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Agenda Item 17 **CX/CF 24/17/17**

April 2024

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

17th Session
15-19 April 2024
Panama City, Panama

GUIDANCE ON DATA ANALYSIS FOR DEVELOPMENT OF MAXIMUM LEVELS AND FOR IMPROVED DATA COLLECTION

(Prepared by Electronic Working Group chaired by European Union and co-chaired by Japan, the Netherlands and USA)

BACKGROUND

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 as it was observed that different approaches were taken by the EWGs. These differences concerned for example the handling of occurrence data without information on LOQ. A general guidance would help future 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 its 13th session[2], the EU as chair of the EWG, informed the CCCF that it has not been possible to prepare in time a discussion paper for consideration by the established EWG. Therefore, a paper prepared by the EU as Chair of the EWG containing a non-exhaustive list of topics that could be considered to be covered by the general guidance on data analysis for ML development was presented and CCCF agreed to extend the scope of the work to address improved data collection.

3. At the 14th session[3] of CCCF (CCCF14), CCCF agreed 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 and CL 2021/78 CF[4], with the Annex to CX/CF 21/14/15 in annex, was circulated in October 2021 with the request for comments on the guidance on data analysis for development of maximum levels and for improved data collection.

4. 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 the comments mentioned at CCCF14. This has resulted in a significant revision of the document also highlighting the necessity to restructure the document. Given the late availability of the document and taking into account the comments received and the significant changes proposed, time was too short for discussion and input by the co-chairs on a document for circulation for comments. The updated document was attached for information only as Appendix I to CX/CF 22/15/14.

5. At the 15th session[5] of CCCF (CCCF15) a virtual side event prior to CCCF15 was held to discuss the workplan for following year and certain aspects of the guidance, in particular the structure and topics to be included in the guidance.

6. CCCF15 agreed:

   a) on holding of three virtual working group meetings in 2022 to obtain input and to advance the document;

   b) 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:

[1] REP18/CF, paras 155-156
[2] REP19/CF, paras 156-165
[3] REP21/CF, paras 186-210
[4] https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/
[5] REP22/CF15, paras 202-208

- 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.

c) that the content of the three virtual working group meetings would reflect the division of the topics among the three subgroups;

d) on the status, goals/objectives and target user to be outlined in the Preamble of the guidance document;

e) on the structure and content of the guidance document, with the understanding that further fine-tuning might be needed following the discussion in the 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

f) 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.

7. The appendix I of CX/CF 22/15/14 "Proposed guidance on data analysis for development of maximum levels and for improved data collection" was shared with the EWG for providing comments by 1 October 2022.

8. 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, the second virtual working group meeting on 19 October 2022 chaired by the USA on data collection /data submission/data extraction and the third virtual working group meeting on 20 October 2022 chaired by Japan on statistical analysis.

9. The draft guidance document divided into three separate parts (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)), updated by the respective chairs of the virtual working groups, taking into account the discussions that has taken place in the virtual working group meetings and comments received, was circulated to the EWG for comments.

10. The draft guidance document in Appendix IV to CX/CF 23/16/12 was the compilation by the chair of the EWG of the three updated parts into one document. In Annex to the draft guidance document a glossary of terms was provided. Due to the very late availability of the document by the Chair of the EWG, the document was not circulated for comments and was provided for information only to CCCF16.

11. At CCCF16, agreement was achieved on the changes in the GEMS/Food database as recommendations to the GEMS/Food administrator for review (Appendix I)[6]. After feedback by the GEMS/Food database administrator on which of the recommendations can be effectively implemented and on the timeframe of their implementation, the section "data collection and submission and data extraction" would need to be updated taking into account the feedback from GEMS/Food database administrator. The updated section would be circulated for comments to the EWG and finalised for submission to the Codex secretariat for circulating for comments in view of finalisation of this section at CCCF17.

12. At CCCF16, it was agreed to update the sections "Data extraction/selection/clean-up" and "data analysis" containing the basic elements and principles and to circulate the updated sections to the EWG for comments and to submit the outcome of the EWG consultation to the Codex secretariat for circulating for comments in view of a possible provisional agreement at CCCF17[7]. It was furthermore agreed that a list of topics of sections "Data selection/clean up – generating overview of data" and "statistical analysis" should be elaborated for consideration and agreement of CCCF17 for further discussion after CCCF17[8].

[6] REP23/CF16 para 98 (i) and (ii)
[7] REP23/CF16 para 98 (iii) and (iv)
[8] REP23/CF16 para 98 (v)

WORK NOT PERFORMED /PERFORMED SINCE CCCF16

13 However, the GEMS/Food administrator was much too late consulted by the Chair of the EWG and therefore the section "Data collection and submission" could not be updated taking into account the feedback from GEMS/food database administrator and be circulated for comments to the EWG and submitted to CCCF17 for finalisation. The section "data collection and submission and data extraction" of the guidance document, as it currently stands, is provided in Appendix II. This part needs still to be updated once the feedback from the GEMS/Food Administrator on the feasibility and acceptance of the recommended changes by CCCF16 has been received.

14. The sections "Data extraction/selection/clean-up" and "data analysis" were not updated by the Chair of the EWG and not submitted for comments to EWG. Therefore, no updated document of the sections "Data selection/clean up – generating overview of data" and "statistical analysis" is submitted to CCCF17 for discussion and possible provisional agreement.

15. A list of headings/topics to be addressed in the sections "Data extraction/selection/clean-up" and "data analysis" for possible discussion at CCCF 17 is provided in Appendix III of this document.

16. Appendix IV of this document contains for information only the sections "Data extraction/selection/clean-up" and "data-analysis" as presented in Appendix IV of CX/CF 23/16/12, in which the outcome of the discussions at CCCF16 have been integrated.

POINTS FOR DISCUSSION

17. Discussion on the changes in the GEMS/Food database as recommendations to the GEMS/Food administrator for review as provided in Appendix I based on the prelimiary feedback from the GEMS/Food Database Administrator. Due to the very late consultation by the Chair of the EWG of the GEMS/Food Database adminstratro, final feedback will be provided post CCCF17.

18. Discussion on the topics for the sections "Data selection/clean-up" and "data analysis" as provided in Appendix III, in particular the proposed merging/combining of certain parts from the section "data analysis" with topics of the section "data selection/clean up".

19. Discussion on the level of detail/complexity of certain parts of the section "Data analysis" needed for the guidance document.

20. Discussion on the topics identified and listed in Appendix III for which further discussion is needed in the future (i.e. post CCCF17).

21. Confirmation of the correctness of the integration of the outcome of the dicussions at CCCF16 into the sections "Data selection/clean-up" and "data-analysis".

CONCLUSION

22. As the work on the draft Guidance on data analysis for development of maximum levels (MLs) and for improved data collection has not progressed as initially foreseen, due to the inactivity of the Chair of the EWG, another work procedure is proposed for discussion at CCCF17.

RECOMMENDATIONS

23. It is noted that the recommendations do not pertain to the content of the guidelines but on the approach to be taken from now onwards to enable progress of this work by CCCF.

24. As the guidelines on data analysis are being developed for internal CCCF working procedure, it is proposed to convert this work from an EWG into a pre-session working group (which could operate in a physical or virtual mode) or in an in-session working group (hereafter referred to as "the WG"), similar to the WGs on the work of JECFA and the review of standards. In this WG the guidance can be developed further, other matters related to data analysis emerging from discussions on agenda items could additionally be taken up in the WG, if relevant. For this, the agreed draft guidance would be included in the CCCF meeting report.

25. A circular letter would be issued requesting comments on the draft guidance. Comments will be compiled in a working document and included in the agenda. The chair of the WG would prepare a proposal for discussion in the WG, after which recommendations for revision of the draft guidance would be presented to the plenary session of CCCF. An agreed new draft will then be included in the meeting report. A chair is to be determined at CCCF17.

LIST OF APPENDICES

- APPENDIX I: Changes to the GEMS/Food database as recommended by CCCF16, submitted to the GEMS/Food administrator for review which of the recommendations can be effectively implemented and timeframe of implementation.
- APPENDIX II: Section "data collection and submission and data extraction" of the guidance document, as it currently stands (**for information only**)
- APPENDIX III: A list of headings/topics to be addressed/included in the sections "Data selection/clean-up" and "data analysis"
- APPENDIX IV. Sections "Data selection/clean-up" and "data-analysis", in which the outcome of the discussions at CCCF16 have been integrated with glossary of terms (**for information only)**
- APPENDIX V. List of Members of the Electronic Working Group (EWG)

APPENDIX I

Proposed changes to the GEMS/Food database (submitted to the GEMS/Food database administrator for review/acceptance)

(For consideration)

Part A: Modifications to existing fields – fields with a grey background are fields where no changes are proposed.

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 *on Worksheet 2: Food Mapping*": "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		Change field name in "Submitting Country/Region" and/or 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 • Random sampling • Targeted sampling • Unknown	Mandatory		*Change field title:* Sample representativeness *Change dropdown menu*: - no change to the dropdown menu • Random sampling • Targeted sampling • Unknown 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.	Note: The request is to remove "reliability" from the field name and to add (routine) after random in the dropdown menu field. *(Proposed clarification: The term "random sampling" should be chosen for routine sampling, even if targeted at specific food types or specific importing countries.* *Testing a wide range of imported samples of a certain food category for the presence of a certain contaminant would be "random".* *The term "targeted sampling" should be chosen for follow-up sampling following specific findings of contamination. For example, if a country identifies a sample from a particular manufacturer as having high levels of a contaminant, additional sampling of the same lot or lots produced at the same time by the same manufacturer would be "targeted".)*
L	Laboratory Identification	Free text	Optional			
M	Analytical Quality Assurance	Menu • Internal QA only • Successful proficiency testing • Officially accredited	Optional			
N	Measurement units for Contaminant Levels	Drop-down • mg • ug • ng • pg • bg	Mandatory		• 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 **Change the order of the fields: field O to come after field P**	Note: This can become Optional only if the LOQ is mandatory.
P	LOQ	Free text	Mandatory for results not quantified if LOD is not provided		Mandatory **Change the order of the fields: field P to come before field O.**	"Mandatory" would replace "Mandatory for results not quantified if LOD is not provided". **(Mandatory would only apply to**

						new submissions in order to maintain the validity of previously submitted data, without reporting of LOQ)
Q	Results based on	Drop-down menu •Fat content •Dry weight •As is (raw, fresh) •As consumed	Mandatory		*Change dropdown menu to:* • As is (raw, fresh, as sold) • As consumed • Fat content ---- Fat content % [free text, allow specific # or range] to consider this information (%) in new field "compositional information • Dry weight ----- Water content % [free text, allow specific # or range] to consider this information (%) in new field "compositional information"	Note: The request is to make changes to the drop-down menu.
R	Portion Analysed	Menu •Edible only •Total food (edible + inedible)	Mandatory		*Change dropdown menu to:* •Edible only •Whole food (edible + inedible) *Add to flag:* 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 Analysed	Menu •Cooked •Raw •Unknown	Optional		*Change title to*: State of food analysed (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.	*Change flag to:* "Numeric result is mandatory if LOD or LOQ are not provided."	For clarification. In relation to the proposed change of Field O in "mandatory". The flag although not relevant anymore for new submissions if change to Field O is accepted, remains relevant for previously submitted datasets.
U	Aggregated sample	Menu •Individual •Aggregated	Optional		Proposed to make this field mandatory	
V	Confidentiality of Data	Menu •Yes •Blank	Optional		*Change dropdown menu to:* •Yes •No	To improve clarity; the meaning of "blank" is unclear.
W	Remarks/ References	Free text	Optional			

Part B: Proposed new fields.

Col	Proposed Field	Field type/ Drop-down items	Mandatory or optional	Flag language	Requested new language	Rationale
--	Year 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 See field Q: add fat content or water content, as appropriate	N/A – new field	Optional --does not apply to all samples.
--	Country/Region of Origin/production	Menu • Unknown • Countries (A-Z)	Optional	Name of country of origin or production for finished products, refer to country of origin as mentioned on the label	N/A – new field	Information may not be available
--	ML in Sampling Country/Region	Menu: • 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	Menu: • 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: • Unknown • Farm • Bulk transport • Import collection	Mandatory		N/A – new field	The field can be mandatory with the options of Unknown and Other field

		• Industry • Wholesale • Retail • Other				
--	Method of Analysis (Method of analysis principle/ approach)	Menu • Method A • Method B • Method Z • Other • Unknown	Optional		N/A – new field	May provide valuable information in conjunction with LOQ/LOD. 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

APPENDIX II

Section "data collection and submission and data extraction" of the guidance document

Draft Guidance on data analysis for development of maximum levels (MLs) and for improved data collection, as it currently stands.

(For information only)

TABLE OF CONTENTS

PREAMBLE

1. The steps in development of a maximum level (ML) can include:

   - Identification of a new health or trade issue relevant to a contaminant – commodity/food combination
   - Development of a discussion paper that explores preliminary occurrence data, exposure data, and global significance of the contaminant-commodity/food combination. The discussion paper needs also to consider the data availability and quality to enable an informed decision on possible new work[9]
   - Agreement by CCCF to begin new work, including discussion of Terms of Reference, and submission of a proposal for new work to the CAC.
   - Development of a document recommending MLs in the Codex step process and a more in-depth analysis of occurrence data, exposure data, global significance of the contaminant-commodity/food combination, and impact of proposed MLs.
   - Recommendation to send MLs to the CAC for adoption.

2. The primary data source for CCCF is GEMS/Food, an international database run by the World Health Organization, containing data on contaminant levels in different foods. Member countries submit data from their national monitoring programs either on a routine basis or in response to calls for data from CCCF; the data must meet certain criteria for submission (such as including a limit of quantification (LOQ) or limit of detection (LOD) for non-quantified data). CCCF analysts extract data from the GEMS/Food database to develop ML proposals. External data, such as data from scientific literature, may be referenced, but are typically not used in setting MLs.

3. Prior to starting work on a discussion paper or ML document, CCCF may establish terms of reference (TOR) for the working group and issue a Call for Data. As outlined in the CAC Procedural Manual, 21st Ed., the TOR shall clearly state the objective(s) to be achieved by the establishment of the working group, the language(s) to be used, and the time frame by which the work is expected to be completed. The Call for Data typically identifies the contaminant and food/commodities of interest and the date range of requested data. Previous Calls for Data have also asked for information such as the LOQ and LOD of the analytical method and specific sample names; they also have identified fields in the GEMS/Food database where information should be entered and identified the appropriate basis of results.

4. Establishing TOR and planning the scope of a Call for Data is an important step in the data collection process. Careful attention to the TOR and Call for Data will result in better quality data for use in establishing MLs.

5. The management of data is a key step in the work of elaborating standards, and it is of common interest to have data of good quality (reliability of the information collected, enabling statistical analysis whenever needed, data which reflect an accurate picture of the contamination of food …).

6. The aim of this guidance document is to provide the elements for ensuring good quality data and to ensure a harmonised use and analysis of the available occurrence data by the different EWG in the development/elaboration of Codex MLs.

