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Agenda Item 3

**CX/FO 24/28/3
November 2023**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FATS AND OILS
Twenty-Eighth Session
Kuala Lumpur, Malaysia, 19 - 23 February 2024**

CONSIDERATION OF THE RECOMMENDATIONS OF THE REPORTS OF THE 90TH AND 91ST MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

Background

1. CCFO27¹ agreed:
 - (i) to defer discussion of Agenda Item 3 to CCFO28 at which time it would fully deliberate on the outcome of the JECFA evaluations as summarised in document CX/FO 21/27/3 Rev of July 2021 as attached in the Appendix to this document; and
 - (ii) to request the Codex secretariat to advise all members when the JECFA reports became available and to issue a Circular Letter requesting comments on the recommendations of JECFA 90 and 91 in order to facilitate discussions at CCFO28.
2. Circular letter [CL 2022/81/OCS-FO](#) requesting comments on the recommendations of JECFA90 and JECFA91 - Assessment of substances proposed as previous cargoes was issued in December 2022. The comments in reply to the [CL 2022/81/OCS-FO](#) are compiled in document CX/FO 24/28/3 Add.1.
3. The reports of 90th and 91st Joint FAO/WHO Expert Committee on Food Additives (JECFA) meetings can also be accessed through the following links:
 - 90th Report: <https://www.who.int/publications-detail-redirect/9789240036925>
 - 91st Report: <https://www.who.int/publications/i/item/9789240054585>

¹ REP22/FO paragraph 25-32



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APPENDIX

Agenda Item 3

CX/FO 21/27/3 Rev
July 2021

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FATS AND OILS

Twenty-Seventh Session

Virtual, 18 - 26 October 2021

MATTERS OF INTEREST ARISING FROM FAO/WHO AND FROM THE 90TH AND 91ST MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

Matters for information from the 90th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

1. The 90th meeting of JECFA Expert Committee on Food Additives (JECFA) was held on a virtual online platform (26 October – 6 November 2020, with an additional day for approval of the report on 24 November 2020) and it was dedicated to the evaluation of the acceptability of certain substances as previous cargoes and the safety assessment of certain food contaminants. The summary of the meeting has been published and is available at <http://www.fao.org/3/cb2379en/cb2379en.pdf> and at [https://www.who.int/publications/m/item/90th-meeting-joint-fao-who-expert-committee-of-food-additives-\(jecfa\)](https://www.who.int/publications/m/item/90th-meeting-joint-fao-who-expert-committee-of-food-additives-(jecfa)). The meeting report (WHO Technical Report Series) and the toxicological and dietary exposure monographs (WHO Food Additive Series No 81) will be accessible through the WHO JECFA publications website: <http://www.who.int/foodsafety/publications/jecfa/en/>.

2. JECFA evaluated 18 substances that may occur as previous cargoes and the trichothecenes T-2 and HT-2. The tasks before JECFA were: a) to elaborate principles governing the evaluation of the acceptability of previous cargoes; b) to undertake toxicological evaluations and dietary exposure assessments, and c) to undertake toxicological evaluations and dietary exposure assessments in relation to contaminants in food. It became apparent during the meeting that the time limitations precluded the toxicological evaluation of the trichothecenes T-2 and HT-2. The toxicological evaluation and overall risk assessment will therefore follow at a future meeting.

3. Table 1 below is summarizing the results for the evaluated 18 substances that may occur as previous cargoes.

Matters for information from the 91st meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

4. The 91st meeting of JECFA Expert Committee on Food Additives (JECFA) was held on a virtual online platform (1 to 12 February, with an additional day for approval of the report on 25 February 2021) and it was dedicated to the evaluation of the acceptability of certain substances as previous cargoes and the safety assessment of certain food contaminants as well as to revise the specifications on steviol glycosides.

5. The summary of the meeting has been published and is available at <http://www.fao.org/3/cb3689en/cb3689en.pdf> and at [https://www.who.int/publications/m/item/ninety-first-meeting--joint-fao-who-expert-committee-of-food-additives-\(jecfa\)](https://www.who.int/publications/m/item/ninety-first-meeting--joint-fao-who-expert-committee-of-food-additives-(jecfa)). The meeting report (WHO Technical Report Series) and the toxicological and dietary exposure monographs (WHO Food Additive Series No 82) will be accessible through the WHO JECFA publications website: <http://www.who.int/foodsafety/publications/jecfa/en/>.

