

Monosodium salt of 5-MTHF as source of folate

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European Commission proposes to allow monosodium salt of L-5-methyltetrahydrofolic acid (5-MTHF) in foods and food supplements

Draft Commission Delegated Regulation amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council to allow the use of monosodium salt of L-5-methyltetrahydrofolic acid as a source of folate in infant formula and follow-on formula, processed cereal-based food and baby food, total diet replacement for weight control and in food for special medical purposes

Draft Commission Regulation amending Annex II to Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards monosodium salt of L-5-methyltetrahydrofolic acid as a source of folic acid added to foods and as a source of folate used in the manufacture of food supplements

Update

The European Commission has informed the World Trade Organization Technical Barriers to Trade (WTO TBT) Committee that it intends to authorise the use of monosodium salt of L-5-methyltetrahydrofolic acid (5-MTHF), a source of folate, in infant formula and follow-on formula, baby and weight control foods, and foods for special medical purposes.

The Commission has also informed the WTO TBT Committee that, based on its authorisation as a novel food, it intends to include 5-MTHF in the list of vitamin and mineral substances that may be used in the manufacture of food supplements (Annex II to Directive [2002/46/EC](#)), and in the list of vitamins and minerals that may be added to foods (Annex II to Regulation [1925/2006](#)).

Impacted products

Infant formula, follow-on formula, processed cereal-based food, baby food, total diet replacement for weight control, food for special medical purposes

What is changing?

The European Commission proposes to authorise the use of monosodium salt of 5-MTHF as a source of folic acid in the following categories of food:

- infant formula and follow-on formula
- processed cereal-based food and baby food
- total diet replacement for weight control
- food for special medical purposes.

The substance must also be included in the Union list of substances allowed in these categories of food (Regulation [609/2013](#)).

The Commission also intends to include 5-MTHF in the list of vitamin and mineral substances that may be used in the manufacture of food supplements (Annex II to Directive [2002/46/EC](#)), and in the list of vitamins and minerals that may be added to foods (Annex II to Regulation [1925/2006](#)).

Why?

The European Food Safety Authority has concluded that monosodium salt of 5-MTHF is a safe source from which folate is bioavailable ([EFSA 2023](#)).

Timeline

The Regulations are expected to be adopted in approximately the third quarter of 2025.

Recommended Actions

Competent authorities of non-EU countries that are WTO members may comment on the EU proposals by emailing the [EU TBT Enquiry Point](#) until **4 May 2025** ([G/TBT/N/EU/1111](#)) and **12 May 2025** ([G/TBT/N/EU/1115](#)).

Background

Folic acid is the synthetic version of the vitamin folate, also known as vitamin B9. L-5-methyltetrahydrofolic acid (5-MTHF) is a form of folic acid that becomes more bioavailable when present in active form.

[EFSA \(2023\)](#) assessed the bioavailability of various forms of folate added to food. Annex II of Directive [2002/46/EC](#) lists folic acid as authorised for use in foods in the EU.

Regulation [2024/1037](#) authorises 5-MTHF to be placed on the EU market as a novel food, and to be included in the [Union list of novel foods](#) (Regulation [2017/2470](#)).

Resources

EFSA (2023) [Safety of monosodium salt of L-5-methyltetrahydrofolic acid as a novel food pursuant to Regulation \(EU\) 2015/2283 and the bioavailability of folate from this source in the context of Directive 2002/46/EC, Regulation \(EU\) No 609/2013 and Regulation \(EC\) No 1925/2006](#). EFSA Journal, 21: e8417.

[Union list of novel foods](#)

Sources

[Draft](#) Commission Delegated Regulation to allow the use of monosodium salt of L-5-methyltetrahydrofolic acid as a source of folate in infant formula and follow-on formula, processed cereal-based food and baby food, total diet replacement for weight control and in food for special medical purposes

[Draft](#) Commission Regulation as regards monosodium salt of L-5-methyltetrahydrofolic acid as a source of folic acid added to foods and as a source of folate used in the manufacture of food supplements

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