

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 15

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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REPORT OF THE PRE-SESSION WORKING GROUP ON THE FOLLOW-UP TO THE OUTCOMES OF JECFA EVALUATIONS AND FAO/WHO EXPERT CONSULTATIONS

(Prepared by the EU as Chair of the WG on the Follow-up to the outcomes of JECFA evaluations and FAO/WHO expert consultations)

INTRODUCTION

1. CCCF15 (2022)¹ agreed to re-convene the in-session WG at CCCF16 chaired by EU and make recommendations on possible follow-up actions to recent Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) and FAO/WHO expert consultation for consideration by CCCF16.
2. CCCF15 agreed to reconsider follow-up actions to the FAO/WHO Expert Meeting (2020) on tropane alkaloids² at CCCF16.
3. Ergot alkaloids were evaluated by JECFA at its ninety-first meeting taking place virtually from 1-12 February 2021. The summary and conclusions³ were published on 5 March 2021, the report of the meeting⁴ was published on 23 November 2022 and the WHO toxicological monograph⁵ on 31 March 2023.
4. T-2, HT-2 and diacetoxyscirpenol were evaluated by JECFA at its ninety-third meeting taking place virtually from 24 March to 1 April 2022. The summary and conclusions⁶ were published on 12 April 2022, the report of the meeting⁷ was published on 31 March 2023. The WHO toxicological monograph has not yet been published.
5. The pre-session WG was held on 11 April 2023 and chaired by the EU.

OBJECTIVE OF THE WORKING GROUP

6. The objective of the WG is to consider follow-up actions to the outcome of the JECFA evaluations and FAO/WHO expert consultations and to discuss and agree on possible recommendations to the CCCF for consideration and agreement

PRESENTATION OF THE TOPICS

7. Some background was provided to the outcome of the JECFA evaluations and FAO/WHO expert consultations. It was clarified that the order of presentation of the items was not reflecting any prioritization.

¹ REP22/CF15 para 224

² <https://doi.org/10.4060/cb1857en>

³ https://cdn.who.int/media/docs/default-source/food-safety/jecfa/summary-and-conclusions/jecfa91-1to12march2021-summary-and-conclusions.pdf?sfvrsn=1d79351f_5&download=true

⁴ WHO technical report series; 1036. Available at: <https://apps.who.int/iris/rest/bitstreams/1480488/retrieve>

⁵ WHO Food additives series; Available at: <https://apps.who.int/iris/rest/bitstreams/1495716/retrieve>

⁶ https://cdn.who.int/media/docs/default-source/food-safety/jecfa/summary-and-conclusions/jecfa93-summary-and-conclusions-april2022.pdf?sfvrsn=33db6aca_3&download=true

⁷ WHO technical report series; 1040. Available at: <https://apps.who.int/iris/rest/bitstreams/1495726/retrieve>

8. **(-) Scopolamine and (±) hyoscyamine (tropane alkaloids):** The FAO/WHO Expert Meeting (2020) was convened to respond to a request for scientific advice from the World Food Program (WFP) after poisoning incidents from the distributed food aids. The Expert Meeting had proposed operational limits that should be health protective for adults and children for WFP products, but that these limits could be extended also to other cereals and grain products when consumed in comparable quantities.
9. In addition, based on the deliberations of the expert meeting a guidance document was developed to provide specific recommendations on the limits for physical toxic *Datura stramonium* seed contamination in cereals and grains, which makes the document beneficial for screening purposes at the field level. This document was also published in 2020 and is available online <https://www.fao.org/publications/card/ar/c/CB2105EN>
10. On tropane alkaloids, divergent views were expressed in reply to the CL 2021/89-CF issued prior to CCCF15. On the one hand, there was the view that no further work is to be undertaken by CCCF given that the FAO and WHO expert consultation outcome contains operational health protective limits and a guidance to avoid contamination of cereals by *Datura* seeds has already been elaborated. On the other hand, there is the view that given the relevance for public health protection Codex risk management measures should be considered as priority.
11. At the pre-session WG on the outcome of the JECFA evaluations and FAO/WHO expert consultations before CCCF15 it was recommended that an EWG be established to prepare a discussion paper on tropane alkaloids to look into the need and feasibility of possible follow-up actions for consideration by CCCF16.
12. CCCF15 agreed to reconsider possible follow-up actions on tropane alkaloids at CCCF16.
13. **Ergot alkaloids:** JECFA91 established an Acute Reference Dose (ARfD) of 0,4 µg/kg bw as a group ARfD for the simple sum of total ergot alkaloids and a Tolerable Daily Intake (TDI) of 0,4 µg/kg bw is established as a group TDI for the simple sum of total ergot alkaloids. The Committee noted that some estimates of the chronic dietary exposure exceeded the ergot alkaloid group TDI and some estimates of the high percentile acute dietary exposure exceeded the ergot alkaloid group ARfD and that this may indicate a human health concern.
14. JECFA91 recommended:
 - that additional data on the ergot alkaloids to allow for the derivation of toxic equivalency factors (TEFs);
 - that additional data on the occurrence of ergot alkaloids (at least for the 12 considered at this meeting – i.e. ergometrine, ergocornine, ergocristine, ergotamine, ergocryptine (α- and β-analogues) and ergosine, as well as their -inine epimers) in wheat and wheat-based products and in rye and rye products from WHO regions and clusters where no data were submitted for this evaluation;
 - the establishment of sampling plans for ergot alkaloids
15. CCCF15 agreed to request JECFA to issue a call for data on the occurrence of ergot alkaloids to be submitted to the GEMS/Food database. However, this call for data has not been issued.
16. **T-2, HT-2 and diacetoxyscirpenol (DAS):** JECFA 93 established a group ARfD for T-2, HT-2 and DAS of 320 ng/kg bw and recommended a relative potency factor of 0.2 for acute exposure to DAS and a group TDI of 25 ng/kg bw for T-2, HT-2 and DAS, alone or in combination and the relative potency factor of 0.2 should be applied in comparing dietary exposure to DAS with the group TDI. JECFA93 noted that there was insufficient information available to estimate combined acute exposure to T-2, HT-2 and DAS. The acute dietary exposure estimates for T-2 and HT-2 calculated indicate no health concern. JECFA93 concluded that chronic dietary exposure estimates for the sum of T-2 and HT-2 at the mean and at the 95th percentile are higher than the group TDI of 25 ng/kg bw, indicating a possible health concern.
17. JECFA93 recommended:
 - the development of analytical multi-mycotoxin methods and standards for the quantification of type A trichothecenes and their various metabolites that occur in planta;
 - research on the spatial distribution of T-2 and HT-2 in agricultural commodities to ensure standard sampling methods for mycotoxins are appropriate;
 - that occurrence data for T-2, HT-2 and DAS 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
 - conducting chronic toxicity studies of T-2, HT-2 and DAS with adequate characterization of T-2, HT-2 and DAS doses as well as the background concentrations of other related mycotoxins in the basal feed; and
 - additional information on the toxicity of relevant (for example, those that co-occur) mycotoxin mixtures.

