Novel food: phytosterols/phytostanols

Published by AGRINFO on 06 Aug 2025

EU amends specifications for use of phytosterols/phytostanols

Commission Implementing Regulation (EU) 2025/1509 of 25 July 2025 amending Implementing Regulation (EU) 2017/2470 as regards the specifications of the novel food phytosterols/phytostanols

Update

Phytosterols/phytostanols have been authorised as a novel food under certain conditions of use since 2018. This new Regulation increases the amount of other sterols/stanols allowed in phytosterols/phytostanols that are extracted from plants, including sunflower. The changed specifications do not affect the safety of this novel food.

Impacted products

Products containing phytosterols/phytostanols

What is changing?

In 2018, the European Union (EU) authorised as a novel food phytosterols/phytostanols made from plants, including sunflower, with a maximum level of other sterols/stanols below 3.0%.

The EU has now approved a request by an Argentinian company – Advanced Organic Materials SA – to update the specifications for this novel food. These changes allow the use of phytosterols/phytostanols with a content of "other sterols/stanols" of between 3.0% and 7.0%.

Only Advanced Organic Materials SA is authorised to sell phytosterols/phytostanols with a higher content of sterols/stanols on the EU market over the next 5 years, unless the company permits it, or if another company obtains a novel food authorisation for this product without reference to scientific data protected by Advanced Organic Materials SA.

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Why?

The request by Advanced Organic Materials SA to change the levels of sterols/stanols does not affect the European Food Safety Authority's assessment of the safety of this novel food (EFSA 2025), and does not alter the conclusions that supported the initial authorisation.

Timeline

The revised specifications apply from **17 August 2025**.

Background

This Regulation updates the Annex to Regulation 2017/2470 which lists authorised novel foods (see Union list of novel foods). For further information on the EU novel foods authorisation process, see Novel foods explained.

Resources

EFSA (2025) Safety of a change of specifications of phytosterols/phytostanols as a novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal, 23(1): e9162.

Regulation 2015/2283 on novel foods

Regulation 2017/2470 establishing the Union list of novel foods

Sources

Regulation 2025/1509 as regards the specifications of the novel food phytosterols/phytostanols

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