CODEX ALIMENTARIUS COMMISSION

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**Agenda item 15** **CX/CF 22/15/14**

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

**15th Session**
**Virtual**
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# GUIDANCE ON DATA ANALYSIS FOR DEVELOPMENT OF MAXIMUM LEVELS AND FOR IMPROVED DATA COLLECTION

(Prepared by the EU
as Chair of the Electronic Working Group)

## BACKGROUND

1. At the 12th session (2018)[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 electronic working groups (EWGs). These differences concerned for example the handling of occurrence data without information on limit of quantification (LOQ). A general guidance would help future EWGs to take consistent approaches for data analysis. CCCF agreed to establish an EWG chaired by the European Union (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 (2019)[2], the EU as chair of the EWG, informed the CCCF that it had 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 covered by the general guidance on data analysis for development of maximum levels (ML) was presented and CCCF agreed to extend the scope of the work to address improved data collection

3. At the 14th session (2021)[3], CCCF was informed that the discussion paper in the Annex to CX/CF 21/14/15 was prepared by the EWG Chair and that due to the very late availability of the paper, no consultation with the Co-Chairs and EWG members had taken place.

4. CCCF14 agreed that:

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

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

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

5. CL 2021/78 CF[4] was circulated in October 2021 with the request for comments on the guidance on data analysis for development of MLs and for improved data collection. The deadline for comments was 15 December 2021.

6. Comments in reply to the CL 2021/78 CF were received from Australia, Brazil, Canada, Chile, Cuba, India, Iran, Japan, Kenya, Republic of Korea, United Kingdom, USA, International Special Dietary Food Industries (ISDI) and International Council of Beverages Associations (ICBA) (details of the comments can be found in Appendix II).

[1] REP18/CF12, paras 155-156
[2] REP19/CF13, paras 156-165
[3] REP21/CF14, paras 186-210
[4] https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/

7. CX/CF 21/14/15 has been updated to consider 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 considering 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 document has not been shared with the EWG formed after CCF14. The document in Appendix I is the paper prepared by the EWG Chair and is provided for information only on its current status.

8. As outlined in paragraph 192 of REP21/CF14, input from the JECFA Secretariat providing concrete information on how the different topics mentioned in the draft guidance document are handled by JECFA when evaluating available occurrence data for exposure assessment is considered to be of important added value to the discussion. EHC 240 describes how JECFA handles occurrence data for exposure assessment. In addition, information from JECFA secretariat/experts on how the occurrence data are handled in practice would provide added value. It is also important to clarify that some aspects of handling of occurrence data for the purpose of exposure assessment under the responsibility of JECFA may be different from that for the purpose of ML setting under the responsibility of CCCF as risk manager.

9. Considering these developments, a virtual side event will be held before the plenary session to discuss the status of the document, and address key issues identified in paragraphs 10 and 11 to progress work on the guidelines, and next steps for the further development of the document. The outcomes of the discussion will be reported to the plenary session of CCCF. The content of the proposed guidance will not be discussed at the plenary session but is presented in Appendix I for information and to aid discussion on the key points identified in the paragraphs below).

**RECOMMENDATIONS FOR CONSIDERATION**

10. Consider the following topics:

a) The workplan for next year:

- Discuss holding three virtual working group meetings or webinars in 2022 to obtain input and to advance the document. For example, these could include a meeting with the GEMS/food database administrator to discuss possible changes to the database. An EWG meeting in a virtual format could allow for additional exchange of ideas among EWG members to develop the guidance.
- Discuss the possibility of three subgroups chaired by Co-Chairs and the division of the topics to be discussed in the three subgroups.
- Identify other suggestions that will facilitate completion of a draft for CCCF16.

b) Considerations for content of the guidance document

- The general goals/objectives of the guidance document with respect to providing guidance on improving data collection, data analysis, and data presentation. These goals/objectives would help guide the discussion on the scope and level of detail needed in the guidance.
- The structure of the guidance document to address the areas of data collection, data analysis, and data presentation (see § 11) and additional topics not considered in the Appendix I (topics from the Appendix outlined in §11).
- Identify topics, if any, which may require additional time to address by the working group and which are not expected to be finalised at CCCF16 for inclusion in this guidance document and may need to be addressed in an update to this guidance.

c) Agree to re-establish the EWG to elaborate the draft of a general guidance on data analysis for ML development and improved data collection considering the outcome of the discussion at CCCF15 for discussion at CCCF16 (2023).

11. Topics for structuring the guidance document:

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

**A. OCCURRENCE DATA COLLECTION /SUBMISSION**

- data generation and upload data to the GEMS/Food Database
- balance between need to provide additional detailed information and burden of submitting data to GEMS/Food database

**B. OCCURRENCE DATA ANALYSIS**

Extraction of data from the GEMS/Food database

- collaboration with GEMS/Food administrator
- select relevant food category and products
- select relevant period
- only GEMS Food data (or not)

data selection: clean-up of data

- data with missing information
- data with incorrect information (unit, expression basis)
- data from fraudulent practices/adulteration
- LOQ considerations (appropriateness of LOQ values, rate of data below the LOQ values, sum of values including those below the LOQ, etc.)

data analysis: generating overview of data

- overview which countries, how many data points, which years
- decision of sufficient geographical coverage of the available dataset
- decision on period coverage of the provided occurrence data

data analysis: statistical analysis

- minimum number of samples for reliable percentiles
- handling of datasets with low number of data
- handling of datasets with a large proportion of left censored data
- determination of outliers/extreme values and handling thereof
- generation of statistics/percentiles/distribution curves
- analysis of combined and individual datasets (per year, per region/country, per year per region?)
- decision on datasets with different contamination pattern, need to separate or not
- inclusion of analysis of rejection rates at hypothetical MLs
- inclusion of analysis of effects of hypothetical MLs on the reduction of dietary exposure?

**C. DATA PRESENTATION**

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

**APPENDIX I**
**ORIGINAL LANGUAGE ONLY**

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

**(For information)**

**PREAMBULE**

**To be completed: objectives, scope, general considerations, target users, …**

Framing of the guidance document in the existing principles and criteria – in that context reference can be made to the criteria for the establishment of maximum levels in food and feed related to analytical data as provided for in the Annex I to the Preamble of CXS 193/1995[1] e.g.

- **Validated qualitative and quantitative analytical data on representative samples** should be supplied. Information on the analytical and sampling methods used and on the validation of the results is desirable. A statement on the representativeness of the samples for the contamination of the product in general (e.g., on a national basis) should be added. The portion of the commodity that was analyzed and to which the contaminant content is related should be clearly stated and preferably should be equivalent to the definition of the commodity for this purpose or to existing related contaminant regulation.
- **Information on appropriate sampling procedures** should be supplied. Special attention to this aspect is necessary in the case of contaminants that may not be homogeneously distributed in the product (e.g., mycotoxins in some commodities).

**I) OCCURRENCE DATA COLLECTION /SUBMISSION**

**Reference is made to INSTRUCTIONS FOR ELECTRONIC SUBMISSION OF DATA ON. CHEMICALS IN FOOD AND THE DIET (update 7 December 2021):**

Available at: https://cdn.who.int/media/docs/default-source/food-safety/gems-food/gems-instructions-for-electronic-submission-of-data.pdf?sfvrsn=c79dd32c_7

**Important information to be provided when reporting occurrence data**

1) Information on the stage in production and production chain where the sampling took place (farm, wholesale, import, retail), year and location (country/region) of sampling. If known, origin of product sampled.
2) Information on application of relevant Codex Code of Practice, if known.
3) Information on type of sampling: targeted sampling, or random sampling; and factors that were considered when designing sampling plan.
4) Food and feed to be correctly identified, if the commodity is segregated as food or feed (if marked, indicated, or described in the accompanying document) and reported with detailed information on the food or feed concerned (correct identification, state of the food/feed (fresh, dried, ready-to-eat, etc.).
5) Information on the portion of food analysed (e.g., peeled or not, edible part or whole fruit, etc.).
6) Identification of analytes, and if appropriate their forms, free or conjugated.
7) The unit of the data measurement (e.g., µg/kg, mg/kg, mg/l), how data are reported (total versus individual) and the basis on which the data are expressed (e.g., fat basis vs whole weight).
8) Information on the methods of analysis (and their validation data) used for generating occurrence data with information on the LOQ/LOD of the method (and how the LOQ/LOD were derived).
9) Information on the accreditation status of the involved analytical laboratory.
10) Information on how levels of contaminants which were sum of compounds are calculated when one or more component(s) is (are) not quantified (lower bound versus upper bound).
11) Data should be provided to GEMS/Food.

[1] "Criteria for the establishment of maximum levels in food and feed" in Annex I of CXS 193-1995 General Standard for Contaminants and Toxins in Food and Feed

**It is very important that the call for data specifies data requirements related to specific food-contaminant data combinations:** what and how to provide exact information on the commodity analysed: for example, for rice important information such as grain, husked, grain, polished etc are provided in the field "local food identifier"; which is a free text field not making easy to sort data on this characteristic.

It is of major importance that information, important for filtering, sorting of data, can be provided in specific fields and does not have to be provided in the "comment field", "free text field".

**This section of the guidance should be completed, if appropriate, addressing the following topics (taking into account the comments received on CL 2021/78/CF)**

- **Important:** When considering the possible issues to improve the data collection, it is appropriate to ensure that the **entering data in the GEMS/Food database does not become overly burdensome**. When considering additional data fields, it is important that the field and the information requested to provide has a clear added value to the dataset (furthermore it needs to be specified if the new field is mandatory or optional).
- It is the responsibility of member countries to submit data to GEMS/Food database, however some member countries may **lack the resources for data collection and submission to GEMS/Food database**. This could be discussed and subsequent options to address this could be put forward by the EWG.

**Overall, it would be helpful if the GEMS/Food database guidance is more detailed, in particular, additional clarification as regards the different options in the dropdown menus (some specific examples, not exhaustive hereunder).**

- **Mandatory requirements on information to be provided:** in the GEMS/food database there are mandatory fields and optional fields; Is this, OK? Is there a need for additional fields? Is it appropriate to foresee that it would be impossible to upload data that does not contain all information for the mandatory fields?
- **Information on sampling point:** Appropriate to add such a field with dropdown menu with a non-exhaustive list: farm, wholesale, retail, food processing plant, …. However not relevant for all food commodities – so not as mandatory field.
- **Representative samples**: information must be provided if it concerns targeted sampling, random sampling or unknown. It is found necessary to provide for a clear definition of targeted sampling versus random sampling. However, this information relates to individual sampling results but does not provide information on how representative a dataset of individual random samples is to produce a certain food in a certain country/region.
- **Information on the sampling method:** is there a need to be able to provide in the GEMS/Food database more information on the sampling method?
- **Origin of the sample**: information is relevant for contaminants whose concentrations vary geographically. Field I in the GEMS Food Database provide for 4 options: domestic, imported, mixed origin or unknown. This might not be specific enough for the cases where concentrations might vary geographically.
- **Food and feed to be correctly identified and reported:** it could be appropriate to use descriptions as already mentioned in GSCTFF or descriptions already used in ongoing discussions. This could be specified in specific calls for data.

As regards the state of the food (field Q) of the GEMS/Food data base: it might be appropriate to provide more details on e.g., "as is", "as consumed", to avoid misunderstanding. In the case of reporting on the fat, it is appropriate to provide the fat content.

- **LOQ/LOD (field O and P):** should it be mandatory to report LOD or LOQ when numerical quantified results are reported? (Currently it is not)
  Would it be appropriate that LOD and LOQ requirements for data submitted to GEMS/food are specified in the call for data as standard practice?
- **information on the methods of analysis:** Current fields are foreseen related to methods of analysis (field M: Analytical Quality Assurance, Field O: limit of detection (LOD), Field P: Limit of Quantification.) Divergent views are expressed as regards the need for more details related the method of analysis: the method of analysis itself, qualitative or quantitative, etc.… (with additional fields).

**II) OCCURRENCE DATA ANALYSIS**

**A) Extraction of data from the GEMS/Food database**

- **collaboration with GEMS/Food administrator**
- **select relevant food category and products**
- **select relevant period**
- **only GEMS Food data (or not)**

**A1) Handing of the data not provided to the GEMS/food database**

In the future data that are not submitted to GEMS/Food Database cannot be used for e.g., the determination of the 95$^{th}$ percentile in the frame of discussing MLs. These data can only be used in a complementary analysis.

In any case these data can only be considered for further data analysis.

- In case there are only limited data available in the GEMS/food database, it could be considered useful to use these data in a complementary analysis.
- In case there are extensive data available in the GEMS/food database, these data are not to be used in further data analysis (they could only be considered for complementary analysis in case the data are from a region for which there are no or limited data available in the GEMS/Food database.

In case data used are not provided to the GEMS/Food database, these data must be assessed against basic criteria for data quality and validity and the relevant metadata must be provided to enable such an assessment.

**B) data selection: clean-up of data**

- **data with missing information**
- **data with incorrect information (unit, expression basis)**
- **data from fraudulent practices/adulteration**
- **LOQ considerations (appropriateness of LOQ values, rate of data below the LOQ values, sum of values including those below the LOQ, etc.)**

**B1) Lack of information on data provided**

In case all mandatory fields are completed (see SECTION I) and the data are allowed for uploading in the GEMS/Food database, data should as a rule not be excluded.

It must be considered to which extend the missing information makes the data unusable. In case of missing information, the submitting country should be contacted as first step to allow to complete the missing information. In case missing information is provided by the submitting country, the GEMS/Food administrator should be informed so that the provided information is also be introduced in GEMS/food database, and not only in the dataset handled by the EWG Chair.

However, no blanket rules should be set that may result in unnecessary exclusion: in case of limited data available, data with missing information might still be useful, also some missing information might not be necessary for the discussion on a maximum level in a certain commodity such as grains, beverages. Also, in certain cases some missing information can be deduced from other information provided. If the sample relate to dried paprika, then it is evident that the state of the food analysed is “dried” even if the Field S is not completed.

Examples of missing information by which data cannot be used for further data analysis:

- All data from a dataset are reported as < LOQ and the LOQ is not provided (more information in point 2 in Chapter D) (for information: as this is mandatory for upload in GEMS/food database, this situation might not occur when data used from the GEMS/Food database but could occur when considering data directly submitted to the EWG outside the GEMS/Food database)/.
- the unit in which the result is reported is missing or the basis on which the result is expressed
- the state of the food sampled (e.g., dried or fresh)

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, …
- method of analysis used

**B2) 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.**

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, these data should be excluded from further data analysis. Alternatively, the point of contact for the country that submitted the data can be contacted for corrections.

For some foods (e.g., fruits), if there are clear indications that the portion analysed is not clear (e.g., peeled vs whole fruit, or husked rice vs polished rice), these data should be excluded from further data analysis unless the necessary information is obtained.

In any case records must be kept from excluded data with rationale for exclusions and details on the data excluded (from a specific region, from a specific year, from a specific data submitter, ….)

Examples of "clear indications":

- 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 putting these data in a frequency distribution curve (see a) they would be identified as possible outlier.
- Levels from a food with a typical fat content of 5 % within a data set of 200 results of which all data are expressed on whole weight. 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. When putting these data in a frequency distribution curve (see a) they would be identified as possible outlier.

**B3) Data originating from suspected fraudulent/economically adulterated samples**

- In case certain data are clearly related to fraudulent/economically adulterated samples, these data should be excluded from the database and the exclusion must be documented.

**B4) Limit of Quantification (LOQ) considerations**

Several situations applicable to datasets provided can occur and the guidelines to be elaborated should provide guidance on how to handle the datasets in the different situations.

- No LOQ/LOD 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.

    LOQ 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 ML under consideration.

**Guidance for the abovementioned scenarios**

- In case no LOQ/LOD is provided for a specific dataset (the submitting country could be contacted as first step to allow to provide as yet the LOD/LOQ) or possibly only one of both).
- In case dataset contains (nearly) all quantified results (*need to define "nearly all", e.g., 90 %*?): the data set could be used.
- In case 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).

If most data in the dataset are below the LOQ, it is not possible to obtain scientifically appropriate high percentile values. When there are many values <LOQ and a smaller number of quantitative values, there is a need to consider whether it is appropriate to calculate high percentile values using only the quantitative values, which may result in unnecessarily high proposal for MLs.]

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).

**Levels of contaminants which are a sum of components and for which certain components are not quantified**

- 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. However, in such cases, information on the LOQ of the individual components of the sum must be provided.
- In specific cases, it can be appropriate that levels of contaminants that are a sum of components are to be reported as upper bound, but these cases should be clearly identified in advance before data submission.

**C) Data analysis: generating overview of data**

- **overview which countries, how many data points, which years**
- **decision of sufficient geographical coverage of the available dataset**
- **decision on period coverage of the provided occurrence data**

**C1) Geographical coverage of the provided occurrence data**

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

There should be at minimum a representativeness 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. 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 as the food has to comply with the requirements of the importing country. It might 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.

In addition to comments noted, the guidance could address whether geographical representation is needed in all cases, e.g., is it needed for foods produced and consumed primarily in a few clusters/regions.

**In case datasets lack geographic coverage:**

- the region(s) for which data are lacking is/are important production region(s):
    - on the condition of a clear commitment from producing regions, some additional years are allowed for data collection before continuing the discussion on ML. After expiry of the granted additional years, the discussion on ML is continued based on available data, regardless of geographic coverage has been reached or not.
- In case there is no commitment from the producing region(s) to provide the additional data, the discussion on ML is continued based on available data.
- the region(s) for which data are lacking is/are not important production region(s): the discussion on ML is continued based on available data.

