CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 4.5

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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COMMENTS ON DRAFT STANDARDS AND RELATED TEXTS SUBMITTED BY THE 54TH SESSION OF CODEX COMMITTEE ON FOOD ADDITIVES FOR ADOPTION BY THE 47TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

BACKGROUND

1. This document compiles the comments on the amendments/revision as indicated in the relevant Circular Letter (CL 2024/62-CAC). The comments are those received through the Codex Online Commenting Systems (OCS)[1], or via email by the time this document was issued. The comments are as shown in Appendix I.

EXPLANATORY NOTES ON APPENDICES I AND II

2. The comments received are presented in a table format, with two columns as follows:

   - **First column –** Presents the comments with the rationale.
   - **Second column –** Presents the provider of the comments (name of Member or Observer).

[1] OCS is an online tool that enables Codex Contact Points to submit comments on draft texts in a standardised way, thus providing more transparency and better management of comments on different Codex texts as requested through Circular Letters. Since its launching at CAC39 (2016), the OCS has been used for different Codex Committees.

Appendix I

THE DRAFT STANDARDS AND RELATED TEXTS SUBMITTED BY 54TH SESSION OF THE CODEX COMMITTEE ON FOOD ADDITIVES FOR ADOPTION BY THE 47TH SESSION OF THE COMMISSION

COMMENTS IN REPLY TO CL 2024/62-CAC

Comments by Costa Rica, Ecuador, Egypt, Thailand, United Arab Emirates and ICUMSA, IFAC

COMMENT	MEMBER / OBSERVER
Costa Rica apoya la adoción de las enmiendas y revisiones propuestas.	**Costa Rica**
ECUADOR ESTÁ DE ACUERDO CON LA ADOPCIÓN DE LOS TEXTOS PROPUESTOS	**Ecuador**
Egypt appreciates the work which done CCFA54 and agrees on the adoption pf proposed standards and related texts submitted by CCFA	**Egypt**
Thailand does not object the adoption of the amendments/revisions to the mentioned texts, except the INS number of carbomer (INS 1210) as recommended by CCEXEC86. Thus, we propose CCFA to review the dulplication of INS number of carbomer with sodium polyacrylate (INS 1210).	**Thailand**
Regarding the invitation to submit comments regarding whether the amendments/revision to the above-mentioned texts are ready for adoption or not, United Arab Emirates, UAE consider that the amendments/revision are ready for adoption with the suggestion to note that there are several jurisdictions had been withdrawal titanium dioxide from their approved food additive lists according to their risk assessment conclusions, therefore UAE suggest to make re-evaluation of titanium dioxide by the Codex Committee on Food Additives, taking in consideration the following related points: - WHO JECFA Secretariat, based on the recommendation of CCFA54, reported that JECFA conclusion had reaffirmed the previously established ADI “not specified” for titanium dioxide (INS 171). - The EU noting that the full JECFA monograph was not yet published, pointed out that the available information was indicating limitations and some equivocal findings in the available evidence for genotoxicity and the lack of suitable testing methodologies for nanoparticles. In addition, the EU, referring to the latest scientific opinion of the European Food Safety Authority, pointed out that titanium dioxide (INS 171) was not authorised for use in food in the EU. - The following points mentioned in Table 1. Food additives evaluated toxicologically and/or considered for specifications at the 97th JECFA meeting, PART B: From 97th JECFA Meeting, regarding the acceptable daily intakes (ADIs) and other toxicological or safety recommendations and dietary exposure information of the Titanium dioxide (TiO2), -- JECFA considered additional toxicological studies relevant to the safety assessment of INS 171 that investigated the toxicokinetics, acute toxicity, short-term toxicity, long-term toxicity and carcinogenicity, genotoxicity, and reproductive and developmental toxicity, as well as special studies addressing the short-term initiation/promotion potential for colon cancer. -- JECFA identified a number of TiO2 test materials that were considered representative of INS 171. Further, JECFA recognized that a large number of toxicological studies have been conducted using test materials, including nanoparticles, having size distributions and physico-chemical properties not comparable to INS 171. These studies on non-representative materials were evaluated by JECFA, but it was concluded that they were not relevant to the safety assessment of INS 171.	**United Arab Emirates**

-- JECFA noted that INS 171 was poorly absorbed from the gastrointestinal tract of mice and rats. No adverse effects were observed in short-term studies in mice and rats receiving INS 171 in the diet, with NOAELs of 15 000 mg/kg bw per day and 5000 mg/kg bw per day in mice and rats, respectively, the highest doses tested. JECFA noted that the available data did not provide convincing evidence of genotoxicity for INS 171, but recognized the limitations in current methodologies with respect to the testing of poorly soluble particulate materials. Although there were uncertainties in the genotoxicity data, JECFA took into account the fact that INS 171 was not carcinogenic in adequately conducted 2- year studies in mice and rats at doses of up to 7500 mg/kg bw per day for mice and 2500 mg/kg bw per day for rats, the highest doses tested. There was no evidence of reproductive or developmental toxicity in studies in rats at INS 171 doses up to 1000 mg/kg bw per day, the highest doses tested. -- Available studies in humans and postmortem analysis of tissues suggested that the oral bioavailability of TiO2 in humans is very low. JECFA noted that there are currently no epidemiological studies that allow any conclusions to be drawn with respect to an association between dietary exposure to INS 171 and human health effects. -- At the 97th JECFA meeting JECFA estimated the dietary exposure to INS 171. Based on the estimates considered, JECFA selected a high P95 estimate of exposure to INS 171 of 10 mg/kg bw per day for the evaluation. Considering the very low oral absorption of INS 171, and in the absence of any identifiable hazard associated with INS 171 in the diet, JECFA reaffirmed the ADI “not specified” established at the Thirteenth meeting. Regarding the invitation to submit comments regarding whether the amendments/revision to the above-mentioned texts are ready for adoption or not, United Arab Emirates, UAE consider that the amendments/revision are ready for adoption with the suggestion to note that there are several jurisdictions had been withdrawal titanium dioxide from their approved food additive lists according to their risk assessment conclusions, therefore UAE suggest to make re-evaluation of titanium dioxide by the Codex Committee on Food Additives, taking in consideration the following related points: - WHO JECFA Secretariat, based on the recommendation of CCFA54, reported that JECFA conclusion had reaffirmed the previously established ADI “not specified” for titanium dioxide (INS 171). - The EU noting that the full JECFA monograph was not yet published, pointed out that the available information was indicating limitations and some equivocal findings in the available evidence for genotoxicity and the lack of suitable testing methodologies for nanoparticles. In addition, the EU, referring to the latest scientific opinion of the European Food Safety Authority, pointed out that titanium dioxide (INS 171) was not authorised for use in food in the EU.	
The amended texts seem suitable for publishing.	**ICUMSA**
IFAC supports draft and proposed draft food-additive provisions of the GSFA and revisions to adopted provisions, paragraph 103i and Appendix VI, Part B as written. The text is ready for adoption.	**IFAC**