Rejection of a health claim for monacolin K in red yeast rice

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EU to reject health claim for monacolin K in red yeast rice

Draft Commission Regulation refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health

Annex

Update

The European Commission has informed the World Trade Organization Technical Barriers to Trade (WTO TBT) Committee that it will reject a health claim linking monacolin K in red yeast rice to the maintenance of normal blood low-density lipoprotein (LDL)-cholesterol concentrations (G/TBT/N/EU/1026).

Impacted products

Red yeast rice

What is changing?

The European Commission proposes that the health claim that "a daily intake of at least 2.4 g of SYLVAN BIOred yeast rice, corresponding to 4.08 mg of monacolin K, contributes to the maintenance of normal blood LDL-cholesterol" should not be included in the EU list of permitted health claims.

Why?

The applicant did not provide evidence that the effect of this product on blood LDL-cholesterol concentrations is different from that of other red yeast rice preparations. The levels at which monacolins from red yeast rice could lower blood LDL-cholesterol concentrations are above those considered to be safe (EFSA 2013; EFSA 2018).

Timeline

Expected date of adoption: second quarter of 2024.

Expected date of entry into force: approximately 1 month after adoption.

The Commission will take a decision on whether monacolins from red yeast rice may be continued to be used in food supplements by 2026 at the latest, taking into account EFSA's opinion.

Recommended Actions

Comments or concerns about potential impacts can be submitted via the National TBT notification authority of the country concerned to the EU TBT Enquiry Point before 26 December 2023.

Background

After EU Member States raised safety concerns about the consumption of foods containing monacolins from red yeast rice, the Commission requested EFSA to review their safety. EFSA (2018) confirmed that monacolin K in lactone form is equivalent to lovastatin, which is used in several authorised medicinal products. EFSA found that levels of lovastatin in medicines should be limited to below 3 mg per day. Therefore the use of monacolins from red yeast rice in food supplements has also been limited to below 3 mg per day (Regulation 2022/860) – see Monacolin K from red yeast rice.

Due to scientific uncertainty about the safety of monacolins from red yeast rice, its use in supplements was also placed "under scrutiny" (listed in Regulation 1925/2006 on food supplements, Annex III, Part C) and will be reviewed by 2026.

Resources

EFSA (2013) Scientific Opinion on the substantiation of a health claim related to monacolin K in SYLVAN BIO red yeast rice and maintenance of normal blood LDL-cholesterol concentrations. EFSA Journal, 11(2): 3084.

EFSA (2018) Scientific opinion on the safety of monacolins in red yeast rice. EFSA Journal, 16(8): 5368.

Regulation (EU) 2022/860 as regards monacolins from red yeast rice

Regulation 1924/2006 on nutrition and health claims made on foods

Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

Sources

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