6. JECFA evaluated the contaminants cadmium and ergot alkaloids, and 5 substances that may occur as previous cargoes, as well as revising the specifications for steviol glycosides. The tasks before JECFA were (a) to undertake toxicological evaluations and dietary exposure assessments in relation to certain contaminants in food and (b) to revise the specifications for certain food additives.

7. Table 2 below is summarizing the results for the evaluated 5 substances that may occur as previous cargoes.

Requests for scientific advice

8. Both organizations continue to jointly prioritize the requests for scientific advice taking into consideration the criteria proposed by Codex as well as the requests for advice from Member Countries and the availability of resources. A list of all pending requests for scientific advice by JECFA will be posted on the respective FAO and WHO websites

9. In scheduling the JECFA meetings and developing the agenda, the Joint Secretaries have to take into account the priorities requested by CCFA, CCCF, CCFO and CCRVDF. Due to the increasing requests for scientific advice to JECFA, not all requests can be addressed in the subsequent meeting. In prioritizing the work the JECFA Secretariat takes into account existing criteria, on-going Codex work and available resources.

10. To facilitate provision of extra-budgetary resources for scientific advice activities, please contact Dr Markus Lipp, FAO Food Safety and Quality Unit (jecfa@fao.org) and Kim Petersen, Department of Nutrition and Food Safety, WHO (jecfa@who.int).

Future work and recommendations from the 90th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

11. The Committee recommended that the Codex Committee on Fats and Oils (CCFO) consider revising Criterion no. 2 in RCP-36-1987 as adopted by CAC 34 (2011).

- Based on the consumption of fats and oils by infants and young children, there is no health concern for the general population from dietary exposure to previous cargo chemical substances if the ADI or TDI is sufficiently protective, for example, the ADI or TDI is greater than, or equal to 0.3 mg/kg bw per day. Substances for which there is no numerical ADI or TDI should be evaluated on a case by case basis (e.g. margin of exposure (MOE) approach).
- Where there are additional sources of dietary exposure to the previous cargo chemical substances, they should be considered in the exposure assessment.

12. The Committee recommended that sufficient chemical and toxicological information that allows the evaluation of montan wax as shipped should be made available prior to the next evaluation. At a minimum this information should address the following:

- degree of refinement and chemical constituents;
- repeat dose toxicological data on representative products in a relevant animal model.

13. The Committee recommended that sufficient chemical and toxicological information that allows the evaluation of non-food-grade calcium lignosulfonate liquid as shipped should be made available prior to the next evaluation. At a minimum this information should address the following:

- molecular weight range(s), chemical component identification and relative composition;
- toxicological data on representative products.

14. The Committee recommended the following:

- development of multi-mycotoxin methods and standards for the quantification of type A trichothecenes and their various metabolites that occur in planta;
- research to investigate the spatial distribution of T-2 and HT-2 in agricultural commodities to ensure standard sampling methods for mycotoxins are appropriate;
- that occurrence data from a wider range of countries be generated using analytical methods with suitably low LODs, to decrease the uncertainty in dietary exposure estimates and confirm the geographical distribution of these toxins.

Future work and recommendations from the 91st meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

15. The Committee reiterated the recommendations made at the ninetieth meeting that the Codex Committee on Fats and Oils (CCFO) consider revising Criterion no. 2 in RCP-36-1987 as adopted by CAC 34 (2011).

- Based on the consumption of fats and oils by infants and young children, there is no health concern for the general population from dietary exposure to previous cargo chemical substances if the ADI or TDI is sufficiently protective, for example, the ADI or TDI is greater than, or equal to 0.3 mg/kg bw per day. Substances for which there is no numerical ADI or TDI should be evaluated on a case-by-case basis (e.g. margin of exposure (MOE) approach).

- Where there are additional sources of dietary exposure to the previous cargo chemical substances, they should be considered in the exposure assessment.

16. The Committee recommended that sufficient chemical information that allows the evaluation of acetic anhydride and cyclohexane transported as previous cargoes be made available prior to the next evaluation. At a minimum this information should address the following: • product grade(s) and composition, including characterization and levels of impurities arising from all methods of manufacture.