7. This guidance is for internal use in CCCF but national/regional authorities my use the relevant information contained in this guidance document for the development/elaboration of national/regional MLs.

DATA COLLECTION AND SUBMISSION

8. The introductory page for the WHO GEMS/Food database is Global Environment Monitoring System (GEMS) / Food Contamination Monitoring and Assessment Programme. The data submission (upload) and data extraction (download) process begin at the website, GEMS/Food Contaminants Database.

9. The database page opens to a Welcome page with two tabs, a Home Page tab and a Search tab. For full functionality, members must register and log in to their accounts. After logging in, the data submitter will have access to an Upload tab, in addition to the Home Page tab and Search tab. The submitter will also be able to access regular and bulk templates for uploading data, the GEMS/Food e-learning tool, and useful links such as Frequently Asked Questions.

10. Prior to submitting data, submitters should review materials on the GEMS/Food home page (Nutrition and Food Safety (who.int)) or linked GEMS/Food pages. Detailed instructions are found in the document, INSTRUCTIONS FOR ELECTRONIC SUBMISSION OF DATA ON CHEMICALS IN FOOD AND THE DIET on the GEMS/Food home page.

[9] REP23/CF16 para 95 and para 98 (ix)

This document provides instructions on registering an account, logging into the GEMS/Food database, inserting data into the Excel template, and uploading the Excel template. Familiarity with Excel is very helpful.

11. Data can be submitted to the GEMS/Food database on any food at any time, not just in response to a Call for Data specifying specific foods or time periods of interest. If data are submitted in response to a specific Call for Data, consider noting this information in the Remarks field. Data that fall outside the date frame referenced in a Call for Data can also be submitted. These data may be informative for study of contaminant levels over time.

12. If questions arise about technical aspects of data submissions, the submitter should contact the GEMS/Food coordinator. Questions could include error messages on upload, registration problems, how to name samples, what fields are mandatory, the definition of fields, problems with mapping, etc.

13. If questions arise about whether data align with a specific Call for Data, the submitter should consult the EWG Chair and, if needed, the Codex Secretariat. Questions could include whether the samples correspond to the definitions provided in the Call for Data or the TOR of the EWG.

14. Data submitters should develop and retain metadata associated with data submissions. The metadata will help answer questions that might arise from the EWG. Metadata could include the year of sample collection, the year of production, the overall Limit of Detection (LOD) and Limit of Quantitation (LOQ) range associated with a data set, information on product labels, information on location of collection (e.g., import or retail), names of staff who submitted the data and when the data were submitted, the batch ID associated with the submitted dataset, etc.

15. Data quality should be assessed by the submitter before data are uploaded to GEMS/Food. If serious questions arise about data quality (missing information, suspect analyses), do not submit the data until these questions can be addressed.

16. If the submitter identifies a problem with a dataset after submission, consult with the GEMS/Food coordinator on withdrawing or correcting the dataset, which should be identifiable by batch ID.

Filling out the GEMS/Food template

17. The template worksheet for regular (non-bulk) submissions[10] contains five tabs, which include (1) a checklist for submitting institutions, (2) Food Mapping of the sample, (3) a template for Individual Analysis results, (4) the WHO and FoodEx2 classification system, and (5) chemicals currently listed as options for submission in a drop-down menu.

18. The first step when submitting data is to fill out Tab “1. Start”, which contains a checklist for the Institution preparing a dataset for submission, including identification of the chemical of interest. (Note that an option is outlined in the INSTRUCTIONS for chemicals that are not available in the drop-down menu.)

19. The second step is to review the food/feed/product names in the dataset and map the national food classification with the WHO and FoodEx2 classification. Tab “2. Food Mapping” contains the mapping tool: the Local Food Identifier (column A, free text) and two levels of classification in drop-down menus, i.e., Level 1: Food Group (Column B) and Level 2: WHO Food Identifier (Column C). After the Local Food Identifier, Food Group, and WHO Food Identifier fields are filled in, the WHO Food Code, FoodEx2 code, and the FoodEx2 name are generated automatically in columns E, F and G of Tab 2.

20. One source of confusion in data submissions is how often each food needs to be mapped on the food mapping template. For example, if the submitter is uploading three foods with the following “Local Food Identifiers” -- Ginger, crystallized; Ginger powder, dried; and Ginger slices, dried -- all three would be entered separately on the food mapping template, Tab 2, and mapped to WHO “Herbs, spices, and condiments” (Column B) and “Ginger, root” (Column C). However, if the submitter is uploading 100 additional data points for “Ginger, crystallized,” the mapping only needs to be done once for all the “Ginger, crystallized” samples.

21. The INSTRUCTIONS also state that mapping should be done only once if the national classification is stable. While some countries or regions may have centralized data submission, in other countries, different institutions or parts of institutions may have accounts and submit data separately. If this is the case, institutions should attempt to coordinate how they are mapping food in order to have consistency across submissions.

[10] See INSTRUCTIONS FOR ELECTRONIC SUBMISSION OF DATA ON CHEMICALS IN FOOD AND THE DIET for discussion of bulk template submissions.

22. The third step in filling out the GEMS/Food template is to enter Individual Analysis results in Tab 3. "Individual Analysis Results." Fields include the Local Food Identifier (previously mapped to codes in Tab 2), chemical concentration, units of measurement, LOD, LOQ, etc. Because the Local Food Identifiers have been mapped in Tab 2, columns B, C and D on Tab 3 will be filled automatically with the information from the mapping exercise. Column A will automatically indicate an error if any of the fields on this Tab are incorrectly filled out. The remaining columns should be filled following the detailed instructions in INSTRUCTIONS.

23. Note that columns with blue headings in the GEMS/Food template are mandatory. Columns with white headings are optional (can be left blank) if the information is not available.

24. The current fields for Individual Analysis Results in the GEMS/Food database are listed in Guidance Table 1. Paragraphs 25 to 31, below Guidance Table 1, provide additional commentary on certain fields where guidance to data submitters will be helpful.

Guidance Table 1: Current fields in GEMS/Food template

Column	Field	Field type	Mandatory or Optional	Comments
E	Local Food Identifier	Free text	Mandatory	Name given to food in national database
F	Serial no of the Record	Free text	Mandatory	One serial number is used for each sample. Data on different contaminants in the same sample should have the same serial number.
G	Country/Region	Drop-down menu	Optional	Reflects countries or regions submitting data; this is not the Country of Production
H	Contaminant	Drop-down menu	Optional	Optional when contaminant name entered in Worksheet 1
I	Food Origin	Drop-down menu	Optional	• Domestic • Imported • Mixed origin • Unknown
J	Sampling Date	Free text (YYYY)	Mandatory	
K	Sample representativeness/ reliability	Drop-down menu	Mandatory	• Random sampling • Targeted sampling • Unknown
L	Laboratory Identification	Free text	Optional	Laboratory submitting results
M	Analytical Quality Assurance	Drop-down menu	Optional	• Internal quality assurance and reference standards only. • Successful participation in relevant proficiency tests during the sampling and analysis period. • Official accreditation for the relevant methods during the sampling and analysis period. • Unknown quality assurance of the lab.
N	Measurement units for Contaminant Levels	Drop-down	Mandatory	• mg • ug • ng • pg • Bq
O	LOD	Free text	Mandatory for results not quantified if LOQ is not provided	
P	LOQ	Free text	Mandatory for results not	

			quantified if LOD is not provided	
Q	Results based on	Drop-down menu	Mandatory	•Fat content •Dry weight •As is (raw, fresh) •As consumed
R	Portion analysed	Drop-down menu	Mandatory	•Edible only •Total food (edible + inedible)
S	State of food analysed	Drop-down menu	Optional	•Cooked •Raw •Unknown
T	Results	Free text	Mandatory	
U	Individual vs Aggregated data	Drop-down menu	Optional	•Individual •Aggregated
V	Confidentiality of Data	Drop-down menu	Optional	•Yes •Blank
W	Remarks/References	Free text	Optional	

25. **Local food identifier**. When possible, the data submitter should provide names in English. Adding details to the name can help the data analyst with sample classification (e.g., "pineapple-orange juice" versus "juice.") On the other hand, an overly long sample name (e.g., listing all ingredients in a multi-ingredient food) can complicate the work of analysts. Supplemental name information can also be added to the Remarks column.

26. **Units**. Ensure that the reporting unit is the same for results, LOD, and LOQ. Ideally, the data submitter should provide both the LOQ and LOD, even though these fields are currently only mandatory for non-quantified results.

27. **Serial number**. One serial number (Sample ID) should be used for each sample. If information on multiple contaminants is submitted for one sample, the same serial number should be used. (Note that multiple contaminants can be entered in one template.) National institutions should coordinate using the same serial number for all submissions of the same sample.

28. **Country/region**. This field reflects countries or regions submitting data; this is not the country of production or country of origin.

29. **Aggregated data**. Aggregated data refers to results based on pooled samples, such as samples from Total Diet Studies. Aggregated data are often excluded from violation rate analyses conducted to determine appropriate MLs, which are based on observing the distribution of the data and upper percentiles exceeding proposed maximum levels (MLs). However, aggregated data can be included in the GEMS/Food database and limited data have been included in CCCF analyses in in the past. The GEMS/Food coordinator or a statistician should be consulted before including aggregated data. If aggregated data are included in an ML analysis, this fact should be noted in the EWG paper.

30. **Confidential data**. Countries can submit data as "Confidential" if they wish to limit access to use by FAO, WHO and related technical bodies, such as Codex. The GEMS/Food Administrator can provide records marked "Confidential" to EWG Chairs; therefore, EWG Chairs should always consult with the GEMS/Food Administrator on data extraction before downloading data. If a country submitted data as "Confidential" in response to a Call for Data, the submitting country also should make the EWG Chair aware of this fact during the data extraction/analysis phase.

31. **Remarks/references**. This field is used for noting remarks and/or references relevant to the data. Typically, data submitters will use this column to add information that is not captured by the template fields. Examples of information that has been included in this column in the past are information on product labels (such as main ingredients or detailed product names), compositional information (such as percent cocoa solids), country of origin or production, method used for analysis, etc. Other information that may be entered in this column is a reference to a specific Call for Data.

32. **Errors**. Prior to upload, the data submitter should review the file carefully for errors. During upload, the data file is scanned to identify problems before writing data into the database. The data submitter is responsible for correcting errors and re-submitting the template. Datasets can be rejected for a variety of reasons, some of which are listed below. The GEMS coordinator can be contacted for assistance.

    a. Reported result < LOD, missing LOQ or LOD when result is ND, reported LOD > LOQ

b. Dates entered in the wrong format
c. Mandatory fields incomplete
d. Duplicate entries in the current worksheet or in the database

DATA EXTRACTION

33. The data extraction process begins at the database website: GEMS/Food Contaminants Database. As noted above, for full functionality, analysts must register and log in to their accounts. After logging in, analysts will see a Welcome page with two tabs, a Home Page tab and a Search tab. The Home Page tab contains a limited number of prepared extracted datasets by region and contaminant. For specific searches, the analyst selects the Search tab. The Search function allows the analyst to filter data by WHO Region, Contaminant, Food Category, and Food Name, and Sampling Period. These filters will allow the analyst to identify data responsive to a particular Call for Data or TOR.

34. To identify the most accurate dataset for extraction for development of ML proposals, it is best to consult with the GEMS/Food coordinator. Data submitters may make choices when submitting data that could result in data being missed during extraction. For example, data uploaded as “food for infants and children” may be missed in a search limited to “fruit and vegetable juices.” Another example is that juice data may be mistakenly mapped as “fruit and fruit products” although the Local Food Identifier or Remarks field clearly identifies the samples as juice. Consultation with the GEMS/Food coordinator before extraction may help the EWG ensure they have extracted all the relevant data for the ML analysis from GEMS/Food.

35. Confidential data is another reason EWG Chairs should always consult with the GEMS/Food Administrator on data extraction before downloading data. The GEMS/Food Administrator can provide records marked “Confidential” to EWG Chairs. These records will not show up in a routine search as described above. EWG members who are interested in more detailed analysis of confidential data can consult with the EWG Chair.

36. It is important to maintain a record of all filters and search terms for the EWG report.

APPENDIX III

A list of headings/topics to be addressed in the sections "Data selection/clean-up" and "data analysis".

(For consideration)

Data Selection /clean-up of data

General considerations

Lack of information on data provided

Selection and clean-up - Handling of data

- with a lack of information
- for which an error in reporting is assumed
- originating from suspected fraudulent/ adulterated samples
- from targeted sampling
- outliers/extreme values (including methods to determine outliers/extreme values)
- Limit of Quantification (LOQ) and Limit of Detection (LOD) considerations

Data analysis: generating overview of data

- Overview which countries, how many data points, which years, period of data coverage
- Decision on geographical coverage of the provided occurrence data (including consideration of combining or keeping separate different datasets)
- Decision on period coverage of the provided occurrence data

Statistical analysis of occurrence data / handling of datasets for ML development

General considerations

Sufficient number of samples

- minimum number of samples for estimating high percentile values

Handling of datasets

- with low number of data points
- with data on individual food(s) are insufficient, but data for the food group are sufficient
- with a large proportion of left-censored data (including use of substitution methods)

Conducting statistical analysis

- Drawing charts/graphs and plots on distribution of occurrence data
- Data aggregation and calculation of descriptive statistics

Calculation of rejection rates at hypothetical MLs

- Estimation of hypothetical MLs
- Calculation of rejection rates at the hypothetical MLs
- Assessment of impact of an ML on rejection rate
- Improvement of calculation of rejection rates

Calculation of effects of MLs on the reduction of dietary exposure at hypothetical MLs

- Calculation of dietary exposure and reduction at hypothetical MLs
- Assessment of impact of ML on dietary exposure
- Improvement of calculation of exposure reduction rates

Data presentation in EWG reports to CCCF

ANNEX: Glossary of terms

Topics for additional discussion (post CCCF17)

- Minimum number of samples for estimating high percentile values with high confidence (REP23/CF16, paras 93 and 94, para 98 (vi) (a)).
- Further guidance to be provided on which dataset the ML should be based or to which database should be given priority for ML development (combined dataset, dataset showing the higher contamination patterns as long as the commodity was produced through good practice, datasets from major producing countries or regions, datasets from importing countries reflecting the levels of a contaminant in a commodity in international trade, dataset to be used to be decided on a case-by-case) (REP23/CF16, para 98 (vi) (b)).
- Further consider the role of the Committee in calculating dietary exposure reduction rates when considering MLs. (calculation of dietary exposure is a risk assessment function that should be undertaken by JECFA and JECFA provides the scientific advice on which the risk management decisions of the Committee are based – it is important to clarify the roles of JECFA and CCCF as risk assessor and risk manager respectively, in the calculation of dietary exposure reduction rates when considering MLs (REP23/CF16, paras 90 and 91 and para 98 (vi) (c).
- More structured process for elaborating calls for data (REP23/CF16, para 98 (viii)).
- Identification of appropriate rejection rates in ML establishment (guidance on elements which should be considered to define the appropriate rejection rate) (CX/CF 22/15/14 chapter IV of appendix I, CF16/CRD06 para 32).
- Appropriateness of GEMS/Food market-based cluster diets for ML elaboration (reconcile realistic estimates from national consumption data with the “supply utilization market data in GEMS/Food cluster diets (e.g., sugar, spices/herbs, teas, coffees).

