

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

Food additives: Steviol glycosides

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EU authorises steviol glycosides produced by fermentation using Yarrowia lipolytica as food additive (sweetener)

Commission Regulation (EU) <u>2025/652</u> of 2 April 2025 amending Regulation (EC) No 1333/2008 of the European Parliament and the Council and Commission Regulation (EU) No 231/2012 as regards the use of Steviol glycosides produced by fermentation using Yarrowia lipolytica

Update

The European Union (EU) has authorised the use of steviol glycosides made from rebaudioside M produced by fermentation using *Yarrowia lipolytica* (E 960b) as a food additive (sweetener).

Impacted products

Sweeteners (steviol)

What is changing?

The EU has authorised the use of steviol glycosides made from rebaudioside M produced by fermentation using *Yarrowia lipolytica* (E 960b) as a food additive for sweetening purposes. This additive is included in the existing group of steviol glycosides (E 960a–960d), meaning that it can be used in the same food categories as those additives and at the same maximum levels (see Regulation 2023/447).

As the production of E 960b may lead to different impurities from other steviol glycosides, separate specifications are established for this additive in Annex II of the Regulation.

Why?

The European Food Safety Authority (<u>EFSA 2023</u>) has concluded that there is no safety concern for rebaudioside M produced by fermentation using *Y. lipolytica* to be used as a food additive within an acceptable daily intake (ADI) of 4 mg/kg body weight per day (expressed as steviol equivalents).





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EFSA considers that separate specications are needed for the food additive rebaudioside M produced by fermentation using *Y. lipolytica*, as the production method may result in different impurities.

Timeline

This authorisation applies from 23 April 2025.

Background

The EU approves food additives and sets out their conditions of use. The list of approved food additives can be updated on request by the EU, or following an application.

Steviol glycosides obtained by three different manufacturing processes are regulated in combination as food additives (Regulation <u>1333/2008</u>, Annex II, Part C) with maximum limits expressed as steviol equivalents. The other authorised steviol glycosides are:

- steviol glycosides from Stevia (E 960a)
- enzymatically produced steviol glycosides (E 960c)
- glucosylated steviol glycosides (E 960d).

In September 2021, an application was received to include a new method for the production of steviol glycosides: rebaudioside M produced from fermentation by *Yarrowia lipolytica*. *Yarrowia lipolytica* consists of not less than 95% rebaudioside M, D, A, and B, and is obtained by fermentation of a source of simple sugar, using the genetically modified strain VRM of *Y. lipolytica*.

For the most recently updated list of approved food additives and conditions of use, see Regulation <u>1333/2008</u>: click on the date that follows "Current consolidated version".

Resources

EFSA (2023) <u>Safety evaluation of the food additive steviol glycosides, predominantly</u> <u>Rebaudioside M, produced by fermentation using *Yarrowia lipolytica* VRM. EFSA Journal, 21: e8387.</u>

Regulation <u>1331/2008</u> establishing a common authorisation procedure for food additives, food enzymes and food flavourings

Regulation 1333/2008 on food additives





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Sources

Regulation <u>2025/652</u> as regards the use of Steviol glycosides produced by fermentation using Yarrowia lipolytica

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