

Consultation on the determination of the status of a novel food under Article 4 (2) of Regulation (EU) 2015/2283

Information according to Article 7 of Implementing Regulation (EU) 2018/456

Recipient Member State: Germany

1. Name and description of the food in question

Dicholine L-5-methyltetrahydrofolate (DCMTHF)

DCMTHF is prepared by crystallization of L-5-methyltetrahydrofolic acid and choline hydroxide from 1-propanol and water.

2. Status as a novel food

The product is a novel food.

3. Food category

The food falls within the category referred to in Article 3 (2) (a) (i) of Regulation (EU) 2015/2283 (“new molecular structure”).

4. Reason

The German federal states’ authorities responsible for food surveillance as well as the competent authorities of the EU Member States and the European Commission were consulted.

There is no information available indicating that the product has been used for human consumption to a significant degree in the Union before 15 May 1997.

The anionic component (MTHF) of the salt is the same as in two compounds that have already been approved as novel foods: (6S)-5-methyltetrahydrofolic acid, glucosamine salt, and calcium L-methylfolate. The cationic component (choline) was allowed by Regulation (EU) No 609/2013 in foods for special medical purposes and infant formulae. Choline is also permitted as other substance in food supplements by national regulations of some Member States.

However, DCMTHF is not a mixture of choline and MTHF but a new compound which falls under the Regulation (EU) 2015/2283, as do the other two MTHF compounds which have already been approved as novel foods ((6S)-5-methyltetrahydrofolic acid, glucosamine salt, and calcium L-methylfolate).