

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 12

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON CONTAMINANTS IN FOODS
16th Session**

**18-21 April 2023 (physical plenary meeting)
26 April 2023 (virtual report adoption)**

**REPORT OF THE PRE-SESSION WORKING GROUP ON THE GUIDANCE ON DATA ANALYSIS FOR DEVELOPMENT OF
MAXIMUM LEVELS AND FOR IMPROVED DATA COLLECTION**

(Prepared by the EU as Chair of the WG on the Guidance on data analysis for development of maximum levels and for improved data collection)

INTRODUCTION - BACKGROUND

1. CCCF15 (2022)¹ agreed
 - i) on holding of three virtual working group meetings in 2022 (September – November) to obtain input and to advance the document;
 - ii) on the creation of three subgroups chaired by the Co-chairs and the following division of the topics to be discussed in the three subgroups:
 - 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), and
 - aspects related to data presentation are closely linked to the data analysis and therefore to be discussed in connection with the data analysis in the relevant subgroups.
 - iii) that the content of the three virtual working group meetings would reflect the division of the topics among the three subgroups;
 - iv) on the status, goals/objectives and target user to be outlined in the Preamble of the guidance document;
 - v) on the structure and content of the guidance document, with the understanding that further fine-tuning might be needed following the discussion in the Electronic Working Group (EWG). 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; and
 - vi) to re-establish the EWG chaired by the EU, co-chaired by Japan, the Netherlands and USA, working in English only, with the understanding of the creation of 3 subgroups within the EWG, to elaborate a proposal for a general guidance on data analysis for ML development and improved data collection

¹ REP22/CF15 para 208

WORK PERFORMED SINCE CCCF15 in EWG

2. The appendix I of CX/CF 22/15/14 "Proposed guidance on data analysis for development of maximum levels and for improved data collection"² was shared with the EWG for providing comments by 1 October 2022.
3. Three virtual working group meetings have been organised:
 - a) the first virtual working group meeting has been held on 11 October 2022 chaired by The Netherlands on data selection /clean-up of data and generating overview of data,
 - b) the second virtual working group meeting on 19 October 2022 chaired by the USA on data collection /data submission/data extraction and
 - c) the third virtual working group meeting on 20 October 2022 chaired by Japan on statistical analysis.The presentations given at the three virtual working group meetings have been made available on the EWG Codex platform
4. The draft guidance document has been divided into three separate parts/sections i.e.
 - a) Data collection and data submission and extraction of data from GEMS Food database,
 - b) Data selection /clean-up of data and generating overview of data (aspect of data analysis) and
 - c) Statistical analysis (aspect of data analysis),

and these parts/sections have been updated by the respective chairs of the virtual working groups, taking into account the outcome of the discussions in the virtual working group meetings and comments received. The updated parts of guidance documents were circulated to the EWG for comments.

The three separate parts/sections were again updated by the respective chairs of the virtual working group meetings taking into accounts the comments received from the EWG following this last circulation for comments.

5. More details on discussions and comments related to the part/section on data collection, data submission and extraction of data from GEMS Food database are provided in Appendix I of CX/CF 23/26/12, to the part/section on data selection /clean-up of data and generating overview of data (aspect of data analysis) in Appendix II of CX/CF 23/26/12, and to the part/section on statistical analysis (aspect of data analysis) in Appendix III of CX/CF 23/26/12.

In addition, a table with details on how the individual comments have been handled for the part/section "Statistical analysis (part of data analysis)", as prepared by Japan as co-chair has been uploaded on the EWG Codex platform. For the parts/sections on "Data collection and data submission and extraction of data from GEMS Food database" and "Data selection/clean-up and generating overview of data (aspect of data analysis)", all relevant information can be found in Appendix I and II of CX/CF 23/16/12, respectively.

6. The draft guidance document in Appendix IV of CX/CF 23/26/12 is the compilation by the chair of the EWG of the three updated parts/sections into one document. In Annex to the draft guidance document a glossary of terms is provided. Due to the very late availability of the document by the Chair of the EWG, the document has not been circulated for comments and is provided for information only and will not be discussed at the meeting of CCCF16.

