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

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EU revokes health claim for monacolin K in red yeast rice

Commission Regulation (EU) 2024/2041 of 29 July 2024 amending Regulation (EU) No 432/2012 as regards the health claim on monacolin K from red yeast rice

Update

The European Commission has revoked the health claim on monacolin K from red yeast rice.

Impacted products

Red yeast rice

What is changing?

The European Commission has revoked the health claim on monacolin K from red yeast rice in view of the current prohibition of its use other than in food supplements.

Why?

The possibility of harmful effects on health associated with the use of monacolins from red yeast rice cannot be ruled out considering that monacolins from red yeast rice may only be used in food supplements. The extent of use of those food supplements could not be determined by the European Food Safety Authority (EFSA 2018).

Timeline

Applies from **19 August 2024**.

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Recommended Actions

Interested parties are invited to submit data to EFSA demonstrating the safety of monacolins from red yeast rice.

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 (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 (EU) 1924/2006 on nutrition and health claims made on foods

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

Sources

Regulation 2024/2041 as regards the health claim on monacolin K from red yeast rice

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