# CODEX ALIMENTARIUS COMMISSION

**Food and Agriculture Organization of the United Nations**

**World Health Organization**

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

**15th Session**
**Virtual**
**9-13 and 24 May 2022**

**REPORT OF THE SIDE EVENT ON THE GUIDANCE ON DATA ANALYSIS FOR DEVELOPMENT OF MAXIMUM LEVELS AND FOR IMPROVED DATA COLLECTION**

(Prepared by EU as Chair of the EWG)

**INTRODUCTION**

1.   At the 12th session[1], CCCF considered the proposal of the JECFA Secretariat to develop a general guidance on data analysis for ML development that would help EWGs to take consistent approaches for data analysis. CCCF agreed to establish an EWG chaired by EU, co-chaired by the United States of America, the Netherlands and Japan, working in English, to prepare a discussion paper

2.   At the 14th session[2] of CCCF (CCCF14), CCCF14 was informed that the discussion paper in the Annex to CX/CF 21/14/15 was prepared by the EWG Chair and that due to the very late availability of the paper, no consultation with the Co-Chairs and EWG members had taken place.

3.   CCCF14 agreed:

(i) that the work should be focused on data collection, data analysis and data presentation as a priority and that discussion on elements for consideration such as appropriate rejection rates would not be taken up for now;

(ii) that a CL would be issued requesting Codex members and observers to submit comments on the topics identified in the Annex to CX/CF 21/14/15, for consideration by the EWG in addition to the comments made at CCCF14; and

(iii) to re-establish the EWG chaired by EU, co-chaired by Japan, the Netherlands and USA, working in English only, to prepare guidance on data analysis for development of MLs and for improved data collection based on the comments provided at this session and those in reply to the CL.

4.   CL 2021/78 CF[3], with the Annex to CX/CF 21/14/15 in annex, was issued in October 2021 requesting Codex Members and observers to submit comments on the different topics of the draft guidance on data analysis for development of maximum levels and for improved data collection.

5.   Comments in reply to the CL 2021/78 CF were received from Australia, Brazil, Canada, Chile, Cuba, India, Iran, Japan, Kenya, Republic of Korea, United Kingdom, USA, International Special Dietary Food Industries (ISDFI) and International Council of Beverages Associations (ICBA) and are available in Appendix II to CX/CF 22/15/14.

6.   CX/CF 21/14/15 has been updated to take into account the comments received in reply to the CL 2021/78 CF as well as the comments mentioned at CCCF14. This has resulted in a significant revision of the document also highlighting the necessity to restructure the document in line with the proposed structure (put forward for discussion at this side event). Given the late availability of the document and taking into account the comments received and significant changes proposed, time was too short for discussion and input by the co-chairs on a document for circulation for comments. The document has not been shared with the EWG formed after CCCF14.

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[1] REP18/CF, paras 155-156
[2] REP21/CF, paras 186-210
[3] https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/

7.  The proposed guidance on data analysis for development of maximum levels and for improved data collection in Appendix I to CX/CF 22/15/14 is a document prepared by the EWG Chair and **is provided for information only** on its current status and as such, it would not be discussed at the plenary session.

**OBJECTIVE OF THE SIDE EVENT**

8.  The objective of the virtual side event held before the plenary session was to discuss the workplan for next year and consider certain aspects of the guidance document (in particular the structure) in view of formulating recommendations to CCCF15 for consideration and agreement.

**SIDE EVENT DISCUSSION**

9.  The virtual side event was held on 6 May 2020 and discussed the topics mentioned in §10 and §11 of CX/CF 22/15/14.

**Workplan for next year**

10. Taking into account the comments received on the CL 2021/78 CF, it is evident that a discussion in meeting on certain aspects of the guidance document would be beneficial to come to a conclusion. Therefore, it was proposed to have three virtual working group meetings (webinars) in 2022 (period of September - November) to obtain input and to advance the document. In addition, it was proposed to create within the EWG three subgroups each chaired by one of the co-chairs of the EWG. The division of the topics to be dealt with could reflects the content of the three virtual working group meetings. It was clarified that these three subgroups would operate within the EWG and that all members of the EWG can provide input to any of the three subgroups.

11. Following requests for clarification, it was confirmed that:

    - this guidance document is intended to be an internal guidance document for CCCF to facilitate and harmonise the work within the different EWG of CCCF working on the development of MLs. The Codex Secretariat clarified that given that it is a document for internal use within CCCF, there is no need for a project document or to make a proposal for new work.
    - the starting document for the virtual working group meetings and subgroups would be the document in Appendix I to CX/CF 22/15/14 split into three separate parts in accordance with the responsibilities of the subgroups for discussion in the virtual working group meetings/subgroups.
    - in case of need, after discussions in the three virtual working group meetings and further discussions in the three proposed subgroups, further virtual working group meetings of the EWG can be held to obtain a mature document for presentation at CCCF16.