BACKGROUND AND OBJECTIVE OF THE PRE-SESSION WORKING GROUP

7. During the discussions in the EWG virtual working group meetings and comments received, several topics have been identified for which a discussion and conclusion in CCCF16 would be appropriate to enable the finalisation of the guidance document. These topics relate to
 - changes to the existing and additional fields to the GEMS/Food database,
 - need to define number of samples needed for estimation of percentile values,
 - the use of combined or individual dataset for developing MLs,
 - on the appropriateness on calculation of dietary exposure reduction rates in impact assessment of hypothetical MLs.

² Available at: <https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCCF&session=15>

8. In CX/CF 23/16/12, para 19, following recommendations to the CCCF are formulated
 - a) To agree on changes to the existing fields and on additional fields of the GEMS/food database (CX/CF 23/16/12 § 13 and 14, Appendix I, including Annex part A and B);
 - b) To agree whether there is a need to determine specific minimum number of samples for percentile calculations and if this is the case to agree on a preferred option (CX/CF 23/16/12 §15, Appendix IV, paras 76-80);
 - c) To agree whether to use a combined dataset or individual datasets for developing MLs (CX/CF 23/16/12 § 16, Appendix IV, paras 99-110);
 - d) To agree on the appropriateness to include dietary exposure reduction rates calculations in impact assessment of hypothetical MLs (CX/CF 23/16/12 § 17, Appendix IV, paras 142-157);
 - e) To consider to recommend to WHO the development of additional training materials and opportunities for the data submission to and data extraction from the GEMS/Food database;
 - f) To agree on a more structured process for elaborating Calls for data.
 - g) To agree on the consideration of data availability and quality before deciding on new work.
9. A virtual pre-session working group was held on Wednesday 12 April 2023, continued in an in-person pre-session working group on Monday 17 April 2023, chaired by the EU. In the pre-session working group, the recommendations referred to in the paragraph above and a workplan for the coming year were discussed in view of establishing recommendations to the CCCF16 for consideration and agreement.

PRESENTATION OF THE TOPICS AND DISCUSSION IN THE PRE-SESSION WG

Section "Data collection and submission" - GEMS/Food database

10. Before starting the detailed discussion on the different proposed changes on the GEMS/Food database, following information was provided ,following an exchange of views with the GEMS/Food database administrator prior to pre-session working group
 - a) Changes to existing flags and providing new flags are in principle no problem.
 - b) Changes to dropdown menus: adding new options in the dropdown menu is in principle also not a problem, modifications to current options in the dropdown menu might be more problematic as it might create difficulties in interpreting/comparing already submitted data with newly submitted data.
 - c) Additional fields, in principle no problem but it is important that these additional fields have an added value, as they increase the burden of submission of data to the GEMS/Food database.
11. The changes to the existing fields in the GEMS/Food database as discussed and recommended by the EWG relate to the following fields: Local Food Identifier (Col E) , Serial Number of the Record (Col F) , Country/Region (G), Contaminant (H), Sample Representativeness/Reliability (Col K), Measurement Units (Col N), LOD (Col O), LOQ (Col P), Results Based on (Col Q), Portion Analyzed (Col R), State of Food Analyzed (Col S) , Results (Col T) , and Confidentiality of Data (Col V). Details of the proposed changes can be found in Annex , part A of Appendix I to CX/CF 23/16/12.
12. Some delegations indicated not to be able to take final position on the proposed changes at the WG meeting given that the document was very late available. It was clarified that no final decisions are taken in the WG but the aim is to agree on recommendations to the Plenary for discussion.
13. It was also clarified that the part/section "Data collection and submission" in the draft guidance as presented in Appendix IV to CX/CF 23/16/12 is reflecting the GEMS/Food database as it is currently. The proposed changes to the GEMS/Food database can be found in the Annex part A and B of Appendix I to CX/CF 23/16/12. The part/section "data collection and submission" will in the coming year be updated taking into account the changes to the GEMS/food database as agreed at this meeting of CCCF and accepted for change by the GEMS/food database administrator.