APPENDIX IV

Sections "Data selection/clean-up" and "data-analysis" of the draft Guidance on data analysis for development of maximum levels (MLs) and for improved data collection, in which the outcome of the discussions at CCCF16 have been integrated with glossary of terms.

(For information only)

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DATA SELECTION /CLEAN-UP OF DATA

General issues

37. For the clean-up of data, it is recommended to involve an expert on the specific contaminant, as to have insight in which patterns in data are irregular or not.

38. All steps taken in the clean-up of data should be recorded and described in the final document, e.g., reasons for exclusions, how many exclusions in every clean-up step, etc. In any case records must be kept from excluded data and the details on the data excluded (from a specific region, from a specific year, from a specific data submitter, ….).

39. A sensitivity analysis on the impact of exclusion of the data can be performed to determine the impact of excluding the data.

40. Clean-up relates only to the extracted dataset, while the original data in the GEMS/Food database will not be modified and remain unaffected by the steps indicated below.

41. For development of MLs, only data in the GEMS/Food database are to be used. Non-GEMS/Food data can only be used for complimentary analysis, when there are limited data available in the GEMS/Food database or when data are not available in the GEMS/food database for certain time periods or regions, particularly from primary producing countries.

    When dealing with data directly submitted to EWG by country(ies) or observer (s) or obtained through the literature search without going through the GEMS/food database, these data are also subject to the clean-up procedure, as necessary.

Lack of information on data provided

42. If all mandatory fields are completed (see section data collection and submission) and the data are allowed for uploading in the GEMS/Food database, as a rule data should not be excluded.

43. In some cases, data in GEMS/Food database do not provide all the information that would be helpful for the EWG to complete an analysis (e.g. it is not clear if food is dried or fresh) In case of missing information, the contact point for the data submitting country or organization should be contacted as a first step to allow for a complete data set to be obtained.
    The contact point for the country or organization submitting the data may need to contact those involved in the process of data development, such as sampling, chemical analysis, data analysis, to identify any missing information, when contacted by the EWG.

44. In case missing information is provided by the submitting country or organization, the GEMS/Food administrator should also be informed by the data submitter so that the provided information is included in the GEMS/food database, and not only in the dataset under analysis by the EWG Chair.

45. Secondly It must be considered to which extent the missing information affects data analysis.
    No blanket rules should be set that may result in unnecessary exclusion: data with missing information might still be useful. The same level of detail (i.e., volume of information) concerning samples may not be necessary for the development/elaboration of all maximum levels. For example, certain commodities such as beverages may not require the same level of detail to be collected as that for grains, such as the processing stage, in order to propose maximum levels. Further, in some cases missing information can be deduced from other information provided. For example, if the sample is described as dried paprika, then it is evident that the state of the food analysed is “dried” even if Field S in the GEMS/Food database not completed.

46. Examples of missing information whereby data should possibly be excluded from further data analysis:

    - All data from a dataset are reported as < LOQ and the LOQ is not provided As LOQ information is mandatory for upload in the GEMS/food database if analytical result is < LOQ, this situation might not occur when all the data were extracted from the GEMS/Food database but could occur when considering data directly submitted to the EWG without going through the GEMS/Food database.
    - the unit in which the result is reported or the basis on which the result is expressed is missing.
    - the state of the food sampled (e.g., whether dried or fresh) is missing.
    - adequate product description (e.g., the analysis is being performed on “mackerel”, but the product is described as “fish”)

47. Examples of missing information but the data could still be used for further data analysis (this is to be assessed on a case-by-case basis, as for certain food-contaminant combinations the information below might be considered as necessary and therefore the missing information might be a basis for exclusion):

- sampling information: type of sampling, year of sampling, location of sampling, …
- state of the product, for example fresh or dried
- method of analysis used, its validation data and performance characteristics (such as recovery, uncertainty, LOQ
- incorrect food mapping was used to describe the product
- Code of Practice used or not, years since its implementation
- when ML is set at or considered for sum-of-components and data are reported not for all the components but for that(those) contribute(s) significantly to the sum

Handling of data for which it can be reasonably assumed that the unit of the data provided or the basis on which the data are reported (e.g., fat basis vs whole weight) is not correct (relevant parts of paragraphs 111 – 120 - Determination of outliers/extreme values and handling them to be integrated in this part).

48. If there are clear indications that the unit in which the data are expressed is incorrect or the basis on which the data are expressed is incorrect, the point of contact for the country that submitted the data can be contacted for corrections. Data can be changed to a corrected unit only if the data submitter agrees. If an error cannot be confirmed and corrections cannot be made and these samples are indeed reported incorrectly, these data should be excluded from further data analysis. Samples with incorrect information and their corrected values should be recorded and presented in the final document.

49. Examples of "clear indications" to contact submitters for possible correction and resubmissions:

- Levels within a data set of 200 results are in the range of 0 to 20. All data are expressed as µg/kg, except 5 quantified data points expressed as mg/kg. When plotting these data in a frequency distribution curve, after having converted them in the same unit, they would be identified as possible outliers (see paragraph 117).
- Levels from a food with a typical fat content of 5 % within a data set of 200 results of which all data are designated as being expressed on whole weight basis. 195 results are falling in the range of 0-20 mg/kg; however, 5 data points are falling within in the range of 100 – 400 mg/kg, possibly suggesting they were reported on a fat basis rather than the designated whole weight basis. When plotting these data in a frequency distribution curve they would be identified as possible outlier (see paragraph 117).

50. For some foods (e.g., fruits, rice), if the portion analysed is not clear (e.g., peeled vs whole fruit, or rice grains vs husked rice vs polished rice), similar arguments apply as in section B2. It should be reflected whether the unclear information is important or relevant for the contaminant in question and the final concentration found in the product. In addition, for some foods it may be assumed that the portion was analysed in the state that it is usually sold/consumed, e.g., citrus fruit is usually fresh. Any such assumptions made should be recorded and presented in the final document. If the information is relevant to the data analysis and a reasonable assumption cannot be made, these data should be excluded from further data analysis unless the necessary information is obtained.

Data originating from suspected fraudulent/economically adulterated samples (relevant part of paragraphs 111 – 120 - Determination of outliers/extreme values and handling them to be integrated in this part)

51. Data that are clearly related to fraudulent/economically adulterated samples based on the relevant information provided by the data submitter, should be excluded from the analysis and the exclusion must be documented. Possible signs of fraudulent/economically adulterated samples are

- certain samples are an order of magnitude higher than others, e.g., 1 versus 15 µg/kg) or
- temporal variability in data, e.g., data are much higher in one year of the dataset.

However, such contrast could also occur from natural variability (e.g., high level of mycotoxins due to specific climate conditions in a certain region) so the nature of the contaminant must be taken into account when assessing the data.

Data from targeted sampling (relevant parts of paragraphs 111 – 120 - Determination of outliers/extreme values and handling them to be integrated in this part)

52. Targeted sampling differs from random sampling in that with targeted sampling there is a distinct sampling strategy aimed at specific consignments. In principle, these data should not be used in the derivation of MLs, as data from targeted sampling do not reflect achievable levels in regular situations.

53. It should be noted that even in random sampling, some bias could be introduced as there might be reasons for sampling more extensively in specific regions or types of products. Such data could include higher or lower levels than the normal range and should not be excluded without further consideration as these reflect natural variation in the occurrence data.

New part: Outliers/extreme values (including methods to determine outliers/extreme values) (relevant parts of paragraphs 111 – 120 to be included here)

Limit of Quantification (LOQ) and Limit of Detection (LOD) considerations (see also paragraphs 90-92)

54. It should be noted that different methods of analysis provide different LODs and LOQs. A high LOQ does not automatically mean that the data should be excluded. Appropriateness of LOQ of dataset that can be used for the derivation of ML should be evaluated in relation to the proposed ML under consideration as described below.

- When no LOQ/LOD is provided for a specific dataset:
  - Dataset contains (nearly) all quantified results.
  - Dataset contains a significant part of left-censored data (i.e., < LOQ) and no LOQ/LOD provided.
- When LOQ is provided for a specific dataset:
  - Dataset with LOQ significantly lower than the ML under consideration.
  - Dataset with LOQ in the range of the ML under consideration
  - Dataset with LOQ above the proposed ML under consideration

55. Guidance for the abovementioned scenarios (paragraph 54)

- In the case where no LOQ/LOD is provided for a specific dataset
  - the submitting country could be contacted as a first step to allow provision of such information (i.e. LOD and/or LOQ).
  - In the case where the dataset contains (nearly) all quantified results: the data set could be used.
  - In the case where the dataset contains a significant part of left-censored data: data set should not be used.
- In case LOQ is provided:
  - Cut-off level to be determined for the LOQ (examples: LOQ < ML under discussion, ML < 0.5 ML under discussion).

56. If almost all data in the dataset are below the LOQ/reported as non-detects (ND), it is not possible to estimate high percentile values to establish rejection rates. When there are many data <LOQ and a smaller number of quantitative values, the dataset should be handled on a case-by-case basis following the guidance noted in paragraphs 81 – 98. It is not appropriate to calculate high percentile values using only the quantitative values, which may result in unnecessarily high proposal for MLs.

57. Criteria should be developed outlining when certain data should be excluded from the dataset due to an inadequate LOD (e.g., LOD is larger than the proposed ML, LOD is 'x' orders of magnitude greater than the lowest LOD in the dataset) or if the whole dataset should be excluded from the analysis, as removing individual data can introduce bias.

58. Levels of contaminants which are a sum of components and for which certain components are below LOQ.

- The general rule is that levels of contaminants that are a sum of components are reported as lower bound, i.e., the non-quantified components are put equal to 0. Information on the LOD or LOQ of the individual components of the sum must be provided, however in the case of all non-detects, it could be considered to not exclude the data if LOQ for the individual components is not reported, as the result of the sum will be 0 irrespective of LOQ.

- When only data on individual components are reported without a total result, the individual data can be summed into a sum-result: the LOD or LOQ needs to be provided in this case.
- In specific cases, it may be appropriate to report levels of contaminants that are a sum of components using a middle bound or upper bound approach; however, but these cases should be clearly identified in advance before data submission. In these cases, LODs or LOQs for the data of the individual components are required.

Data analysis: generating overview of data

Overview which countries, how many data points, which years, period of data coverage

59. After cleaning the dataset, the remaining data are considered to be of sufficient quality for the analysis. An overview of these remaining data with details (e.g., country of origin, production year, amount of included and excluded data) should be provided in a table. All steps taken in the clean-up, the rationale and assumptions made should be provided with the overview. In addition, it could be useful to provide information (e.g., from FAO) on which are the major production regions for the commodity under discussion. Based on this overview, further selection of relevant geographical coverage and period coverage can be done.

Decision on geographical coverage of the provided occurrence data, including consideration of combining or keeping separate different data sets (relevant parts of handling multiple datasets paragraphs 99-110 to be integrated into this part)

60. Countries submitting data to GEMS/Food should ensure that the submitted data are as nationally representative as possible.

61. There should be at minimum representation of production regions that are important to international trade. Therefore, it is important that the origin of the food is reported in the GEMS/Food Database (see Section Data Collection and Submission). In that context data from producing regions should be considered in relation to data from countries importing the food, as the latter might be biased if the food has to comply with the requirements of the importing country such as an ML already established in that Country. However, data of importing countries also reflect food (ingredient) as traded internationally and as consumed. Indeed, as during transport from the producing country additional contamination could have taken place (e.g., mycotoxin production).

62. In some cases, it could be appropriate to give priority to datasets from producing countries above data sets from importing countries but in that case, guarantees should be provided that the datasets from producing countries do reflect the implementation of good practices as provided in Codex Codes of Practice and are representative of products that would be traded internationally.

63. If possible, a sensitivity analysis on using data from producing versus importing countries could be performed to guide the selection of data.

64. As Codex MLs are global standards, a default approach for data processing is to analyse data by regions. Only if there is enough data that show an indication of large differences in reported levels between countries in a region, analysis could be performed by country. It should be noted that for a country approach, that this should be done for major producing countries in the region and that sufficient data should be available. The number of datapoints that are considered sufficient should be discussed on a case-by-case basis.

65. Guidance for datasets that lack geographic coverage:

- If the region(s) for which data are lacking is/are important production region(s) and on the condition of a clear commitment from producing regions, some additional years are allowed for data collection before continuing the discussion on ML proposals. After expiry of the granted additional years, the discussion on MLs is continued based on available data, regardless of whether geographic coverage has been reached or not.
- If the region(s) for which data are lacking is/are not important production region(s): the discussion on ML will be continued based on available data.
- If there is no commitment from the important producing region(s) to provide the additional data, the discussion on MLs is to be continued based on available data or it may be decided to discontinue the discussion of an ML.

Decision on period coverage of the provided occurrence data (relevant parts of handling multiple datasets paragraphs 99-110 to be integrated into this part)

66. It is appropriate that that the provided occurrence data relate to several production years for ML development (can be different for different types of contaminants: mycotoxins, plant toxins, marine biotoxins, processing contaminants, environmental contaminants in function of the assumed year to-year variation or evolution of contamination in time).

67. For contaminants such as mycotoxins which are known to have year-to-year variation, data from the last 10 years may provide a very good representation of the year-to-year variation; however, there may be cases where more than 10 years of data should be considered (e.g., sampling effort reduced in recent years or fewer higher quality data sets available). For other contaminants, year-to-year variation is less relevant and possibly more recent data can be selected. In any case it should be discussed whether data older than 10 years are relevant for the analysis.

68. Further, it could be relevant to investigate/include older data to learn whether certain species/subgroups from a group tend to have higher levels.

69. Further It could be relevant in certain cases to perform time trend analysis. In these cases, data from more than 10 years are to be considered to determine if concentrations have changed/is changing with time and this could be used to determine whether a certain number of years of data should be used for ML elaboration to represent current concentrations.

70. In case a Code of Practice (COP) has been established and implemented, the data under consideration should be from the years after the implementation of that COP to reflect good practices, unless indicated by a country that the good practices had already been implemented before the establishment of the Code.

    Elements that could indicate whether a Code of Practice was implemented could be:

    - A consistent drop in levels after a certain year, and
    - Differences in levels from neighbouring countries within one region which cannot be explained by geographical factors.

71. It is often difficult to judge from datasets themselves whether or not a Code of Practice has been implemented. Preferably, information on implementation of a Code of Practice is requested in the call for data and whether the Country submitting that data has any of their own already established MLs in place. If the EWG excludes data on the basis of failure to apply a COP, the exclusions and rationale should be clearly documented in the WG paper.