18. CCCF15 agreed to request JECFA to issue a call for data on the occurrence of T-2, HT-2 and DAS to be submitted to the GEMS/Food database. However, this call for data has not been issued.

WORKING GROUP DISCUSSION

19. As regards **tropane alkaloids ((-) Scopolamine and (±) hyoscyamine)** no objections were raised to re-iterate as recommendation the outcome of the pre-session WG of last year, i.e. to establish an EWG, working in English, to prepare a discussion paper on tropane alkaloids to look into the need and feasibility of possible follow-up actions for consideration by CCCF17;
20. As regards **ergot alkaloids**, no objections were raised to recommend to the Plenary to establish an EWG, working in English, to prepare a discussion paper on ergot alkaloids to look into the need and feasibility of possible follow-up actions for consideration by CCCF17. In this discussion paper, it is appropriate to define the minimum requirements for submission of data to the GEMS/Food database for consideration by CCCF17 in view of issuing a call for data on the presence of ergot alkaloids in food and feed. These minimum requirements can relate to analytical performance criteria with which methods of analysis have to comply with to ensure that data are obtained with methods of analysis with e.g. sufficient sensitivity and precision and to determine if ergot alkaloids are to be quantified individually or if they can be determined as sum of ergot alkaloids. In case of analysing individual ergot alkaloids, it could be relevant to determine which ergot alkaloids at least should be analysed.
21. One member raised the question of the time frame for the call for data given that they need to validate a method before launching a survey and this requires time. The Chair acknowledged this and indicated that it might be appropriate to have the call for data open for more than a year but that the time frame for the call for data has to be discussed and agreed when defining the minimum requirements for submission of data to the GEMS/Food database.
22. As regards **T-2, HT-2 and diacetoxyscirpenol (DAS)**, no objections were raised to recommend to the Plenary to establish an EWG, working in English, to prepare a discussion paper on T-2, HT-2 and DAS to look into the need and feasibility of possible follow-up actions for consideration by CCCF17. In this discussion paper, it is appropriate to define the minimum requirements for submission of data to the GEMS/Food database for consideration by CCCF17 in view of issuing a call for data on the presence of T-2, HT-2 and diacetoxyscirpenol (DAS) in food and feed. These minimum requirements can relate to analytical performance criteria with which methods of analysis have to comply with to ensure that data are obtained with methods of analysis with e.g. sufficient sensitivity and precision.
23. The chair noted that the 96th meeting of JECFA scheduled from 27/06/2023 to 06/07/2023 and the 97th meeting of JECFA scheduled from 31/10/2023 to 10/11/2023, have no contaminant/toxins scheduled for evaluation. In case there are no remaining open issues from the meeting of CCCF this year, there seems to be no need to reconvene the in-session WG at CCCF17.
24. No other issues were raised by the participants in the pre-session WG for consideration.

WORKING GROUP RECOMMENDATIONS TO CCCF16

25. The following recommendations are put forward to CCCF16 for consideration and agreement:
- (i) as regards **tropane alkaloids ((-) Scopolamine and (±) hyoscyamine)**: to establish an EWG, working in English, to prepare a discussion paper on tropane alkaloids to look into the need and feasibility of possible follow-up actions for consideration by CCCF17 as regards pyrrolizidine alkaloids;
 - (ii) as regards **ergot alkaloids**: to establish an EWG, working in English, to prepare a discussion paper on ergot alkaloids to look into the need and feasibility of possible follow-up actions for consideration by CCCF17. In this discussion paper, minimum requirements for submission of data to the GEMS/Food database should be considered in view of issuing a call for data on the presence of ergot alkaloids in food and feed;
 - (iii) as regards **T-2, HT-2 and diacetoxyscirpenol (DAS)**, to establish an EWG, working in English, to prepare a discussion paper on T-2, HT-2 and DAS to look into the need and feasibility of possible follow-up actions for consideration by CCCF17. In this discussion paper, minimum requirements for submission of data to the GEMS/Food database should be considered in view of issuing a call for data on the presence of T-2, HT-2 and diacetoxyscirpenol (DAS) in food and feed;
 - (iv) not to reconvene the in-session WG at CCCF, in case there are no remaining open issues from this meeting of CCCF given that there are no JECFA evaluations on contaminants/toxins scheduled prior to CCCF17.