**C2) Period coverage of the provided occurrence data**

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).

- For contaminants such as mycotoxins with a year-to-year variation, data from the last 10 years provide already a very good representation of the year-to-year variation.
- In case a Code of Practice has been established and implemented, the data under consideration should be from the years after the implementation of the code to reflect good practices.
- It can also be relevant in certain cases to perform time trend analysis and 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 a certain number of years of data to be used for ML elaboration to represent current concentrations.

**D) Data analysis: statistical analysis**

- **Minimum number of samples for reliable percentiles**
- **Handling of datasets with low number of data**
- **Handling of datasets with a large proportion of left censored data**
- **Determination of outliers/extreme values and handling thereof**
- **Generation of statistics/percentiles/distribution curves**
- **Analysis of combined and individual datasets (per year, per region/country, per year per region?)**
- **Decision on datasets with different contamination pattern, need to separate or not**
- **Inclusion of analysis of rejection rates at hypothetical MLs**
- **Inclusion of analysis of effects of hypothetical MLs on the reduction of dietary exposure?**

**D1) Minimum number of samples needed for the use of percentiles**

**Background information**

To apply the above criterion "*MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed*", (Annex I to the Preamble of CXS 193/1995), high percentiles are used to define that level. The reliability of high percentiles depends on the number of data used to calculate them. Percentiles calculated on a small number of subjects should be treated with caution as the results may not be statistically robust.

A clear indication concerning the minimum number of observations necessary to estimate a given percentile is not provided in literature. Different options can be used, none of them being a widely accepted standard.

A very simple option is to require that the calculated percentile must at least be different from the maximum value within the sample. This means that at least 20 observations are needed to identify the single observation at the $95^{th}$ percentile and 100 observations are needed for the $99^{th}$ percentile.

In statistics, the coverage probability of a confidence interval is the probability that the interval contains the true value of interest (e.g., 95th or 99th percentiles). When the number of observations is not large enough, the coverage probability may not attain the nominal value, and drops below, for example, 95%. This is more likely to occur at high percentiles, e.g., 95th or 99th. Therefore, the coverage probability has been used to set guidelines to determine the minimum number of samples for which (extreme) percentiles can be computed. In the case of significance level ($\alpha$) being set at 0.05 to determine a 95% confidence interval, the coverage probability should target 95%. In this case, this is achieved for $n \geq 59$ and $n \geq 298$ for the 95th or 99th percentiles, respectively.

In the case a (very) large proportion of the data are left-censored (left-censored date are data below detection/quantification limits), there might be a need to have more samples than outlined above. In this case it is decided to keep the datasets from different regions /continents separately, the minimum number of samples needed apply to each individual dataset.

**Guidance on minimum number of samples needed**

The minimum number of samples relates to the analytical data after possible exclusion of certain data (see above°

How to know the contamination pattern with this limited number of data? If limited number of data is to be considered, there should not be an analyses of subsets (e.g., by region)

Some guidance may also be available in the following documents:

- *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*
- *EFSA Journal, 2014. Guidance on the EU Menu methodology. 12(12):394*
- *NCHS 1996 - National Center for Health Statistics (NCHS), 1996. Analytic and Reporting Guidelines: the Third National Health and Nutrition Examination Survey, NHANES III (1988-94). https://www.cdc.gov/nchs/data/nhanes/nhanes_03_04/nhanes_analytic_guidelines_dec_2005.pdf*
- *CDC (2013). National Health and Nutrition Examination Survey: Analytic Guidelines, 1999–2010. (Vital and Health Statistics. Series 2, Number 161). Hyattsville (MD): Center for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). Available at: https://www.cdc.gov/nchs/data/series/sr_02/sr02_161.pdf*


**D2) Data sets with low number of data (e.g., less than 60) for development of ML**

In situations where it can be concluded that the data, despite the low number, are sufficient for the development of an ML (e.g., despite limited geographical coverage, no large variation in occurrence observed despite data originating from different regions/from different years, etc.), an ML could be considered. However, the setting of the ML should in that case not necessarily be based on statistical considerations but based on the analysis of the limited number of data available.

It is also to be observed that most of these cases where only limited data are available, relate to foods that are not commonly consumed and therefore do not fulfil the criteria that 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.

When at the occasion of the review of existing MLs, it can be observed that only few data /data from limited regions are available and it is (very) likely that no new data will be generated, the MLs should be revoked.

**D3) Using data sets with a large proportion of left-censored data for ML development**

In certain cases, the analytical results for one specific contaminant are produced with a battery of different analytical methods and/or the same analytical method but with very different sensitivities. Consequently, there could be a wide range of limits of detection (LOD) and limits of quantification (LOQ) for a particular contaminant and food matrix in a given dataset, composed of datasets from different sources. This situation is particularly relevant when the occurrence datasets used for the ML development contain a high ratio of non-quantified/non-detected data (left-censored data).

The standard approach to deal with left-censored data is the use of the substitution. In this method, at the lower-bound (LB), results below the LOQ and LOD are replaced by zero; at the upper-bound (UB) the results below the LOD are replaced by the numerical value of the LOD and those below the LOQ are replaced by the value reported as LOQ. Additionally, as a point estimate between the two extremes, the middle-bound (MB) scenario is calculated by assigning a value of LOD/2 or LOQ/2 to the left-censored data.

**(-** How to handle the (accepted) results < LOQ/LOD in datasets being used for ML elaboration. Should a lower-bound, a medium-bound or an upper-bound approach be followed for data < LOQ/LOD in the datasets to be used for ML setting? Can this be case specific? If so, in which cases which approach to be followed, e.g., indicate the proportion of positive results.
Or is the choice of lower-bound, medium-bound, or upper bound approach relevant for exposure assessment but not that relevant for handing datasets for ML setting.)

**D4) Determination of outliers/extreme values and handling thereof**

**What are outliers (extreme values)?**

There is no mathematical definition of what constitutes an outlier, and a clear distinction must be made between outlier and extreme values

- Determining whether or not an analytical result is an outlier is ultimately a subjective exercise
- Outliers can have many causes: 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)

There are different statistical tests to determine outliers However, in most cases they assume a normal distribution of the data which is frequently not the case for contaminants and are therefore in most cases not applicable.

Another (arbitrary) way is to visually inspect the data with a frequency distribution and identify those data which appear disconnected from the rest of the data → possible outlier.

There may be cases where extreme values are scientifically valid depending on production conditions and weather and other potential factors.

As there can be many causes for outliers and these values may be extreme values and not outliers if combined with data from other countries/region. → possible extreme value.

**The following stepwise approach could be followed in relation with extreme values/outliers (on certain aspects more details are provided in other parts of the guidance document)[2]**

The decision to exclude outliers from further data analysis is to be taken on a case-by-case basis thereby considering the following elements (not exhaustive)

*1. Generate frequency distribution curve using the data in question.*

*2. Determine the expected variability of the contaminant in the food in question.*

*3. Determine the geographic representativeness of the data submitted to ensure reasonable data are available across for the range of contaminant concentrations expected in the food.*

*4. Investigate data extremes to determine if possible outliers can be explained.*

*Outliers may include adulterated samples, incorrectly reported results (e.g., wrong units. expression of result, decimal separator, sample misclassification, non-food matrix*

*The EWG should contact the submitting country with any questions on potentially incorrect data, units, etc. for data submitted to GEMS/Food, to clarify any questions. In case of confirmation of errors by the submitting country the GEMS/Food administrator should be informed so that corrections to data should also be done in GEMS/food database, and not only in the dataset handled by the EWG chair.*

*If confirmed, it can be decided to exclude these data from further data analysis:*

- *Outliers (clearly) due to adulteration/fraudulent action → it can be decided, in consultation and agreement with the data provider/representatives from the respective country/region from where the data originate, to exclude these data from further data analysis.*
- *no valid justification can be provided for these extreme values) → it can be decided, in consultation and agreement with the data provider/representatives from the respective country/region from where the data originate to exclude these data from further data analysis.*
- *a valid justification can be provided for extreme values /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.*

*5. Assess the impact of outliers on the summary statistics (mean, median, upper percentiles).*

*6. Conduct an outlier test for data extremes that require further investigation. Statisticians should be engaged to recommend outlier tests suitable to the use of CCCF.*

**Another suggested approach to identify outliers is to follow a statistical evaluation approach, i.e., entries exceeding 75$^{th}$ percentile + 1.5 x interquartile range (IQR)**

A statistical evaluation of the raw dataset provides an objective approach to removing outliers and ensures that the analysis is not skewed by questionable data. The formula proposed – i.e., '75th percentile + 1.5*Interquartile range (IQR)' – is a standard approach to identify outliers used in statistical summaries. Other advantages the IQR approach provides are:

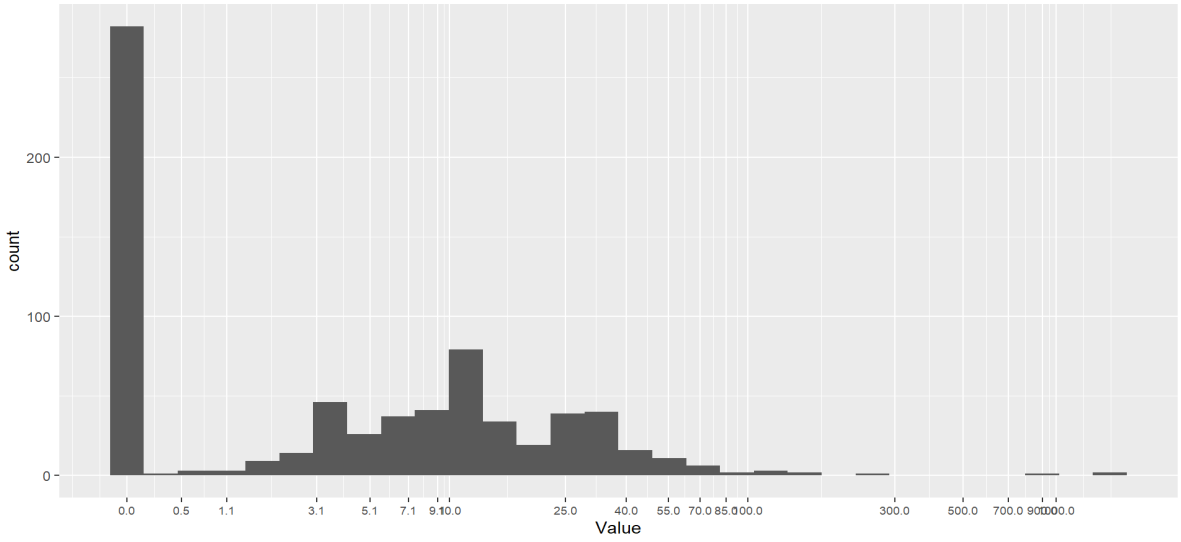
[2] In case this stepwise approach is maintained then it would be appropriate to cross-reference the different steps with other parts in this draft guidance in which more details are provided on certain steps.

- It is non-parametric and does not make assumptions about the distribution (particularly for datasets with smaller sample sizes).
- It is easy to compute and does not require complex statistical methods.
- It is typically not affected by non-detects.
- It does not rely on the arithmetic mean which may be affected by outliers.
- It has been shown to be more "conservative" than other methods in that it may allow some outliers in the distribution.

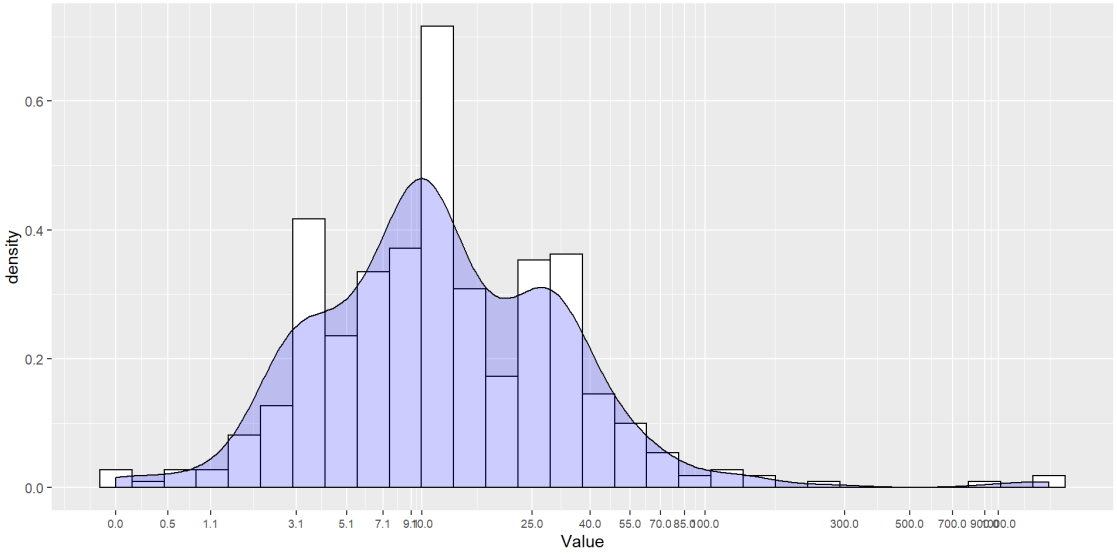
**D5) Generation of statistics/percentiles/distribution curves**

**Example EU data on sum of T-2 and HT-2 toxin in oat milling products (717 results of which 438 quantified results)**

**Histogram: all results**




**Histogram/density of quantified results**




In case no justification for the data with levels > 500 µg/kg can be provided, these data could be considered as outliers. This kind of outlier analysis can be valid only when the number of data is sufficiently large.

However, before coming to such a conclusion there should be clear decision rule and, in any case, it should be examined if there could be an acceptable justification for these "extreme" values, before deciding to remove these extreme data points.

Are these extreme values from a specific (period of the) year, from a specific region?
No data should be automatically excluded from a dataset and if excluded, the exclusion should be well documented (and scientifically defensible). See stepwise approach above.

**D6) Handling of datasets with a different contamination pattern (e.g., as consequence of originating from different regions, different production years)**

- Datasets from different regions/continent in the world might show a different contamination pattern and a valid reasoning for the difference can be provided (e.g., different climate conditions, different production conditions (including soil conditions) /techniques), local regulations).
- In certain situations, the datasets could be kept separate for assessment. This must be determined on a case-by-case basis as different contamination patterns are typically dependent on a specific commodity being examined and a rationale for the separate treatment of the datasets should be provided.
- If the combined dataset shows a multimodal distribution, it may be beneficial to keep the data separate for statistical assessment.
- For comparing the data from different regions or from different years, use of non-parametric tests, such as Mann-Whitney U test or Kruskal-Wallis H-test, are useful. If there are no significant difference between data, the dataset can be combined for assessment.

## III. DATA PRESENTATION IN EWG REPORTS TO CCCF

It is important that the data are represented in such a way in the EWG report to CCCF to enable an informed discussion on appropriate MLs to be established. This means that the data are reported with inclusion of all assumptions (see section II), e.g., how many data were excluded and the reasons why, how left censored data are managed, were data outside GEMS/Food database considered etc, accompanied with a detailed rationale.

The detail of reporting depends on the amount of data available and of the nature of the contaminant.

**Elements of consideration for the reporting of data (not exhaustive)**

- If there is a significant year-to-year variation in occurrence, it is appropriate to provide an analysis of the data per year and in case of a significant difference in contamination pattern, the analysis should consider presenting data by geographical region.
- If there is a significant difference in contamination pattern between regions for causes, such as climate conditions or production methods, it is appropriate to provide an analysis per region or continent of the data per year.
- It is important to present summary data for all individual foods within a food group, in addition to summary data for the broader group. This type of analysis allows for an understanding how a proposed ML impact the individual foods and to determine if the setting of an ML for a broad food category is more appropriate than setting an ML for individual foods within the broad category. The description of the data should provide a clear view on the data set e.g.:
    - Number and proportion of positive (quantified results).
    - Mean, median and range of positive results and standard deviation.
    - P90, P95, P99 (and/or any relevant percentile values).
    - histograms/density of positive results.
- The impact of ML by geographical area could be considered.
- Presentation could also cover the recommended ML and the next nearest MLs (higher or lower) showing how the data are affected, what is the rejection rate (% of data above the hypothetical MLs).

It is important to present summary data for all individual foods within a food group, in addition to summary data for the broader group.

## IV) POSSIBLE TOPICS FOR <u>FUTURE</u> DISCUSSION FOR POSSIBLE FUTURE INCLUSION IN THE GUIDANCE ONCE CONCLUDED

**1) Identification of appropriate rejection rates in ML establishment**

At the 13$^{th}$ session of CCF it was clarified that the basis on which the MLs should be proposed (i.e., rejection rate, occurrence data and reduction risk) was outside the scope of the guidance (§ 162, REP19/CF)

However, there is the explicit request to the CCCF in relation with the discussion on MLs for lead and total aflatoxins whether different rejection rates should be applied for different types of products and contaminants. Therefore, CCCF might agree that it is appropriate to provide in this guidance, elements which should be considered to define the appropriate rejection rate. This should increase the transparency on the basis on which grounds a maximum level has been set.