STATISTICAL ANALYSIS OF OCCURRENCE DATA /HANDLING OF DATASETS FOR ML DEVELOPMENT

General considerations

72. For ML development, overall data quality is the key. Occurrence data, obtained ideally through statistically based sampling (Ref. CXG 50-2004 General Guidelines on Sampling), and analysis using validated methods with appropriate LOQ and LOD for purpose in laboratories that have quality assurance systems. Data obtained should be carefully reviewed and extracted/cleaned. Statistical analysis should be conducted on the extracted/cleaned-up data. However, for developing an appropriate ML, not only the results of statistical analysis but also any health risk associated with the contaminant/toxin of concern (toxicity and dietary exposure in combination or alone) should be considered.

73. In deciding what statistical method should be used, the distribution pattern of the dataset should be carefully considered. In general, the distribution of contaminant data in food tends to be skewed with a long tail to the right, e.g., a log-normal distribution. For such distributions, use of parametric statistical methods, which are based on the normal distribution, is not appropriate.

74. The General Standard on Contaminants and Toxins in Food and Feed (CXS 193-1995) (hereafter referred to as GSCTFF) states in Annex I, "*MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed."* This means that to develop an ML, there is a need to estimate/determine high percentile values (generally 95 percentile values) with significantly high confidence level. In food safety, a confidence level of 95% is usually used. The figure below (Figure 1) explains, using a modelled distribution, the relationship among a high percentile value, hypothetical ML (usually rounded value of the percentile value) and percentage of samples that exceed the proposed ML when the ML is the same as the 98th percentile value.

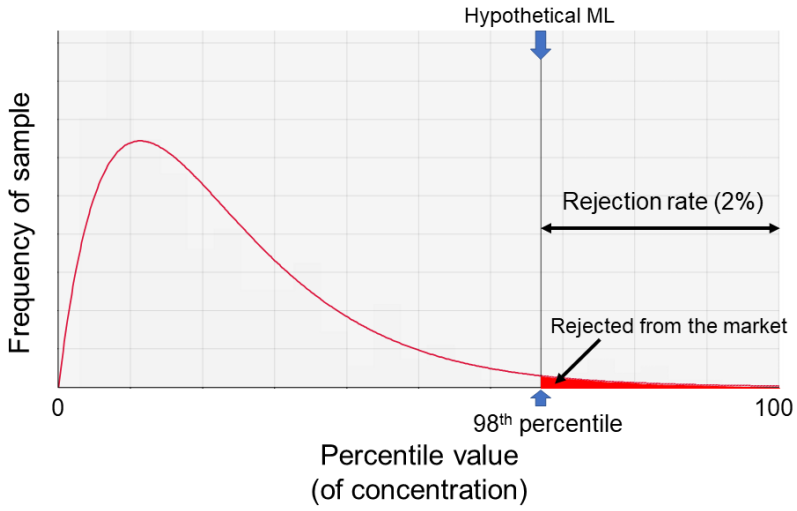

Figure 1. Simplified depiction of the relationship among a high percentile value, hypothetical ML, rejection rate and percentage of samples exceeding the proposed ML.

Note: In the above, it is assumed that the hypothetical ML is the same as 98th percentile value.

75. The following sections explain considerations before conducting a statistical analysis and how the results of statistical analysis should be presented in the EWGs for developing globally applicable MLs.

Sufficient number of samples

The reliability of estimated high percentile values depends on the number of data points available for the calculation. Percentile values calculated on a small number of data may not be statistically robust.

While a number of guidelines on the minimum number of data points necessary to calculate a given high percentile value are available, none has been officially used by the CCCF. The minimum number of samples is one of many important factors to consider when designing surveys (e.g., TOR and call for data) to improve data collection.

The GSCTFF stipulates as follows:

"*When there is evidence that contamination patterns are sufficiently understood and will be comparable on a global scale, more limited data may be enough*";

"*MLs may be set for product groups when sufficient information is available about the contamination pattern for the whole group, or when there are other arguments that extrapolation is appropriate*"; and

"*MLs should be set only for those contaminants that present both a significant risk for public health and a known or expected problem in international trade and only for food that is significant for the total exposure of the consumer to the contaminant*".

Minimum number of samples for estimating high percentile values

76. For development of an ML, it is necessary to estimate high percentile values (generally 95 percentile values) of a dataset as mentioned in para. 74. Whether these high percentile values can be estimated with high confidence level depends on the number of samples. Therefore, it is important to check if the number of samples (or data) is sufficient for estimating high percentile values. Usually, the minimum number of samples should be determined at the time of designing surveys of contaminants.

77. Currently three options are available for calculating the minimum number of samples required in relation to estimating high percentile values.

- **Option 1**: Calculation based on the concept that a dataset contains one or more values higher than a certain percentile occurring with a probability at a certain confidence level. This is based on the binominal distribution. The minimum number of samples is obtained from the following formula:
  $n=\log(1-CL)/\log(p)$, ($CL=1-\alpha$, confidence level ($0<CL<1$); p, percentile/100 ($0<p<1$); and n, number of samples).
  In general, a 95% confidence level (CL=0.95) is used in the food safety area. If there is any need for higher confidence level, n can be calculated with a CL higher than 0.95.

- **Option 2**: Calculation based on the rule by Kroes *et al.* (2002)[11]. The minimum number of samples for high percentile (>75th percentile) values can be obtained from the following formula:
  $n \geq 8/(1-p)$, (p, percentile/100 ($0<p<1$); and n, number of samples).

  No information is available in the reference about confidence levels.

- **Option 3**: Calculation based on the descriptions by Conover (1971)[12] using a binomial distribution and on the concept that a dataset contains one or more values higher than a certain percentile and one or more value lower than the percentile occurring with a probability at a certain confidence level. The minimum number of samples is obtained from the following formula:
  $n \approx 1/4 * x_{1-\alpha} * (1+p)/(1-p) + 1/2$ (CL=1-α, confidence level ($0<CL<1$); p, percentile/100 ($0<p<1$); n, number of samples; and $x_{1-\alpha}$, (1-α) quantile of chi-squared random variable and value of $x_{1-\alpha}$ are 9.488 (α=0.05), 11.14 (α=0.025) and 13.28 (α=0.01))

78. The formula using the same concept as Option 1 (replacing percentile/100 with (1-violation rate/100)) has been used for the compliance tests developed by CCPR (CXG 33-1999) and CCRVDF (CXG 71-2009). Some guidelines[13][14] recommend the numbers obtained from Options 2 and Option 3 (at 99 % confidence level) for a survey design for collection of food consumption data. The following table shows the calculated minimum number of samples for deriving 95th, 96th, 97th, 97.5th and 98th percentile values using the above three options at 95 % confidence level.

Table 1. Minimum number of samples to obtain high percentile values.

	Minimum number of samples to obtain the following percentile values				
Option	95th	96th	97th	97.5th	98th
Option 1 (CL=0.95) [Option 1 (CL=0.99)]	59 [90]	74 [113]	99 [152]	119 [182]	149 [228]
Option 2 (CL: not provided*)	160	200	267	320	400
Option 3 (CL=0.95) [Option 3 (CL=0.99)]	93 [130]	117 [164]	157 [219]	188 [263]	236 [330]

* No information on confidence level is described in the original literature of Kroes *et al.*

79. Table 1 and the formula for each option can be used to determine how a high percentile value can be calculated with a high confidence level (such as 95%) from the number of data points in the clean-up dataset on a case-by-case basis. Numbers derived from Option 1 has the advantage of requiring the smallest number of samples comparing with other options and is the most feasible and most used in the previous ML development by the CCCF taking into consideration the number of data available to EWGs.

80. Table 1 serves as guide for understanding the minimum number of samples needed for the dataset which will be used to estimate hypothetical MLs or to propose MLs. Such a dataset is usually/ideally a global dataset which consists of individual datasets submitted to GEMS/foods or directly to CCCF from countries and/or organizations and covers worldwide occurrence of contamination. If datasets can be combined, it is not necessary that each of individual datasets submitted by member country(ies) or organization(s) contains a greater number of data points than the minimum number shown in Table 1. However, when individual datasets per region and/or per year are separately used for deriving high percentile values rather than, or in addition to, the global dataset, the minimum number of samples are required. For handling of multiple datasets and decision on whether to combine them, see paragraphs 99 -110.

CCCF16 agreed to a **provisional** minimum number of 59 samples for a 95th percentile estimation with 95% confidence (option 1 in table 1) (REP23/CF16 paragraphs 93, 94, 98 (vi) (a). However, CCCF16 also agreed that the minimum number of samples for estimating high percentile values with high confidence needs to be further discussed (REP23/CF16 paragraphs 93 and 98 (vi) (a))

Handling datasets with low number of data points

81. When the associated risk is significant such that it is considered necessary to establish an ML, a smaller sample size than that specified in Table 1 would still be considered adequate as long as the confidence level of the estimated

[11] Kroes, Robert, et al. "Assessment of intake from the diet." Food and Chemical Toxicology 40.2-3 (2002): 327-385.
[12] Conover WJ, 1971. Practical nonparametric statistics. Wiley, New York, USA.
[13] EFSA Journal, 2009. General principles for the collection of national food consumption data in the view of a pan-European dietary survey. 7(12):1435
[14] EFSA Journal, 2014. Guidance on the EU Menu methodology. 12(12):394

high percentile values are only slightly lower than the expected high confidence level, such as 95%. For example, confidence level for Option 1 can be obtained from the following formula.

$CL=1-p^n$

(CL=1-α, confidence level (0<CL<1); p, percentile/100 (0<p<1); and n, number of samples)

82. If the sample size collected is insufficient for developing ML, additional data calls could be issued as needed (see Occurrence data collection/submission). However, if after repeated data calls, the available number of samples is still much lower than the required minimum number of samples, a decision should be made on a case-by-case basis on whether to develop an ML using the limited dataset or to discontinue the work depending on the level of risk (toxicity, dietary intake, etc.). MLs should be established even if there is a small number of samples available, when an ML is urgently needed from the perspective of consumers' health protection. Should sufficient data become available in future, revision of the previously established ML can be considered.

83. For commodities not consumed routinely and/or not traded internationally, data available on occurrence may be insufficient. The EWG tasked with establishing MLs should consider recommending to the CCCF that the ML requested for the commodity/contaminant combination may not meet the criteria described in the GSCTFF and Procedural Manual ("Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Feed Groups") for the establishment of MLs.

84. If the number of data is significantly less than required for each option in Table 1, and there is no strong reason for developing an ML immediately, there is no need to perform further statistical analyses. Additional data calls may be necessary to establish a statistically robust ML, or the work should be postponed until more data are provided.

85. In reviewing existing MLs, even if only few data from limited regions may become available and it is likely that no new data will be generated, the MLs should not be automatically revoked because of the small sample size unless the ML value is inconsistent with current good practices or current toxicological data. If a potentially significant risk exists from consuming the commodity, an option would be to maintain the existing ML, and if there is no longer a significant health risk, an option would be to revoke the ML. In some cases, it may be possible to expand the application of the ML for a food group, from which a commodity was excluded, to the excluded commodity if for this commodity only a small number of data are available. (e.g., removing an exclusion for canned *Brassica* from a canned vegetables ML, if there are not sufficient samples to maintain the ML for canned *Brassica*).

In the case where available data on individual food(s) are insufficient, but data for the food group are sufficient.

86. Even when the sample size is sufficient for a whole food group, if the data are separated according to individual foods in that food group, the sample size may be small for individual foods. In general, whether MLs are to be established for food group(s) or subgroup(s) or individual food(s) should be decided at the time of preparation of a project document before initiating new work on ML development or, at the latest, development and consideration of a discussion paper. If after the data call and data collection, it is found that there are less data available than initially expected, the food(s) that the ML should target may need to be changed to a broader range of foods, e.g., individual food(s) to food subgroups or food subgroup to food group.

87. To consider whether it is appropriate to establish an ML for a food group depends on whether the distribution patterns of individual foods within the group are similar. Non-parametric statistical tests, such as Mann-Whitney U test (for 2 datasets) or Kruskal-Wallis H-test (for 2 or more datasets), can be used to determine if the distribution patterns of those foods in the group can be considered to be from the same population, even when the number of data is relatively small (for statistical test, see paragraphs 99- 110: Handling of multiple datasets). If the number of data is relatively small, comparison of datasets by box-and-whisker plots is also useful, as long as the left censored data are less than 25 percent of the respective dataset.

88. If a certain individual food shows a different distribution pattern from other individual foods in the food group being compared, two different MLs may need to be established, one for the food group excluding the individual food that shows a different contamination pattern, and the other for the specific individual food that is excluded and also of concern. Similar approaches/decisions can be made for subgroup(s) in the food group. If there is insufficient data for individual food(s) to meet the required minimum number of samples, additional data calls will be issued for those foods for which it is considered necessary to establish MLs. If the consumption of an individual food showing a different distribution pattern from the food group does not contribute to the total exposure to the contaminant of concern and can be negligible from a consumer health protection point of view, no additional data calls are required and its exclusion from the application of the ML for the food group would be an option (e.g. ML for lead in salt, edible grade excluding salt from marshes). As for food groups and their sub-groups, reference can be made to the commodity covered by relevant Codex Commodity Standards, Classification of Foods and Animal Feeds (CXA 4-1989) (used also by CCPR), and other food categorization systems used by CCFA on processed foods.

89. When developing an ML for a broader food group because of limited data availability for individual foods or subgroups, if there are only a few subgroups with distribution patterns that may be different from other subgroups of the same food group but for which there is not sufficient data to set up a separate ML, those foods or food subgroups could be excluded from the application of the ML.

Handling of datasets with a large proportion of left-censored data (including use of substitution methods)

In certain cases, the analytical results for a contaminant are produced with a variety of analytical methods and/or the same analytical method but with very different sensitivities. Therefore, when datasets from different sources are combined, there could be a wide range of limits of detection (LODs) and limits of quantification (LOQs) for this contaminant and food matrix in the combined dataset.

The appropriateness of the LOQs used to obtain datasets from various sources should be considered during the data clean-up process, and datasets determined to be inappropriate are excluded before statistical analysis. Datasets only from analytical methods with appropriate LOQs should be used for statistical analysis (see Chapter B for details).

The GSCTFF stipulates, "*MLs should not be lower than a level which can be analysed with methods of analysis that can readily be set up and applied in food and feed control laboratories, unless public health considerations necessitate a lower ML which can only be controlled by means of a more elaborate and sensitive method of analysis with an adequate lower detection limit".*

90. The "dataset" in this section refers to a dataset or datasets which is (are) among the dataset(s) selected to be used for ML development (see paragraphs 99-110). This section is particularly relevant when the occurrence datasets used for ML development after data clean-up still contain a high ratio of non-quantified data (e.g., due to low sensitivity of available analytical methods for the concentration in the samples; extremely low frequency of occurrence; etc.).

91. Though no official definition of the term "left-censored" is found in any of Codex documents, in statistics, individual data without quantified (finite) values are called left-censored data generally referred to as data less than the reported LOQs.