14. All changes to existing fields were presented at the WG and on the following proposed changes a discussion in the WG took place:
- a) Field G "Country/region": instead of adding a flag, the field name could be changed to "Submitting Country/Region"
 - b) Field K "Sample representativeness/reliability": comments were made as regards the need to maintain "unknown" in the dropdown menu, the appropriateness to add "routine" to random sampling, as it is mixing two notions: one refers to the method of sampling and the other to the context of sampling. Better to add a flag to explain and refer to the definitions of the terms "random sampling" and "targeted sampling" and to ensure a consistent use of these terms through the guidance document.
It was concluded to maintain the unknown in the dropdown menu in order not to force the data submitter to choose between "random" and "targeted" even if it is unknown for the data submitter given that it is a mandatory field. The terms "random sampling" and "target sampling" are defined in the glossary of terms and clarification can be provided in a "flag" or in the "Instructions for electronic submission of data on chemicals in food and the diet" or in both.
 - c) Field O "LOD" and field P "LOQ": An extensive discussion on these two fields has taken place: Different views were expressed: LOQ mandatory and LOD optional or making both fields mandatory. It was said that in case both fields would be mandatory, the requirement of LOD being mandatory would be a large drawback for an important data provider, making now LOQ mandatory could result that some historical data could no longer be used. On this latter point it could be clarified that the mandatory nature of the LOQ field is only applicable for newly submitted data. It was concluded to propose to change the order of the fields O "LOD" and P "LOQ", and to make the field "LOQ" mandatory and the field "LOD" optional.
 - d) Field Q "Results based on" : As regards the proposed changes to the drop down, it was clarified by the GEMS/Food Database administrator that the changes would cause a big problem for the use of the 8 million existing data and particular the proposed change "as is (raw, fresh)" to "as sold" is in that sense problematic. It could also be considered to have the % fat content and % water content in the field "remarks" or in the proposed new "compositional information". In order to address the concern from the GEMS/food database administrator, it was proposed to replace "as is (fresh, raw)" by "as is (raw, fresh, as sold)"
 - e) Field V "Confidentiality of data: this field is optional and provides two options "yes" or "blank". "Blank" does not indicate if data are confidential or not and is therefore unclear. It is therefore proposed to change the dropdown menu to "yes" or "no" and to make the field mandatory for newly submitted data.
 - f) Finally a comment was made to make the field U "Aggregated Sample" mandatory to fill while it is currently "optional". In case of change also this would only be applicable for newly submitted data.
15. All new fields were presented at the WG and on following proposed new fields a discussion in the WG took place:
- a) Field "compositional information" it has to be considered to include here also the fat percentage or water content (see comments field Q)
 - b) For the new field "Country/Region of origin", following discussion, it was proposed to change the field name in "Country/Region of origin/production and to add to the flag "for finished products, refer to country of origin as mentioned on the label"
 - c) The usefulness of the fields "ML in country/region of origin" and "ML in sampling country/region" , the usefulness of these additional fields was questioned. There is a clear interest to have information on the ML in sampling country/region to assess if the data from these countries on imported products are ,biased as the consequence of the import requirements but this information can also be relatively easily obtained *a posteriori* in case of need. While it is acknowledged that this is the case when the data are used for development of a Codex ML (direct contact with competent authorities of these countries), in case the data are downloaded and used for other purposes, this might not be that obvious for the data user to obtain that information (no direct contact with/no information of competent authorities), while this information is important to be able to assess the data in the right context. It was therefore proposed to maintain the additional field of ML in Sampling Country /Region but to delete the field "ML in Country of Origin"

