



## Monacolins from Red Yeast Rice: On May 13, EU Member States voted in favor of the draft regulation aimed at banning monacolins from red yeast rice

- On May 13, EU Member States voted in favor of the draft regulation aimed at banning monacolins derived from red yeast rice.
- **Projected timeline:** The regulations could be published in October 2026, with implementation within the 20 days following, and a one-year phase-out period for products placed on the market prior to the measure's implementation (October 2027).
- **Strategic impact for Valbiotis:** This regulatory change reinforces the validity of Valbiotis' scientific approach to cardiometabolic prevention and provides a new commercial growth driver for its product portfolio, particularly Valbiotis<sup>PRO®</sup> Cholesterol.

La Rochelle, May 27, 2026 (5:40 pm CEST) – Valbiotis (FR0013254851 – ALVAL, PEA / PME eligible), a French laboratory specializing in cardiometabolic health, **draws attention to the vote by European Union Member States of the draft regulation providing for a ban on monacolins from red yeast rice in dietary supplements.** This change in European regulations was initiated following scientific assessments conducted by the European Food Safety Authority (EFSA) and reinforces the relevance of the scientific approach developed by Valbiotis in the prevention of cardiometabolic imbalances, notably through Valbiotis<sup>PRO®</sup> Cholesterol, a solution formulated without red yeast rice or monacolins.

### A major regulatory milestone at the European level

Monacolins from red yeast rice have been under review by European regulatory authorities for several years following concerns over their safety.

**In a scientific opinion published in 2018, the EFSA** concluded that serious adverse effects could occur even at low intake levels. Based on these findings, the European Commission adopted restrictive measures in 2022 concerning the use of monacolins within the European Union.

Industry players were subsequently granted a period of time during which they could submit additional data regarding the safety of these substances. After reevaluating the available evidence, the European authorities continued the regulatory discussions surrounding these ingredients.

On May 13, Member States meeting within the SCoPAFF\* voted in favor of the draft regulation presented by the European Commission regarding a ban on monacolins from red yeast rice.

The text must now continue through the institutional process, which includes:

- A three-month review period by the European Parliament and Council.
- Approval by the European Commission and publication in the Official Journal of the European Union.

The regulation will then enter into force 20 days after publication, with a transitional period for the clearance of existing stocks placed on the market prior to the entry into force of the new provisions scheduled to last until October 2027.

### **A regulatory change aligned with Valbiotis' approach**

This change in regulations underscores the relevance of Valbiotis' scientific approach to preventing cardiometabolic disorders.

Through its Valbiotis<sup>PRO</sup>® range, Valbiotis develops innovative, expert nutritional solutions based on ingredients selected for their efficacy and safety profiles, in response to the expectations of healthcare professionals and consumers. **In this context, Valbiotis<sup>PRO</sup>® Cholesterol, a solution designed to help maintain normal cholesterol levels, was developed without monacolin K or red yeast rice.** The product is based on the proprietary, 100% natural-origin, active ingredient Lipidrive®, which was the result of more than 10 years of research and development and incorporated into a clinically tested formula.

Studies conducted by Valbiotis have demonstrated **efficacy on LDL cholesterol in as little as 6 weeks\*\***, providing an innovative response to the challenges related to the prevention of cardiometabolic disorders.

Valbiotis' scientific approach is built on **an unprecedented clinical research program in the dietary supplements sector**, comprising 13 proprietary, randomized, multicenter, international clinical studies, several of which were double-blind, placebo-controlled trials, involving a total of over 1,500 participants.

The results of this research have been presented at **scientific conferences recognized by leading international learned societies, demonstrating the scientific rigor of the solutions developed by Valbiotis** (15 publications in peer-reviewed international journals and 64 conference presentations since 2021).

Valbiotis thus continues to pursue its mission to provide scientifically validated, innovative nutritional solutions tailored to public health challenges linked to cardiometabolic disorders.

This change in regulations, which is expected to support the renewal of offerings in the cardiometabolic prevention segment, provides the Company with greater visibility for Valbiotis<sup>PRO</sup>® Cholesterol, a scientifically validated alternative formulated without monacolin K, as well as for its broader product portfolio. It further strengthens Valbiotis' positioning with its partners and prescribers, healthcare professionals and pharmacy groups, as well as across its sales channels, both in pharmacies and online. With this new catalyst for commercial growth, Valbiotis is poised to support a continued ramp-up of its revenues.

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\* Standing Committee on Plants, Animals, Food, and Feed

*\*\* Double-blind, placebo-controlled clinical trial involving 340 participants starting 6 weeks after taking Lipidrive®*

## About Valbiotis

Valbiotis is a French laboratory specializing in the creation and distribution of dietary supplements scientifically tested to maintain health at every stage of life. Through an innovative approach combining scientific excellence, plant expertise and a wealth of natural ingredients, Valbiotis offers a new generation of dietary supplements to support cardiometabolic balance and well-being, and address everyday health issues such as sleep, fatigue, mood management, immunity and vitality. Created at the beginning of 2014 in La Rochelle, France, Valbiotis has forged numerous partnerships with leading academic centers.

Valbiotis is a member of the "BPI Excellence" network and has been recognized as an "Innovative Company" by the BPI label. Valbiotis has received major financial support from the European Union for its research programs via the European Regional Development Fund (ERDF). Valbiotis is a PEA-SME eligible company.

For more information on Valbiotis®, please visit: [www.valbiotis.com](http://www.valbiotis.com)

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