# Food additives: sorbates and propyl gallate

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EU to revise specifications and conditions of use of sorbates and propyl gallate

Draft Commission Regulation 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 (E200), potassium sorbate (E 202) and propyl gallate (E 310)

Draft Annexes

## Update

The European Commission has informed the World Trade Organization Sanitary and Phytosanitary Measures (WTO SPS) Committee that it intends to reduce the current maximum limits for arsenic, lead, and mercury, and to set a maximum limit for zinc, in the authorised food additives sorbic acid (E 200), potassium sorbate (E 202), and propyl gallate (E 310). Sorbic acid and potassium sorbate will be authorised for use as preservatives in fruit-flavoured water-based gelatine desserts (G/SPS/N/EU/773).

## Impacted products

fruit-flavoured water-based gelatine desserts

## What is changing?

The European Commission proposes 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

Competent authorities of countries that are members of the WTO can submit comments on the EU's proposal by emailing the EU SPS Enquiry Point until **19 August 2024**.

Expected date of adoption: Last quarter of 2024.

Foods complying with current rules placed on the market within 6 months after this Regulation enters into force (until approximately mid-2025) may remain on the market until their date of minimum durability or use-by date. From approximately mid-2025, all foods containing these additives must comply with the new specifications.

## 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

Comments or concerns about potential impacts can be submitted via the National SPS notification authority of the country concerned to the EU SPS Enquiry Point until **19 August 2024**.

## 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 the assessment and approval of food additives within the European Union.

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”.

The Regulation also specifies the maximum allowable amounts that can be used in food products. These limits are determined based on two main principles:

- quantum satis (Latin for "as much as is enough"), which means that the food additive can be used in a food product in any amount necessary to achieve the desired effect, without a specified upper limit, provided it is safe and in accordance with good manufacturing practices
- detailed specifications for each food additive as set out in Regulation 231/2012.

## 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

Draft Commission Regulation as regards the use of sorbic acid (E 200) and potassium sorbate (E 202) and as regards the specifications for sorbic acid (E200), potassium sorbate (E 202) and propyl gallate (E 310)

Draft Annexes