- d) The field “product form”: it was proposed to change the field name in “product type”. It was suggested to add “concentrate” in the dropdown menu (for fruit juices) and to make the field mandatory. On these suggestions it was clarified that the addition of “concentrate” was not needed as this was already provided through the food mapping and that it was not appropriate to make the field mandatory as long as the terms “destined for further processing” versus “ready to eat” are not fully clarified/defined to ensure a harmonised use of these terms by all data submitters/providers. In the dropdown menu it was agreed to add the option “not applicable” as this field will not be relevant for/applicable to all commodities
- e) The field “Sampling location in Production chain” . It was proposed to add “Industry” to the dropdown menu.
- f) The field “Method of Analysis” : in the drop down menu the choice should be limited to analytical method principles/approaches, such as TLC, HPLC, GS-MS, LC-MS/MS, ELISA, NMR, ... and not to methods described in detail.
- g) The field “Call for Data Reference”: the comment was made that the reference to the Circular letter changes each year for the same call for data for a specific contaminant and a reference to a call for data might therefore be more confusing than helpful. It was confirmed by the FAO representative that it was not appropriate to keep a call for data running/open for several years with the same initial Circular Letter reference. Member Countries do usually not pay attention to Circular Letters from previous years but only respond to circular letters that are recently issued. Therefore, it is proposed to delete this additional field.
16. The changes to new existing fields are presented in part A of the Annex to this document and the proposed new fields in part B of the Annex to this document. The changes, proposed following the discussions at the pre-session Working Group, are provided in track changes.

Workplan for next year for the section “Data collection, data submission and data extraction”

17. The following workplan for the coming year for the section “Data collection, data submission and data extraction” was proposed to the pre-session working group:
- Agreement on proposed modifications to GEMS/Food database template at CCCF16.
 - Feedback by GEMS/Food database administrator before summer break 2023
 - which of the recommendations from CCCF16 can be effectively implemented, and
 - timeframe of implementation
 - Update of the section “Data collection and submission” of the draft guidance taking into account the feedback from GEMS/Food database administrator.
 - Circulation of the updated section “data collection, data submission and data extraction” of the draft guidance to the EWG for comments (1 round)
 - Finalisation of the section “Data collection, data submission and data extraction” of the draft guidance taking into account the comments received from the EWG
 - Submission of the section “data collection, data submission and data extraction” to the Codex secretariat end of January 2024 for circulating for comments in view of finalisation of this section at CCCF
18. Upon request, it was clarified that the section “Data collection, data submission and data extraction” is complementary to the GEMS/Food database “Instructions for electronic submission of data on chemicals in food and the diet”. There might be some overlap but this is not considered to be a problem.
19. The pre-session working group did not raise any comments to the proposed workplan for next year for the section “Data collection, data submission and data extraction”

Sections “Data selection/clean-up – generating overview of data” and “statistical analysis “

20. The topics to be addressed in first instance in the sections “Data selection/clean-up – generating overview of data” and “statistical analysis “were presented
- Data selection/clean up: all steps taken in the clean-up of data to be recorded and described (reasons for exclusion)
 - Only GEMS/Food database data to be used in ML development. Other data only to be used for complimentary analysis/ in support.
 - How to handle lack of information on data provided (e.g. LOQ missing, state of the food analysed)

- Handling of data which it can be reasonably assumed that the unit of the data provided or on the basis on which the data are reported is not correct (including elements currently in the section statistical analysis – paras 111 -124 of Appendix IV of CX/CF 23/16/12).
- Data originating from suspected fraudulent/economically adulterated samples (including elements currently in the section statistical analysis – paras 111 -120 of Appendix IV of CX/CF 23/16/12).
- Data from targeted sampling (including elements currently in the section statistical analysis – paras 111 -120).
- Limit of Quantification (LOQ) and Limit of Detection (LOD) considerations (including elements currently in the section statistical analysis – paras 90 -92 of Appendix IV of CX/CF 23/16/12)
- Overview of countries covered, how many data points, which years, period of data coverage
- Guidance on geographical coverage of the provided occurrence data (including elements currently in the section statistical analysis – paras 99 -110 of Appendix IV of CX/CF 23/16/12)
- Guidance on period coverage of the provided occurrence data (including elements currently in the section statistical analysis – paras 99 -110 of Appendix IV of CX/CF 23/16/12)
- Minimum number of samples (basic)
- Determination and handling of outliers/extreme values (basic information)
- Calculation of rejection rates at hypothetical MLs
- Calculation of effects of MLs on the reduction of dietary exposure at hypothetical MLs (basic information)

Workplan for the coming year for the sections “Data selection/clean-up – generating overview of data” and “statistical analysis “

21. The following two options for the workplan for the coming year for the two sections “Data selection/clean-up – generating overview of data” and “statistical analysis “ were proposed

Option 1:

- To work in the coming year on sections « selection/clean up of data and data analysis » containing the basic elements and principles (see para 20 of this CRD) for **provisional** agreement of the sections « selection/clean-up and data analysis » at CCCF17
- To agree on further work at CCCF17 on the more « complex » aspects of the sections « Data selection/clean up and data analysis” in view of updating and finalization of these sections for agreement at CCCF18 or later.

