

# Novel food: phytosterols/phytostanols

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## 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 between 3.0% and less than 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.

## 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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