Food additives: Celluloses

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EU restricts use of cellulose gum in dietary foods for infants and reduces maximum limits for toxic elements in 11 cellulose additives

Commission Regulation (EU) 2025/666 of 4 April 2025 amending Annex II and Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sodium carboxy methyl cellulose, cellulose gum (E 466) and the Annex to Commission Regulation (EU) No 231/2012 as regards specifications for cellulose (E 460), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), sodium carboxy methyl cellulose, cellulose gum (E 466), cross-linked sodium carboxy methyl cellulose, cross linked cellulose gum (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469)

Update

The European Union (EU) has withdrawn the authorisation of sodium carboxy methyl cellulose (cellulose gum, E 466) in dietary foods for infants and babies, and of its addition to nutrients used in foods for infants and young children.

It has also amended its specifications for the following cellulose additives, reducing the permitted levels of toxic elements (arsenic, lead, mercury, and cadmium):

- cellulose (E 460)
- methyl cellulose (E 461)
- ethyl cellulose (E 462)
- hydroxypropyl cellulose (E 463)
- hydroxypropyl methyl cellulose (E 464)
- ethyl methyl cellulose (E 465)
- sodium carboxy methyl cellulose (cellulose gum, E 466)
- cross-linked sodium carboxy methyl cellulose (cross linked cellulose gum, E 468)
- enzymatically hydrolysed carboxy methyl cellulose (E 469).

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Impacted products

Cellulose food additives; dietary foods for infants, babies and young children; foods for special medical purposes

What is changing?

Cellulose gum

The EU has withdrawn its authorisation of sodium carboxy methyl cellulose (cellulose gum, E 466) in:

- "dietary foods for infants for special medical purposes and special formulae for infants" (food category 13.1.5.1), e.g. special formula for infants with low birth weight
- "dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC" (food category 13.1.5.2), e.g. food for helping the dietary management of children with gastrointestinal disorders or food allergies.

E 466 may no longer be added to nutrients intended to be used in foods for infants and young children. It is removed from the Union list of approved food additives (Regulation 1333/2008, Annex III, Part 5, Section B).

Toxic elements in celluloses

The new Regulation also amends the specifications, in particular the maximum limits for toxic elements (arsenic, lead, mercury, and cadmium) allowed in the following additives:

- cellulose (E 460)
- methyl cellulose (E 461)
- ethyl cellulose (E 462)
- hydroxypropyl cellulose (E 463)
- hydroxypropyl methyl cellulose (E 464)
- ethyl methyl cellulose (E 465)
- sodium carboxy methyl cellulose (cellulose gum, E 466)
- cross-linked sodium carboxy methyl cellulose (cross linked cellulose gum, E 468)
- enzymatically hydrolysed carboxy methyl cellulose (E 469).

Details of these changes can be found in Annex III of Regulation 2025/666.

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Why?

Following a re-evaluation of celluoses as food additives, the European Food Safety Authority (EFSA) concluded that there was insufficient data to demonstrate the safety of E 466 in dietary foods for infants, babies, and young children. EFSA identified no safety concerns relating to the use of E 466 in other food categories. However, it advised revising the maximum limits for toxic elements (arsenic, lead, mercury, and cadmium) for E 466 and several other cellulose food additives (EFSA 2018, EFSA 2022).

Timeline

To allow businesses time to find alternatives to cellulose gum (E 466), its use in dietary foods for infants, babies, and young children for medical purposes, or in nutrients used in these foods, will not be permitted from **27 April 2027**.

The new specifications for cellulose food additives (E 460–E 466, E 468–E 469) apply from **27 October 2025**. Where these additives are put on the EU market before this date and comply with the old specifications, they may be added to food until stocks are exhausted. Foods containing these additives and placed on the EU market before 27 October 2025 may continue to be marketed until their best before or use-by date.

Background

Regulation 1333/2008 outlines the rules for assessment and approval of food additives within the EU.

- The list of approved food additives (Annex II) specifies which food additives may be used in various categories of food products according to the specified conditions.
- The list for specific applications (Annex III) details which food additives can be used in the manufacture of other food additives, enzymes, and flavourings.

Regulation 1333/2008 also specifies the maximum amounts that can be used in food products, based on two main principles:

- minimal necessary quantity: additives should be used in the smallest quantity needed to achieve their intended function, such as food preservation or flavour enhancement
- safety considerations: the quantities used must ensure safety for all consumer groups and reflect the acceptable daily intake (ADI) levels, particularly for populations with potentially higher consumption.

Specifications for each food additive are set out in Regulation 231/2012.

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For further information on the food categories in Part E of Annex II to Regulation No 1333/2008, see Commission guide on food categories.

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

Resources

EFSA (2018) Re■evaluation of celluloses E 460(i), E 460(ii), E 461, E 462, E 463, E 464, E 465, E 466, E 468 and E 469 as food additives. EFSA Journal, 16(1): 5047.

EFSA (2022) Opinion on the re■evaluation of sodium carboxy methyl cellulose (E 466) as a food additive in foods for infants below 16 weeks of age and follow■up of its re■evaluation as food additive for uses in foods for all population groups. EFSA Journal, 20(12): 7665.

European Commission (2024) Commission guide on food categories.

Regulation 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation 1333/2008

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

Regulation 1333/2008 on food additives

Sources

Commission Regulation (EU) 2025/666 […] as regards the use of sodium carboxy methyl cellulose, cellulose gum (E 466) and […] as regards specifications for cellulose (E 460), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), sodium carboxy methyl cellulose, cellulose gum (E 466), cross-linked sodium carboxy methyl cellulose, cross linked cellulose gum (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469)

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