concerning the annulment of relevant provisions of Commission Regulation (EU) 2021/468, insofar as those proceedings concern the interpretation and application of the same Article 8 procedure and may therefore provide relevant guidance as to the scope of the Commission's powers and the requirements applicable to measures adopted pursuant to that provision;
7. Calls on the Commission to conduct a comprehensive impact assessment of the public-health consequences of a prohibition, including the potential loss of LDL-cholesterol-lowering benefits for consumers with elevated cholesterol who are not receiving statin therapy, the potential shift of consumers towards pharmaceutical alternatives or products obtained from outside the Union, and the economic implications for the existing lawful market;
8. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.