CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/CF 13/7/5**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

Seventh Session
Moscow, Russian Federation, 8 – 12 April 2013

PROPOSED DRAFT REVISION OF THE MAXIMUM LEVELS FOR LEAD IN SELECTED COMMODITIES IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CODEX STAN 193-1995): Fruit juices, milk, infant formula, canned fruits and vegetables, and cereal grains (except buckwheat, cañihua and quinoa)

(AT STEP 3)

Codex Members and Observers wishing to submit comments at Step 3 on the proposed draft revision of the maximum levels for lead in the above commodities as stated in point 1-5 of paragraph 35 of the Summary and Recommendations, including possible implications for their economic interests, should do so in conformity with the *Uniform Procedure for the Elaboration of Codex Standards and Related Texts* (Codex Alimentarius Commission Procedural Manual) before **25 March 2013**. Comments should be directed:

to:	with a copy to:
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Note: Supportive information is presented in paragraphs 1 through 34 and Appendix I and is not subject to comments at Step 3. In addition, Codex members and observers may wish to provide their views on the recommendations in paragraph 35 (points 6 and 7) and paragraph 36 which are neither subject to the Step Procedure but will be considered by the Committee.

BACKGROUND

1. The 6th Session of the Committee on Contaminants in Foods (CCCF), held in Maastricht, the Netherlands, from 26 March to 30 March 2012, agreed to establish an electronic Working Group (WG) led by the United States of America to revise the maximum levels (MLs) for lead in fruit juices, milk and milk products, infant formula, canned fruits and vegetables, fruits, and cereal grains (except buckwheat, cañihua and quinoa) in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF). The Committee also agreed to consider consolidating the MLs for canned fruit and vegetable products.[1] The 35th Session of the Codex Alimentarius Commission, held in Rome, Italy, from 2-7 July 2012, approved this work as new work for the CCCF.[2] A list of countries and nongovernmental organizations (NGOs) that joined the WG can be found in Appendix 2.

2. The United States of America requested that WG members submit data on lead levels in the listed foods from the last 10 years to the GEMS/Food[3] database of the FAO/WHO Joint Expert Committee on Food Additives (JECFA). In response, the following countries submitted new data on lead levels in foods: Argentina, Australia, Canada, China, the European Union, Japan, New Zealand, Thailand, and the United States. The International Council of Grocery Manufacturers Associations (ICGMA) and FoodDrink Europe also submitted data. Data submitted previously by the countries listed above, as well as previously submitted data from Brazil, Mali and Singapore, were also used in the analysis.

[1] REP12/CF, para. 127.
[2] REP12/CAC, Appendix VI.
[3] Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme, http://www.who.int/foodsafety/chem/gems/en.

3. The United States prepared the draft paper with the technical assistance of the JECFA Secretariat. Comments were received from the following countries/NGOs: Australia, Canada, China, the European Union, Japan, Spain, FoodDrinkEurope, ICGMA, and the International Federation of Fruit Juice Producers (IFU). Due to the length of time needed for data submission and analysis, the WG reviewed only one draft of the paper.

INTRODUCTION

4. As a reminder, this work was undertaken in response to the new toxicological evaluation of lead in food conducted by JECFA at its 73rd meeting, at the request of CCCF. In the evaluation[4], JECFA stated that exposure to lead is associated with a wide range of effects, including various neurodevelopmental effects, impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. Because of the neurodevelopmental effects, foetuses, infants and children are the subgroups that are most sensitive to lead. JECFA withdrew the previously established provisional tolerable weekly intake (PTWI) of 25 µg/kg bw and concluded that it was not possible to establish a new PTWI that would be considered to be health protective. JECFA also concluded that, in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources and foods and, if appropriate, to identify methods of reducing dietary exposure that are commensurate with the level of risk reduction.

5. Since no safe level of lead has been identified by JECFA, the focus of the paper was to review occurrence data to determine what percentage of samples can meet proposed new MLs. The paper did not propose MLs based on levels of exposure or on consumption. This approach is consistent with the approach presented in last year's paper[5].

WORK PROCESS

6. The collection of data and initial analysis of results (e.g., generation of percentage tables) were performed by the JECFA Secretariat, and based on the GEMS/Food database. Decisions about which data were excluded, how data should be presented, and what recommendations should be included were made by the WG.

7. The first step in analysis of the data was to remove data that did not meet basic criteria. For example, for cereals, we removed processed cereal products. This process left us with our raw dataset.