92. For statistical analysis of datasets containing left-censored data, conventionally substitution methods are considered. If the dataset contains a high ratio of left-censored data, statistical analysis using only finite values (quantified values) is not recommended because this practice introduces bias into the results of the statistical analysis. Another method is to model the distribution using only finite values in a dataset and estimate high percentile values by considering percentage of left-censored data. As this method has not been previously used in the CCCF, it is not included in the Guidance. (See also paragraphs 121-130)

Substitution methods

93. The conventional approach to deal with left-censored data for statistical analysis is the use of one or more of the following substitution scenarios:

- Lower-bound (LB) scenario: results below the LOQ are replaced by zero, or by LOD if the LOD is known (results <LOD are replaced by zero);
- Upper-bound (UB) scenario: results below the LOQ are replaced by the reported LOQ value; and
- A point estimate between the two extreme scenarios (LB and UB), the middle-bound (MB) scenario: calculation by assigning a value of LOQ/2, square root of the LOQ, or (LOD +LOQ)/2 if the LOD is known for analytical results below the reported LOQ.

If the LOQ is not reported and only the LOD is reported, use the LOD as an alternative, although it should be carefully considered whether the analytical results can be used without reporting the LOQ value of the method used.

94. In general, depending on the distribution of data, these substitution methods may be used for the purpose of calculating measures of central tendency such as the arithmetic mean when calculating dietary exposure (See paragraphs Section D7 and EHC 240[15]). The choice of LB, MB or UB scenarios may affect the calculated arithmetic mean and the estimated average exposure based on the arithmetic mean. However, for the development of an ML, unless a large majority of data points are left-censored (i.e., <LOD or <LOQ), the effect of left-censored values on the calculation of high percentile values is negligible and there is little impact on the derivation of the proposed ML regardless of which scenario is chosen. (See Section D5).

[15] ENVIRONMENTAL HEALTH CRITERIA 240, Principles and methods for the risk assessment of chemicals in food (WHO, 2009)

95. The datasets with a large proportion of left-censored data should be handled on a case-by-case basis, depending on the toxicity of the contaminant and the consumption of the food concerned. Ideally, all of LB, MB and UB should be calculated and presented. It is more important to know the distribution pattern of finite values than the percentage of left-censored data when estimating high percentile values using a modeled distribution for establishing MLs.

96. When the dispersion of finite values is within a narrow range (values close to each other) and close to the reported LOQ, developing an ML would be unnecessary unless the contaminant is highly toxic. If estimated dietary exposure under the UB scenario is well below the health-based guidance value (HBGV) even without ML, and a proposed ML is at or about the LOQ value, there would be little impact of ML on reducing dietary exposure and an ML would not be necessary. HBGVs may not be established for some contaminants. For such contaminants, even if all the data are <LOQ but if there is certain health concern, ML(s) would be established at the LOQ value for the time being. However, if most of the data are <LOQ and there is no or little health concern, there is no need to establish ML(s). For example, a combined dataset of lead in fresh chicken eggs contained 99% of left-censored data after data clean-up and finite values ranging from 0.001 to 0.257 mg/kg. The calculated impact on exposure reduction at hypothetical ML was low, and a proposed ML was within the range of reported LOQs. Therefore, development of ML for chicken eggs was discontinued (ref. CX/CF 22/15/7).

97. If the estimated exposure by the UB scenario is close to or above the HBGV or the margin of exposure is not sufficiently high for toxicity profile, development of an ML should be considered even if a proposed ML is close to the reported LOQs or within the range of reported LOQs, provided that there is a validated analytical method(s) with appropriate LOQ. If necessary, additional calls for data using more sensitive analytical methods with lower LOQ values may be recommended.

98. When finite values show a large variation and reach significantly high value(s), it is advisable to develop an ML in order to eliminate highly contaminated foods from the international market. If the contaminant is highly toxic or a genotoxic/carcinogenic and found in the foods that are consumed in high volumes, an ML would be necessary to protect consumer health, even if rejection rate is low. For example, the combined dataset of total aflatoxins in sorghum grains contained 94% of left-censored data after clean-up, and the upper range of quantified concentrations in this dataset exceeded 200 µg/kg. This indicates that an ML based on high percentile values would have a large impact on reducing dietary exposure of aflatoxins from sorghum grains. A draft ML was proposed for aflatoxins in sorghum (ref. CX/CF 22/15/9).

Handling of multiple datasets – Decision on whether or not to combine datasets, especially when distribution patterns are different, and analysis of combined and individual datasets (per year, per region/country, per year per region) (no separate part: relevant parts of this part to be integrated into the part Decision on geographical coverage of the provided occurrence data (paragraphs 60-65) and the part Decision on period coverage of the provided occurrence data (paragraphs 66-71);

Datasets from different regions/continents in the world may show different distribution patterns for various reasons (e.g., different climatic conditions, different production conditions, including soil/techniques, local regulations, etc.).

Since the GSCTFF stipulates, "*Proposals for MLs in products should be based on data from various countries and sources, encompassing the main production areas/processes of those products…*", combined datasets have been conventionally used for developing MLs that will be applied globally regardless of whether there were differences in distribution patterns in each dataset.

In order to know if the distribution patterns of contaminant concentrations differ by region or year, it is necessary to create individual datasets for comparison. If individual regional or annual datasets are available to determine geographical or yearly coverage, they can be used for comparison of distribution patterns

CCCF16 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 (combined dataset, dataset showing the higher contamination patterns as long as the commodity was produced through good practice, datasets from major producing countries or regions, datasets from importing countries reflecting the levels of a contaminant in a commodity in international trade, dataset to be used to be decided on a case-by-case).

This topic requires further discussion after CCCF17 (REP23/CF16, para 98 (vi) (b)

99. As Codex MLs are for global application, they should be ideally based on global datasets. Whether ML to be based on global dataset or dataset of specific region/year should be decided by the CCCF.

100. Recommended statistical methods for comparing distribution patterns of individual datasets per region/country or per year include non-parametric tests. The null hypothesis is that all datasets are assumed to be from the same population. Such tests include Mann-Whitney U test (for 2 datasets) or Kruskal-Wallis H-test (for 2 or more datasets).

101. Many templates for non-parametric statistical methods are available on the Internet. Among them, MS Excel templates for performing Mann-Whitney U test and Kruskal-Wallis H-test are available for download from the FAO's JMPR website[16].

102. In addition, it is helpful to draw box-and-whisker plots or histograms of each dataset to compare if there are visual differences in distribution patterns before combining the datasets. It is preferable to draw a histogram only when the dataset contains a sufficient number of data points (see paragraphs 72-80). For a dataset with a smaller number of datapoints, it is difficult to know the shape of the distribution by a histogram, and a box-and-whisker plot is more helpful (See paragraphs 121-130 for drawing method).

Cases where datasets can be combined

103. Proposing an ML(s) using combined dataset(s) has been done conventionally in EWGs without statistical considerations. When statistical tests show that multiple datasets from different sources may be from the same population, they can be combined for statistical analysis for deriving an ML. However, individual datasets should be kept for further assessment on impact of ML (see paragraphs 131-157).

104. In some cases, statistical tests show that multiple datasets may not be from the same population but the differences in distribution may be small based on visual inspection of histograms or box-and whisker plots. The more the data points are included in the datasets, the higher the statistical power[17]. If the difference in the distribution is small, e.g., equal to the measurement uncertainty of the analytical methods, then each dataset may be combined and used for statistical analysis.

105. When the number of data points is significantly different between individual datasets from different regions/countries, but the statistical test indicates that they are from the same population, the resultant combined dataset reflects mostly the conditions of a country/region with significantly larger datapoints, rather than equally the conditions of the countries/regions submitting the data. To solve this problem, it would be effective, although requiring rather a complex process, to balance the datasets by weighting them by the production or trade volume ratio or on any other reasonable factors. The methodology and justification for the use of data weighting are yet to be considered.

Cases where individual datasets are used

106. If statistical analysis indicates that distribution patterns of major datasets are not from the same population, the datasets should be kept separate for statistical analysis for ML development. However, this should be decided on a case-by-case basis as different distribution patterns are typically dependent on the specific commodity being examined. A rationale for keeping the dataset separate should be provided and if a rationale cannot be found, the combined dataset can be used.

107. When considering the use of individual datasets which were kept separate, it is recommended to compare the statistical results, such as high percentile values of the separate datasets to those which were combined, through sensitivity analysis. It should be noted that robust high percentile values cannot be obtained for individual datasets whose sample size are lower than any of the three previously identified options for calculating the minimum required number of samples (see paragraphs 72-80).

108. It should be noted that when multiple datasets are considered individually, multiple ML candidates may be identified. While it is outside of the scope of this Guidance to determine which candidate value should be selected as an ML, the possibilities of having to deal with multiple ML candidates should be recognized, as well as enforcing multiple MLs.

109. In reference to the previous paragraph, if the datasets from different regions/countries are analyzed separately through the statistical methods recommended in this Guidance, it is necessary to consider the results from: the major producing regions/countries and/or importing countries; implementation of the related codes of practice for

[16] "Appendix XIV Electronic Attachments (2020_Nov)" and open "XIV 12 Spreadsheet for Kruskal_Wallis 20 group.xls" to carry out Mann-Whitney U test and Kruskal-Wallis H-test.
https://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/

[17] In statistics, the power of a binary hypothesis test is the probability that the test correctly rejects the null hypothesis when a specific alternative hypothesis is true. The null hypothesis of Mann-Whitney U test or Kruskal-Wallis H-test is each dataset is from same population.)

reduction and prevention of the contaminants of interest; and/or the presence of regulatory limits for the contaminants in the commodity of interest. The EWG tasked with developing MLs should discuss which datasets should be regarded as the main dataset. If there is assurance that the datasets with high concentrations are for commodities produced under good practices (Codex COP or GAP, GMP, etc.), then the focus should be on the high concentration datasets to consider globally applicable MLs.

110. Whether the data analysis in the EWG tasked with developing MLs uses a combined dataset or individual datasets, it is an opportunity for and responsibility of those Codex Members to check the impact of the draft ML (or hypothetical ML(s)) against their own (country) data and to provide comments on the result of their statistical analysis to the EWG.

Determination of outliers/extreme values and handling them (no separate part – relevant parts to be integrated into the relevant parts of data selection and clean up (paragraphs 48-53) and into the new part outliers/extreme values in the section Selection and clean up of data

The term "outliers" is defined in the Codex document (CXG 72-2009) as follows:

Outliers: A member of a set of values which is inconsistent with other members of that set

Note:

The following practice is recommended for dealing with outliers.

a) Tests such as Cochran's (for within laboratory variation) or Grubb's (for between laboratory variation) tests are applied to identify stragglers or outliers:

- if the test statistic is less than or equal to its 5 % critical value, the item tested is accepted as correct;

- if the test statistic is greater than its 5 % critical value and less than or equal to its 1 % critical value, the item tested is called a straggler and is indicated by a single asterisk;

- if the test statistic is greater than its 1 % critical value, the item is called a statistical outlier and is indicated by a double asterisk.

b) It is next investigated whether the stragglers and/or statistical outliers can be explained by some technical error, for example:

- a slip in performing the measurement,

- an error in computation,

- a simple clerical error in transcribing a test result,

- analysis of the wrong sample.

Where the error was one of the computation or transcription type, the suspect result should be replaced by the correct value; where the error was from analysing a wrong sample, the result should be placed in its correct cell. After such correction has been made, the examination for stragglers or outliers should be repeated. If the explanation of the technical error is such that it proves impossible to replace the suspect test result, then it should be discarded as a "genuine" outlier that does not belong to the experiment proper.

c) When any stragglers and/or statistical outliers remain that have not been explained or rejected as belonging to an outlying laboratory, the stragglers are retained as correct items and the statistical outliers are discarded unless the statistician for good reason decides to retain them.

Outliers are a type of extreme values, usually determined by statistical tests as describe above.

Some statistical tests to determine outliers (such as Cochran's or Grubb's tests) are available but mostly they assume a normal distribution. Therefore, they are not suitable for applying to the occurrence data on contaminants in foods if they do not follow normal distribution or other distribution that can be converted to normal distribution.

111. The presence of outliers in datasets has a significant impact on the arithmetic mean and maximum values, but not on the median or, to some extent, on the high percentile values if there are a sufficient number of reliable data points. However, consideration should be given to the percentage any potential outliers represent of the available data as a whole. Since it is the high percentile values, not the maximum values, that are used as a basis for ML, the impact of handling outliers on derived MLs is usually small, but in cases where a notable percentage of data points (e.g. 2–5%) are excluded, this could affect interpretations of the achievability of MLs under consideration.

112. Extreme values can have many causes including: errors in measuring and processing of data (including incorrect calculation), human error in reporting (unit of measurement), fraudulent behavior (adulteration), natural variation of measured contaminant (climate change, weather conditions, soil condition, etc.) or differences in sampling methods (especially for mycotoxins with heterogeneous distributions).

Before the determination of outliers

113. If, during the data clean-up process, it is determined through consultation with the data submitter that some of the extreme values are due to errors in measurement and/or reporting etc., such data will need to be either corrected or excluded from the dataset prior to performing statistical analysis. However, extreme values which had no clear reason of their cause(s) should be retained as a possible outlier in the dataset after data clean-up.

114. As there can be many causes for extreme values and some of these values in certain datasets may not be regarded as extreme values if combined with data from other sources (countries/regions, different years, etc.), whether an extreme value is a possible outlier that could be excluded should be evaluated on the combined dataset after clean-up. If the decision is made to analyze individual datasets, more careful consideration should be given to the exclusion of extreme values as outliers.

Statistical outlier test

115. There are some statistical approaches to identify outliers by a non-parametric approach, such as the interquartile (IQR) approach. This method determines values above "75th percentile values + 1.5 × interquartile" in the dataset as outliers. The IQR approach is widely used as an easy method in a variety of fields to identify outliers. The IQR method assumes that data points equivalent to the median ± 2.7σ in a normal distribution fall within the range of median ± 2 IQR. If the distribution is characterized with high kurtosis and skewness, as in the case of occurrence data of contaminants in food, many data on the right side (higher concentrations) may be determined as outliers. This is because high kurtosis results in smaller IQR and high skewness means greater variability.

116. Since excluding many data points in the higher concentration range from a dataset will significantly affect the calculation of high percentile values depending on a sample size of the dataset, and subsequently any ML proposals, it is not recommended to exclude data as outliers solely based on the results of the IQR approach without considering pattern of the contamination (e.g., homogeneous vs heterogeneous).

Other methods to identify possible outliers

117. Another (arbitrary) way to identify possible outliers is to visually inspect the data with a frequency distribution and identify those data which appear disconnected from the rest of the data. However, this is not a sufficient basis to exclude disconnected data as outliers. Figure 2 is an example of EU data on the sum of T-2 and HT-2 toxin in oat milling products, where a relatively small number of data points have levels exceeding 500 µg/kg. In such circumstances, and knowing the nature of the contaminant, unless it can be determined that such levels are definitively outside the natural variance of the contaminant, these data should remain in the dataset.

