

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 7

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-Fifth Session

Comments of Brazil with support of Chile, Paraguay, Colombia, Costa Rica, Uruguay, El Salvador, Peru and Mexico

Agenda item 7

Request

Brazil kindly requests that Erythrosine (INS 127) be placed on the JECFA priority list for the purposes of conducting a safety reassessment. Erythrosine is currently permitted in certain food categories in Brazil and internationally, including its listing in the General Standard for Food Additives of the Codex Alimentarius. The recent revocation of Erythrosine's authorization by the U.S. Food and Drug Administration (FDA) highlights the need for a review of the latest scientific evidence regarding its safety. Given the potential impact of this decision on international regulatory frameworks, a new JECFA evaluation would provide updated risk assessment data to guide member countries' regulatory actions.

Background

On January 16, 2025, the FDA announced the revocation of Erythrosine's authorization as a food additive due to a U.S. legal provision that prohibits the approval of additives or colorants found to cause cancer in animals. This decision is based on studies conducted in male rats, which showed an association between high-dose exposure and cancer development.

However, the FDA has acknowledged the following considerations:

- The mechanism responsible for cancer development in rats does not occur in humans.
- Human dietary exposure levels to Erythrosine are significantly lower than the doses associated with adverse effects in animal studies.
- The FDA has been aware of this evidence since 1990 and had previously determined that there was no safety concern for human consumption at typical exposure levels.
- The decision is not based on new scientific evidence, but rather on compliance with specific U.S. regulatory requirements.

Erythrosine was last evaluated by JECFA in 2006, establishing an Acceptable Daily Intake (ADI). A subsequent reassessment in 2018 confirmed these conclusions, indicating that no changes were necessary, and that dietary exposure posed no health concerns.

Rationale for JECFA Reassessment

- The FDA's recent regulatory action may prompt international discussions regarding the safety of Erythrosine and its continued use in food products.
- A new JECFA safety assessment would provide updated scientific data for international regulatory alignment.

Although the FDA's decision was not based on new scientific evidence, the regulatory impact of this measure justifies a reassessment by JECFA. A new safety evaluation would allow for a comprehensive review of the most up-to-date scientific data, ensuring that international food additive regulations remain aligned with the best available evidence.