8. The second step was to prepare a second dataset based on the limit of quantitation (LOQ) of the method associated with each sample (LOQ-limited dataset). We found that many results in the raw dataset were obtained with methods with a reported LOQ higher than the Codex ML for that food. Further, some of these samples had results reported as nondetects (NDs). NDs obtained with a method with an LOQ higher than the ML may actually be higher than the ML. Furthermore, methods with an LOQ higher than the ML cannot accurately determine whether a food meets the ML. Therefore, for each food, we prepared a second dataset excluding all results obtained with a method with an LOQ higher than the ML. We also excluded samples that were entered in the GEMS database without an LOQ, as we could not evaluate whether these samples met the LOQ criteria[6]. Since we believe this dataset is more informative than the raw dataset, which includes results obtained with methods with LOQs higher than the ML, our conclusions are based primarily on the LOQ-limited dataset.

9. The final step in the analysis was to prepare tables showing the percentage of lead level results in the LOQ-limited dataset that meet the current and hypothetical lower MLs[7].

10. Both the raw and LOQ-limited datasets contained NDs, which were treated as zeros in the analysis. In exposure analyses, NDs may be replaced by such values as zero, or a value between zero and the limit of detection (LOD) to provide a more conservative indicator of exposure. In this project, we are not conducting an exposure analysis, but determining what percentage of samples can meet current or proposed new MLs. In this case, replacing NDs by a value between zero and the LOD would underestimate the ability of foods to meet the proposed MLs. Therefore, we replaced NDs with zeros.

11. The original proposal was to revise MLs for fruit juices, milk and milk products, infant formula, canned fruits and vegetables, fruits, and cereal grains (except buckwheat, cañihua and quinoa). Due to the significant amount of work involved in gathering and analyzing data, milk products and fruits were not included in this year's work. We recommend that these products be included in future work.

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[4] JECFA. Evaluation of Certain Food Additives and Contaminants. Seventy-third report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series 960.
[5] CX/CF 12/6/13.
[6] This exclusion may remove a small number of samples with valid results. The WG determined that this risk was offset by the benefits of having a consistent approach to an LOQ requirement and by the possibility that including samples with no reported LOQ could have resulted in inclusion of samples that did not meet our LOQ requirement.
[7] These tables are calculated with the Excel rank function. Rank function results are slightly different than results calculated with the Excel percentile.exc function, which is considered more accurate. However, the rank function has the advantage of allowing us to view the impact of specific hypothetical MLs, and therefore was chosen as more appropriate for this document.

ANALYSIS OF INDIVIDUAL FOODS

12. **Fruit Juice**. 3461 results mapped to fruit juice in the GEMS/Food database for fruit juice samples analyzed between 1999 and 2012. To obtain the raw dataset, we excluded 395 samples that did not meet the definition of fruit juice in the Codex standard[8]. This exclusion step left 3066 results in the fruit juice raw dataset. We then excluded 363 samples with an LOQ > 0.05 mg/kg or no reported LOQ to obtain the LOQ-limited set of 2703 samples. Tables FJ-1 and FJ-2 (in Appendix 1) show the breakdown by country of the raw dataset and the LOQ-limited dataset.

13. Our next step was statistical analysis of the datasets. Table FJ-3 shows the mean and maximum lead levels associated with the fruit juice datasets. Table FJ-4 shows the percentage of fruit juice samples meeting current and hypothetical MLs for the LOQ-limited dataset.

14. For fruit juices, 99 percent of the samples in the LOQ-limited dataset (i.e., results obtained with a method with an LOQ ≤ 0.05 mg/kg) met the current Codex ML of 0.05 mg/kg (Table FJ-4). This table also indicates that 98.0 percent of samples may meet a hypothetical ML of 0.04 mg/kg, 96 percent of samples may meet a hypothetical ML of 0.03 mg/kg, and 92 percent of samples may meet a hypothetical ML of 0.02 mg/kg. Thus, lowering the ML to the hypothetical level of 0.03 mg/kg would eliminate approximately 4 percent of the samples in international trade, while lowering the ML to the hypothetical level of 0.02 mg/kg would eliminate approximately 8 percent of the samples in international trade. These results suggest that 0.03 mg/kg would be an appropriate ML for fruit juices.

15. Several WG members suggested that certain juices (such as cherry juice) may need a higher ML. One possibility that could be considered for future work is whether fruit juices should be analyzed separately, and whether more than one ML should be considered for fruit juices. The current terms of reference do not cover proposing new MLs.

