

THE LATEST ON EU AGRI-FOOD POLICIES IMPACTING LOW-INCOME & MIDDLE-INCOME COUNTRIES

Food supplements: calcidiol monohydrate

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EU lists calcidiol monohydrate as vitamin D source allowed in food supplements

Commission Regulation (EU) <u>2025/352</u> of 21 February 2025 amending Directive 2002/46/EC of the European Parliament and of the Council as regards calcidiol monohydrate used in the manufacture of food supplements

Update

The European Union (EU) has included calcidiol monohydrate as a source of vitamin D in its list of vitamins and minerals allowed for use in food supplements.

Impacted products

Food supplements

What is changing?

Following its authorisation as a novel food in 2024, the EU has now added calcidiol monohydrate, a source of vitamin D, to the list of vitamin and mineral substances that may be used in the manufacture of food supplements (Annex II to Directive 2002/46/EC).

Why?

The European Food Safety Authority has concluded that the use of calcidiol monohydrate as a source of vitamin D in food supplements is safe (<u>EFSA 2021</u>).

Timeline

Applies from 16 March 2025.





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Background

Previously, Regulation <u>2024/1052</u> authorised calcidiol monohydrate as a novel food ingredient in food supplements excluding those for infants and young children.

Resources

EFSA (2021) <u>Safety of calcidiol monohydrate produced by chemical synthesis as a novel food pursuant to Regulation (EU) 2015/2283</u>. EFSA Journal, 19(6): 6660.

Regulation (EU) <u>2024/1052</u> authorising the placing on the market of calcidiol monohydrate as a novel food

Sources

Regulation (EU) <u>2025/352</u> as regards calcidiol monohydrate used in the manufacture of food supplements

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