12. No further suggestions to facilitate the completion of the draft guidance were made.

**Content/structure of the guidance document**

13. It is important to clearly define the general goals/objectives of the guidance document as clear understanding of these goals/objectives would help the discussion on the scope and level of detail needed in the guidance. It is also important to clearly define the aim of the guidance document that it is intended for internal purposes of CCCF(see §11, first indent) and the objectives/goals as regards:
    - data collection: to ensure that submitted occurrence data contain all information necessary for ML development
    - data analysis: to ensure that data are analysed in a way addressing all legitimate considerations raised when possible MLs are discussed (e.g., year–to-year variation, regional variation, etc.)
    - data presentation: to ensure that data /data analysis are presented in a clear way providing (elements of) reply to legitimate considerations raised when possible MLs are discussed.

14. It was requested to include in the scope the topics for possible future inclusion in the guidance document, such as discussion on appropriate rejection rates for ML establishment or revisiting the GEMS/food cluster diets for ML elaboration. It can be reflected in the scope that these other aspects can be included in the guidance document following a decision of CCCF.

15. As regards the structure/content of the guidance document as outlined in §11 of the CX/CF 22/15/14, the participants at the side event were requested to identify the topics which may require significant additional time to discuss, i.e., which are not expected to be finalised at CCCF16 for inclusion in this guidance document (inclusion in a later update of the guidance document) and to identify additional relevant topics not yet mentioned (with the exclusion of the topics mentioned in section IV of Appendix I to CX/CF 22/15/14 e.g. appropriate rejection rates for ML development).   Such topics were not identified at the side event during the discussion on the structure and the content of the guidance document.

16.     As regards the Preamble, it was agreed that it should contain information on the scope of the document, the target users, the goals and objectives (see § 11 first indent §§ 13-14)

17.     As regards section A) Occurrence data collection and submission, it was highlighted that this should be more worked out and certain elements mentioned under section B) Occurrence data analysis, such as, inter alia, collaboration with GEMS/Food administrator, how to use GEMS/Food database, are also relevant for section A)It was also mentioned that those who upload the data may not be the ones who analyse data and that one topic may be considered in different phases of the guidance.
        All aspects referred to in the instructions for electronic submission of data on chemicals in food and the diet in the GEMS/food database[4] are relevant for the section A (important information to be provided when reporting occurrence data, mandatory data requirements, …)

18.     The section B) Occurrence data analysis, with subsections Extraction of data from the GEMS/Food database, data selection: clean-up of data, data analysis: generating overview of data, data analysis: statistical analysis was presented.

        A comment was made that it would be more appropriate to put the inclusion of analysis of rejection rates at hypothetical MLs and of effects of hypothetical MLs on the reduction of dietary exposure under the section of data presentation rather than under the section of data analysis. Following discussion it was clarified that data analysis and data presentation are closely related and that calculation of violation rates is a separate issue from the selection of an appropriate violation rate, and it was decided for the time being to maintain these aspects under data analysis.

19.     It was agreed that section C) Data presentation is closely related the aspects mentioned under the section data analysis.

20.     It was noted that the structure and contents of the guidance document and appropriate location of certain elements/topics may need to be revisited after discussions by the EWG.

21.     Although the division of the topics between the three virtual working group meetings/subgroups within EWG fall within the remit of the Chair and the co-chairs of the EWG, a suggested division of topics among the three virtual working group meetings/subgroups was presented for input:

        -    All topics related to data collection and data submission and extraction of data from GEMS Food database

        -    All topics related to data selection /clean-up of data and generating overview of data (aspect of data analysis)

        -    All topics related to statistical analysis (aspect of data analysis)

        Aspects related to data presentation are closely linked to the data analysis and is therefore proposed that the aspects related to "presentation" aspects are discussed in connection with the data analysis in the relevant subgroup.

        No comments/inputs on this suggested division of topics among the three virtual working group meetings/subgroups were provided at the side event.

        As outlined in § 192 of REP21/CF, input from

        - the GEMS/Food Database administrator on what is possible and feasible as regards changes to the GEMS/food database and to provide clarifications as regards the use of the GEMS Food database, and
        - the JECFA Secretariat providing concrete information on how the different topics mentioned in the draft guidance document are handled by JECFA when evaluating available occurrence data for exposure assessment

        is considered to be of very important added value to the discussion in the virtual working group meetings /subgroups of the EWG.

        EHC 240[5] describes how JECFA handles occurrence data for exposure assessment. In addition, information from JECFA Secretariat/experts on how the occurrence data are handled in practice for exposure assessment would provide added value. It is also important to clarify that some aspects of handling of occurrence data for the purpose of exposure assessment under the responsibility of JECFA may be different from that for the purpose of ML setting under the responsibility of CCCF as risk manager.

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22. It was clarified that the aim is that the three subgroups would operate within the Codex online platform of the EWG but each with its own space (like break-out groups) within the EWG Platform. The three subgroups, each under the lead of the co-chair, would operate independently from each other. The Codex Secretariat was of the opinion that this is feasible and committed to confirm this with the IT people as soon as possible.