16. **Milk**. 6187 results mapped to milk in the GEMS/Food database for samples analyzed between 1998 and 2011. To obtain the raw dataset, we excluded 318 samples corresponding to milk powder, concentrated milk, condensed milk, dried milk, chocolate milk, evaporated milk, and cream. This exclusion step left 5869 results in the fluid milk dataset, including milk of cattle and other species. We then excluded 1043 samples with an LOQ > 0.02 mg/kg or no reported LOQ to obtain the LOQ-limited set of 4826 samples. Tables M-1 and M-2 show the breakdown by country of the raw dataset and the LOQ-limited dataset.

17. Our next step was statistical analysis of the datasets. Table M-3 shows the mean and maximum lead levels associated with the milk datasets. Table M-4 shows the percentage of milk samples meeting current and hypothetical MLs for the LOQ-limited dataset.

18. For milk, 94 percent of the samples in the LOQ-limited dataset (i.e., results obtained with a method with an LOQ ≤ 0.02 mg/kg) met the current Codex ML of 0.02 mg/kg (Table M-4). This table also indicates that 90.0 percent of samples may meet a hypothetical ML of 0.015 mg/kg and that 85 percent of samples may meet a hypothetical ML of 0.01 mg/kg. Thus, lowering the ML to the hypothetical level of 0.015 mg/kg would eliminate approximately 10 percent of the samples in international trade, while lowering the ML to the hypothetical level of 0.01 mg/kg would eliminate approximately 15 percent of the samples in international trade. These results suggest that it would be challenging to lower the ML for milk.

19. **Infant formula**. 322 results mapped to infant formula in the GEMS/Food database for samples analyzed between 2000 and 2011. To obtain the raw dataset, we excluded 147 samples of powdered formula, as ready to use formula is specified in the GSCTFF. (Powdered formulas are discussed further in paragraph 23.) This exclusion step left 175 liquid formula results in the infant formula raw dataset. We then excluded 37 samples that had an LOQ > 0.02 mg/kg or no reported LOQ, leaving 138 samples in the LOQ-limited dataset. Tables IF-1 and IF-2 show the breakdown by country of the raw dataset and the LOQ-limited dataset.

20. Our next step was statistical analysis of the datasets. Table IF-3 shows the mean and maximum lead levels associated with the infant formula datasets. Table IF-4 shows the percentage of infant formula samples meeting current and hypothetical lower MLs for the LOQ-limited dataset.

21. For infant formula, 100 percent of the samples in the LOQ-limited dataset (i.e., results obtained with a method with an LOQ ≤ 0.02 mg/kg) met the current Codex ML of 0.02 mg/kg (Table IF-4). This table also indicates that 99 percent of samples may meet a hypothetical ML of 0.01 mg/kg, 95 percent of samples may meet a hypothetical ML of 0.005 mg/kg, and 92 percent may meet a hypothetical ML of 0.003 mg/kg. Given the importance of infant formula in infant diets, an ML of 0.005 may be appropriate; however, based on the limitations of the current dataset, we would recommend an ML of 0.01 mg/kg. One limitation of this dataset is narrow geographical representation. Another limitation is that the majority of the samples in this dataset are NDs (zeros). Therefore, we looked more closely at the 11 quantifiable results of the 138 total results in this dataset (Table IF-5). These results ranged from 0.0014 to 0.011 mg/kg, with all but one result ≤ 0.01 mg/kg, supporting the conclusion that 0.01 mg/kg may be a reasonable ML.

22. In last year's Discussion Paper[9], we stated that current methods using inductively coupled plasma mass spectrometry (ICP-MS) can achieve LOQs for lead of 0.003 to 0.01 mg/kg in ready to use infant formula. We recommend that the Codex Committee on Methods of Analysis and Sampling (CCMAS) be consulted about the LOQs associated with current methodology if the Committee proceeds with a proposal to revise the ML for infant formula.

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[8] Excluded samples included juice concentrates, juice drinks or juice cocktails containing less than 100 percent fruit juice, tea, dehydrated/powdered juice, coconut isotonic drink, custard apple juice, vegetable juices (including tomato juice), alcohol-containing drinks, and canned fruits.

[9] CX/CF 12/6/13.