Possible elements for consideration (not exhaustive):

- Nature of the product:
    - raw cereals of which already large part is used for feed: non-compliance with the food ML might not necessarily result in economic damage as it can still be used as feed.
    - processed products intended for human consumption: non-compliance with the food ML will result in economic damage as possible alternative uses will result in lower return or in certain cases the lot must be destroyed.
- Different regional contamination patterns:
    - worldwide dataset might have a rejection rate lower than 5 % at a certain ML while regional datasets might have for the same ML much different (lower or higher) rejection rate.

**2) Appropriateness of GEMS/Food market-based cluster diets for ML elaboration.**

**APPENDIX II**
**ORIGINAL LANGUAGE ONLY**

**Comments in reply to CL 2021/78-CF**

*Comments of Australia, Brazil, Canada, Chile, Cuba, India, Iran, Republic of Korea, United Kingdom, United States of America (USA), International Special Dietary Foods Industries (ISDI)*

**Background**

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/78-CF[1] issued in October 2021. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

**Explanatory notes on the appendix**

2. The comments submitted through the OCS are presented in table format.

3. In addition, comments from Kenya, Japan, and the International Council of Beverages Association (ICBA) were received outside the OCS and are hereby included for completeness

[1] Codex circular letter, including CL 2021/89-CF, are available on the Codex webpage/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/
or on the dedicated Codex webpage/CCCF/Circular Letters:
http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF

**GENERAL COMMENTS**

| COMMENT | MEMBER/OBSERVER |
|---|---|
| Brazil thanks the opportunity to contribution the CL2021/78-CF Request for comments on the topics identified in relation to the guidance on data analysis for development of maximum levels and for improved data collection.<br>We observe that there is a focus on how data should be submitted to GEMS/FOOD Database. Some of the requirements listed are already on the Procedural Manual. Regarding submitting to the Database, perhaps a training would be a good approach so that there are more quality data available that can be handled.<br>Although we agree that the document should give instructions of how to improve data submitted, the document should also give recommendations of how the data available should be analysed. We suggest that the information should be divided into three sectors: how to submit data; how to analyse data available; how to present the data available.<br>We observe that today some information listed as requirements (validated data, representative samples), are today not obligatory information and many data available do not give information about those. | **Brazil** |
| The guidance being prepared on data collection, analysis and presentation and should indicate that all assumptions, methods and decisions on these topics that are employed by any EWG should be clearly documented in all discussion papers.<br>As per paragraph 208 of REP21/CF, CCCF14 agreed:<br>i) that the work should be focused on data collection, data analysis and data presentation as a priority in the coming year and that discussion on elements for consideration such as appropriate rejection rates would not be taken up for now. Therefore, the scope of the discussion paper being prepared in advance of CCCF15 should include only items B) through E) of this document.<br>Canada suggests that the discussion paper be organized in sections that reflect the scope agreed upon by CCCF14, i.e.:<br>(i) occurrence data collection (topic A of this document)<br>(ii) occurrence data analyses (topics C&D of this document)<br>(iii) occurrence data presentation (topic E of this document)<br>An Annex could be added to the discussion paper which maintains a list of “Other Topics for Possible Future Consideration” (e.g. topic F of this document (rejection rates)). | **Canada** |
| Cuba apoya los documentos que tienen en cuenta las cartas circulares CL 2021/78-CF yla CL/CF 21/14/5 | **Cuba** |
| The UK appreciates the work on the guidance on data analysis for development of maximum levels and welcomes the opportunity to make the following comments in relation to the work already carried out to date on this important area | **United Kingdom** |
| Thank you for the opportunity to comment on CL 2021/78-CF requesting comments through the Online Comment System (OCS) on the topics identified in relation to the guidance on data analysis for development of maximum levels and for improved data collection. We look forward to further development of this guidance as one of the co-chairs of the working group. | **USA** |

**SPECIFIC COMMENTS**

**A) CRITERIA FOR THE ESTABLISHMENT OF MAXIMUM LEVELS IN FOOD AND FEED[1]**

| COMMENT | MEMBER/OBSERVER |
|---|---|
| • Australia agrees that an introductory section dealing with general criteria is very useful, however queries whether the heading could be renamed 'Criteria for analytical data for the establishment of maximum levels in food and feed', as a more accurate reflection of the subject of this guidance document.<br>• It is important to be conceptually consistent with the principles for establishing MLs described in the Codex Procedural Manual.<br>• It is noted that the information in Section A has been copied directly from Annex I of CXS 193-1995. However, some of that information may not be considered directly relevant for this guidance. For example, the sentence "foods that are evidently contaminated by local situations or processing conditions that can be avoided by reasonably achievable means shall be excluded in this evaluation" is not a relevant consideration in this instance, as this guidance document will focus on the collection and analysis of data.<br>• It might also be useful to clarify that this guidance includes a consideration of occurrence data only, and does not cover issues related to consumption data.<br>• It should also be noted that the breadth of information captured in association with a particular dataset is going to be dependent on the data entry fields currently included on GEMS data. | **Australia** |
| What would representative samples be?<br>On GEMS FOODS this information is relative to sampling (random, target and unknown). Is it a recommendation to improve the Database? How this information would be submitted and further analyzed?<br>How the validated method would be reported on the database? Today the database does not define how to report information about the validation of the method. Even if the data are qualitative and quantitative validated, it does not mean that they are reliable. Today the Database contemplates a space to report if the laboratory is accredited and if the sample is representative, but these information are not obligatory and it is possible to upload data without them.<br>The database gives information about individual results. How the information about representativeness would be submitted?<br>It would be important to define which information should be considered as requirements and the results should therefore not be upload lacking those and which should be considered as desirable. It would also means that data available today that doesn't have information considered as requirement should not be considered when data are analyzed. | **Brazil** |
| This information is available on the field "representativeness" of the GEMS FOOD Database as random sampling, target and unknown. If the aim is to have other kind of information, there should be an explanation about what should be supplied and how this information would be reported. Also, it is important to define how the Committee should handle the information. | **Brazil** |
| Rejection rates should also be considered<br>Brazil wonders if this means that local contamination will not be considered or only if there is an environmental issue (oil leak, for instance). Perhaps a difference should be made related to permanent contaminations due to local characteristics of the soil or if there is an environmental issue. | **Brazil** |

| COMMENT | MEMBER/OBSERVER |
|---|---|
| A reflection should be made on the situations where even after several calls for data, the data are not still global representative. On these cases, how to handle? For example, MLs for aflatoxins on cereals were discussed on several occasions and even after several call for data the data is still not global representative<br><br>What sources means here? The process?<br><br>The focus should be on the main areas that produce or export | **Brazil** |
| Why not 0.20 for example? If ML is set at 0.2, it is acceptable results that are higher than 0.15.<br><br>While we understand that this comes from CXS 193-1995, why not consider an arithmetic scale?<br><br>For example, for aflatoxins in cereals, MLS proposed are on the range of 20 mcg/kg. If a geometric scale is considered, this would mean for example considering MLS of 20, 10, 2. However, if an arithmetic scale is considered, we could analyze MLS of 20, 15, 10, 5, which seems more reasonable. | **Brazil** |
| As per footnote 1 of this document, Annex I of the GSCTFF provides detailed criteria for the establishment of MLs in food. Most or perhaps all of Section A) of this document is taken directly from that Annex and would only need to be generally referenced. Rather than including section A, the discussion paper could cite specific criteria from Annex I of the GSCTFF, as needed, under the relevant sections:<br><br>(i) occurrence data collection<br>(ii) occurrence data analyses<br>(iii) occurrence data presentation | **Canada** |
| In relation to the request of information regarding sampling procedures, it will be convenient to ask for this data though specific options available in the GEMS/Food spreadsheet, if this is possible, in order to uniform this information. | **Chile** |
| The text is proposed to be amended as follows:<br><br>"MLs should be set as low as necessary to protect the consumer. Providing it is acceptable from the toxicological point of view, MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed that are produced with current adequate technological methods, in order to avoid undue disruptions of food and feed production and trade. Where possible, MLs should be based on GMP and/or GAP considerations in which the health concerns have been incorporated as a guiding principle to achieve contaminant levels as low as necessary to protect the consumer. Foods that are evidently contaminated by local situations or processing conditions that can be avoided by reasonably achievable means shall be excluded in this evaluation, unless a higher ML can be shown to be acceptable from a public health point of view and significant economic aspects are at stake."<br><br>Rationale: Primary criteria for establishment of MLs should be based on the outcome of food safety risk assessment. Achievability at levels lower than those necessary to protect consumer based on risk assessment should not be the primary criteria for establishment of MRLs because this would result in increase in food waste without any gain in food safety. | **India** |

| COMMENT | MEMBER/OBSERVER |
|---|---|
| Maximum Levels should be:<br>1. Sufficiently low to – Protect the health of consumers; and – Prevent "bad practice", such as mixing the non-compliant food with the compliant food for selling (ethical problem)<br>2. Sufficiently high to – Protect honest farmers/manufacturers following the "good practice" – Be able to be analyzed (MLs must be higher than the LOQ of the method according to codex manual) | **Iran** |
| Where these qualitative methods are used, information on the sensitivity and reporting levels should be included and be clear when submitting data | **United Kingdom** |
| The paper covers two general areas, which should be clearly separated:<br>(1) improvements suggested to GEMS (e.g., new data fields and new guidance) and<br>(2) guidance for data submitters and users. Topic 1 might be best placed in the Introduction or Recommendations to CCCF. | **USA** |
| This section contains information directly from the GSCTFF. If included, this text should be clearly indicated as coming from the GSCTFF. It may be best placed in the Introduction. Another alternative is to cite the GSCTFF (and/or the Procedural Manual) as having relevant information, but to not repeat the material in this guidance. | **USA** |
| CXS 193-1995 defines many principles for the establishment of MLs, many of which are captured within this proposed guidance document. However, it should be noted that while the principles captured here may be the most relevant for this discussion, that all of the principles outlined in CXS 193-1995 are applicable for this discussion. | **International Special Dietary Food Industries** |

**B) IMPROVED DATA COLLECTION**

| COMMENT | MEMBER/OBSERVER |
|---|---|
| Australia queries whether there is scope to restructure/expand Section B, to consider good data management practices under specific headings such as sampling and analysis; data collection; data entry etc., to help highlight the fact that the accurate and comprehensive recording of data and associated metadata is an essential component from the very start of the process | **Australia** |
| Some information like local food name are submitted on other languages than English and are discarded. Although we understand that some information cannot be translated (ie feijoada, tapioca), it may be advisable to translate whenever possible to english.<br>For example, when analyzing aflatoxins on rice, some data are submitted as rice on the food category and details such as if it is grain, husked, etc. are described on the column "local food name" on languages others than English.<br>This could be an instruction to better submit data on the GEMS FOOD Database.<br>We consider that perhaps there should be an advice that call for data should instruct how the information should be submitted. | **Brazil** |
| All the information that would be considered as important should be stated as recommendations to improve the GEMS FOOD Database in order to create columns for the specific information. Otherwise, submission will include on the column remarks, which is difficult to handle | **Brazil** |
| What does suspect sampling means? All those options will be used to set MLs? Would be any difference when handling data? | **Brazil** |
| A reflection should be made if the sample is analyzed "dried weight", water content should be also informed? | **Brazil** |
| Today this information is not required, so many samples do not have either LOD nor LOQ if a numerical result is reported. | **Brazil** |
| It should be a clear differentiation between outliers and extreme values. In order to better understand the impact of data removal and how to work with them, Brazil presents some considerations at the end of this document. Lead data from the past 10 years were extracted from the GEMS FOOD Database by the WHO secretariat for the categories for which we are working on the ewg to establish ML for lead. The data for one specific food category (spices) were analysed in deep to see the impact of removing outliers. Considering the information provided further on the document, we are of the view that the work of the EWG should discuss how to identify outliers and extreme values and how to proceed with the withdraw of these values. The elimination of outliers on the dataset tends to correspond to a removal more important to the one that is currently done by CCCF (i.e up to 5% rejection rate). This could generate a huge impact on some countries. In this sense, it should be considered whether only the application of the 95 percentile would be enough. Also, many of the values may be associated with various factors (natural environmental contamination, different stages of COP application, environment condition and not only fraud). | **Brazil** |
| There may be case-specific data requirements for some food-contaminant data combinations. As noted in paragraph 195 of REP21/CF, the important elements to be provided when reporting occurrence data should be specified in Calls for Data to the GEMS/Food database. For example, information on the food packaging material may be requested for food contaminants that originate from food packaging. | **Canada** |

| COMMENT | MEMBER/OBSERVER |
|---|---|
| Many of the items listed in B) 1-6 under 'Improved Data Collection' are already fields in the GEMS/Food database that need to be populated when data are submitted.<br>The EWG should be solicited for any key additions or changes to the fields already included in GEMS/Food.<br>Canada suggests that the following additional fields may be considered useful when data are submitted to GEMS/Food: country of origin, single or composite sample, date the sample was harvested or manufactured, as applicable.<br>Any additional data fields or information requested when submitting data GEMS/Food should add clear value to the dataset. As data are often lacking for MLs being considered for elaboration by CCCF, additional information requirements should be considered carefully so that potentially useful data are not excluded from the GEMS/Food database. Any additional fields of information should be clearly indicated as being either 'required' or 'optional, upon availability', when information to populate the fields is available. | **Canada** |
| Including information on country of origin of the sample would be useful, particularly for contaminants whose concentrations vary geographically.<br>Specifying where sampling took place is likely less useful on a global scale, where terminology and steps in the production chain may differ, than specifying the state of the food.<br>The descriptions of the state of the food should be developed in consideration of:<br>i) descriptions already used in the GSTCFF (e.g. DON ML for cereal grains that are 'Destined for further processing');<br>ii) descriptions currently being discussed by CCCF for ML elaboration (e.g. lead MLs for cereal-based foods for infants and young children on an 'as is', 'dry matter' or 'as consumed' basis); and<br>iii) previous challenges CCCF has encountered when trying to determine the basis of the food residue data submitted to GEMS/Food (e.g. tea leaves versus tea-based beverages, as consumed).<br>Descriptions should be clear and encompass the terminology used globally, when possible.<br>Describing the state of the food for which data should be submitted to GEMS/Food at the outset of any Call for Data should become standard practice, if possible, and would help ensure Codex members collect and submit data that are useful for ML elaboration. | **Canada** |
| The types of sampling (e.g. targeted, suspect, random) should be clearly defined and should encompass the terminology used globally, if possible. | **Canada** |
| The EWG should provide guidance, in consultation with CCMAS, as needed, regarding if the method of analysis and/or the LOQ, LOD and other performance criteria are required. CCCF is currently developing a sampling plan for aflatoxins in cereals and there is a discussion around performance criteria, in that if performance criteria are established, there may not be a need to also recommend specific analytical methods.<br>Specifying LOD and LOQ requirements for data submitted to GEMS/Food at the outset of any Call for Data should become standard practice, if possible, and would help ensure Codex members, particularly producing regions, collect and submit data that are useful for ML elaboration. | **Canada** |
| In relation to the request of information regarding method of analysis and its validation, it will be convenient to ask for this data though specific columns available in the GEMS/Food spreadsheet, beside the LOQ and LOD columns that the spreadsheet already has, in order to uniform this information. | **Chile** |

| COMMENT | MEMBER/OBSERVER |
|---|---|
| Year of occurrence (or sampling) is an important basic element for which data is selected. It should be included as one of important elements to be provided when reporting occurrence data (currently not included). | **Republic of Korea** |
| There may be a number of sampling points that could be represented as a non-exhaustive list i.e. (e.g. farm, wholesale...) | **United Kingdom** |
| • General comments: The EWG should consider what can be provided readily and what is only a "best case" scenario (i.e., mandatory/optional). Entering data in GEMS/Food should not become overly burdensome. Many problems can be addressed by developing clearer GEMS guidance and pull-down menus. | **USA** |
| • Would require new GEMS fields and may be burdensome. Would be useful for particular commodities like grains or nuts, but not for finished foods, so should not be mandatory. | **USA** |
| • It is not clear how this information would be used. Most data come from compliance programs and target commodities of interest. Definitions of "targeted", "suspect", and "random" may vary by country. | **USA** |
| • Food vs feed: If clearly labeled as food or feed, identify as such in product name or remarks. It may not be possible to identify raw grains as food or feed as they may not be marked for one or the other use.<br>• State of food: "as is" and "dried matter" should be reported separately and clarified, based on discussion at CCCF14. An explanation to GEMS drop down menu should be added.<br>• State of food: Information from the label such as percentage of food (e.g., cocoa solids), major ingredients for mixed foods, etc., may be helpful but should not be mandatory. | **USA** |
| • Clarify dropdown menus and provide more detailed GEMS guidance. | **USA** |
| • Does this mean include a column in GEMS on method used for analysis, such as AOAC 2015.01, or a general distinction such as "ICPMS" vs. "atomic absorption"? The EWG should clarify how this information would be used.<br>• Validation studies – Is the expectation that future EWGs will review reported methods and validation studies? This seems beyond the means and time constraints of EWG operations. If method review and validation is required, it will have to be linked to GEMS submissions. | **USA** |
| Additional guidance may be helpful in regards to "as-is" versus "dry weight basis". It may also be helpful to encourage reporting of data "as-is" to better reflect concentrations in the commodities that are traded | **ISDI** |