Table 1. Substances as previous cargoes evaluated toxicologically at the 90th JECFA meeting

Previous cargoes	Evaluation
Alcohols (Group 2)	
Tridecyl alcohol, myristyl alcohol and unfractionated fatty alcohols	JECFA concluded that tridecyl alcohol, myristyl alcohol and unfractionated fatty alcohols <u>meet</u> the criteria for acceptability as previous cargoes.
Isodecyl alcohol, isononyl alcohol and isoctyl alcohol	JECFA concluded that isodecyl alcohol, isononyl alcohol and isodecyl alcohol <u>meet</u> the criteria for acceptability as previous cargoes.
1,3-Propanediol (1,3-PD)	JECFA concluded that 1,3-propanediol <u>meets</u> the criteria for acceptability as a previous cargo.
1,4-Butanediol (1,4-BD)	JECFA concluded that 1,4-butanediol <u>meets</u> the criteria for acceptability as a previous cargo.
Butyl ethers (Group 5)	
Methyl tertiary butyl ether (MTBE)	JECFA concluded that MTBE <u>meets</u> the criteria for acceptability as a previous cargo for edible fats and oils.
Ethyl tertiary butyl ether (ETBE)	JECFA concluded that ETBE <u>meets</u> the criteria for acceptability as a previous cargo for edible fats and oils.
Oils and waxes (Group 3)	
Mineral oil, medium and low viscosity, class II and class III	JECFA concluded that mineral oil, medium and low viscosity, class II and class III <u>meet</u> the criteria for acceptability as previous cargoes provided the mineral oil hydrocarbons (MOH) is food grade. Commercial MOH products range from being free of mineral oil aromatic hydrocarbons (MOAH) (food grade mineral oil) to containing 30% MOAH (crude mineral oil). JECFA noted that crude mineral oil is banned as a previous cargo and MOAH, which contain mutagenic and carcinogenic substances, would be unacceptable as previous cargoes. The current evaluation is based on the assumption that MOH products shipped as previous cargoes are highly refined food-grade products free of MOAH.
Montan wax	JECFA determined that the available evidence was not sufficient to characterize the risk of montan wax; as a result, it was concluded that montan wax <u>does not meet</u> the criteria for acceptability as a previous cargo for edible fats and oils
Propylene tetramer	JECFA took into consideration of the fact that this substance is not known or anticipated to be a food allergen, JECFA concluded that propylene tetramer <u>meets</u> the criteria for acceptability as a previous cargo for edible fats and oils.
Soybean oil epoxidized (ESBO)	JECFA concluded that ESBO <u>meets</u> the criteria for acceptability as a previous cargo for edible fats and oils.
Solutions (Group 4)	
Calcium nitrate and calcium ammonium nitrate	JECFA concluded that calcium nitrate and calcium ammonium nitrate <u>meet</u> the criteria for acceptability as previous cargoes for edible fats and oils.
Calcium ligno-sulfonate	In the absence of relevant toxicological data on test substances that are sufficiently representative of different molecular weight fractions constituting the non-food grade calcium lignosulfonate that is shipped as a previous cargo, JECFA concluded that the non-food-grade calcium lignosulfonate <u>does not meet</u> the criteria for acceptability as a previous cargo for edible fats and oils.

Table 2. Substances as previous cargoes evaluated toxicologically at the 91st JECFA meeting

Previous cargoes	Evaluation
Solvents/reactants (Group 1)	
Acetic anhydride	Although exposure to acetic anhydride and acetic acid as a result of transporting acetic anhydride as a previous cargo does not appear to be a health concern, there is uncertainty concerning the purity or “grade” of acetic anhydride that is transported as a previous cargo. Since acetic anhydride may contain impurities (e.g. diketene), which are potentially genotoxic, JECFA could not reach a conclusion on the safety of transporting acetic anhydride as a previous cargo for edible fats and oils until the nature and quantities of these impurities have been clarified.
sec-Butyl acetate	JECFA concluded that sec-butyl acetate <u>meets</u> the criteria for acceptability as a previous cargo for edible fats and oils.
tert-Butyl acetate	JECFA concluded that tert-butyl acetate <u>meets</u> the criteria for acceptability as a previous cargo for edible fats and oils.
<i>n</i> -Pentane	Exposure to impurities in n-pentane is not anticipated to contribute significantly to background exposures. Therefore, JECFA concluded that n-pentane <u>meets</u> the criteria for acceptability as a previous cargo for edible fats and oils.
Cyclohexane	Although exposure to cyclohexane as a result of transporting cyclohexane as a previous cargo does not appear to be a health concern, there is uncertainty concerning the purity or “grade” of cyclohexane that will be transported as a previous cargo. Since cyclohexane may contain carcinogenic impurities in amounts that could significantly increase dietary exposure, JECFA <u>could not reach a conclusion</u> on the safety of transporting cyclohexane as a previous cargo for edible fats and oils until the nature and the quantities of these impurities in cyclohexane has been clarified.