Option 2

- To suspend the work on sections “data selection/clean-up” and “data analysis” for one year and resume the work on these sections after CCCF17

22. Following a discussion at the pre-session WG, the very large majority of the delegations present are in favour of option 1. One delegation indicated not to exclude option 2 as a possibility.

23. Taking into account that the pre-session WG opted for option 1, the concrete workplan for the coming year for the sections “Data selection/clean-up – generating overview of data” and “statistical analysis “ were proposed

- Update of the sections “Data extraction/selection/clean-up” and “data analysis” containing the basic elements and principles (see elements mentioned in para 20 of this CRD)
- Circulation of the updated sections to the EWG for comments (1 round)
- (eventually) Organisation of an Virtual Working Group (VWG) in November 2023 to discuss issues where divergent views are expressed (if needed some aspects of the section “data collection, data submission and data extraction ” can be addressed if VWG is organized)
- Finalisation of the sections “data selection/clean-up and data analysis” taking into account the discussions at VWG or, if no VWG is organised, taking into account the comments of a possible second round of consultation of EWG.
- Submission of the sections “Data selection/clean-up and data analysis” to the Codex secretariat end of January 2024 for circulating for comments in view of **provisional** agreement of these sections at CCCF17. Also, a list of topics of these sections, which require further discussion, will be simultaneously be submitted for circulating for comments in view of consideration by CCCF17 for further work on these topics.

24. The pre-session working group did not raise any comments to the proposed workplan for next year for the sections “Data selection/clean-up – generating overview of data” and “statistical analysis”

Need to determine specific minimum number of samples for percentile calculations and if this is the case to agree on a preferred option (§15, Appendix IV, paras 76-80 of CX/CF 23/16/12);

25. In relation to the number of samples for estimating high percentile values with high confidence level, three options are described in the current draft of Guidance for deriving the minimum number of samples (see CX/CF 23/16/12 Appendix IV, § 78, table 1).

Some members of the EWG preferred larger minimum number of samples in the table for statistically robust ML(s) while some others preferred smaller minimum number of samples because of previously available number of samples in the CCCF work and a need to establish an ML.

There were also comments that it should be decided on a case-by-case basis

26. After discussion in the pre-session WG, it was concluded that a minimum number of samples is needed and established a minimum number of 59 samples. It was also proposed to put this topic on the list of topics to be further discussed/elaborated after CCCF17.

To use a combined dataset or individual datasets for developing MLs (§ 16, Appendix IV, paras 99-110 of CX/CF 23/16/12))

27. If combined dataset or individual datasets should be used for developing MLs, divergent views were expressed in the EWG. As Codex MLs are for global application, use of combined dataset for developing Codex MLs would be appropriate. However, if there are significant and meaningful differences in the distribution patterns of a contaminant datasets per region or per year, individual datasets can be considered in addition to the combined dataset.

Some members of the EWG were of the opinion that the guidance should indicate which dataset should be given priority for developing ML such as datasets from country(ies)/region that produced most of the commodity in question should be given priority or for data analysis, consideration of weighting the data according to production volume should be considered.

28. The different options mentioned in the EWG to develop a globally applicable ML were
- a) to use a combined dataset; or
 - b) to use the dataset showing the highest contamination patterns, as long as the commodity was produced through good practice;
 - c) to use datasets from major producing countries or regions;
 - d) to use datasets from importing countries reflecting the levels of a contaminant of the commodity in international trade
 - e) to decide on a case-by-case which dataset is to be used.
29. After discussion in the pre-session working group, it was concluded that at this stage the combined global dataset is to be used for the development of the ML and the individual datasets per year or per region are provided for additional consideration in the ML development. But at this stage there would be no guidance given on which dataset the ML development should be based or to which database should be given priority for ML development. To have more guidance on this can be listed as a topic for further discussion after CCCF17.

