

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-sixth Session

PROPOSED DRAFT SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 100TH JECFA MEETING

(Comments of European Union and Kenya)

European Union

The European Union (EU) would like to submit the following comments:

Recommendation to review the specifications designated as “Full” for the food additives listed in Annex

The EU would like to thank JECFA for preparing the draft specifications arising from the 100th JECFA meeting. The EU generally supports the adoption of the full specifications for substances listed in Annex.

However, the EU has some specific comments as outlined below.

Gardenia (Genipin) Blue (INS 165)

In case of the draft specifications for INS 165 Gardenia (Genipin) Blue the EU considers that the maximum limit for inorganic arsenic (iAs) of not more than 2 mg/kg should be lowered to ensure a better level of health protection. The EU observes that the limit of inorganic arsenic of not more than 2 mg/kg is relatively high for a new food additive with new specifications.

The EU would like to refer to the low Reference Point, i.e. BMDL05 of 0.3 µg iAs/kg bw per day identified for iAs by JECFA¹. The EU further notes the lower Reference Point of 0.06 µg iAs/kg bw per day identified by EFSA².

As the exposure to inorganic arsenic is linked with adverse effect including various forms of cancer (lung, bladder, and skin), the EU considers that the overall dietary exposure should be minimised to the extent possible following the ALARA³ principle.

In that regard the EU wonders whether the limit of 2 mg/kg reflects the proposal of the applicant or whether it takes into account the results for the analysis of arsenic in several batches submitted as part of the application. The EU observes that the analytical data in the application for the authorisation of Gardenia (Genipin) Blue in the EU indicate much lower achievable levels of arsenic (all levels are below 0,6 mg/kg).

Therefore, the EU is of the view that it is appropriate to lower the limit for arsenic in the proposed specifications based on the analytical data in the application, i.e. not exceeding 0,6 mg/kg.

Information on strains of microorganisms used in the production of food additives and processing aids in their specifications

The EU considers that information on production strains is essential in the safety assessment of food additives and processing aids produced by fermentation using microorganisms.

¹ [Microsoft Word - JECFA 101 summary report_ER#3_revision](#)

² [Update of the risk assessment of inorganic arsenic in food - - 2024 - EFSA Journal - Wiley Online Library](#)

³ As Low As Reasonably Achievable

Food additives and processing aids are widely used in foods around the globe, and safety evaluations with different outcomes have been carried out for different individual strains used in their production. For example, the European Food Safety Authority has issued several scientific opinions for food enzyme α -amylase from different strains of the genetically modified *Bacillus licheniformis*. Among those opinions, there is an opinion for a particular strain in which EFSA could not exclude genotoxicity and carcinogenicity concerns based on the data provided on the presence of citrinin in the food enzyme preparation.

Information on strains clearly identifies substances produced using microorganisms that have been subject to the respective safety assessments. In the EU's view such information promotes safe use and trade of food additives, processing aids and foods produced with them.

Therefore, information on strains should be listed in their specifications, where relevant and appropriate.

The EU would welcome the views and comments of the Committee and JECFA on these issues.

Kenya

Comment: Kenya supports the adoption of the new and revised draft specifications for food additives and processing aids arising from the 100th JECFA meeting, including Gardenia (Genipin) Blue, glycolipids, thaumatin II, gellan gum variants, and ascorbyl palmitate. These specifications provide clarity, align with current scientific knowledge, and strengthen consumer protection while facilitating harmonized trade. Kenya also welcomes the reduction of lead limits in carob bean gum for infant formula to 0.5 mg/kg as a critical safeguard for infant health.