Food additives: sorbates and propyl gallate

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EU revises specifications and conditions of use of sorbates and propyl gallate

Commission Regulation (EU) 2024/2597 of 4 October 2024 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sorbic acid (E 200) and potassium sorbate (E 202) and the Annex to Commission Regulation (EU) No 231/2012 as regards the specifications for sorbic acid (E 200), potassium sorbate (E 202) and propyl gallate (E 310)

Update

For the authorised food additives sorbic acid (E 200), potassium sorbate (E 202), and propyl gallate (E 310), the European Commission has reduced the current maximum limits for arsenic, lead, and mercury, and has set a maximum limit for zinc. Sorbic acid and potassium sorbate are authorised for use as preservatives in fruit-flavoured water-based gelatine desserts.

Impacted products

fruit-flavoured water-based gelatine desserts

What is changing?

The European Commission has made the following changes to the use of sorbates and propyl gallate as food additives.

- Sorbic acid (E 200) and potassium sorbate (E 202): Reduction of maximum levels for arsenic and lead to 0.1 mg/kg, and for mercury to 0.01 mg/kg. A new maximum limit of 0.1 mg/kg for zinc.
- Potassium sorbate (E 202): Amendment of description to include the granular form.
- Propyl gallate (E 310): Amendment of description to restrict the use of catalysts in the manufacturing process of the food additive; reduction of maximum limits for arsenic and mercury to 0.1 mg/kg, and for lead to 0.3 mg/kg.
- Sorbic acid (E 200) and potassium sorbate (E 202): Authorisation of their use in fruit-flavoured water-based gelatine desserts at a maximum level of 1000 mg/kg.

Why?

The European Food Safety Authority has recommended the reduction of maximum limits for arsenic, lead, and mercury in these food additives (EFSA 2019).

The description of potassium sorbate (E 202) currently refers only to its powder form, which is produced from the granular form, although both physical forms (powder and granular) have the same purity.

The use of hydrochloric acid as a catalyst during the manufacturing process of propyl gallate could result in chlorinated by-products, with uncertainty as to their safety (EFSA 2014).

The authorisation of sorbic acid and potassium sorbate in fruit-based desserts aligns the EU with the Codex General Standard for Food Additives (GSFA).

Timeline

Applies from **27 October 2024**.

Foods containing sorbic acid (E 200), potassium sorbate (E 202), or propyl gallate (E 310) that were placed on the market before 27 April 2025 can be sold until stocks are exhausted.

What are the major implications for exporting countries?

Exporting countries must ensure that their food products meet the latest EU requirements on conditions of use and specifications for food additives. Failure to comply could result in refusal of entry into the EU market.

Recommended Actions

Suppliers of foods containing sorbates and propyl gallate must comply with the new maximum levels and restrict the use of catalysts in the manufacturing process of propyl gallate (E 310).

Background

An EFSA (2019) opinion changed the temporary acceptable daily intake (ADI) of sorbic acid (E 200) and its potassium salt (potassium sorbate, E 202) to a new group ADI of 11 mg/kg body weight per day.

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

- List of Approved Food Additives (Annex II) specifies which food additives are allowed to be used in various categories of food products. Only the additives listed here are permitted for use, and they must be used according to the specified conditions.
- List for Specific Applications (Annex III) details which food additives can be used in the manufacturing of other food additives, enzymes, and flavourings. Additives must be used as outlined in this list to comply with the Regulation.

Regulation 1338/2008 also specifies the maximum amounts that can be used in food products. These limits are 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 ADI levels, particularly for populations with potentially higher consumption.

Resources

Regulation (EC) No 1333/2008 on food additives

Regulation (EU) No 231/2012 laying down specifications for food additives

Commission database on food additives

EFSA (2014) Scientific Opinion on the re-evaluation of propyl gallate (E 310) as a food additive. EFSA Journal, 12(4): 3642.

EFSA (2015) Scientific Opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives. EFSA Journal, 13(6): 4144.

EFSA (2019) Opinion on the follow-up of the re-evaluation of sorbic acid (E200) and potassium sorbate (E202) as food additives. EFSA Journal, 17(3): 5625.

Sources

Commission Regulation (EU) 2024/2597 as regards the use of sorbic acid (E 200) and potassium sorbate (E 202) and as regards the specifications for sorbic acid (E 200), potassium sorbate (E 202) and propyl gallate (E 310)

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