**C) HANDLING/ACCEPTANCE OF DATA WITHIN A DATASET**
**D) IMPORTANT TOPICS TO BE CONSIDERED FOR DATA ANALYSIS**

| COMMENT | MEMBER/OBSERVER |
|---|---|
| 1) Regarding outliers and the sentence, "In case the data are outside the range of distribution of the data and no justification can be provided for these extreme results (such as data from a year with extreme weather conditions, data from a specific region/continent, …)" - Australia queries whether there is currently any capacity to record details such as extreme weather conditions in GEMS at the present time and, if not, it is unlikely that this sort of information would be available to the eWG to inform its assessment.<br>2) Regarding data not in GEMS, Australia would like to suggest some further commentary here advising that for any data not currently in GEMS, it would still need to be assessed against basic criteria for data quality and validity before being used, and the relevant metadata would need to be provided to enable such an assessment.<br>3) Regarding data sets with different contamination patterns, Australia suggests that this section may be better placed under Section D, as it is not so much about handling data where there are issues, but more about the most appropriate way the eWG should assess the data. In this way, it may fit well with other similar topics under Section D, namely 4) Geographical coverage of the provided occurrence data, and 5) Period coverage of the provided occurrence data.<br>It is also It is important to note that a consideration of data based on different contamination patterns is typically dependent on the particular commodity being examined. For example, for cadmium in cocoa, it was important to assess regional datasets separately, due to differences in cadmium concentrations due to different cultivation soils. | **Australia** |
| How this value was defined? Only looking on the histogram?<br>Would a normal distribution always be considered? Non parametrical distribution should be considered on specific cases with heterogenic distribution. For mycotoxins, for example, a blox plot could be used to consider outliers.<br>If outliers are removed and after a rejection rate is considered, this could remove more than 5% of the samples on the market.<br>A definition should be done about outliers: extreme values? Incorrect reports?<br>An analysis about these outliers should be included…they are all from one region? From one period of the year or a specific year? | **Brazil** |
| Results that are submitted as < LOQ, LOQ information is necessary and the Database does not permit submission. However, in some cases the results are reported as < X, but LOQ or LOD is not reported.<br>In cases numerical results are reported, information about LOD or LOQ are not reported. On these situations, it is not possible to affirm that the results are < LOQ or > LOQ | **Brazil** |
| There is no column on GEMS FOOD Database about the method. Is there a recommendation to insert this? | **Brazil** |
| For the future, all data should be submitted to GEMS FOOD. Data not provided to GEMS FOOD should not be considered.<br>On the documents that are already being considered by CCCF, data that have already been submitted may be considered as exception | **Brazil** |
| What data? Data that are not on GEMS FOOD? | **Brazil** |

| COMMENT | MEMBER/OBSERVER |
|---|---|
| Datasets extracted from GEMS FOOD Database.<br>Perhaps this section should be elsewhere. | **Brazil** |
| Is this a recommendation that in all cases the dataset should considerer different regions to see if there is a difference in the contamination pattern to after define if the dataset should be considered as a whole or split? This include the soil characteristics of the region?<br>It will be considered to set ML…or it will mean that different MLs will be set for different climate conditions? | **Brazil** |
| There is no consideration regarding the type of the distribution. If the distribution is not normal, will this minimum number of samples required be the same?<br>In left censored data, the minimum number required may be higher.<br>This minimum number is applicable to the whole database or also for region datasets? | **Brazil** |
| We believe that information about LOD and LOQ are always important because this allows to verify the consistency of the results reported. In this sense, there should be a recommendation that at least one of these fields should be mandatory when submitting data to GEMS FOOD.<br>LOD and LOQ are also important to analyze the possibility to apply the proposed ML globally. | **Brazil** |
| If the data available today do not contain information about LOD or LOQ, there should be a recommendation on how to handle data considering the two different situations mentioned. | **Brazil** |
| Yes. There should be a guidance on how to handle these cases considering the performance criteria of the Procedural Manual. The second and third bullets may be considered together. | **Brazil** |
| Regarding the performance criteria, the conclusions on how to handle both datasets should be the same. | **Brazil** |
| All of them should be used? One method should be preferred considering the proportion of results < LOD or the consideration should be done considering the specific case?<br>The guidance should stablish when to use each of these methods. | **Brazil** |
| There should be at minimum a representativeness of production regions that are important to international trade. A consideration should be done in relation to the origin of the data provided. If the origin of the data is provided and are related to the main production areas.<br>Geographical coverage is desired. However, it should be discussed how to handle situations where data are not provided from important regions even after several calls for data. | **Brazil** |
| Using data for the last 10 years may already cover the year to year variation.<br>If a COP is stablished, data should be collected X years after the implementation and considering that the best practices are in use | **Brazil** |
| How to know the contamination pattern with this limited number of data?<br>If limited number of data is to be considered, there should not be an analyzes of subsets (e.g. by region)<br>The discussion here should be linked to the discussion related to “Minimum number of samples needed for the use of percentiles “ | **Brazil** |

| COMMENT | MEMBER/OBSERVER |
|---|---|
| Statisticians should be engaged on all topics covered in Sections C) and D) in order to ensure that all the necessary factors are considered and that a single approach, or case-specific approaches, if needed, are developed in order to ensure that all the necessary factors are considered for the various food-contaminant combinations evaluated by CCCF (e.g. datasets with different contaminant distributions, sample sizes, detection rates).<br>Statistical expertise will vary between EWGs, and that any guidance should be very clear and consider the ease of any necessary computations. | **Canada** |
| Canada supports the action discussed at CCCF14 (2021) and outlined in paragraph 192 of REP21/CF, that the JECFA Secretariat will provide information on how outliers and extreme values, as well as other issues of data analysis as indicated in this circular letter (CL_2021-78-CF), are handled by JECFA when evaluating available occurrence data for exposure assessments.<br>Some guidance may also be available in:<br>• International Programme on Chemical Safety, 2009. Principles and Methods for Risk Assessment of Chemicals in Foods. Environmental Health Criteria (EHC) 240. (Canada believes EHC 240 is in the process of being revised). | **Canada** |
| No data should automatically be excluded from a dataset. If data are excluded from a dataset this should be scientifically defensible and well-documented.<br>Heterogeneous contaminant distributions in a food (common in mycotoxins in grain) and year-to-year variation due to, for example, climate change, weather conditions and geographic variation, are not reasons to remove data from occurrence datasets without careful consideration and scientific rationale.<br>Canada suggests that criteria used to assess and handle data extremes be developed. These criteria could then be applied by EWGs tasked with assessing if datasets are fit for purpose.<br>A step-wise process could possibly include the following:<br>1. Generate frequency distribution curve using the data in question.<br>2. Determine the expected variability of the contaminant in the food in question.<br>3. Determine the geographic representativeness of the data submitted to ensure reasonable data are available across for the range of contaminant concentrations expected in the food.<br>4. Investigate data extremes to determine if possible outliers can be explained.<br>Outliers may include: adulterated samples, incorrectly reported results (e.g. wrong units - see Section C) 2).<br>The EWG should contact the submitting country with any questions on potentially incorrect data, units, etc. for data submitted to GEMS/Food, in order to clarify any questions.<br>5. Assess the impact of outliers on the summary statistics (mean, median, upper percentiles).<br>6. Conduct an outlier test for data extremes that require further investigation. Statisticians should be engaged to recommend outlier tests suitable to the use of CCCF. | **Canada** |
| When the reporting units are in question, the submitting country should be contacted as a first step. | **Canada** |
| When certain sample information is missing in GEMS/Food, the submitting country should be contacted as a first step. | **Canada** |

| COMMENT | MEMBER/OBSERVER |
|---|---|
| Canada agrees with the statement in paragraph 197 of REP21/CF, that in order for data to be used to support CCCF ML elaboration, it must be submitted to the GEMS/Food database. | **Canada** |
| Clear guidance should be developed as to the minimum number of samples required to establish MLs for contaminants in food.<br>This will require knowledge of the variability of the dataset as well as other factors, e.g. coverage probability of the confidence interval.<br>Some guidance may also be available in the following documents:<br>• 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<br>• EFSA Journal, 2014. Guidance on the EU Menu methodology. 12(12):394<br>• NCHS 1996 - National Center for Health Statistics (NCHS), 1996. Analytic and Reporting Guidelines: the Third National Health and Nutrition Examination Survey, NHANES III (1988-94). https://www.cdc.gov/nchs/data/nhanes/nhanes_03_04/nhanes_analytic_guidelines_dec_2005.pdf<br>• CDC (2013). National Health and Nutrition Examination Survey: Analytic Guidelines, 1999–2010. (Vital and Health Statistics. Series 2, Number 161). Hyattsville (MD): Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS). Available at: https://www.cdc.gov/nchs/data/series/sr_02/sr02_161.pdf | **Canada** |
| 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).<br>Canada supports that guidance be developed regarding how to handle datasets when an LOQ is and is not provided, under the various scenarios outlined in Section D)2) of CL_2021-78-CF. | **Canada** |
| Canada supports that guidance be developed as to how results < LOQ (non-detected results) are handled in datasets being used for ML elaboration. This guidance should indicate the proportion of positive results in a given dataset that should lead to the use of 0, 1/2 or LOD or LOQ values, or a combination thereof.<br>Guidance should also be provided regarding if there are any situations in which the LOQ or ½LOQ should be used as the substituted value instead of the LOD or ½LOD. | **Canada** |
| Countries submitting data to GEMS/Food should ensure that the submitted data are as nationally representative as possible.<br>Trend analysis could be conducted by the EWG of datasets from different regions so that it can be determined if concentrations vary geographically. If different geographic contamination patterns are identified, the EWG should endeavor to explain the cause(s) (e.g. climatic conditions, soil characteristics, good agricultural practices (GAP) or good manufacturing practices (GMP) not followed), which would help facilitate a decision regarding if certain data are used for ML elaboration. If identified geographic differences cannot be explained, then guidance should be provided regarding if the questionable data should remain part of the dataset used for ML elaboration.<br>Canada supports that consideration be given to the statement in paragraph 200 of REP21/CF, which indicates that, when possible, data from producing regions should be given priority as data for imported foods may be biased if the food has already complied with requirements of the importing country.<br>Perhaps CCCF can offer support to producing countries to submit necessary data, e.g. by allowing more time for data collection, if needed, providing guidance on the number of samples required for which foods, etc.<br>It is the responsibility of member countries to submit data to GEMS/Food, however some member countries may lack the resources for data collection and submission to GEMS/Food. Canada questions if this should be considered in the discussion and subsequent options put forward by the EWG. | **Canada** |

| COMMENT | MEMBER/OBSERVER |
|---|---|
| Criteria would need to be developed to determine if datasets lack geographic coverage. In datasets lacking geographic coverage, options on a path forward would need to be laid out. In certain cases in recent years, CCCF has allowed for additional years of data collection in order to allow for more geographically representative data to be submitted. For example, in the case of aflatoxins in cereal grains, if no further data are provided existing datasets will be used to progress the ML (REP21/CF, paragraph 137 ii) and iii)). | **Canada** |
| Typically, the most recent 10 years of data are requested in calls for data submitted to GEMS/Food, which Canada considers a reasonable starting point as the period of coverage for occurrence data provided.<br>If the dataset spans a certain number of years (a criterion may have to be developed, e.g. 10 or more years), time trend analysis could be recommended to be conducted by the EWG so that it can be determined if concentrations have changed with time and therefore if only certain years of data should be used for ML elaboration in order to, for example, represent current concentrations. | **Canada** |
| Canada supports that guidance also be developed (in concert with guidance on the minimum sample size) regarding the criteria that, when fulfilled, would support the use of datasets with a low number of samples for ML elaboration. | **Canada** |
| It would be useful to explain in a more specific way, in which cases regarding sampling information and method of analysis, will make data unusable. | **Chile** |
| It would be useful to clarify, if the analysis of datasets would be differentiated, if this could mean that eventually different ML will be proposed related to the region origin or not. | **Chile** |
| 'Year of sampling' - it should be deleted from the 'examples of missing information but the data could still be used for further data analysis' because dataset with no sampling year cannot be analyzed within a certain occurrence period. | **Republic of Korea** |
| We agree to a need of guidance on cut-offs and dataset handling. | **Republic of Korea** |
| 'sufficient/appropriate' - These expressions are abstract so that a definition or detailed criterion is needed. | **Republic of Korea** |
| 'sufficient' - This word is abstract so that a definition or detailed criterion is needed. | **Republic of Korea** |
| This makes sense however how would we assess the different patterns of the additional data to determine the at which level to exclude. | **United Kingdom** |
| Consideration should be given to country of origin of commodities particularly where datasets submitted may include import data as this would may need to be separated. | **United Kingdom** |
| • General comment: The document should also consider whether composite data such as TDS should be used for determining percentiles for setting MLs. | **USA** |
| • Exclusion of data as "outliers" may be risky as sometimes the reason for extreme values may not be known, but the data points are valid. We can consider general variability (extremes) based on similar published data.<br>• One option is to say that removal of outliers is an option, but the EWG must provide a statistically valid analysis for removal of outliers and supply justification.<br>• Keep records of excluded data for review if requested. Give summary in paper of exclusions.<br>• The decision rule in the example needs to be clearer. Why cut at 500 vs 300 or 700? An example should also address whether an acceptable justification was ruled out before removing the extreme data points. | **USA** |

| COMMENT | MEMBER/OBSERVER |
|---|---|
| • Data points with possible incorrect units can be evaluated as potential outliers, and then if no justification found, as expressed above, then they could be excluded. Some data may seem clearly incorrect and subject to removal (e.g., a sample in a batch submitted by one country that has different units than other samples in the batch).<br>• Alternatively, the point of contact for the country that submitted the data can be contacted for corrections.<br>• Keep records of excluded data. Give summary in paper of exclusions and rationale for exclusions. Identify exclusions by country. | **USA** |
| • If GEMS/Food allows submission with missing data fields and reasonable assumptions can be made, data do not have to be excluded. However, the extent to which missing information make the data unusable may hinge on the relative availability of data. If few data are available, samples with certain missing information may be acceptable for the purposes of understanding the current distribution of the contaminant levels.<br>• "the state of the food sampled (dried/fresh)": This information may not be reported and may not be relevant for some analyses, e.g., beverages, grain, so the fact that the field is not filled out is not grounds for exclusion.<br>• State of food submission may not be necessary for all samples, e.g., listed as dried spice in product name, but state of food term left blank. Blanket rules may result in unnecessary exclusion.<br>• The example is given, "All data from a dataset are reported as < LOQ and the LOQ is not provided." We understand this is not possible in GEMS, as datasets are rejected in this situation. | **USA** |
| It has to be considered if these data can be taken into further data analysis.<br>• In general, this is not desirable as the basis of determining 95th percentile for setting MLs, etc. The analysis should be based on data in GEMS/Food submitted by member countries and organizations.<br>• External data can be used in a complementary analysis, e.g., presentation of literature review.<br>• If there are no data available in GEMS after repeated requests, and there is a pressing need, use of such data could be considered. However, if no GEMS data are available, this raises questions about how important the issue is.<br>• Whether there are globally representative data could also be considered as a reason to use external data. | **USA** |
| • If datasets show different, valid contamination patterns, it should be noted, but the data do not have to necessarily be separated. If separated, a rationale for the treatment of the datasets should be provided. | **USA** |
| • <u>General comment</u>: Some additional topics to consider include:<br>o Discussing the influence of existing country or regional regulations on reported contaminant levels.<br>o How to handle suspected fraudulent/economically adulterated samples.<br>o Potentially split guidance into chapters/annexes (like the mycotoxin COP) so that information is available on some topics before the entire document completed, as some topics may be controversial/take longer to resolve.<br>o What to do when samples are aggregate or composite (Total Diet Study samples)<br>o Inform CCCF that some data are uploaded confidentially and the EWG chair should work with the GEMS/Food administrator to make sure they have all the relevant data. | **USA** |

| COMMENT | MEMBER/OBSERVER |
|---|---|
| • The question "[If the] dataset contains a significant part of left-censored data (i.e. < LOQ) and no LOQ provided, should the guidance provide for different conclusions as regards how to handle the dataset in case the quantified results (significantly lower than the ML under consideration) in the dataset provide an indication that the LOQ is (very) low compared to datasets where the quantified results do not provide that indication?" is not clear. Please provide an example for comment.<br>• LOQ provided – Yes, there should be guidance on cut-offs used for analytical results.<br>• The question "Should the guidance provide for different conclusions as regards how to handle the dataset in case the dataset contains nearly all quantified results compared to a dataset with nearly all left-censored data?" is unclear. Perhaps provide an example for comment. | **USA** |
| • Does the procedure described have to be applied for generating percentage rejection/ML development? It seems more appropriate for exposure assessments.<br>• An alternative is using either LOQ or LOQ/2 (or LOD or LOD/2) for "0". | **USA** |
| • In addition to comments noted, the guidance could address whether geographical representation is needed in all cases, e.g., is it needed for foods produced and consumed primarily in a few clusters/regions. | **USA** |
| • Guidance should also cover how to proceed with removal/revocation of MLs when few data/data from limited regions are available and it is likely that no new data will be generated (e.g., the situation with review of existing lead MLs with obscure products like canned brassica or chestnut paste). | **USA** |
| Additional guidance would be helpful in how to determine which datapoints are outliers. It would be useful to have a recommendation of a statistical test or other guidance. For example, would the Maximum Normalized Residual Test be appropriate, or under what conditions would it be. Would it be reasonable to eliminate all datapoints more than 2 standard deviations greater than the mean?<br>It would also be helpful to provide guidance on how to include left-censored data in the tests of outliers, as those would still be important data points to consider when determining whether a datapoint is an outlier. | **ISDI** |
| Handling data which is likely the result of reporting an incorrect unit may be able to be covered under the first bullet. In addition for seeking clarification from the data submitter, if there is no follow up, then reporting error that results in data that is significantly outside of normal distribution could be addressed by the same processes that address other datapoints that are outliers. | **ISDI** |
| We are aligned that clearly defining which parameters are required versus optional will be helpful in updating the forms for collecting data. | **ISDI** |
| We would recommend that the chairs of the electronic working group (EWG) should feel empowered to make their own decisions on how to manage data that is not submitted to the GEMS food database, with the provision that how that data is (or is not) considered should be documented in the discussion papers drafted by the EWG. | **ISDI** |
| We agree with the recommendation that if a scientific rationale exists for separating out datasets for consideration, that the electronic working groups should have the ability to do so. | **ISDI** |

