



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 3(b)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD ADDITIVES

Fifty-fifth Session

PROPOSED DRAFT SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES ARISING FROM THE 99TH JECFA MEETING

COMMENTS AT STEP 3 IN REPLY TO CL 2025/01-FA

(Comments by Egypt, European Union, Peru, Uzbekistan and EFEMA, ICUMSA)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2025/01-FA issued in January 2025. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the Annex

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

ANNEX I

GENERAL COMMENTS

COMMENT	MEMBER / OBSERVER
Egypt appreciates the work which done by JECFA & agrees on the proposed draft specifications for the identity and purity of food additives arising from the 99th JECFA meeting. Also, Egypt recommends their adoption.	Egypt
Polyglycerol esters of fatty acids (INS 475) (R) The EU takes note of the revised specifications for INS 475 prepared at the 99th JECFA (2024) and published in FAO JECFA Monographs 34 (2025) which require the use of edible food grade precursors and raw materials prepared in a manner consistent with the Codex Alimentarius “Code of Practice for the Reduction of 3-Monochloropropane-1,2- Diol Esters (3-MCPDEs) and Glycidyl Esters (GEs) in Refined Oils and Food Products Made with Refined Oils” (CXC 79-2019) to mitigate the occurrence of contaminants. The EU would like to inform that the specifications in the EU for the food additive polyglycerol esters of fatty acids (E 475) were amended in June 2023 in accordance with the scientific opinions of the European Food Safety Authority (EFSA) to reduce the potential exposure to impurities from the use of E 475 in food. The definition of the food additive (E 475) was amended in order to restrict the use of glycerol in the production of E 475 to glycerol compliant with the specifications for the food additive (E 422). The existing limits for toxic elements (lead, arsenic, cadmium and mercury) were reduced on the basis of the occurrence data submitted by the interested business operators in reply to an open public call of data . Maximum limits for impurities and constituents ((3-MCPD, glycidyl fatty acid esters and erucic acid) of safety concern were established taking into account the level which is currently achievable by the application of good manufacturing practices. In the EU’s view, the maximum limits for toxic elements, impurities and constituents of safety concern should be established based the lowest technologically achievable levels in the commercial food additive reported by business operators to reduce the potential exposure to these impurities from the use of E 475 in food. The EU is thus of the opinion that the following Maximum Limits should be used for the specifications of INS475: - Lead: Not more than 0,3 mg/kg instead of 0,5 mg/kg - Arsenic: Not more than 0,1 mg/kg instead of 0,2 mg/kg - Cadmium: Not more than 0,1 mg/kg instead of 0,2 mg/kg - Mercury: Not more than 0,1 mg/kg instead of 0,5 mg/kg - Sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD: Not more than 2,5 mg/kg - glycidyl fatty acid esters expressed as glycidol: Not more than 5 mg/kg - erucic acid: Not more than 2 %	European Union

Perú no tiene observaciones a las especificaciones de identidad y pureza de los aditivos alimentarios formulados en la reunión 99ª del JECFA. Gracias.	Peru
We acknowledge the specifications for Natamycin (INS 235), Nisin A, and Polyglycerol esters of fatty acids (INS 475) as full under FAO JECFA Monographs 34 (2025). Additionally, we recognize the new full specifications for processing aids, including Endo-1,4- β -xylanase (various sources) and Glucosidase from <i>Aspergillus niger</i> , as valuable contributions to food processing technologies.	Uzbekistan
EFEMA's comments on the revised specifications for polyglycerol esters of fatty acids (INS 475): EFEMA, the European Food Emulsifiers Manufacturers Association, includes producers of polyglycerol esters of fatty acids (INS 475) in its membership and wishes to: • Call for the establishment of maximum limits for 3-MCPDs and glycidyl esters, similar to the limits provided by Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives • Suggest the deletion of the following sentence from the proposed new definition: "To mitigate the occurrence of contaminants coming from raw materials, only edible food grade precursors and those that have been prepared in a manner consistent with the Codex Alimentarius "Code of Practice for the Reduction of 3-Monochloropropane-1,2- Diol Esters (3-MCPDEs) and Glycidyl Esters (GEs) in Refined Oils and Food Products Made with Refined Oils" (CXC 79-2019) may be used". This deletion should be replaced by the establishment of maximum limits in the Monograph. While 3-MCPDs are not formed in the manufacturing process of Polyglycerol esters of fatty acids, glycidyl esters (GEs) can be formed during the manufacturing process. Due to this, the content of 3-MCPDs and GEs in the used raw materials are of great importance for food emulsifiers producers. However, the reference to a Code of Practice for the production of oils and fats in the Monograph for INS 475 is difficult to enforce. Emulsifier producers cannot verify if their oil suppliers comply with the standard, as the manufacturing details of the oils are usually confidential information. To our knowledge, the EU is the only region where 3-MCPDs and glycidyl esters are regulated in food emulsifiers. Considering the toxicological profile of these contaminants and in order to create a level playing field for all food emulsifiers manufacturers as well as facilitate trade, it is paramount to set the same limits in the JECFA Monograph too.	EFEMA
The content is fine.	ICUMSA