**SIDE EVENT RECOMMENDATIONS TO CCCF15**

23. The following recommendations are put forward to CCCF15 for consideration:

    (i)   to agree on holding of three virtual working group meetings or webinars in 2022 (September - November) to obtain input and to advance the document.

    (ii)  to agree on creation of three subgroups chaired by Co-Chairs and the following division of the topics to be discussed in the three subgroups (eventually subject to further fine tuning by the EWG Chair and co-chairs in case of need)

        -   All topics related to data collection and data submission and extraction of data from GEMS Food database

        -   All topics related to data selection /clean-up of data and generating overview of data (aspect of data analysis)

        -   All topics related to statistical analysis (aspect of data analysis)

        Aspects related to data presentation are closely linked to the data analysis and therefore the aspect of presentation is to be discussed in connection with the data analysis in the relevant subgroups.

    (iii) to agree that the content of the three virtual working group meetings reflects the division of the topics among the three subgroups

    (iv)  to agree on the status, goals /objectives and target user to be outlined in the Preamble of the guidance document (see Annex to this CRD)

    (v)   to agree on the structure and content of the guidance document as outlined in the Annex to this CRD, with the understanding that further fine-tuning might be needed following the discussion in the EWG

    (vi)  to agree to re-establish the EWG, with the understanding of the creation 3 subgroups within the EWG, to elaborate the draft of a general guidance on data analysis for ML development and improved data collection taking into account the outcome of the discussion at CCCF15 for discussion at CCCF16 (2023).

**ANNEX**

**STRUCTURE AND TOPICS/CONTENT OF THE PROPOSED GUIDANCE DOCUMENT**

**PREAMBLE (to indicate objectives, scope, general considerations, target users)**

**Outline (to be further elaborated)**

- this guidance document is intended to be an internal guidance document for CCCF to facilitate and harmonise the work within the different EWG of CCCF working on the development of MLs.

The goals/objectives of this guidance document are as regards:

- data collection: to ensure that submitted occurrence data contain all information for ML development
- data analysis: to ensure that data are analysed in a way addressing all legitimate considerations raised when possible MLs are discussed (e.g. year –to-year variation, regional variation etc.)
- data presentation: to ensure that data /data analysis are presented in a clear way providing (elements of) reply to legitimate considerations raised when possible MLs are discussed.

Other aspects can be included in this guidance document following a future decision of CCCF such as discussion on appropriate rejection rates for ML establishment or revisiting the GEMS/food market based cluster diets for ML elaboration.

### A. OCCURRENCE DATA COLLECTION /SUBMISSION

o   data generation and upload data to the GEMS/Food Database: all aspects referred to in the instructions for electronic submission of data on chemicals in food and the diet in the GEMS/food database[6] (important information to be provided when reporting occurrence data, mandatory data requirements, … )

o   balance between need to provide additional detailed information and burden of submitting data to GEMS/Food database

o   collaboration with GEMS/Food administrator(*)

o   choose relevant food category and products (*)

o   choice of relevant period (*)

(*) these aspects are of relevance from the angle of data submission as well as from the angle of extraction of data (different persons responsible for data submission and data analysis)

### B. OCCURRENCE DATA ANALYSIS
**Extraction of data from the GEMS/Food database**

o   collaboration with GEMS/Food administrator (*)

o   select relevant food category and products (*)

o   select relevant period (*)

o   only GEMS Food data (or not)

(*) these aspects are of relevance from the angle of data submission as well as from the angle of extraction of data (different persons responsible for data submission and data analysis)

**Data selection: clean-up of data**

o   data with missing information

o   data with incorrect information (unit, expression basis)

o   data from fraudulent practices/adulteration

o   LOQ considerations (appropriateness of LOQ values, rate of data below the LOQ values, sum of values including those below the LOQ, etc.)

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6      INSTRUCTIONS FOR ELECTRONIC SUBMISSION OF DATA ON. CHEMICALS IN FOOD AND THE DIET (update 7 December 2021). Available at: https://cdn.who.int/media/docs/default-source/food-safety/gems-food/gems-instructions-for-electronic-submission-of-data.pdf?sfvrsn=c79dd32c_7

**Data analysis: generating overview of data**

o   overview which countries, how many data points, which years

o   decision of sufficient geographical coverage of the available dataset

o   decision on period coverage of the provided occurrence data

**Data analysis: statistical analysis**

o   minimum number of samples for reliable percentiles

o   handling of datasets with low number of data

o   handling of datasets with a large proportion of left censored data

o   determination of outliers/extreme values and handling thereof

o   generation of statistics/percentiles/distribution curves

o   analysis of combined and individual datasets (per year, per region/country, per year per region?)

o   decision on datasets with different contamination pattern, need to separate or not

o   inclusion of analysis of rejection rates at hypothetical MLs

o   inclusion of analysis of effects of hypothetical MLs on the reduction of dietary exposure

**C. DATA PRESENTATION**

Data presentation: closely related with the different aspects mentioned under data analysis (see above)