| COMMENT | MEMBER/OBSERVER |
|---|---|
| If a dataset is submitted in which a number of datapoints is reported as Not Detected without an LOQ provided, efforts should be made to identify the LOQ. However, if this is not possible, we agree that in order to prevent influencing the data (by only considering quantified results and discarding left-censored data), a dataset presented with > 10% of the values reported as Not Detected without a reported LOQ should be discarded in its entirety. If < 10% of the values reported in a dataset are Not Detected without a reported LOQ, then the LOQ for those Not Detected values could be set to the lowest reported value, at the discretion of the electronic working group with the consideration that this would be required to be documented in the discussion paper from the electronic working group. | **ISDI** |
| LOQ provided.<br>For datasets where the LOQ is provided, the data should always be considered. If the LOQ is above the ML under consideration, caution should be given as to how to account for left-censored data (see below). | **ISDI** |
| This seems to be an issue that would most likely occur for commodities that are not as commonly consumed. As such, guidance on datasets with a low number of samples should also align with the principle in CXS 193-1995 that MLs should only be set for contaminants in commodities in which they would represent a significant risk to public health or an issue with international trade.<br>As described in the Codex Procedural Manual in Section IV: Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods of Food Groups, the following criteria can be used to identify when a food/commodity would be considered to be a significant source of a contaminant:<br>1. Foods or food groups for which exposure to the contaminant or toxin contributes approximately 10% or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food Consumption Cluster Diets; or<br>2. Foods or food groups for which exposure to the contaminant or toxin contributes approximately 5% or more of the tolerable intake (or similar health hazard endpoint) in tow or more of the GEMS/Food Consumption Cluster Diets; or<br>3. Foods or food groups that may have a significant impact on exposure for specific groups of consumers, although exposure may not exceed 5% of the tolerable intake (or similar health hazard endpoint) in any of the GEMS/Food Consumption Cluster Diets<br>If less than 60 (or another number) of samples is provided for a contaminant in a food or food group, this should trigger an evaluation of whether the food or food group meets the criteria above. If the analysis above still indicates that setting an ML would be appropriate, then additional data collection should be conducted. If the analysis above indicates an ML would not be appropriate, then setting an ML could be deprioritized. | **ISDI** |

**E) GUIDANCE ON HOW TO PRESENT THE DATA IN EWG REPORTS TO CCCF**

| COMMENT | MEMBER/OBSERVER |
|---|---|
| Per region? | **Brazil** |
| Assessing temporal and geographic variation in datasets should first be captured in the 'data analysis' section, and, if warranted, further discussed in the 'data presentation' section. | **Canada** |
| It is important to present summary data for all individual foods within a food group, in addition to summary data for the broader group. For example, for the lead ML elaboration in spices that is underway by CCCF, data for all of the individual spices (e.g. cumin seeds, fennel seeds) in a given category ('spices from seeds') should be presented, as well as data for the combined category (e.g. all data for individual spices from seeds). This type of analysis allows for an understanding of the individual foods that may impact proposed ML values for combined/broad food categories and if a single ML for a food category or individual MLs are most suitable. | **Canada** |
| Canada requests that the EWG provide guidance on when it would be most appropriate to use the arithmetic mean, geographic mean, median, other measures of central tendency, or higher percentile values, when elaborating MLs. This should include considerations of, for example, the distribution (or skewedness) of the dataset, if the contaminant poses an acute of chronic health risk based on exposure levels from food, etc.<br>Guidance is also requested on if, or which, measures of variability (standard deviation, standard error) should be reported. | **Canada** |
| An addition of a flow chart or checklist for data preparation would be useful for stepwise examination of the data. | **Republic of Korea** |
| If there is a significant year-to-year variation in occurrence it is appropriate to provide an analysis of the data per year.<br>• In addition to year-to-year variation and production method, if there is a significant difference in contamination pattern, the analysis should consider presenting data by geographical region.<br>• The impact of MLs by geographical area could also be considered.<br>• The analysis should also provide standard deviation in addition to mean, median, and range.<br>• Suggest that the presentation also include the recommended ML and the next nearest MLs (higher and lower) to see how the data are affected.<br>• The example is missing in the last bullet. | **USA** |
| The presentation of data should also include assumptions, such as those described above (how left-censored data was managed, whether data outside of the GEMS database was considered) should also be included. | **ISDI** |

**F) ISSUES IDENTIFIED IN THE DATA ANALYSIS FOR POSSIBLE MLs OF LEAD and MLs of TOTAL AFLATOXINS NOT MENTIONED BEFORE**

| COMMENT | MEMBER/OBSERVER |
|---|---|
| The last section relates to establishing an ML when there are different regional contamination patterns, specifically, where the worldwide rejection rate is under 5%, whilst a particular region's rejection rate is greater than 5%. Australia agrees that it would be useful to provide guidance on how much weight should be given to the worldwide rate of rejection in favour of a region's rate of rejection (especially when it is notably higher than the worldwide rate), when establishing a proposed ML. | **Australia** |
| It is necessary to clarify if the recommendation is to remove outliers and additionally consider rejection rates. Is this is the situation, it will mean that a considerable amount of data would be removed and consequently remove from trade. | **Brazil** |
| Different rejection rates should be considered depending on the product – contaminant. | **Brazil** |
| Exclude 5% of the commodity that are not processed is different to reject a product that is ready for consumption. For example, excluding 5% of wheat, the wheat may be further processed in a way to reduce the contamination. However, if a rejection rate of 5% is decided for wheat flour, it will mean to throw away 5% of the products on the market. | **Brazil** |
| Paragraph 208 of REP21/CF, CCCF14 agreed: i) that the work should be focused on data collection, data analysis and data presentation as a priority in the coming year and that discussion on elements for consideration such as appropriate rejection rates would not be taken up.<br>Canada suggests that an Annex could be added to the discussion paper on this item that maintains a list of "Other Topics for Possible Future Consideration." Items that could be included in this Annex are:<br>• rejection rates used for ML elaboration<br>• reasonableness of GEMS/Food market-based cluster diets for ML elaboration | **Canada** |
| It must be considered in the possible elements to apply for a different rejection rate, issues regarding food security. | **Chile** |
| • CCCF14 agreed that the work should be focused on data collection, data analysis and data presentation as a priority in the coming year and that discussion on elements for consideration such as appropriate rejection rates would not be taken up for now; that rejection rates should not be covered in this document.<br>• With regards to suggesting/establishing acceptable rejection rates, allowance for a case-by-case basis is needed.<br>• The connection posed between rejection rates and possible use as feed is not clear. | **USA** |
| In addition to the percentage of a commodity that may be rejected, it may be useful to include a calculation of the net value of the commodity that could be rejected to support the discussion on the impact to trade. | **ISDI** |

**JAPAN**

**For background information, please see CL 2021/78-CF and CX/CF 21/14/15**

**A) CRITERIA FOR THE ESTABLISHMENT OF MAXIMUM LEVELS IN FOOD AND FEED[1]**

**Selection of criteria has been made of relevance for improved data collection and analysis of data for setting MLs**

– Validated qualitative and quantitative analytical data on representative samples should be supplied. Information on the analytical and sampling methods used and on the validation of the results is desirable. A statement on the representativeness of the samples for the contamination of the product in general (e.g., on a national basis) should be added. The portion of the commodity that was analyzed and to which the contaminant content is related should be clearly stated and preferably should be equivalent to the definition of the commodity for this purpose or to existing related contaminant regulation.

– Information on appropriate sampling procedures should be supplied. Special attention to this aspect is necessary in the case of contaminants that may not be homogeneously distributed in the product (e.g., mycotoxins in some commodities).

– MLs should be set as low as reasonably achievable and at levels necessary to protect the consumer. Providing it is acceptable from the toxicological point of view, MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed that are produced with current adequate technological methods, in order to avoid undue disruptions of food and feed production and trade. Where possible, MLs should be based on GMP and/or GAP considerations in which the health concerns have been incorporated as a guiding principle to achieve contaminant levels as low as reasonably achievable and necessary to protect the consumer. Foods that are evidently contaminated by local situations or processing conditions that can be avoided by reasonably achievable means shall be excluded in this evaluation unless a higher ML can be shown to be acceptable from a public health point of view and significant economic aspects are at stake.

– Proposals for MLs in products should be based on data from various countries and sources, encompassing the main production areas/processes of those products, as far as they are engaged in international trade. 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.

– Numerical values for MLs should preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5 etc.), unless this may pose problems in the acceptability of the MLs.

**B) IMPROVED DATA COLLECTION**

**Important elements to be provided when reporting occurrence data: A1** *We propose to add the following elements (those already shown as inserts in the text are not shown below)*

1) information on the stage in production and production chain where the sampling took place (farm, wholesale, import, retail), year and location (country/region) of sampling. If known, origin of product sampled.

2) Information on application of relevant Codex Code of Practice to the products, if known.

3) information on type of sampling~~-~~: targeted sampling, suspect sampling, random sampling, and factors that were considered when designing sampling plan

4~~3~~) food and feed to be correctly identified, if the commodity is segregated as food or feed (if marked, indicated, or described in the accompanying document), and reported with detailed information on the food or feed concerned (correct identification, state of the food/feed (fresh, dried, ready-to-eat, etc.)

5~~4~~) information on the portion of food analysed (e.g., peeled or not, edible part or whole fruit, etc...)

6~~5~~) identity of analytes, and if appropriate their forms, free or conjugated

7~~5~~) the unit of the data measurement (e.g., µg/kg, mg/kg, mg/L), how data are reported (total versus individual), and the basis on which the data are expressed (e.g., fat basis vs whole weight)

[1] Reference is made to the criteria for the establishment of maximum levels in food and feed as provided for in Annex I of CXS 193-1995 General Standard for Contaminants and Toxins in Food and Feed

8~~6~~) information on the methods of analysis (and their validation data) used for generating occurrence data with information on the LOQ/LOD of the method (and how the LOQ/LOD were derived)

9) information on the accreditation status of the involved analytical laboratory

10) information on how levels of contaminants which were sum of compounds are calculated when one or more component(s) is (are) not quantified (lower bound versus upper bound)

11) data should be provided to GEMS/Food

**C) HANDLING/ACCEPTANCE OF DATA WITHIN A DATASET**

**1) Handling of outliers/extreme values**

What are outliers (extreme values)?

- There is no mathematical definition of what constitutes an outlier
- Determing whether or not an analytical result is an outlier is ultimately a subjective exercise
- Outliers can have many causes: 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)

  There are different statistical tests to determine outliers However, in most cases they assume a normal distribution of the data which is frequently not the case for contaminants and are therefore in most cases not applicable

  Another (arbitrary) way is to visually inspect the data with a frequency distribution and identify those data which appear disconnected from the rest of the data → possible outlier

  There may be cases where extreme values are scientifically valid depending on production conditions and weather and other potential factors.

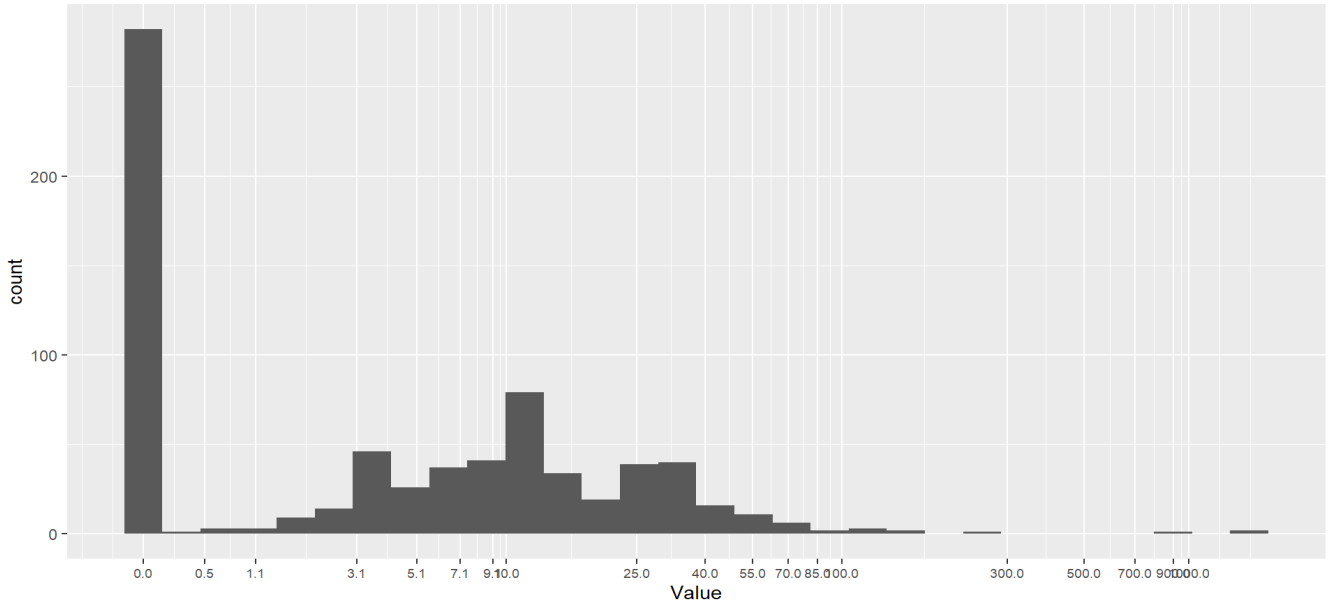
  As there can be many causes for outliers and these values may be extreme values and not outliers if combined with data from other countries/region. → possible extreme value

When to consider data as outliers/extreme values? **A2** *Substantive. Please insert, as planned, the definition of outliers (extreme values) as shown in the text. There may be cases where extreme values are scientifically valid depending on production conditions and weather and other potential factors. Therefore, it is also useful to explain some distinction between the "outlier" and "extreme value" if possible. As there can be many causes for outliers and these values may be extreme values and not an outlier if combined with data from other countries/regions, we propose that the submission should not exclude potential outliers. In the statistical analysis of contaminants, median is the useful and robust representative value as it is not influenced by outliers or extreme values, provided that there are sufficient data.*

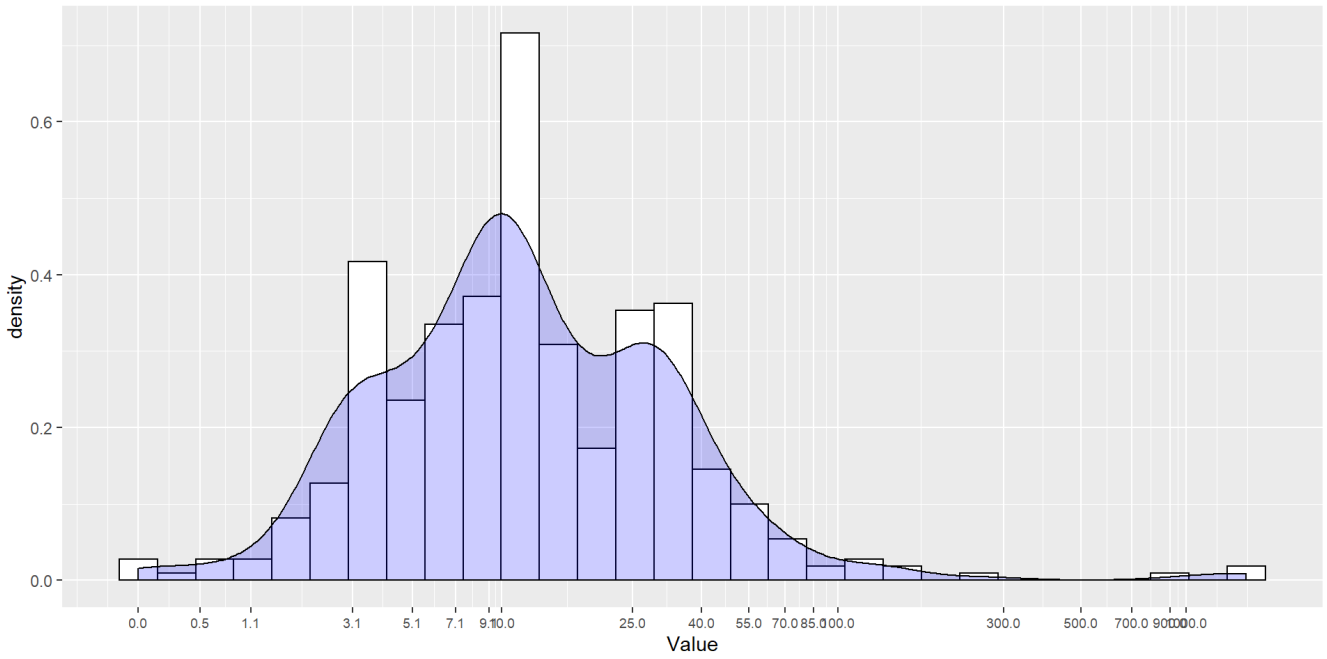
For consideration: In case the data are outside the range of distribution of the data and no justification can be provided for these extreme results (such as data from a year with extreme weather conditions, data from a specific region/continent, …)

**Example EU data on sum of T-2 and HT-2 toxin in oat milling products (717 results of which 438 quantified results):**
**A3** *Editorial. Although these two graphs are not for comparison from each other, it would be preferable if the X-axes are in the same scale, which can be done by dragging the corner of the graph. It may be helpful to state that the outlier analysis can be valid only when the number of data is sufficiently large.*

**Histogram: all results**




Histogram/density of quantified results




In case no justification for the data with levels > 500 µg/kg can be provided these data could be considered as outliers. This kind of outlier analysis can be valid only when the number of data is sufficiently large.

