Food additives: sodium ascorbate (E 301)

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EU authorises use of sodium ascorbate (E 301) in vitamin A preparations for infant formula

Commission Regulation (EU) 2025/1150 of 11 June 2025 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sodium ascorbate (E 301) in vitamin A preparations intended for infant formula and follow-on formula

Update

The European Union (EU) has authorised the use of sodium ascorbate (E 301) as an antioxidant in microencapsulated vitamin A preparations intended for infant formula and follow-on formula. This Regulation amends Annex III of Regulation (EC) No 1333/2008.

Impacted products

Food additives, infant formula, follow-on formula

What is changing?

The EU has authorised the use of E 301 in microencapsulated vitamin A preparations at a maximum level of 50,000 mg/kg, resulting in a maximum carry-over of 1 mg/l in the final formula.

Why?

Prior to this Regulation, E 301 had been authorised for use in vitamin D preparations for infant formula. Following an application for its use in vitamin A preparations for such products, the European Commission decided that, in light of a previous assessment of vitamin A by the European Food Safety Authority (EFSA 2010) and established maximum levels for sodium and vitamin C in infant formula, the requested extended use is not expected to pose any risk to human health.

The use of E 301 in microencapsulated vitamin A preparations is intended to improve their stability and avoid loss of vitamin A. This reduces the need to “overdose” vitamin A during production to ensure sufficient vitamin A content.

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Timeline

The new use of E 301 is permitted from **2 July 2025**.

What are the major implications for exporting countries?

Operators can now use vitamin A preparations containing sodium ascorbate (E 301) in infant and follow-on formula exports to the EU, provided the carry-over does not exceed 1 mg/l and all conditions of use are respected.

Background

Annex III of Regulation 1333/2008 sets out a list of food additives approved for use in food additives, food enzymes, food flavourings, and nutrients, and sets out conditions of use for each additive. Sodium ascorbate (E 301) is already authorised for use in vitamin D preparations for infant formula at a maximum carry-over level of 1 mg/l. It is also allowed as a source of vitamin C in infant formula. The minimum and maximum amounts of vitamin C and sodium in infant formula and follow-on formula are specified in Regulation 2016/127.

Infant formula and follow-on formula products are defined by Regulation 609/2013.

Resources

Commission Delegated Regulation 2016/127 supplementing Regulation (EU) No 609/2013 as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding

Regulation 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

Regulation 1333/2008 on food additives

EFSA (2010) Scientific Opinion on the use of sodium ascorbate as a food additive in vitamin D preparations intended to be used in formulae and weaning food for infants and young children. EFSA Journal, 8(12): 1942.

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Sources

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