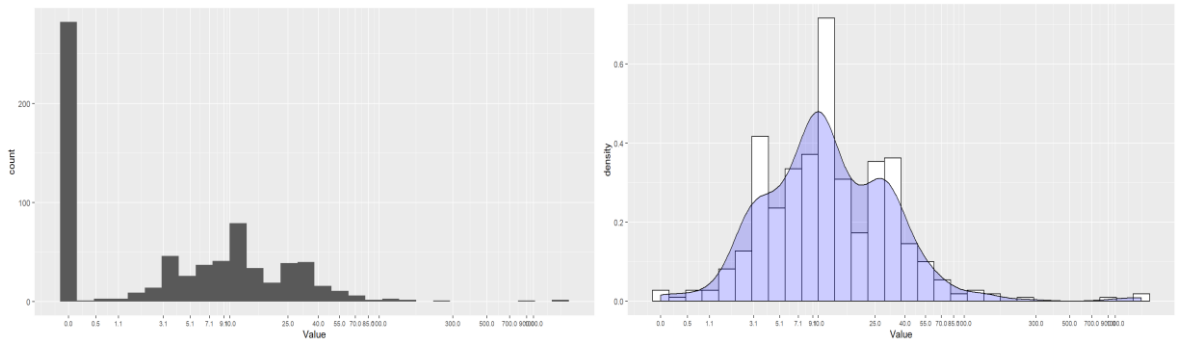

Figure 2. Example EU data on sum of T-2 and HT-2 toxin in oat milling products (717 results of which 438 are quantified results), (left) Histogram: all results, (right) Histogram/probability density curve of quantified results

Decision on the handling possible outliers

118. There may be cases where extreme values are scientifically valid depending on production conditions and weather and other potential factors such as volcanic eruptions, etc. Considering the characteristics of the distribution pattern of occurrence data of a contaminant in food, it is not recommended to simply exclude extreme values based on the results of statistical outlier tests or other methods such as visual inspection. Since the range of concentrations and distribution patterns that can be empirically or theoretically assumed varies significantly depending on the type of contaminant (heavy metals, mycotoxins, etc.), the handling of extreme values must be determined on a case-by-case basis. For example, special consideration should be given to mycotoxins whose concentrations can vary

significantly depending on the sampling methods utilized due to the well-known heterogeneous distribution in a lot, as well as very large annual variation.

119. CXG 72-2009 assumes a dataset of results of repeated analysis of the same sample which shows a normal distribution. It states, "the statistical outliers are discarded unless the statistician for good reason decides to retain them". In contrast, the datasets addressed in this Guidance are analytical results from a variety of samples and from different analytical methods. Because it is unknown what distribution they will take, and they may be combined from multiple sources, it is difficult to predict the range of variation within a dataset. Therefore, this Guidance recommends, "the statistical outliers are not discarded unless good reason to exclude them is identified and scientifically explained".

120. Nevertheless, if extreme values are to be excluded as outliers, it is recommended that the reason for exclusion be clearly reported, and that sensitivity analysis be used to show how the exclusion or non-exclusion of outliers may or may not affect the calculation of high percentile values. It should be reiterated that provided that the total number of data points in the dataset is sufficiently larger than the minimum number of data points required to calculate high percentile values, a few extreme values remaining in the dataset will have little effect on the calculation of the percentile values.

Examples of investigation of a set of values inconsistent with other members of that dataset as possible outliers.

Clean-up of data

a) If confirmed by the data submitter that the extreme values were caused by errors, decide to exclude these data from further data analysis:

- *Outliers (clearly) due to adulteration/fraudulent action or human error (e.g., incorrect data entry) → it can be decided, in consultation and agreement with the data submitter, to exclude these data from further data analysis*
- *no valid justification to exclude these data can be provided from data submitter or can be explained from EWG for these possible outliers → it can be decided not to exclude these data for further data analysis in principle*
- *a valid justification can be provided for possible outliers (such as data from a year with extreme weather conditions, data from a specific region/continent, …) → these data are in principle NOT to be excluded*

Statistical analysis

b) Assess the impact of possible outliers on the summary statistics (arithmetic mean, high percentile values).

Possible outliers should be retained in the dataset unless the sensitivity analysis results in a significant and meaningful impact on the summary statistics. When there is a significant difference in the results of sensitivity analysis, the EWG or CCCF will decide on a case-by-case basis whether it is meaningful, depending on the toxicity of the contaminant and the type of food, and therefore whether to exclude the possible outliers or not.

c) Conduct an outlier test for data extremes that require further investigation, if available. Statisticians should recommend outlier tests suitable to the dataset for the use by CCCF, if necessary. IQR approach may be one option for outlier test, but automatic exclusion of outliers should be discouraged unless there is other justification to exclude them. In general, outlier tests that require a normal distribution are not recommended.

Conducting statistical analysis

Basic statistical analysis and presentation of occurrence data have been a common practice for EWGs tasked with developing MLs but reporting on the results of statistical analyses has been somewhat arbitrary in terms of the content and format.

This Guidance introduces the methods of drawing the chart/graph and plots to show distribution patterns of occurrence data and statistical values that are necessary for reviewing and discussing the appropriateness of the proposed ML.

The statistical analyses presented here are examples and are not exhaustive nor mandatory. Depending on the type of contaminant and the number of available data points, statistical analyses may be performed on a case-by-case basis.

Drawing charts/graphs and plots on distribution of occurrence data

121. As a first step in the statistical analysis, it is recommended to create histograms or box-and-whisker plots for each dataset (e.g., individual and combined datasets) in order to get a perspective on trends in the distribution pattern of the occurrence data. Histograms and box-and-whisker plots can be created using statistical analysis applications, or spreadsheet applications, such as MS Excel.

122. While various applications can be used, an easy way is provided in Microsoft Excel. To perform drawing and statistical analysis in MS Excel, "Analysis ToolPak" should be installed from the Excel add-ins to use various functions useful for statistical analysis. A ribbon menu for "Data Analysis" will be added to the Data tab of MS Excel after the install of the add-ins.

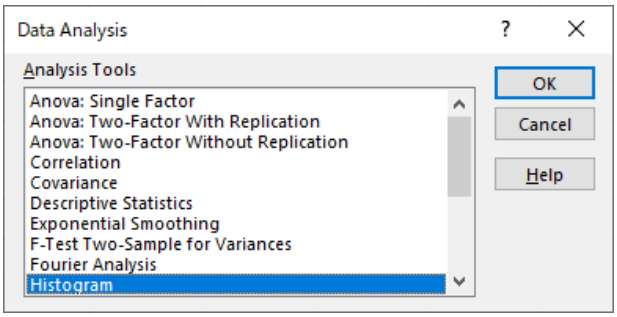

Figure 3. Example of menu of Data Analysis tool in MS Excel

123. Histograms can be created from the Draw Charts menu as well as from the Data Analysis tool in MS Excel. However, it is recommended to use the Data Analysis tool, which offers greater flexibility in customizing the chart drawing. Box-and-whisker plots can be created from the Draw Chart menu, not from the Data Analysis tool.

124. In general, histograms provide a good indication of distribution patters when the data are sufficiently large (ca. 50 or greater). The approximate number of data needed to draw a histogram can be used as a guide for the minimum number of data points needed to calculate high percentile values (see paragraphs 72 to 80). If the number of data points contained in the dataset differs, the vertical axis should be for relative frequency for easier comparison.

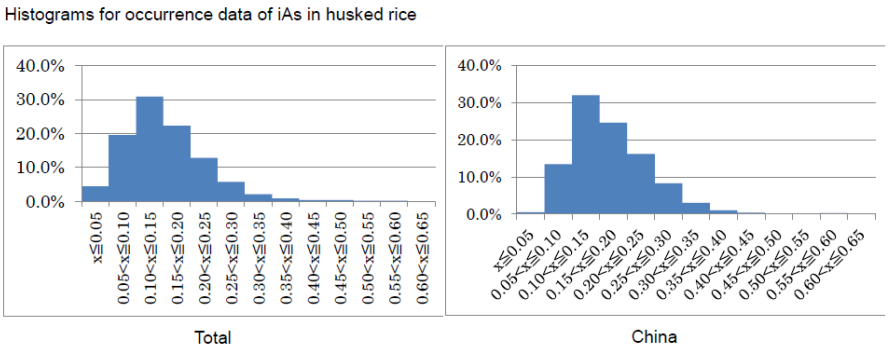

Figure 4. Example of histograms of occurrence data on inorganic As in husked rice (combined and individual dataset) (ref. CX/CF 15/9/7)

125. A cumulative frequency curve can also be added to a histogram. However, MS Excel alone cannot draw distribution curves. A dedicated statistical analysis applications (e.g., SAS, SPSS, R, etc.) should be used, or some add-in applications capable of modelling/simulation (e.g., @Risk, Crystal Ball, etc.) should be used.

126. For a dataset with a small number of datapoints, it is difficult to know the shape of the distribution by a histogram, and a box-and-whisker plot is more helpful because it can be created even when the number of datapoints is 20. For example, the following box-and-whisker plots for inorganic arsenic concentration data in husked rice from various countries could be drawn when the number of data submitted from several countries was too small (e.g., n=9) to draw a histogram. The box-and-whisker plots were drawn for comparisons of individual datasets.

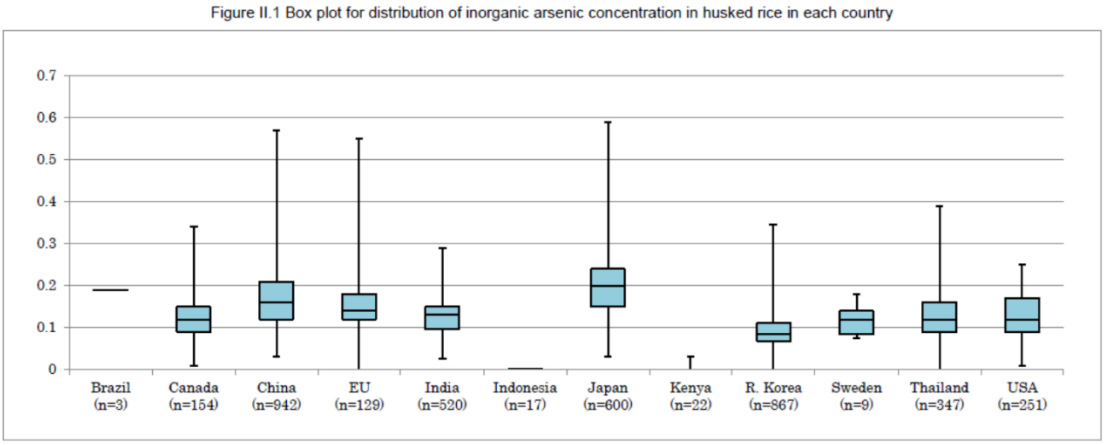

Figure 5. Box-and-whisker plots of individual datasets on inorganic As in husked rice (ref. CX/CF 16/10/5)

127. After drawing histograms or box-and-whisker plots, it is necessary to check if there are possible outliers, and differences in: the distribution patterns of individual datasets, the shapes of the distribution, the central tendency and range of the dataset. The presence of multimodalities in the combined dataset should also be checked. When the combined dataset has possible outliers, or clearly shows a multimodal distribution, it is necessary to go back to the previous process (such as Section D3 or D4) for reconsideration of how to handle the dataset.

Data aggregation and calculation of descriptive statistics

128. The following information and summary statistics can be presented as a summary of a large number of occurrence data:

- Number of total data points;
- Number of data points lower than the reported LOQs, and/or ratio of the number of data <LOQ among the total number of data points;
- Range of LOQs reported (for appropriate LOQs, see Chapter data selection);
- Mean (arithmetic mean), if the dataset contains datapoints below LOQ, three arithmetic means based on three substitutional scenarios of LB, MB and UB could be prepared (if the distribution is or close to normal and symmetric);
- If the distribution is highly skewed, geometric mean using the same approach as above;
- Median (50th percentile values), but if more than 50% of datapoints are below LOQ, the median could be reported as "<LOQ" (or LOQ);
- High percentile values (e.g., 95th, 97th and 98th percentile values, as necessary, depending on discussions in the EWG on appropriate rejection rate(s)); if more than 95%, 97% etc. of samples are below the LOQ, then the associated percentiles could be reported as "<LOQ" (or LOQ);
- Minimum;
- Maximum; in cases where the maximum was identified as a potential outlier and the maximum value was not yet excluded from the dataset, it may be worth reporting the 2nd highest value, 3rd highest value, etc. for additional context;
- Range of quantified data;
- Standard deviation (unbiased standard values), which is a measure of the amount of variation and used as a parameter for probability functions such as normal, lognormal and gamma distributions; and
- Interquartile values, which is a measure of the amount of variation of a non-parametric distribution.

129. Many of these statistics can be easily obtained by using Excel Functions, by using a menu of Descriptive Statistics in Data Analysis tools in MS Excel, or from any other statistical application. Different statistical applications use different calculation protocols and as such return different percentile values for the same set. Therefore, when calculating percentile values using computer applications, the values obtained should be carefully checked against the functions used and state the name of the application used for the calculation.

130. When left-censored data comprise most of the dataset, it may not be possible to calculate high percentile values. In such cases, it is recommended to use the substitution method with LB, MB, or UB scenarios. Although it is on a

case-by-case basis, depending on the number of available finite values and the distribution pattern, methods such as estimating high percentile values from probability density functions by modelling the distribution of occurrence data can be used. (A model simulation application is also necessary and details of how to use such application is not described here.)

Calculation of rejection rates at hypothetical MLs

Identification of appropriate rejection rates when establishing MLs is outside the scope of this Guidance.

Calculation of rejection rates is a separate issue from the selection of an appropriate rejection rate and is one of necessary processes for ML development and therefore it is described in this section.

Presentation of calculated rejection rates is a common practice for EWGs tasked with developing ML in CCCF, but in some cases, the calculation methods and procedures have not been clearly stated in the report.

Estimation of hypothetical MLs

131. From a high percentile value (usually the 95th percentile value) of the target dataset for data analysis, a candidate value for an ML is identified, also considering the precision of the current analytical method and significant figures of the analytical results (e.g., when a calculated percentile value is 0.485 mg/kg, the value used as a candidate ML (hypothetical ML) would be rounded to single significant digit such as 0.5 mg/kg, and if an analytical method with high precision is available or the concentration is one order of magnitude or more higher, a value would be rounded to two significant digits such as 1.0 mg/kg.). There were some exceptions to this where a midpoint value of usually used values might be preferred, such as 0.15 mg/kg, which, despite ending with a digit of "5", could occasionally be chosen when values of 0.10 and 0.20 would be less appropriate (e.g., 0.35 mg/kg for inorganic As in husked rice, 0.15 mg/kg for lead in fortified wine).

132. Once the numerical candidate value of an ML has been determined, the next nearest higher or lower values are also used as hypothetical MLs (For the above example, additional hypothetical MLs would be 0.4 and 0.6 mg/kg). In the case of any revision to existing MLs, the existing ML should also be added as one of the hypothetical MLs. Further, values obtained by rounding the high percentile values (e.g., 95th, 97th and 98th percentile values) can also be used directly as hypothetical MLs.