How to handle outliers?

The decision to exclude outliers from further data analysis is to be taken on a case by case basis thereby considering the following elements (not exhaustive)

Verify, if possible, outlier value is due to data entry mistake

- Wrong unit of measurement (more details see point 5)
- Expression of result (more details see point 5)
- Decimal separator
- Sample misclassification
- Non-food matrix

To be eventually checked (if possible) with data supplier → if confirmed, it can be decided to exclude these data from further data analysis

- Outliers (clearly) due to adulteration/fraudulent action → it can be decided, in consultation and agreement with the data provider/representatives from the respective country/region from where the data originate, to exclude these data from further data analysis

- No valid justification can be provided for these extreme values) → it can be decided, in consultation and agreement with the data provider/representatives from the respective country/region from where the data originate to exclude these data from further data analysis

- A valid justification can be provided for extreme values /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.

**2) 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.**

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, these data should be excluded from further data analysis.

For some foods (e.g., fruits), if there are clear indications that the portion analysed is not clear (e.g., peeled vs whole fruit, or husked rice vs polished rice), these data should be excluded from further data analysis unless the necessary information is obtained.

Examples of "clear indications"

* 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 putting these data in a frequency distribution curve (see a) they would be identified as possible outlier

* Levels from a food with a typical fat content of 5 % within a data set of 200 results of which all data are expressed on whole weight. 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. When putting these data in a frequency distribution curve (see a) they would be identified as possible outlier

**3) Lack of information on data provided**

It has to be considered to which extent~~d~~ the missing information makes the data unusable.

Examples of missing information by which data cannot be used for further data analysis:

- All data from a dataset are reported as < LOQ and the LOQ is not provided (more information in point 2 in Chapter D)
- the unit in which the result is reported is missing or the basis on which the result is expressed
- the state of the food sampled (e.g., dried or fresh) **A4** *There can be other examples, such as peels vs whole, washed vs unwashed*

Examples of missing information but the data could still be used for further data analysis:

- sampling information: type of sampling, year of sampling, location of sampling, …
- method of analysis used

**4) Handing of the data not provided to the GEMS/food**

It has to be considered if these data can be taken into further data analysis

– in case there are only limited data available in the GEMS/food database, it could be considered useful to use these data in further data analysis.

– in case there are extensive data available in the GEMS/food database, it could be considered not to use these data in further data analysis (and certainly not in case the data do not show a contamination pattern different than the data available in the GEMS/food database).

**5) Handling of datasets with a different contamination pattern (e.g., as consequence of originating from different regions, different production years)**

Guidance should be provided on when to combine or keep separate such datasets for assessment

- if datasets from different regions/continent in the world show a different contamination pattern and a valid reasoning for the difference can be provided (e.g., different climate conditions, different production conditions/techniques)~~–~~, then the datasets could be kept separate for assessment. **A5** *Substantive. For comparing the data from different regions or from different years, use of non-parametric tests, such as Mann-Whitney U test or Kruskal-Wallis H-test, are useful and this should be stated somewhere in this document. Guidance on how to analyze combined dataset would be useful when the combined dataset shows multimodal distribution.*
- If the combined dataset shows a multimodal distribution, it may be beneficial to keep the data separate~~ly~~ for statistical assessment.
- For comparing the data from different regions or from different years, use of non-parametric tests, such as Mann-Whitney U test or Kruskal-Wallis H-test, are useful. If there are no significant difference between data, the dataset can be combined for assessment.

**D) IMPORTANT TOPICS TO BE CONSIDERED FOR DATA ANALYSIS**

**1) Minimum number of samples needed for the use of percentiles**

**Background information**

In order to apply the above criterion "*MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed"*, high percentiles are used to define that level. The reliability of high percentiles is related to the number of data used to calculate them. Percentiles calculated on a number of subjects should be treated with caution as the results may not be statistically robust.

A clear indication concerning the minimum number of observations necessary to estimate a given percentile is not provided in literature. Different options can be used, none of them being a widely accepted standard.

A very simple option is to require that the calculated percentile must at least be different from the maximum value within the sample. This means that at least 20 observations are needed to identify the single observation at the 95$^{th}$ percentile and 100 observations are needed for the 99$^{th}$ percentile.

In statistics, the coverage probability of a confidence interval is the probability that the interval contains the true value of interest (e.g., 95th or 99th percentiles). When the number of observations is not large enough, the coverage probability may not attain the nominal value, and drops below, for example, 95%. This is more likely to occur at high percentiles, e.g., 95th or 99th. Therefore, the coverage probability has been used to set guidelines to determine the minimum number of samples for which (extreme) percentiles can be computed. In the case of significance level (α) being set at 0.05 to determine a 95% confidence interval, the coverage probability should target 95%. In this case, this is achieved for n ≥ 59 and n ≥ 298 for the 95th or 99th percentiles, respectively.

**2) Limit of Quantification (LOQ) considerations** **A6** *Substantive. As for summing up the related components, such as total aflatoxins, it is necessary for all data submitters to share the same concept and preferably the same calculation method(s) for when some or many analytical results are lower than the LOQ. The way analytical values lower than the LOQ is handled (0, LOQ value or LOQ/2?) would significantly affect the calculated sum, in particular, when the ratio of <LOQ is large among all the analytical results. It is also useful to refer some existing Codex guidance, such as guidelines on LOQ in the Codex Alimentarius Procedural Manual, section II, Principles for the establishment of Codex Methods of Analysis, Guidelines for Establishing Numeric Values for Method Criteria and/or Assessing Methods for Compliance thereof point 1.2.*

Several situations applicable to datasets provided can occur and the guidelines to be elaborated should provide guidance on how to handle the datasets in the different situations

- No LOQ provided
  - Dataset contains (nearly) all quantified results
  - Dataset contains a significant part of left-censored data (i.e. < LOQ) and no LOQ provided

    In the above situations where the LOQ is not provided, should the guidance provide for different conclusions as regards how to handle the dataset in case the quantified results (significantly lower than the ML under consideration) in the dataset provide ~~a~~ an indication that the LOQ is (very) low compared to datasets where the quantified results do not provide that indication.

- LOQ provided
  - 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 ML under consideration

In the above situations where the LOQ is provided, should there be guidance on cut-offs to be used for the LOQ on the analytical results dataset used for the ML development?

Should the guidance provide for different conclusions as regards how to handle the dataset in case the dataset contains nearly all quantified results compared to a dataset with nearly all left-censored data? **A7** *Substantive. Yes. If most of the data in the dataset is below the LOQ, it may not be possible to obtain high percentile values. However, calculating high percentile values using only the positive data should be carefully considered because it may result in proposed draft MLs with unnecessarily high values.*

If most data in the dataset are~~is~~ below the LOQ, it is not be possible to obtain scientifically appropriate high percentile values. When there are many values <LOQ and a smaller number of finite values, there is a need to consider whether it is appropriate to calculate high percentile values using only the finite values, which may result in unnecessarily high proposal for MLs.

**3) Using data sets with a large proportion of left-censored data for ML development**

In certain cases, the analytical results for one specific contaminant are produced with a battery of different analytical methods and/or the same analytical method but with very different sensitivities. As a consequence, there could be a wide range of limits of detection (LOD) and limits of quantification (LOQ) for a particular contaminant and food matrix in a given dataset, composed of datasets from different sources. This situation is particularly relevant when the occurrence datasets used for the ML development contain a high number of non-quantified/non-detected data (left-censored data).

The standard approach to deal with left-censored data is the use of the substitution. In this method, at the lower-bound (LB), results below the LOQ and LOD are replaced by zero; at the upper-bound (UB) the results below the LOD are replaced by the numerical value of the LOD and those below the LOQ are replaced by the value reported as LOQ. Additionally, as a point estimate between the two extremes, the middle-bound (MB) scenario is calculated by assigning a value of LOD/2 or LOQ/2 to the left-censored data.

**4) Geographical coverage of the provided occurrence data** **A8** *Substantive. For practicability, it is important to make sure that data from the major production countries/regions are available. If a commodity is produced and consumed worldwide, we should consider the geographical coverage worldwide.*

Guidance should be provided to evaluate the appropriateness of the geographical coverage of the provided data for ML development If a commodity is produced and consumed worldwide and a procedure should be developed for situations for which it is concluded that the available data do not provide a sufficient/appropriate geographical coverage.

For practicability, it is important to make sure that data from the major production countries/regions are available.

**5) Period coverage of the provided occurrence data**

Guidance should be provided in which situation it might be required 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, **A9** processing contaminants, environmental contaminants in function of the assumed year to-year variation or evolution of contamination in time) **A9** *Marine biotoxins do not cover only phycotoxins but also of shellfish and fish and therefore, this term should be added (it was there in the original document).*

**6) Data sets with low number of data (e.g., less than 60) for development of ML**

Guidance could be given in which situations it can be concluded that the data, despite the low number, are sufficient for the development of an ML (e.g., despite limited number good geographical coverage, no large variation in occurrence observed despite data originating from different regions/from different years, etc).

**E) GUIDANCE ON HOW TO PRESENT THE DATA IN EWG REPORTS TO CCCF**

It is important that the data are represented in such a way in the EWG report to CCCF to enable an informed discussion on appropriate MLs to be established.

The detail of reporting depends on the amount of data available and also of the nature of the contaminant.

**Elements of consideration (not-exhaustive)**

- if there is a significant year-to-year variation in occurrence it is appropriate to provide an analysis of the data per year.
- if there is a significant difference in contamination pattern between regions of e.g., climate conditions or production methods, it is appropriate to provide an analysis of the data per region or continent~~year~~; **A10** *As the sentence talks about difference between regions, the data should be also for regions but not per year.*
- the description of the data should provide a clear view on the data set e.g.

* Number and proportion of positive (quantified results)

* Mean, median and range of positive results

* P90, P95, P99
* histograms/density of positive results (example see

**F) ISSUES IDENTIFIED IN THE DATA ANALYSIS FOR POSSIBLE MLs OF LEAD (agenda item 8, CX/CF 21/14/8) and MLs of TOTAL AFLATOXINS (agenda item 10 (a) CX/CF 21/14/10 – Part I) NOT MENTIONED BEFORE**

**1) Application of different rejection rates for different types of products and contaminants, deviating from the usual rejection rate of 5%**

At the 13th session of CCF it was clarified that the basis on which the MLs should be proposed (i.e., rejection rate, occurrence data and reduction risk) was outside the scope of the guidance (§ 162, REP19/CF)

However, there is the explicit request to the CCCF in relation with the discussion on MLs for lead and total aflatoxins whether different rejection rates should be applied for different types of products and contaminants. Therefore, CCCF might agree that it is appropriate to provide in this guidance, elements which should be taken into account to define the appropriate rejection rate. This should increase the transparency on the basis on which grounds a maximum level has been set.

Possible elements for consideration (not exhaustive)

- nature of the product:
    - raw cereals of which already large part is used for feed: non-compliance with the food ML might not necessarily result in economic damage as it can still be used as feed.
    - processed products intended for human consumption: non-compliance with the food ML will result in economic damage as possible alternative uses will result in lower return or in certain cases the lot has to be destroyed.
- different regional contamination patterns:
    - worldwide dataset might have a rejection rate lower than 5 % at a certain ML while regional datasets might have for the same ML much different (lower or higher) rejection rate.

**KENYA**

**Kenya Comments on Guidance on Data analysis for MLs development in response to CL 2021/78-CF**

A) Criteria for the establishment

2nd Bullet-Contaminants that may not be homogenously distributed like mycotoxins would be best sampled through incremental samples whose number depend on the lot size. The incremental samples form aggregate sample then the laboratory sample finally the test portion almost ensures an equal chance to the entire lot.

**B Improved data collection**

7) Information on the lot /consignment size from which sample was done

**ICBA**


Adobe Acrobat Document

November 22, 2021

**Re: ICBA Comments in response to CL 2021/78-CF "Guidance on data analysis for development of maximum levels and for improved data collection"**

Dear Sir or Madam,

The International Council of Beverages Associations ("ICBA") appreciates the opportunity to submit comments to the Codex Committee on Contaminants in Foods ("CCCF") electronic working group ("eWG") in response to the request for comments on the topics identified relative to the guidance on data analysis for development of maximum levels and for improved data collection (CL 2021/78-CF).

ICBA represents the interests of the worldwide non-alcoholic beverage industry. ICBA members include national and regional beverage associations and international beverage companies that operate in more than 200 countries and territories and produce, distribute and sell a variety of non-alcoholic sparkling (carbonated) and still (non-carbonated) beverages including soft drinks, sports drinks, energy drinks, bottled waters, flavored and/or enhanced waters, ready-to-drink teas and coffees, 100% fruit or vegetable juices, nectars and juice drinks, and dairy-based beverages. ICBA is a recognized observer at the Codex Alimentarius Commission.

ICBA supports CCCF's efforts to first provide guidance on a consistent approach to collect, analyze and present data. As such, topic F "Issues identified in the data analysis for possible maximum levels for lead and total aflatoxins" (in CL 2021/78-CF) as it pertains to reflections on deviations from the general rule-of-thumb 5 percent (5%) rejection rate (for establishing a maximum limit, "ML") is out-of-scope. In adherence to the terms of reference for this CCCF electronic working group (eWG), ICBA recommends that the discussion draft be organized by key topic areas, specifically: (i) occurrence data collection, (ii) occurrence data analyses and (iii) occurrence data presentation and (iv) other topics for possible future consideration (in which the percent rejection rate could be placed). To that end, ICBA respectfully suggests that the Topics in CL 2021/78-CF be re-arranged as follows: (i) occurrence data collection to comprise Topic B; (ii) occurrence data analyses to comprise Topics C and D; (iii) occurrence data presentation to encompass Topic E; and (iv) other topics for possible future consideration would encompass some aspects of Topic F and other suggestions. Relative to Topic A "Criteria for the establishment of maximum levels in food and feed", only a general reference to the appropriate section in the General Standard for Contaminants and Toxins in Food and Feed is necessary. Specific criteria can be highlighted where appropriate under the broader topic areas (i), (ii), (iii) and (iv).

Aside from re-organizing the broad topic areas (noted below), ICBA also respectfully requests that the CCCF eWG consider the following perspectives and commentary, including additional concepts beyond those reflected in past discussion drafts and reports (CX/CF 19/13/16, CX/CF 21/14/15, REP21/CF). These changes may serve to increase confidence in the quality and robustness of the occurrence data (to inform ML establishment) and to increase the efficiency and effectiveness with which CCCF evaluates the safety of chemicals in foods.

ICBA respectfully addresses each of the broad topic areas in turn.

- (i) Occurrence data collection
    - 'Topic B. Improved data collection' should be subsumed under 'occurrence data collection'
- (ii) Occurrence data analysis
    - 'Topic C. Handling/acceptance of data within a dataset' should be subsumed under 'occurrence data analysis'
    - 'Topic D. Important topics to be considered for data analysis' should be subsumed under 'occurrence data analysis'
- (iii) Occurrence data presentation
    - 'Topic E. Guidance on how to present the data in reports to CCCF eWG' should be subsumed under 'occurrence data presentation'
- (iv) Other topics for possible future consideration.
    - 'Topic F. Issues identified in the data analysis for possible maximum levels for lead and total aflatoxins' should be subsumed under 'other topics for possible future consideration'

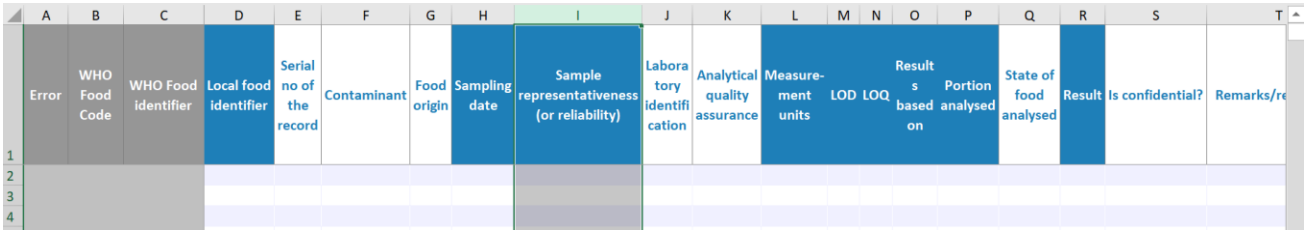
## I. Occurrence Data Collection

ICBA generally supports all relevant criteria related to occurrence data collection stipulated in Annex I 'CRITERIA FOR THE ESTABLISHMENT OF MAXIMUM LEVELS IN FOOD AND FEED' of the General Standard for Contaminants and Toxins in Food and Feed ("GSCTFF", CXS 193-1995).[1]/ In addition, ICBA highlights the following perspectives on occurrence data collection.