The appropriateness to include dietary exposure reduction rates calculations in impact assessment of hypothetical MLs (§ 17, Appendix IV, paras 142-157 of CX/CF 23/16/12);

30. Calculation and presentation of impacts of hypothetical MLs on reduction of dietary exposure, as well as on rejection rates, has been a common practice in CCCF for some years.

Some members of the EWG commented that exposure assessment is the role of JECFA and that it is not necessary when HBGVs are not set. However, the calculation and presentation of exposure reduction rates has already been done by EWGs for such compounds as aflatoxin and lead without HBGV.

It was not questioned that a detailed exposure assessment is to be performed by JECFA, but the impact of hypothetical MLs on exposure reduction could continue to be calculated within the EWGs created for the development of ML for a certain contaminant.

31. Following discussion in the pre-session WG, it was concluded that the inclusion of dietary reduction rate calculations of hypothetical MLs should be optional and left to the discretion of the Chair of the EWG or to the EWG as f-group to decide on the appropriateness. This topic could also be listed as a topic for further discussion after CCCF17.
32. It was also mentioned that the topics for future discussion for possible future inclusion in the guidance as mentioned in chapter IV of appendix I of CX/CF 22/15/14 should be considered for inclusion in the list of topics to be discussed after CCCF17 i.e. identification of appropriate rejection rates in ML establishment and appropriateness of GELMS/food market based cluster diets for ML elaboration.

Consideration of other possible Recommendations to CCCF

33. To consider to recommend to WHO the development of additional training materials and opportunities for the data submission to and data extraction from the GEMS/Food database; The FAO representative indicated that this recommendation can be supported on the condition that sufficient funding is provided for this.
34. To agree on a more structured process for elaborating Calls for data. In view of improving the data collection and given the importance of specific requirements/details for the food-contaminant data to be provided in view of future ML development, a more structured process for elaborating Calls for data, thereby providing more time for review of proposed Calls for data.
35. To agree on the consideration of data availability and quality before deciding on new work, to avoid that work, after it has already started, needs to be put on hold for a few years because e.g. occurrence data of major producing countries/regions are lacking. needed. One delegation mentioned that this could be taken up in the Preamble of the guidance document.
36. It was also confirmed that the Preamble would be finalised in view of agreement also on that part of the Guidance at CCCF17
37. To recommend the holding of an in person pre-session WG prior to CCCF17 to discuss the guidance document.
38. No comments were raised as regards the recommendations mentioned in, paras 33-37 above, but it is also to note that time was limited to discuss these recommendations in detail.

WORKING GROUP RECOMMENDATIONS TO CCCF16

- 39.. The following recommendations are put forward to CCCF16 for consideration and agreement:
 - (i) to agree on the proposed changes to the GEMS/Food database as presented in Annex, part A and B of this CRD
 - (ii) to agree on the proposed workplan for the coming year for the section "Data collection, data submission and data extraction" provided for in para 17 of this CRD
 - (iii) to agree on the topics to be addressed in the sections "Data selection/clean-up – generating overview of data" and "statistical analysis" as listed in para 20 of this CRD
 - (iv) to agree on the proposed workplan for the coming year on the sections "Data selection/clean-up – generating overview of data" and "statistical analysis" as provided in para 23 of this CRD
 - (v) to agree that a list of topics of sections "Data selection/clean-up – generating overview of data" and "statistical analysis" shall be elaborated for consideration and agreement by CCCF17 for further discussion after CCCF17.
 - (vi) to agree on the conclusions as regards
 - Minimum number samples as provided in para 26 of this CRD
 - Whether a combined dataset or individual datasets should be used for developing MLs, as provided in para 29 of this CRD
 - Whether to include dietary exposure reduction rates calculations in impact assessment of hypothetical MLs as provided in para 32 of this CRD