133. When the decision is made to analyze multiple datasets with different distribution patterns separately, hypothetical MLs are determined from the high percentile values of each dataset. If the distribution patterns are significantly different, hypothetical MLs of individual datasets may be significantly different.

134. There is no rule for the number of hypothetical MLs to be proposed, but it is preferable to identify at minimum 2 to 4 values, depending on the condition, for consideration of their effects on reduction of dietary exposure and economic impact arising from rejection rates to be further discussed in the EWG tasked with developing ML and the subsequent Committee meeting.

Calculation of rejection rates at the hypothetical MLs

135. The rejection rate is defined as the equation below. It can be easily obtained using MS Excel functions (such as COUNTIF function) directly or using statistical or modelling/simulation applications after modelling each dataset. If a different method is used to calculate the rejection rate, the method should be clearly stated in the report.

Rejection rate (%) = (number of samples > hypothetical ML) / (total number of sample) ×100

136. It should be noted that the rejection rate obtained may be different from that anticipated from the high percentile due to the rounding process. The smaller the number of samples in the dataset used to calculate rejection rates, the greater the uncertainty in estimating the rejection rate. In the calculation of rejection rate, it is assumed that samples that exceed the hypothetical ML are excluded from the market with 100% probability by enforcement of the ML.

Assessment of impact of an ML on rejection rate

137. To assess the impact on international trade of the commodity, the combined global dataset should be used, and if necessary, datasets for each region. Calculating rejection rates on a country-by-country basis is not recommended because it may incorrectly highlight some economic aspects not related to the scientific basis of ML development and increase the workload of the data analysts.

138. For contaminants known to have large annual variation in concentrations, the rejection rate will be calculated for the dataset of each year, if possible, for year-to-year comparison of rejection rates.

Improvement of calculation of rejection rates

139. At different hypothetical MLs, the calculated rejection rates may not change or change significantly, depending on the distribution pattern. The frequency of data at high percentile range is often much lower than that at low percentile range, which affects the estimation of hypothetical MLs and rejection rates (See Figure 1 for the shape of distribution).

140. If the distribution pattern of the combined (potentially global) dataset shows a single peak, modelling/simulation application (such as @Risk, Crystal Ball, R, etc.) can be used to model the distribution to continuously estimate the distribution near the high percentile values from the distribution function (e.g., inorganic As in rice, ref. CX/CF 16/10/5, CX/CF 15/9/7, CX/CF 14/8/6), and more refined and improved estimates of the rejection rate may be possible.

141. Such an approach requires more data and resources and can be conducted if the work burden of EWGs allows. If more detailed or improved impact assessment regarding rejection rates is needed, requesting an evaluation from the Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an option (e.g., AFT in RTE peanuts, Cd in cocoa products).

Calculation of effects of MLs on the reduction of dietary exposure at hypothetical MLs

The GSCTFF stipulates that *"In order to promote acceptance of Codex MLs, it is therefore important that assessments of the impact of those MLs on dietary exposure are done in a consistent and realistic way. The procedure involves assessment of the dietary intake in relation to the proposed or existing MLs and the toxicological reference value…Proposals for MLs should be accompanied by intake calculations and risk assessment conclusions regarding their impact on dietary intake and use…"*.

This clearly indicates that guidance on impact assessment of proposed MLs on dietary exposure is needed for the CCCF.

The calculation and presentation of effects of the ML on the reduction of dietary exposure has been a common practice for EWGs tasked with developing ML in CCCF recently, but in some cases the calculation methods and procedures have not been explained in the reports.

Further consideration of the role of the Committee in calculating dietary exposure reduction rates when considering MLs is needed. (calculation of dietary exposure is a risk assessment function that should be undertaken by JECFA and JECFA provides the scientific advice on which the risk management decisions of the Committee are based – it is important to clarify the roles of JECFA and CCCF as risk assessor and risk manager respectively, in the calculation of dietary exposure reduction rates when considering MLs (REP23/CF16, paras 90 and 91 and para 98 (vi) (c)

Calculation of dietary exposure and its reduction rate at the hypothetical MLs

142. For ensuring that the proposed ML is appropriate for the protection of consumers' health, it is necessary to quantitatively evaluate the effect of a hypothetical ML in reducing dietary exposure from the target commodity by comparing the exposure with and without an ML (for hypothetical ML, see Section D6). In the case of a revision of an existing ML, the exposure under the already established ML is compared with the exposure under the new hypothetical MLs (revised ML).

143. For all contaminants, long-term/chronic dietary exposure can be calculated using the following equation.

Dietary exposure (µg/person/day) = concentration (µg/g) × food consumption (g/person/day),
Or
Dietary exposure (µg/kg-bw/day) = concentration (µg/g) x food consumption (g/kg-bw/day)

144. To estimate average dietary exposure under hypothetical MLs, arithmetic mean concentrations (or geometric mean concentrations in case where the distribution is highly skewed) under hypothetical MLs need to be calculated using a dataset from which higher concentration data than each hypothetical ML are excluded. In the calculation, it is assumed that samples with concentrations above the hypothetical ML are excluded from the market with 100% probability by enforcement of the ML.

145. Where left-censored data are contained in the occurrence dataset and the distribution permits (e.g., normal distribution), arithmetic means calculated by substitution scenario LB, MB, or UB can be used. For the impact assessment, it is not necessary to calculate using all three scenarios, but the scenario used for calculating arithmetic mean should be reported.

146. In addition to the arithmetic mean, the geometric mean or median, or high percentile values can be used on a case-by-case basis, particularly when the distribution is highly skewed, to help clearly understand where the central tendency lies for different purposes. Which value was used in the calculation should be clearly stated.

147. If a dataset contains concentration data that is much higher than the hypothetical ML, the mean concentration will be significantly lowered after excluding those extremely high values. Since the median is a robust statistic, if the number of data points in the dataset does not change significantly after excluding data points that are much higher than the hypothetical ML, the median under the hypothetical ML may change little compared to the median without ML.

148. A template for calculating the point estimates of chronic dietary exposure (International Estimated Dietary Intake, IEDI) using the GEMS/Food cluster diets (explained below) is available from the URL [18] of the GEMS/Food Programme. In this template, all countries are grouped into 17 clusters and for each cluster there are food consumption data derived from the data in the FAO Food Balance Sheet and some additional data provided by the governments. After entering the concentration data (in this case, the arithmetic mean concentrations calculated for each hypothetical MLs or other alternative values) and clicking the button "Make table", there will be calculated mean intakes for 17 clusters.

149. For foods for which consumption data are not available in the GEMS/Food cluster diet, it may be possible to estimate consumption per capita in the population from available data, such as production volumes. As for food consumption data, other databases are available (e.g., FAO/WHO GIFT, FAO/WHO CIFOCOs, etc.). What data were used and how it was processed should be indicated in the EWG's report.

150. Percentage of decrease in dietary exposure of the contaminant from the foods or food groups concerned under hypothetical ML compared to exposure without ML is regarded as a reduction rate of exposure.

    Reduction rate of exposure (%) = (exposure with no ML – exposure with ML) / (exposure with no ML) × 100

151. For a contaminant for which an ARfD has been established by JECFA, acute/short term exposure should be calculated using the International Estimated Short-term Intake (IESTI) template available at the same URL as the IEDI template. Acute/short term exposure under a hypothetical ML should be well below the ARfD for the general population or children 6 and below, or if ARfD is set for women of child-bearing age, should be well below this ARfD. An ARfD has been recommended only for DON and related compounds, how to conduct the IESTI calculation is not explained here in detail.

152. If a HBGV is established by JECFA for a contaminant/toxin (PMTDI/PTDI, PTWI, PTMI or ARfD, etc.), it may be useful to evaluate the impact on the percentage of exposure from the food to which the ML applied relative to the HBGV. Information on average body weight should be obtained when comparing dietary exposure to HBGV.

    Ratio to the HBGV (%) = exposure with ML (µg/person/day) / average body weight (kg/person) / HBGV (µg/kg bw/day) × 100

    If HBGVs are set on a per week or per month basis, the exposure should be multiplied by the appropriate factor, e.g., 7 or 30.

Assessment of impact of ML on dietary exposure

153. All EWGs tasked with developing ML should evaluate the balance between the rejection rate and the dietary exposure reduction rate at each hypothetical ML and determine which level is as low as reasonably achievable or offer options to the Committee to inform this decision.

154. While it is out of the scope of this Guidance to determine what rejection rate is the most appropriate, the EWG tasked with developing ML should also consider regional and international consumption patterns to determine a proposed draft ML among the hypothetical MLs with respect to protecting consumer health and ensuring food security and fair trade.

Improvement of calculation of exposure reduction rates

155. At different hypothetical MLs, the calculated reduction rates may not change or change significantly, depending on the distribution pattern. The frequency of data at high percentile range is often lower than that at low percentile range, which affects the estimation of hypothetical MLs and exposure reduction rates (See Figure 1 for the shape of distribution).

156. If the distribution pattern of the combined (potentially global) dataset shows a single peak, modelling/simulation applications (such as @Risk, Crystal Ball, R, etc.) can be used to model the distribution to continuously estimate the

[18] https://www.who.int/teams/nutrition-and-food-safety/databases/global-environment-monitoring-system-food-contamination

distribution near the high percentile values from the distribution function, and easily output a mean concentration under a hypothetical ML by applying an arbitrary cut-off value to the modelled distribution curve.

157. Such an approach requires more resources and can be conducted if the work burden of EWGs allows. If more detailed or improved impact assessment regarding dietary exposure is needed, requesting an evaluation from JECFA is an option (e.g., Aflatoxins in RTE peanuts, Cd in cocoa products).

DATA PRESENTATION IN EWG REPORTS TO CCCF

158. It is important that the data are presented in such a way in the EWG report to CCCF that enables an informed discussion on appropriate MLs for deliberation through the Step procedure. This means that the data are reported with inclusion of all assumptions e.g., how many data were excluded and the reasons thereof, how left-censored data are managed, whether data outside GEMS/Food database were considered, etc. A detailed rationale should accompany the report.

Presentation of data analysis: statistical analysis

159. This section provides the elements and examples of templates that can be used by the EWG when presenting the results of statistical analysis of occurrence data for ML development. The EWG may use the templates or modify them on a case-by-case basis, as the detail of reporting depends on the amount of data available and also the nature of the contaminant.

160. For each dataset provided by Members (and Observers) used in statistical analysis, the following elements should be reported:

- Number of data points and proportion of <LOQ data;
- Arithmetic mean (LB, MB and/or UB), median, minimum and maximum;
- Relevant percentile values (e.g., 95th, 97th, 98th); and
- Charts/graphs or plots showing distribution patterns (such as histograms or box-and-whisker plots)

161. In reporting the above elements, Table 2 can be used as a template.

Table 2. Example Template: Summary of basic statistics of the datasets

Food or food group	Total number of samples	Number of <LOQ	Mean (LB-UB) (mg/kg)	Median (mg/kg)	95th %ile (mg/kg)	97th %ile (mg/kg)	98th %ile (mg/kg)	Min (mg/kg)	Max (mg/kg)

Note to table 2: To be filled for the combined dataset (potentially global dataset), %ile: percentile value.

162. If necessary, including the following elements is also useful in interpreting the dataset:

- range of reported LOQs; and
- standard deviation (unbiased).

163. If there is significant year-to-year variation in occurrence for a food or food group, it is appropriate to provide an analysis of the data per year and in case of a statistically significant difference in distribution pattern, the analysis should consider presenting data by geographical region (e.g., continent or Codex region) using Table 3.

Table 3. Example Template: Summary of basic statistics of the datasets per region or per year

Region/ country/ World	Total number of samples	Number of <LOQ	Mean (LB-UB) (mg/kg)	Median (mg/kg)	95th %ile (mg/kg)	97th %ile (mg/kg)	98th %ile (mg/kg)	Min (mg/kg)	Max (mg/kg)

Note to table 3a: To be filled in by region or global, %ile: percentile value.

Year	Total number of samples	Number of <LOQ	Mean (LB-UB) (mg/kg)	Median (mg/kg)	95th %ile (mg/kg)	97th %ile (mg/kg)	98th %ile (mg/kg)	Min (mg/kg)	Max (mg/kg)

Note to table 3b: To be filled in by per year/global or per year/region, %ile: percentile values

164. If the number of samples are higher than the minimum number of samples required for an individual food or an indication that the distribution of concentrations for an individual food is significantly different from other foods despite the lower number of samples, it is important to present a summary of data for all individual foods within a food group, in addition to summary data for the broader food group. This type of analysis allows for an understanding on how a proposed ML impacts the individual foods and to determine if the development of an ML for a broad food category is more appropriate than an ML for individual foods within the broad category.

165. In general, 2–4 hypothetical MLs are estimated based on the distribution. Data presentation should cover these hypothetical MLs showing how the dietary exposure estimates are affected by them, and what the rejection rates would be using Table 4.

166. If necessary, a table, using Table 4 as a template, should be prepared for not only combined (potentially global) dataset but also regional datasets to consider the impact of MLs by geographical area.

Table 4. Example Template: Summary of impact assessment at hypothetical MLs

Hypothetical MLs (mg/kg)	Mean concentration (mg/kg)	Dietary intake (µg/person/day)	Exposure reduction (%)	Rejection rate (%)
Name of Food or food group (total number of samples)				

Note to table 4: Exposure reduction = percentage of decrease in dietary intake of the contaminant from the food or food group concerned

167. Finally, a working document prepared for discussion at the plenary session of CCCF should accompany a table, prepared using Table 5 as a template and in line with the format of GSCTFF, which includes information on the proposed draft/draft MLs as well as explanation notes for the commodities under consideration.