***Data submission only through GEMS/Foods portal***

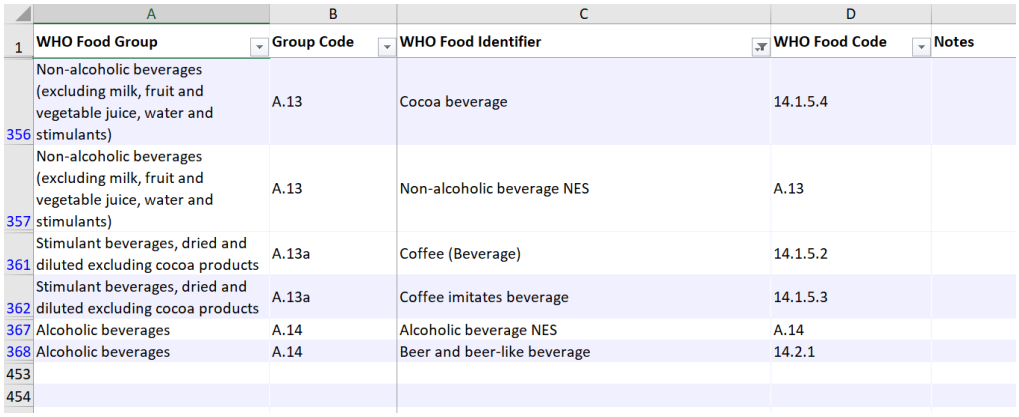
ICBA believes that the WHO Global Environmental Monitoring System ("GEMS")/Foods Programme portal should serve as the single clearinghouse of information on commodity/contaminant pairs to progress CCCF's work. The GEMS/Food system provides much needed transparency in occurrence data collected across regions and across production years. The GEMS/Food system also promotes consistency in what ultimately gets submitted for risk assessment purposes. Details on what type of data are to be provided is reflected in the March 2021 update to the GEMS/Food Programme 'Instructions for electronic submission of data on chemical contaminants in food and the diet' – https://cdn.who.int/media/docs/default-source/food-safety/gems-food/instructions_gemsfood_march2021.pdf?sfvrsn=e2c8737a_8. For example, the instructions suggest there are only two types of sampling techniques, random or targeted, the latter likely to already cover 'suspect' sampling mentioned in the CL. Other details that are required to be provided include state of the food (fresh, dried, ready-to-eat, 'as is', etc.), portion of food analysed (peeled, edible portion, etc.), unit of data (µg/kg, mg/kg, fat content basis, etc.) among others. More importantly, GEMS/Food will not accept any dataset that does not have all relevant fields filled, including those for limits of detection ("LOD") and limits of quantitation ("LOQ"), which must have non-zero values. Electronic submission of data to GEMS/Food should be the only acceptable mechanism by which data are submitted.

Screenshots of the various fields in the GEMS/Foods data submission packet are pasted below.

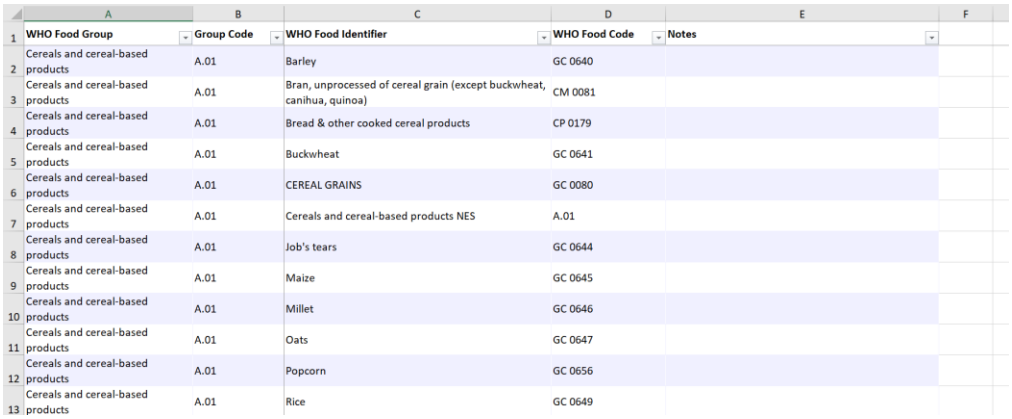



[1]/ Relevant criteria in Annex I 'CRITERIA FOR THE ESTABLISHMENT OF MAXIMUM LEVELS IN FOOD AND FEED' of the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995):

- Validated qualitative and quantitative analytical data (although ICBA is unclear what is meant by 'qualitative' in this context).
- National representativeness of the samples.
- Appropriate sampling procedures especially when contaminants are not homogeneously distributed in product.
- The contaminant as it should be analyzed and to which the ML applies should be clearly defined.
- The product as it should be analyzed and to which the ML applies, should be clearly defined.
- Preferably the product should be defined as it moves in trade.
- MLs should preferably be set for primary agricultural products and may be applied to processed, derived and multi-ingredient food and feed by using appropriate conversion factors.



| | A | B | C | D | |
|---|---|---|---|---|---|
| 1 | WHO Food Group | Group Code | WHO Food Identifier | WHO Food Code | Notes |
| 356 | Non-alcoholic beverages (excluding milk, fruit and vegetable juice, water and stimulants) | A.13 | Cocoa beverage | 14.1.5.4 | |
| 357 | Non-alcoholic beverages (excluding milk, fruit and vegetable juice, water and stimulants) | A.13 | Non-alcoholic beverage NES | A.13 | |
| 361 | Stimulant beverages, dried and diluted excluding cocoa products | A.13a | Coffee (Beverage) | 14.1.5.2 | |
| 362 | Stimulant beverages, dried and diluted excluding cocoa products | A.13a | Coffee imitates beverage | 14.1.5.3 | |
| 367 | Alcoholic beverages | A.14 | Alcoholic beverage NES | A.14 | |
| 368 | Alcoholic beverages | A.14 | Beer and beer-like beverage | 14.2.1 | |
| 453 | | | | | |
| 454 | | | | | |



| | A | B | C | D | E | F |
|---|---|---|---|---|---|---|
| 1 | WHO Food Group | Group Code | WHO Food Identifier | WHO Food Code | Notes | |
| 2 | Cereals and cereal-based products | A.01 | Barley | GC 0640 | | |
| 3 | Cereals and cereal-based products | A.01 | Bran, unprocessed of cereal grain (except buckwheat, canihua, quinoa) | CM 0081 | | |
| 4 | Cereals and cereal-based products | A.01 | Bread & other cooked cereal products | CP 0179 | | |
| 5 | Cereals and cereal-based products | A.01 | Buckwheat | GC 0641 | | |
| 6 | Cereals and cereal-based products | A.01 | CEREAL GRAINS | GC 0080 | | |
| 7 | Cereals and cereal-based products | A.01 | Cereals and cereal-based products NES | A.01 | | |
| 8 | Cereals and cereal-based products | A.01 | Job's tears | GC 0644 | | |
| 9 | Cereals and cereal-based products | A.01 | Maize | GC 0645 | | |
| 10 | Cereals and cereal-based products | A.01 | Millet | GC 0646 | | |
| 11 | Cereals and cereal-based products | A.01 | Oats | GC 0647 | | |
| 12 | Cereals and cereal-based products | A.01 | Popcorn | GC 0656 | | |
| 13 | Cereals and cereal-based products | A.01 | Rice | GC 0649 | | |

***Minimum standard method performance requirements should be stipulated in GSCTFF for each commodity/contaminant pair***

Further, ICBA believes the GSCTFF should specify the minimum analytical method performance requirements, including the LOD and LOQ required, for each commodity/contaminant pair to ensure the necessary sensitivity and accuracy is achieved for submitted data (that will ultimately inform ML establishment). Currently, GSCTFF prescribes LOD and LOQ requirements only for deoxynivalenol and fumonisin. Specifying LOD and LOQ requirements *before* data are collected and submitted should be a *standard practice* for all contaminants. Better understanding the standard method performance requirements in advance will ensure Codex members (particularly in producing regions) are aware and better prepared to meet those standards as they implement their sampling plan and collect data.

This work could be conducted in collaboration with the Codex Committee on Methods of Analysis and Sampling.

***The product as it should be analyzed and to which the ML applies, should be clearly defined.***

Additionally, consistent with the GSCTFF guidance,[2]/ it should be made very clear at *which* stage in the harvesting/processing continuum the product should be analyzed, to ensure this stage

[2]/ "The portion of the commodity that was analyzed and to which the contaminant content is related should be clearly stated and preferably should be equivalent … to existing related contaminant regulation… The product as it should be analyzed and to which the ML applies, should be clearly defined."

aligns with the ML that is eventually applied. This is a much more nuanced position than simply referencing the stages of the production chain *per se* as either farm, wholesale, import or retail. If this nuance is not reconciled before data collection occurs, risk management decisions ultimately made would no longer coincide with the occurrence data provided. Although the GSCTFF suggests MLs should be preferably established for traded products, there are instances where regulatory agencies instead assign MLs after the traded product has been further handled. To illustrate this critical point, we will use the example of deoxynivalenol in cereal grains.

For deoxynivalenol in cereal grains, it becomes absolutely necessary to specify at which point along the harvesting-milling continuum the sample was measured – e.g., before cleaning/sorting, after cleaning/scouring/sorting and before first-stage processing, after first-stage processing, etc. – to distinguish across uncleaned/unsorted raw grains, cleaned/sorted raw grains, first-stage processed grains (subjected to physical or thermal treatment), etc. and to determine at which point the ML applies. Much of the discussion on setting MLs for raw cereal grains revolved around the notion that the adopted ML should have applied to the cleaned/sorted raw grain destined for further processing, not the uncleaned/unsorted raw grain. CCCF7 however concluded, "The Committee agreed to the ML of 2 mg/kg for raw cereals (maize, wheat and barley) *prior* to sorting and removal of damaged kernels with the associated sampling plan … The Delegations of the United States of America and the Russian Federation expressed their reservation to this decision. The Delegation of the European Union expressed their reservation to the associated sampling plan." (REP13/CF 64)

In other words, where along the harvesting and milling continuum are samples tested? This should be the point at which MLs are established (Bianchini *et al*., 2016, https://www.cerealsgrains.org/initiatives/Documents/CFW-60-1-0032-EP.pdf). This case study shows how clarity around the stage at which occurrence data are collected is key to ensuring appropriate risk management decisions are ultimately made and the ML established relates to the same stage of the harvesting/milling continuum the product was sampled.

***MLs should preferably be set for primary agricultural products and may be applied to processed, derived and multi-ingredient food and feed by using appropriate conversion factors.***

At the outset of any data collection endeavor, it should be made very clear whether the primary agricultural product (e.g., tea leaves) or whether the downstream processed product (e.g., finished tea beverage as consumed) will be the subject of investigation. As GSCTFF notes, it is possible to determine appropriate levels for downstream products by using appropriate conversion factors (if elaborated). Reflecting on our experiences with the discussion around lead (Pb) in teas, many 'lead' occurrence data entries in GEMS/Foods for this commodity would appear to be on a dry basis and reported as mg/kg rather than on an as consumed basis or reported as µg/kg, respectively. Brewing transference rates ranging from 0 to 20 percent after steeping (Schulzki et al., 2016), however, combined with low likelihood of surface lead contamination should limit the amount of lead in a typical cup of tea.

***More emphasis should be placed on producing regions data than importing regions data that must meet regulatory requirements***

Finally, more emphasis should be placed on data sampled and collected from producing regions (over importing regions). As CCCF14 noted, "Data from imports are biased as they have to comply with specifications of the importing country and are not necessarily geographically representative for the presence of a contaminant in food commodities. Therefore, consideration should be given to exclude such data sets from the data analysis. (para. 200, REP21/CF)" Separately, submitters should verify that the data collected for a producing region is as nationally representative as possible for that country and not limited to a particular farm for instance.

## II. Occurrence Data Analyses

Once the collected occurrence data meet the relevant criteria noted above and have been submitted, the next phase entails data analyses. Data analyses may include:

- Quality control/quality assurance measures:
    - Application of quality control/quality assurance measures to the overall dataset (e.g., missing data, unrealistic LODs because method was not sensitive enough, unrealistic LOQs, incorrect units applied such as mg/kg rather than µg/kg, etc.),
    - Determination of which data may be considered outliers (without the need for an extensive dialogue with the data submitter, one should be able to quickly determine with reasonable confidence whether some data fall outside the distribution curve),
- Minimum sample size requirements before proceeding with analyses:
    - Minimum sample size rules are general and apply to distributions whether it is food consumption surveys or contaminant occurrence data in foods. The rule of thumb cited for percentiles is: $n\,(1–p) \geq 8$.
    - Further, a qualitative analysis should be conducted afterwards to determine whether there are internal inconsistencies within the statistically robust dataset, for example patterns of contamination vary across production years or across regions which might be explained by climatic conditions or geographical location, respectively, or resulting from the application of good agricultural practices (GAP) or good manufacturing practices (GMP), and
    - A quantitative analysis of the remaining higher quality dataset should finally be undertaken.
- 'Central tendency' considerations when calculating mean.

***Dataset Quality Control/Quality Assurance***

To illustrate the application of quality control/quality assurance measures to an available dataset, ICBA repeats below its previously submitted perspectives for the lead (Pb) dataset. To remove questionable occurrence data, the tiers for statistical trimming (of the dataset) are listed here for completeness: Tier 1 (Dataset Refinement) and Tier 2 (Dataset Verification).

Tier 1 – Dataset Refinement

Step 1: "Trim" dataset to exclude all missing data. Then proceed by excluding all non-detects with an LOD above a reasonable threshold, informed by not only an understanding of the degree of detection sensitivities in commonly employed analytical methods for particular contaminant/matrix combinations but also an evaluation of a natural break in LOD distributions across collected occurrence data (e.g., greater than 25 ppb for lead contaminant analyses based on natural break in distribution curve for LODs included in the dataset).

Rationale 1: The utility of occurrence data with an LOD *greater than* a reasonable threshold (e.g., 25 ppb for lead) *should not be justified* especially if current commonly adopted analytical technological capabilities exist to measure contaminants at much lower LODs (e.g., as low as 1 ppb for lead in some cases). An appropriate LOD threshold can be chosen based on the samples in the dataset that offer a 'natural break' in the LOD distributions (e.g., at 25 ppb for measured levels of lead). Moreover, differences in reported LODs or LOQs spanning five orders of magnitude are far too large a range to accurately analyze any dataset. For example, lead contamination across commodities within GEMS/Foods reported LODs ranging from 0.02 µg/kg to 5.0 mg/kg and LOQs from 0.05 µg/kg to 16.7 mg/kg.

Step 2: Remove "outliers" (after an initial trimming), i.e., entries exceeding '75$^{th}$ percentile + 1.5*Interquartile range ("IQR")'.

Rationale 2: A statistical evaluation of the raw dataset provides an objective approach to removing outliers and ensures that the analysis is not skewed by questionable data. The formula proposed – i.e., '75$^{th}$ percentile + 1.5*Interquartile range (IQR)' – is a standard approach to identify outliers used in statistical summaries, particularly for box and whiskers plots (NIST/SEMATECH, 2012). Other advantages the IQR approach provides are:

- It is non-parametric, and does not make assumptions about the distribution (particularly for datasets with smaller sample sizes);
- It is easy to compute, and does not require complex statistical methods;
- It is typically not affected by non-detects;
- It does not rely on the arithmetic mean which may be affected by outliers;
- It has been shown to be more "conservative" than other methods in that it may allow some outliers in the distribution. In other words, it may not flag some

observations pegged as outliers by other methods (Jones, 2016), such as those relying on estimates of deviation from the mean.

Step 3: Finally, place a value of ½ LOD for non-detects.

Rationale 3: A value of ½ LOD for non-detects is a standard approach used by regulatory agencies and ensures non-detects are not given a value of '0'.

Tier 2 – Dataset Verification

ICBA questions whether submitters of certain occurrence data, for example, for the 'teas and herbal teas' category, had selected appropriate reporting units (i.e., µg/kg versus mg/kg) and/or an appropriate reporting basis (on dry matter versus as consumed). For example, many lead (Pb) occurrence data entries in GEMS/Foods for this commodity would appear to be on a dry basis and reported as mg/kg, not µg/kg. This assumption must then be stated clearly before proceeding with the qualitative and quantitative analyses. If there is an interest by CCCF to establish limits for teas as consumed, the brewing transference rates after steeping (a range of 0 to 20 percent, Schulzki et al., 2016) could be applied thereafter.

Separately, the International Programme on Chemical Safety ("IPCS") Principles and Methods for Risk Assessment of Chemicals in Foods (Environmental Health Criteria "EHC" 240) emphasizes that removing outliers and trimming the dataset are appropriate approaches to remove highly skewed samples.