- (vii) to recommend to WHO the development of additional training materials and opportunities for the data submission to and data extraction from the GEMS/Food database and to recommend the Codex Member countries to provide the necessary funds for this.
- (viii) to agree on a more structured process for elaborating Calls for data
- (ix) to agree on the consideration of data availability and quality before deciding on new work
- (x) to recommend the holding of an in person pre –session WG prior to CCF17 to discuss the guidance document
- (xi) to re-establish the EWG chaired by the EU, co-chaired by Japan, the Netherlands and USA, working in English, to continue the work on a proposal for a general guidance on data analysis for ML development and improved data collection

- ANNEX

Part A: Modifications to existing fields – fields with a grey background are fields where no changes following the discussions in the EWG are proposed . The changes as discussed in the pre-session Working group are in track changes

Col	Field	Field type/ Drop-down items	Mandatory or Optional	Flag Language	Requested new language	Rationale
E	Local Food Identifier	Free text	Mandatory		Add flag <i>on Worksheet 2: Food Mapping</i> : "Provide a detailed name in the Local Food Identifier such as "Orange roughy" instead of "Fish."	Note: This is intended to prompt users to enter names that will be more useful for sorting and analysis.
F	Serial no of the Record	Free text	Mandatory		Add flag: "One serial number (sample ID) is used for each sample. Data on different contaminants in the same sample should have the same serial number."	Provides clarity on serial no of the record.
G	Country/Region	Menu	Optional		<u>Change field name in "Submitting Country/Region" and/or</u> Add flag: "Reflects countries or regions submitting data; this is not the country of production."	Provides clarity to submitters.
H	Contaminant	Menu	Optional	Current flag language: "Please select a contaminant from the list . . . This is optional if a contaminant is provided on the first page."	Modified flag: "Please select a contaminant from the list. A contaminant is required, but manual entry in Column H: Contaminant is optional if a contaminant has been added on Worksheet 1: Start."	The request is to clarify language in the flag as there were questions about why a contaminant is optional.
I	Food Origin	Menu: • Domestic • Imported • Mixed origin • Unknown	Optional			
J	Sampling Date	Free text (YYYY)	Mandatory			

K	Sample representativeness/ reliability	Menu <ul style="list-style-type: none"> • Random sampling • Targeted sampling • Unknown 	Mandatory		<p><i>Change field title:</i> Sample representativeness</p> <p><i>Change dropdown menu:</i> <u>-no change to the dropdown menu</u></p> <ul style="list-style-type: none"> • Random (routine) sampling • Targeted sampling • Unknown <p><u>Add a flag clarifying “random sampling” and “target sampling” and provide the clarification in the instructions for electronic submission – refer to definitions of the terms in the glossary.</u></p>	Note: The request is to remove “reliability” from the field name and to add (routine) after random in the dropdown menu field.
L	Laboratory Identification	Free text	Optional			
M	Analytical Quality Assurance	Menu <ul style="list-style-type: none"> • Internal QA only • Successful proficiency testing • Officially accredited 	Optional			
N	Measurement units for Contaminant Levels	Drop-down <ul style="list-style-type: none"> • mg • ug • ng • pg • bg 	Mandatory		<ul style="list-style-type: none"> • mg/kg • µg/kg • ng/kg • pg/kg • Bq/kg 	This field is already mandatory and currently complete units are shown in the flag. The request is for complete units (mg/kg vs mg) ALSO to appear in the rows.
O	LOD	Free text	Mandatory for results not quantified if LOQ is not provided		Optional <p><u>Change the order of the fields: field O to come after field P</u></p>	Note: This can become Optional only if the LOQ is mandatory. The EWG did not agree that LOD should be mandatory

P	LOQ	Free text	Mandatory for results not quantified if LOD is not provided		Mandatory <u>Change the order of the fields: field P to come before field O</u>	"Mandatory" would replace "Mandatory for results not quantified if LOD is not provided." The EWG agreed that LOQ should be mandatory.
Q	Results based on	Drop-down menu •Fat content •Dry weight •As is (raw, fresh) •As consumed	Mandatory		<p><i>Change dropdown menu to:</i></p> <ul style="list-style-type: none"> • As <u>is (raw, fresh, as sold)</u> • As consumed • Fat content <ul style="list-style-type: none"> ---- Fat content % [free text, allow specific # or range] <u>to consider this information (%) in new field "compositional information"</u> • Dry weight <ul style="list-style-type: none"> ----- Water content % [free text, allow specific # or range] <u>to consider this information (%) in new field "compositional information"</u> 	Note: The request is to make changes to the drop-down menu.