Table 5. Format of the schedule in the GSCTFF

Commodity/Product name	Proposed draft and draft MLs (mg/kg)	Portion of the commodity/Product to which the ML applies	Notes/Remarks

ANNEX

GLOSSARY OF TERMS

Term	Definition/Explanation
Acute reference dose (ARfD)	The estimate of the amount of a substance in food or drinking water, expressed on a body weight basis, that can be ingested in a period of 24 h or less without appreciable health risk to the consumer. It is derived on the basis of all the known facts at the time of evaluation. The ARfD is expressed in milligrams of the chemical per kilogram of body weight. (WHO, EHC 240)
Box-and-whisker plot	A graphical method of displaying the important characteristics of a set of observations. The display is based on the five-number summary of the data with the 'box' part covering the inter-quartile range, and the 'whiskers' extending to include all but outside observations, these being indicated separately. It is often particularly useful for comparing the characteristics of different samples. (Cambridge dictionary of statistics) A box contains data that falls between 25th and 75th percentile and the ends of whisker show in general the minimum and maximum values. Outliers are plotted away from whisker. The median (50th percentile) is shown in the box above 25th percentile and below 75th percentile. The mean is plotted with a symbol, such as "X".
Cochran's test	One of the tests used to identify outliers, which is a test of the within-laboratory variabilities. It should be applied first, then any necessary action should be taken, with repeated tests if necessary. (ISO 5725-2)
Confidence level	A measure of the reliability of a result. A confidence level of 95% or 0.95 means that there is a probability of at least 95% that the result is reliable.
Critical value	The value of the net concentration or amount the exceeding of which leads, for a given error probability α, to the decision that the concentration or amount of the analyte in the analysed material is larger than that in the blank material. It is defined as: $\Pr(\hat{L} > L_C \mid L=0) \leq \alpha$ Where $\hat{L}$ is the estimated value, L is the expectation or true value, and L_C is the critical value. (CXG72-2009)
Distribution curve	A graph of the frequencies of different values of a variable in a statistical distribution.
Exposure assessment	Exposure assessment is the qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant. (Codex Alimentarius Commission Procedural Manual) For the purpose of this document, the term "dietary exposure" refers to the intake of a substance by a person as part of its diet (via food, beverages, drinking water and food supplements).
Extreme value	The largest and smallest variables among a sample of observations. (Cambridge dictionary of statistics) For the purpose of this document, the maximum and nearby values in a dataset are referred to as extreme values.
Finite value	A number that is not infinite, i.e., it could be measured or given a value. For the purpose of this document, finite value means any analytical results at or higher than reported LOQ.
Food group	A set of individual food commodities with similar biological and morphological characteristics and therefore similar potential for concentrations of a chemical of concern and for which a common group maximum level can be set.

Term	Definition/Explanation
Gamma distribution	The probability distribution, $f(x)$, given by $f(x) = \frac{x^{\gamma-1}}{\beta} \frac{\exp(-x\beta)}{\beta\Gamma(\gamma)}, \quad 0 \le x < \infty, \ \beta > 0, \gamma > 0$ β is a scale parameter and γ a shape parameter. The mean, variance, skewness and kurtosis of the distribution are as follows. $\text{mean} = \beta\gamma$ $\text{variance} = \beta^2\gamma$ $\text{skewness} = 2\gamma^{-\frac{1}{2}}$ $\text{kurtosis} = 3 + \frac{6}{\gamma}$ The distribution of $u = x/\beta$ is the standard gamma distribution with corresponding density function given by $f(u) = \frac{x^{\gamma-1}e^{-x}}{\Gamma(\gamma)}$ The function Γ defined by $\Gamma(r) = \int_0^\infty t^{r-1}e^{-t}\mathrm{d}t$ Where r > 0 (r need not be an integer). The function is recursive satisfying the relationship. $\Gamma(r+1) = r\Gamma(r)$ (Cambridge Dictionary of Statistics)
GEMS/Food	The World Health Organization's Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food Programme), which maintains databases on contaminant levels in foods and estimates of dietary exposure to food chemicals. (WHO, EHC 240)
Grubbs' test	One of the tests to identify outliers, which is primarily a test of between-laboratory variability and can also be used (if n>2) where Cochran's test has raised suspicions as to whether the high within-laboratory variation is attributable to only one of the test results. (ISO 5725-2)
Health-based guidance value (HBGV)	A numerical value derived by dividing a point of departure (a no-observed-adverse-effect level, benchmark dose or benchmark dose lower confidence limit) by a composite uncertainty factor to determine a level that can be ingested over a defined time period (e.g., lifetime or 24 h) without appreciable health risk. (WHO, EHC 240)
Histogram	A graphical representation of a set of observations in which class frequencies are represented by the areas of rectangles centred on the class interval. If the latter are all equal, the heights of the rectangles are also proportional to the observed frequencies. (Cambridge Dictionary of Statistics)
International estimated daily intake (IEDI)	A prediction of the long-term daily intake of a pesticide residue on the basis of the assumptions of average daily food consumption per person and median residues from supervised trials, allowing for residues in the edible portion of a commodity and including residue components defined by the Joint FAO/WHO Meeting on Pesticide Residues for estimation of dietary intake. Changes in residue levels resulting from preparation, cooking or commercial processing are included. When information is available, dietary intake of residues resulting from other sources should be included. The IEDI is expressed in milligrams of residue per person. (WHO, EHC 240)

Term	Definition/Explanation
International estimated short-term intake (IESTI)	A prediction of the short-term intake of a pesticide residue on the basis of the assumptions of high daily food consumption per person and highest residues from supervised trials, allowing for residues in the edible portion of a commodity and including residue components defined by the Joint FAO/WHO Meeting on Pesticide Residues for estimation of dietary intake. The IESTI is expressed in milligrams of residue per kilogram of body weight. (WHO, EHC 240)
Interquartile range	A measure of spread given by the difference between the first quartile (25th percentile) and third quartile (75th percentile) of a sample. (Cambridge Dictionary of Statistics)
Joint FAO/WHO Expert Committee on Food Additives (JECFA)	An expert committee that has been meeting since 1956. JECFA has been engaged in collecting and evaluating scientific data on food additives and making recommendations on safe levels of use. This has been accomplished 1) by elaborating specifications for the identity and purity of individual food additives that have been toxicologically tested and are in commerce and 2) by evaluating toxicological data on these food additives and estimating acceptable intakes by humans. In 1972, the scope of the evaluations was extended to include contaminants in food, whereas in 1987, the scope was extended even further to include residues of veterinary drugs in food. (WHO, EHC 240)
Joint FAO/WHO Meeting on Pesticide Residues (JMPR)	The abbreviated title for the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, which has been meeting since 1963. The meetings are normally convened annually. The FAO Panel of Experts is responsible for reviewing residue and analytical aspects of the pesticides considered, including data on their metabolism, fate in the environment and use patterns, and for estimating the maximum residue levels and supervised trials median residue levels that might occur as a result of the use of the pesticide according to Good Agricultural Practice. The WHO Core Assessment Group on Pesticide Residues is responsible for reviewing toxicological and related data on the pesticides and, when possible, for estimating acceptable daily intakes and long-term dietary intakes of residues. As necessary, acute reference doses for pesticides are estimated along with appropriate estimates of short-term dietary intake. (WHO, EHC 240)
kurtosis	The extent to which the peak of a unimodal probability distribution or frequency distribution departs from the shape of a normal distribution, by either being more pointed (*leptokurtic*) or flatter(*platykurtic*). (Cambridge Dictionary of Statistics)
Kruskal-Wallis H-test	A distribution free method that is the analogue of the analysis of variance of a one-way design. It tests whether the group to be compared have the same population median. The test statistic is derived by ranking all the *N* observations from 1 to *N* regardless of which group they are in, and then calculating $H = \frac{12\sum_{i=1}^{k} n_i(\bar{R}_i - \bar{R})^2}{N(N-1)}$ Where n_i is the number of observations in group i, $\bar{R}_i$ is the mean of their ranks, $\bar{R}$ is the average of all the ranks, given explicitly by (*N*+1)/2. When the null hypothesis is true the test statistic has a chi-squared distribution with k-1 degrees of freedom. (Cambridge Dictionary of Statistics)
Left-censored data	Data which are not finite values (quantified values) or are data less than reported LOQs or LODs.

Term	Definition/Explanation
Limit of detection (LOD)	The true net concentration or amount of the analyte in the material to be analysed which will lead, with probability (1-β), to the conclusion that the concentration or amount of the analyte in the analysed material is larger than that in the blank material. It is defined as: Pr ($\hat{L}$ ≤LC | L=LOD) = β Where $\hat{L}$ is the estimated value, L is the expectation or true value, and LC is the critical value. (CXG 72-2009) OR The limit of detection (LOD) is the minimum concentration of a contaminant that can be qualitatively measured in the specific food. The limit of detection is reported by a laboratory, or a value calculated from the LOQ. (GEMS/Food Programme)
Limit of quantification (LOQ)	A method performance characteristic generally expressed in terms of the signal or measurement (true) value that will produce estimates having a specified relative standard deviation (RSD), commonly 10% (or 6%). LOQ is estimated by: LOQ = kQ σQ, kQ = 1/RSDQ Where LOQ is the limit of quantification, σQ is the standard deviation at that point and kQ is the multiplier whose reciprocal equals the selected RSD (The approximate RSD of an estimated σ, based on ν-degrees of freedom is 1/ √2ν.). (CXG 72-2009) OR The limit of quantification (LOQ) is the minimum concentration of a contaminant that can be quantitatively measured in the specific food with an acceptable level of accuracy and precision. The limit of quantification is reported by a laboratory, or a value calculated from the LOD. (GEMS/Food Programme)
Lognormal distribution	The probability distribution of a random variable, X, for which $\ln(X)$ has a normal distribution with mean μ and variance σ^2. The distribution is given by $f(x) = \frac{1}{x\sigma(2\pi)^{\frac{1}{2}}} \exp\left[-\frac{1}{2\sigma^2}\{-(\ln x - \mu)^2\}\right] \qquad 0 \le x < \infty$ The mean, variance, skewness and kurtosis of the distribution are $\text{mean} = \exp(\mu + \frac{1}{2}\sigma^2)$ $\text{variance} = \exp(2\mu + \sigma^2)(\exp(\sigma^2) - 1)$ $\text{skewness} = (\exp(\sigma^2) + 2)(\exp(\sigma^2) - 1)^{\frac{1}{2}}$ $\text{kurtosis} = \exp(4\sigma^2) + 2\exp(3\sigma^2) + 3\exp(2\sigma^2) - 3$ For small the distribution is approximated by the normal distribution. (Cambridge Dictionary of Statistics)
Maximum level (ML)	Codex Maximum Level for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by the Codex Alimentarius Commission to be legally permitted in that commodity. (Codex Alimentarius Commission Procedural Manual)
Mann-Whitney U test	A distribution free method used as an alternative to the Student's t-test for assessing whether two populations have the same location. Given a sample of observations from each population, all the observations are ranked as if they were from a single sample, and the test statistic is the sum in the smaller group. Tables giving critical values of the test statistic are available, and for moderate and large sample sizes, a normal approximation can be used. (Cambridge Dictionary of Statistics)
Measurement uncertainty	Parameter, associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand (i.e., the quantity intended to be measured). (CXG54-2004, amended in 2021)

Term	Definition/Explanation
Mean (Arithmetic)	A measure of location or central value for a continuous valuable. For a sample of observations $x_1, x_2, \ldots, x_n$ the measure is calculated as $\bar{x} = \frac{\sum_{i=1}^{n} x_i}{n}$ Most useful when the data have a symmetric distribution and do not contain outliers. (Cambridge Dictionary of Statistics)
Mean (Geometric)	A measure of location, *g*, calculated from a set of observations $x_1, x_2, \ldots, x_n$ as $g = \left(\prod_{j=1}^{n} x_j\right)^{\frac{1}{n}}$ (Cambridge Dictionary of Statistics)
Median	The value in a set of ranked observations that divides the data into two parts of equal size. When there is an odd number of observations the median is the middle value. When there is an even number of observations the measure is calculated as the average of the two central values. Provides a measure of location of a sample that is suitable for asymmetric distributions and is also relatively insensitive to the presence of outliers. (Cambridge Dictionary of Statistics)
Multimodal distribution	A probability distribution or frequency distribution that has two or more modes (peaks). Multimodality is often taken as an indication that the observed distribution results from the mixing of the distributions of relatively distinct groups of observations. (Cambridge Dictionary of Statistics)
Normal distribution	A probability distribution, $f(x)$ of a random variable, X, that is assumed by many statistical methods. Specifically given by $f(x) = \frac{1}{\sigma\sqrt{2\pi}} \exp\left[-\frac{1}{2}\frac{(x-\mu)^2}{\sigma^2}\right]$ Where μ and σ^2 are, respectively, the mean and variance of x. (Cambridge Dictionary of Statistics)
Outlier	A member of a set of values which is inconsistent with other members of that set. (CXG72-2009)
Parametric test/non-parametric test	Parametric tests assume the data follows a certain distribution model, which is mostly a normal distribution. Non-parametric tests do not assume the data have any particular distribution and can analyse data where no parametric test is applicable.
Percentile	The set of divisions that produce exactly 100 equal parts in a series of continuous values, such as concentration of a certain contaminant in food. For example, a sample with concentration above the 95th percentile has a higher concentration than over 95 % of the other contaminant levels. (Cambridge Dictionary of Statistics, modified for the purpose of this guidance)
Provisional Maximum Tolerable Daily Intake (PMTDI)/Provisional Tolerable Daily Intake (PTDI)	A type of HBGV. An endpoint used for contaminants with no cumulative properties. Its value represents permissible human exposure as a result of the natural occurrence of the substance in food and in drinking-water. In the case of trace elements that are both essential nutrients and unavoidable constituents of food, a range is expressed, the lower value representing the level of essentiality and the upper value the PMTDI. (CXS193-1995)

Term	Definition/Explanation
Provisional Tolerable Weekly Intake (PTWI)	A type of HBGV. An endpoint used for food contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods. (CXS193-1995)
Provisional Tolerable Monthly Intake (PTMI)	A type of HBGV. An endpoint used for a food contaminant with cumulative properties that has a very long half-life in the human body. Its value represents permissible human monthly exposure to a contaminant unavoidably associated with otherwise wholesome and nutritious foods. (CXS193-1995)
Quality assurance (in analytical laboratories)	All those planned and systematic actions necessary to provide adequate confidence that analytical results will satisfy given requirements for quality (CXG72-2009) There are a number of Codex recommendations on quality assurance based on the considerations by the Codex Committee on Methods of Analysis and Sampling (e.g., CXG27-1997, CXG28-1995, CXG64-1995, and CXG65-1997.)
Rejection rate/violation rate	Rejection rate (or violation rate) (%) = (number of samples with higher concentrations of a contaminant than ML)/total number of samples x 100.
Skewness	The lack of symmetry in a probabilistic distribution. (Cambridge Dictionary of Statistics)
Standard deviation	The most commonly used measure of the spread of a set of observations. Equal to the square root of variance s^2, that is given by the following formula: $s^2 = \frac{1}{n-1}\sum_{i=1}^{n}(x_i - \bar{x})^2$ where $x_1, x_2, \ldots, x_n$ are the n sample observations and $\bar{x}$ is the sample mean. (Cambridge Dictionary of Statistics)
Statistical power	In statistics, the power of a binary hypothesis test is the probability that the test correctly rejects the null hypothesis when a specific alternative hypothesis is true. The null hypothesis of Mann-Whitney U test or Kruskal-Wallis H-test is that each dataset comes from the same population.
Random sampling	Is a type of sampling. The term “random sampling” should be chosen for routine sampling, even if targeted at specific food types or specific importing countries. Testing a wide range of imported samples of a certain food category for the presence of a certain contaminant would be “random”
Targeted sampling	Is a type of sampling. The term “targeted sampling” should be chosen for follow-up sampling following specific findings of contamination. For example, if a country identifies a sample from a particular manufacturer as having high levels of a contaminant, additional sampling of the same lot or lots produced at the same time by the same manufacturer would be “targeted.

APPENDIX V

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