> "In some cases, the distribution of concentration data may be **highly skewed to the right-hand side by a small proportion of high values or outliers**, where the mean is considerably higher than the median value. Options available as alternatives to using the arithmetic mean include 1) using the median concentration, particularly for chemicals where there are few data points, 2) **trimming the distribution to remove outlier values** when they are considered to not represent the levels to which people are likely to be exposed, then calculating the arithmetic mean value, or 3) using an alternative method to define the central tendency measure (e.g. mode, geometric mean), which reduces the impact of a small number of very high concentration values. The geometric mean is not commonly used in dietary exposure assessments, but may be of use in cases where the data distribution is skewed and/or the median is below the LOD or LOQ. (p. 6-33, Section 6.3.1.2., Chapter 6, EHC 240)" (emphasis added)

***Minimum sample size requirements must be met***

Before any qualitative or quantitative analysis of the dataset can be performed, the evaluator should ensure the minimum number of samples requirements for high percentile estimates has been met to ensure statistical robustness.

CL 2021/78-CF states, "[T]he coverage probability has been used to set guidelines to determine the minimum number of samples for which (extreme) percentiles can be computed. In the case of significance level (α) being set at 0.05 to determine a 95% confidence interval, the coverage probability should target 95%. In this case, this is achieved for $n \geq 59$ and $n \geq 298$ for the 95th or 99th percentiles, respectively."

However, according to the European Union MENU project, "Percentiles calculated on a limited number of subjects bear large uncertainty, and are likely to provide biased estimates. According to **Kroes et al. (2002),** high percentiles (p) can be assessed with sufficient accuracy if the sample size n satisfies the rule $\mathbf{n\,(1–p) \geq 8}$. The minimum sample sizes for the **95$^{th}$**, 97.5$^{th}$ and 99$^{th}$ percentiles can therefore be estimated to be equal to **160**, 320 and 800, respectively. Apparently, similar conclusions can be derived using a **binomial distribution (Conover, 1971**). In particular, assuming a statistical significance level equal to one percent (1%), the minimum sample sizes for the **95$^{th}$**, 97.5$^{th}$ and 99$^{th}$ can be estimated to be equal to **130,** 263 and 662, respectively. The same assumptions hold true for low percentiles. (p. 15, EFSA2009; p.27, EFSA2014)" Minimum sample size requirements stipulated in EFSA2009 and EFSA2014 are also consistent with guidance provided by others such as the U.S. National Center for Health Statistics ("NCHS", NCHS 1996; https://wwwn.cdc.gov/nchs/data/nhanes/analyticguidelines/99-10-analytic-guidelines.pdf). The utility of this approach has been demonstrated for high consumption level estimates and statistical reliability when dealing with a complex survey design inherent to consumption databases (assuming a design effect of 1.0) (CDC2013, EFSA2009, EFSA2014). A design effect of 1.0 assumes a simple random sample; however, variance from a clustered sample is often greater than that of a simple random sample, typically resulting in a higher design effect requiring a greater minimum sample size to compute a reliable estimate (CDC2013). Relative to occurrence data, sometimes it is not clear how samples were collected, making it difficult to estimate design effect in these cases and therefore one must assume a design effect of 1.0.

Once the minimum sample size requirements have been met, the qualitative analysis can proceed in which internal consistency of the dataset is evaluated across all production years and all regions to assess differences in contamination patterns. If observed differences can be scientifically explained, then the whole dataset should be subjected to a quantitative analysis. On the other hand, if the differences cannot be explained, then there should be a dialogue within CCCF on whether the questionable data should remain part of the dataset.

***Central tendency considerations when calculating the mean***

In the case of estimating exposure to food contaminants, the arithmetic mean may not be the best estimate to characterize typical contamination levels (especially when conducting a risk assessment). Both the average and/or upper percentiles of the distribution curve can be used in risk assessments, depending on whether the assessment is for assessing average exposure-over-time for a chronic effect or a short-term exposure for an acute effect. (Note, if the method used to derive the upper percentile estimate leverages the mean estimate, then discussion around central tendency becomes relevant relative to ML establishment.)

Guidance stipulates the need to identify the shape of the distribution in order to select the most statistically appropriate parameters to characterize intakes of the foods (which could also be applied to characterize the contaminants' occurrence in foods) (USCDC, 2014a). After visualizing and evaluating the shape of the distribution curve, there are statistical tests that could and should be conducted to determine the normality of the data (i.e., symmetrical or skewed). These tests, skewness included, provide insight as to which statistics would be appropriate, given

the shape of the data, to generate national estimates. Further, the guidance states that means are measures of a central tendency and goes on to describe the arithmetic, weighted arithmetic, and geometric means (USCDC, 2014b-f). The NCHS states that geometric means are used when data are highly skewed.

The data – not a prescriptive rule – must determine whether the arithmetic mean, geometric mean, or another measure best represents the average (JECFA, 2017; WHO, 2010). For example, if a distribution of data follows the standard bell-shaped curve of a normal distribution, the arithmetic mean would typically be the statistically appropriate estimate of the average. If the distribution of the data is not bell-shaped (i.e., skewed), the arithmetic mean will be more influenced by the highest (and lowest) statistical values on the distribution curve and becomes less representative of the "average" value. Therefore, for skewed data, estimates based on the geometric mean instead of the arithmetic mean may be more appropriate since the geometric mean is less influenced by the highest and lowest statistical values. In other words, when the distribution of the arithmetic averages for the entire dataset is symmetric, and the arithmetic mean is located where most samples are, then the arithmetic mean can be used to estimate the typical contamination level. However, when that distribution is skewed, then the arithmetic mean is typically not located where most samples are, while the geometric mean is. In that case, the geometric mean is the appropriate representation of the typical contamination level.

Furthermore, it has been noted that "many continuous variables… are by their nature very skewed (USDA, 1995)." NHANES specific guidance recommends the use of the geometric mean instead of the arithmetic mean in cases where the distribution of data is skewed (USCDC, 2014a):

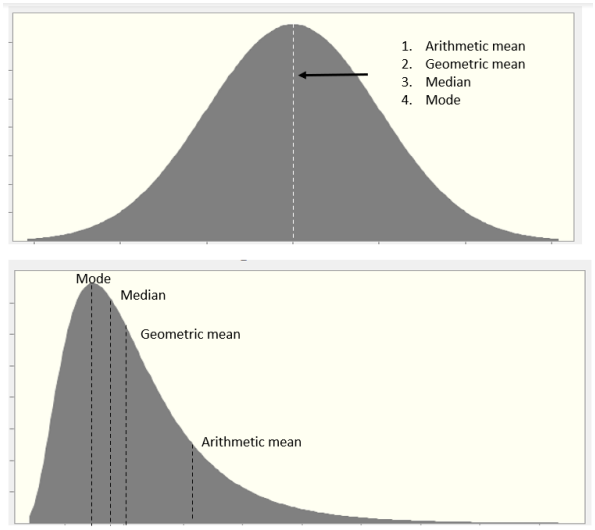
> "Question 6. When should you use geometric means instead of arithmetic means?
> "Answer: In instances where the data are highly skewed, geometric means should be used. A geometric mean, unlike the arithmetic mean, minimizes the effect of very high or low values, which could bias the mean if a straight average (arithmetic mean) were calculated."

The U.S. Center for Disease prevention and Control ("CDC") highlights the importance of considering the shapes of the distribution of values and applying appropriate statistical methods. This guidance to use the geometric mean is provided as part of a tutorial that the CDC recommends all users of the U.S. National Health and Nutrition Examination Survey ("NHANES") data take prior to analyzing data from the surveys.

Basic statistic textbooks provide similar steps when approaching data analysis and calculation of descriptive statistics. In "Fundamentals of Biostatistics," the author states that the first step in the data analysis process is "…to get a general feel for the data by summarizing the information in the form of several descriptive statistics (Rosner, 1999)." These statistics can be evaluated graphically or in tabular form, allowing for selection of the appropriate measure. The author goes on to state that "the appropriate type of descriptive material will vary with the type of distribution considered." The first measure described by Rosner – to be useful for summarizing the center, or middle, of the sample – is a measure of location (i.e., central tendency). Several

options are provided for this measure including the arithmetic mean, the median, the mode, and the geometric mean (*see* Figure 2). The arithmetic mean is described as a widely used measure of central location with the caution, "One of its principal limitations, however, is that it is overly sensitive to extreme values. In this instance it may not be representative of the location of the great majority of the sample points." In contrast, the geometric mean is described in this textbook as being the appropriate measure when the distribution is very skewed and the arithmetic mean is not appropriate.

**Figure 2. Top: Normal distribution; Bottom: Skewed distribution.**




The shape of the distribution helps inform the most statistically appropriate parameters required to characterize food intakes and occurrences. In contrast, the 90$^{th}$ or 95$^{th}$ percentile estimates would better represent outliers on the tail-end of the distribution severely skewing the analysis. Thus, the mean estimate – and especially the geometric mean (rather than the arithmetic mean) when a skewed distribution exists (see below) – is the more appropriate indicator for and better predicts central tendencies for most occurrences and is a more reliable and accurate estimate of the reasonably anticipated rate of intake or exposure (USCDC, 2014a-f).

## III. Occurrence Data Presentation

Relative to guidance on how to present data in reports to CCCF eWG, ICBA recommends that the following be clearly documented in any data package:

- All assumptions (in generating the final completed dataset) should be transparently noted and documented;
- Any determination about internal consistency of the data across production years or across regions and any accompanying scientific justification for inconsistent data should be provided;
- All other relevant contextual information as noted in the CL 2021/78-CF – such as sample size of quantifiable results; histogram of occurrence data; mean, median, P90, P95, P99 estimates – should likewise be included.

## IV. Other factors for possible future consideration

ICBA recommends that CCCF prioritize developing a consistent approach to occurrence data collection, analysis and presentation. Once this priority work is complete, discussions on elements forming the basis of ML establishment should eventually be considered as well, including rejection rates and GEMS/Foods market-based cluster diets.

### *Identification of appropriate rejection rates in ML establishment*

As noted earlier, while the appropriateness of a given rejection rate discussion is not a first priority, it should be retained here as a placeholder for future consideration when CCCF discussions around ML establishment ensue. This is a relevant concept that keeps arising in CCCF deliberations, most recently in the data analysis for possible maximum levels for lead and total aflatoxins. Once CCCF completes its work on data collection, analyses and presentation, at that time the eWG scope could be expanded to include discussions around the appropriateness of rejection rates along with other considerations.

### *Appropriateness of the market-based GEMS/Foods clusters diet in ML establishment*

Aside from rejection rates, ICBA would appreciate having CCCF consider the reasonableness of some of the GEMS/Food cluster commodity consumption amounts leveraged to establish MLs. GEMS/Food clusters are market-based values drawing on supply utilization (i.e., disappearance data which can overestimate consumption), and not consumption-based values (see Section 6.4.4.1 (b) on p. 6-61 of Chapter 6, EHC 240). In contrast, GSCTFF states, "**Food consumption data** for average, most exposed (high consumers) and susceptible consumer groups are desirable for evaluations of (potential) intake of contaminants (see Annex I, GSCTFF)." The main benefit of the GEMS/Food cluster diets is to identify the cluster of countries with anticipated similar food consumption patterns based on a market analysis, but more precise data from food consumption surveys would be more appropriate for ML considerations.

To demonstrate, some values within the GEMS/Food cluster diets neither represent realistic or even high consumption amounts of those foods (e.g., spices/herbs, sugar). Reviewing daily consumption amounts across GEMS/Food cluster diets in Appendix III Table X1 of CX/CF

19/13/9 for 'spices and aromatic herbs' the two highest consuming clusters identified were G15 (36.73 g/day) and G09 (33.68 g/day) with a mean of 17.3 g/day. One teaspoon of spice may contain 2-5 g of the spice (depending of course on the spice). The above cluster amounts would suggest average *per capita* intake of spices as high as 7 - 18 teaspoons. A single person in any one country is unlikely to consume 18 teaspoons of spice every day. Amounts reported for herbs – having a lower density to spices – likewise could erroneously suggest that 36 'tablespoons' of herbs are consumed daily *per capita*. In either scenario, the amounts theoretically consumed on a daily *per capita* basis seem wholly unrealistic. Typical consumption amounts are a fraction of what has been reported in the GEMS/Food cluster diets, even in high consuming markets such as India where most spices consumed were below 1 g per serving (Carlsen et al., 2011; Siruguri and Bhat, 2015).

As another example, ICBA questions consumption values that were reported for 'sugar and confectionary excluding cocoa'. It is not clear whether the market-reported daily amounts were on a sugar commodity basis or a whole finished product basis. The U.S. Food Commodity Intake Database ("FCID") is based on NHANES food intake and FCID recipes to estimate food commodity consumption for the purposes of pesticide dietary exposure assessment (USEPA, 2012). Leveraging the FCID calculator and selecting either sugar-beet or sugar-cane for children/adolescents (< 17 yrs) or adults (>18 yrs) or the general population (all ages), the 'eaters only' intake amounts are reflected in the below distribution:

**Eaters Only Population** — **Single Day Consumption Commodity Mass (g)**

| | | | | | | Percentiles | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | N | Mean | SE | 1% | 5% | 10% | 15% | 20% | 25% | 30% | 35% | 40% | 45% | 50% | 55% | 60% | 65% | 70% | 75% | 80% | 85% | 90% | 95% | 97.5% | 99% | Max |
| **Beet, sugar** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Age Range** | **Gender** | **Race** | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 to < 17 years | All | All | 16,311 | 15.69 | 0.23 | 0.2 | 1.1 | 2.3 | 3.5 | 4.8 | 6.0 | 7.2 | 8.3 | 9.4 | 10.5 | 11.9 | 13.1 | 14.6 | 16.3 | 18.4 | 20.5 | 23.3 | 27.0 | 32.7 | 43.3 | 55.1 | 75.6 | 448.6† |
| 18 years and older | All | All | 28,510 | 15.49 | 0.27 | 0.1 | 0.5 | 1.3 | 2.2 | 3.3 | 4.3 | 5.5 | 6.6 | 7.8 | 9.1 | 10.5 | 12.1 | 13.7 | 15.6 | 17.9 | 20.5 | 23.7 | 28.1 | 34.8 | 47.0 | 61.1 | 83.9 | 378.8† |
| All ages | All | All | 46,512 | 15.48 | 0.23 | 0.1 | 0.6 | 1.4 | 2.4 | 3.5 | 4.7 | 5.8 | 7.0 | 8.2 | 9.4 | 10.8 | 12.3 | 13.9 | 15.8 | 18.0 | 20.5 | 23.6 | 27.9 | 34.0 | 46.2 | 59.5 | 81.5 | 448.6† |
| **Sugarcane, sugar** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Age Range** | **Gender** | **Race** | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 to < 17 years | All | All | 16,311 | 20.26 | 0.32 | 0.2 | 1.4 | 3.0 | 4.5 | 6.2 | 7.7 | 9.2 | 10.6 | 12.0 | 13.5 | 15.1 | 16.9 | 18.7 | 21.0 | 23.7 | 26.3 | 29.9 | 34.8 | 42.2 | 56.4 | 72.6 | 97.1 | 571.0† |
| 18 years and older | All | All | 28,524 | 20.69 | 0.33 | 0.1 | 0.7 | 1.7 | 3.0 | 4.4 | 5.8 | 7.2 | 8.7 | 10.3 | 12.1 | 14.0 | 15.9 | 18.1 | 20.8 | 23.7 | 27.3 | 31.6 | 37.5 | 47.0 | 63.4 | 81.2 | 112.5 | 482.1† |
| All ages | All | All | 46,526 | 20.52 | 0.28 | 0.1 | 0.8 | 1.9 | 3.2 | 4.6 | 6.1 | 7.6 | 9.1 | 10.7 | 12.4 | 14.2 | 16.1 | 18.2 | 20.8 | 23.7 | 27.0 | 31.1 | 36.8 | 45.6 | 61.7 | 79.5 | 108.2 | 571.0† |

**Notes:** '†' indicates estimates are less statistically reliable based on np < 8 * 'Design Effect' guidance published in the *Joint Policy on Variance Estimation and Statistical Reporting Standards on NHANES III and CSFII*

The reported amounts consumed daily for sugar from sugar-beet or sugar-cane at the 95$^{th}$ percentile were 46 g/d or 62 g/d *per capita*, respectively, and at the median, 11 g/day or 14 g/day. These reported consumption amounts do not align with the market-based amounts suggested in CX/CF 19/13/9 Appendix III Table X1 for the highest consuming clusters (i.e., 245 g/d for the G6 cluster or 237 g/d for the G11 cluster) or even for the G10 cluster of which USA is a part (i.e., 194.91 g/d).

Similarly, amounts for coffee and coffee-based products in GEMS/Food clusters seem to represent the roasted beans and/or ground coffee, not the finished coffee beverage. Dried tea leaves are not consumed as such but rather steeped and brewed prior to consumption. Amounts reported in GEMS/Food clusters would appear to reflect dried amounts rather than finished brewed beverage. Transference rates of a contaminant (or otherwise) from roasted beans or

dried tea leaves to the brewed coffee or tea beverage would have to be factored into these calculations if MLs are to be set on the finished beverage.

Thus, ICBA encourages CCCF to consider the discrepancies noted above to 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). Suggestions on how the GEMS/Food cluster amounts for some commodities should be rectified in view of these discrepancies would be welcomed guidance as well.

## V. Conclusion

ICBA welcomes CCCF's efforts to elaborate a consistent approach for collecting, analyzing and presenting occurrence data. ICBA respectfully requests that CCCF address the important themes and critical concepts identified above.

We thank you for your considerations.

Respectfully submitted,

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