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R	Portion Analyzed	Menu •Edible only •Total food (edible + inedible)	Mandatory		<i>Change dropdown menu to:</i> •Edible only •Whole food (edible + inedible) <i>Add to flag:</i> Example: shelled nut (edible) versus unshelled nut (whole food)	This field already exists and is already mandatory. The request is to add examples in the flag like “shelled versus unshelled/peeled versus unpeeled” and to change Total to Whole.
S	State of food Analyzed	Menu •Cooked •Raw •Unknown	Optional		<i>Change title to:</i> State of food analyzed (Cooked/Raw)	The request is to clarify that this field applies to, e.g., cooked fish versus raw fish.
T	Results	Free text	Mandatory	Current flag: Result is mandatory if LOD and LOQ are not provided.	<i>Change flag to:</i> “Numeric result is mandatory if LOD or LOQ are not provided.”	For clarification.
U	Aggregated sample	Menu •Individual •Aggregated	Optional		<u>Proposed to make this field mandatory</u>	
V	Confidentiality of Data	Menu •Yes •Blank	Optional		<i>Change dropdown menu to:</i> •Yes •No	To improve clarity; the meaning of “blank” is unclear.
W	Remarks/References	Free text	Optional			

Part B: Proposed new fields The changes as discussed in the pre-session Working group are in track changes

Col	Proposed Field	Field type/ Drop-down items	Mandatory or optional	Flag language	Requested new language	Rationale
--	<u>Year Date</u> of Production	Free text (YYYY)	Optional		N/A – new field	Optional – may not be known
--	Compositional Information	Free text	Optional	Information from labels such as major ingredients or percent total cocoa solids in chocolate <u>See field Q :add fat content or water content, as appropriate</u>	N/A – new field	Optional --does not apply to all samples.
--	Country/Region of Origin/ <u>production</u>	Menu <ul style="list-style-type: none"> • Unknown • Countries (A-Z) 	Optional	Name of country of origin or production <u>for finished products, refer to country of origin as mentioned on the label</u>	N/A – new field	Information may not be available
-	ML in Country/Region of Origin	Menu: <ul style="list-style-type: none"> • Yes • No • Unknown 	Optional	A numerical value or link to regulation can be added optionally in Remarks	N/A – new field	Optional because ML in the country of origin may not be known to the data submitter.
--	ML in Sampling Country/Region	Menu: <ul style="list-style-type: none"> • Yes • No • Unknown 	Mandatory	A numerical value or link to regulation can be added optionally in Remarks	N/A – new field	The submitter can be responsible for knowing whether there are MLs in the sampling country. This information will inform the EWG on whether national or regional regulations have affected contaminant levels.

--	Product Type Form	Menu: <ul style="list-style-type: none"> • Destined for further processing • Ready to eat • Not applicable • Unknown 	Optional	DFP and RTE are defined in CODEX STAN 193-1995.	N/A – new field	Optional because this does not apply to most samples.
--	Sampling Location in Production Chain	Menu: <ul style="list-style-type: none"> • Unknown • Farm • Bulk transport • Import collection • Industry • Wholesale • Retail • Other 	Mandatory		N/A – new field	The field can be mandatory with the options of Unknown and Other field
--	Method of Analysis	Menu <ul style="list-style-type: none"> • Method A • Method B • Method Z • Other • Unknown 	Optional		N/A – new field	May provide valuable information in conjunction with LOQ/LOD. <u>The dropdown menu should provide options between methods of analysis principles/approaches and not provide a very long list of methods, specifying all possible variants of a certain method of analysis principle/approach</u>
--	Call for Data Reference	Menu <ul style="list-style-type: none"> • Circular Letter Name 1 • Circular Letter Name 2 • <p>[or Free Text]</p>	Optional		N/A – new field	Countries may submit data at any time; not relevant to all samples; some data may apply to multiple data calls