

# 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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