23. Several members of the working group suggested that we incorporate the excluded powdered infant formula results (which were all follow-on formulas) in our analysis. Because the GSCTFF specifies ready to use formula, we decided to conduct separate analyses for the powdered follow-on formulas. Starting with the 147 samples of powdered formula, we then excluded 98 samples that had an LOQ > 0.02 mg/kg or no reported LOQ, leaving 49 samples in the LOQ-limited dataset. We assumed the results in the GEMS/Food database were for the powder, and applied a 1:8 dilution factor to correct for users diluting formula before use. Table IF-6 show the percentage of powdered infant formula samples in the LOQ-limited dataset meeting current and hypothetical lower MLs for ready to use formula. Based on this analysis, the powdered samples meet all the hypothetical MLs for ready to use formula. One option for the Committee to consider would be to add a note in the note/remarks column in the GSCTFF that the ML also applies to powdered formula with a dilution factor of, e.g., 1:8.

24. **Canned foods**. In last year's discussion paper[10], the WG recommended that CCCF establish one ML or a more limited number of MLs for canned fruit and vegetable products versus the 18 MLs currently listed in the GSCTFF[11] for canned foods. Therefore, the WG has analyzed the 18 canned foods in the GSCTFF as two groups, canned fruits and canned vegetables.[12] Tables C-1 and C-2 show the individual food results in these two categories from the GEMS/Food database.

25. **Canned fruits**. 1198 results mapped to canned fruits in the GEMS/Food database for samples analyzed between 2001 and 2012. To obtain the raw dataset, we excluded 277 samples corresponding to jams and jellies (including products listed as conserves) and olives. This exclusion step left 921 results in the canned fruits raw dataset. No results exceeded the current Codex standard of 1.0 mg/kg and no LOQs associated with the results exceeded 1.0 mg/kg. Therefore, no further exclusions were made and there is only one dataset for canned fruits. Table C-3 shows the breakdown by country of this dataset.

26. Our next step was statistical analysis of the dataset. Table C-4 shows the mean and maximum lead levels associated with the canned fruits dataset. Table C-5 shows the percentage of canned fruit samples meeting current and hypothetical lower MLs.

27. As noted above, for canned fruits, 100 percent of the samples meet the current Codex ML of 1.0 mg/kg (Table C-5). This table also indicates that 98.0 percent of samples may meet a hypothetical ML of 0.1 mg/kg, 95 percent of samples may meet a hypothetical ML of 0.05 mg/kg, but that only 76 percent may meet a hypothetical ML of 0.02 mg/kg. Thus, lowering the ML to the hypothetical level of 0.1 mg/kg would eliminate approximately 2 percent of the samples in international trade, while lowering the ML to the hypothetical level of 0.05 mg/kg would eliminate approximately 5 percent of the samples in international trade. These results suggest that it would be feasible to lower the ML for canned fruits at least 10-fold.

Canned vegetables. 595 results mapped to canned vegetables in the GEMS/Food database for samples analyzed between 2001 and 2012. To obtain the raw dataset, we excluded 200 samples corresponding to processed tomato concentrates. This exclusion step left 395 results in the canned vegetables raw dataset. No results exceeded the current Codex standard of 1.0 mg/kg and no LOQs associated with the results exceeded 1.0 mg/kg. Therefore, no further exclusions were made and there is only one dataset for canned vegetables. Table C-6 shows the breakdown by country of this dataset.

28. Our next step was statistical analysis of the dataset. Table C-7 shows the mean and maximum lead levels associated with the canned vegetables dataset. Table C-8 shows the percentage of canned vegetable samples meeting current and hypothetical lower MLs.

29. As noted above, for canned vegetables, 100 percent of the samples meet the current Codex ML of 1.0 mg/kg (Table C-8). This table also indicates that 99.0 percent of samples may meet a hypothetical ML of 0.1 mg/kg, 96 percent of samples may meet a hypothetical ML of 0.05 mg/kg, and 89 percent of samples may meet a hypothetical ML of 0.02 mg/kg. Thus, lowering the ML to the hypothetical level of 0.1 mg/kg would eliminate approximately 1 percent of the samples in international trade, lowering the ML to the hypothetical level of 0.05 mg/kg would eliminate approximately 4 percent of the samples in international trade, and lowering the ML to the hypothetical level of 0.02 mg/kg would eliminate approximately 11 percent of the samples in international trade. These results suggest that it would be feasible to lower the ML for canned vegetables at least 10-fold.

Cereals. 13134 results mapped to cereals in the GEMS/Food database for samples analyzed between 1996 and 2012. To obtain the raw dataset, we excluded 3769 samples that did not meet the Codex standard, such as raw buckwheat and quinoa grains or processed cereal products.[13] This exclusion step left 9365 results in the cereals raw dataset. We then excluded 285 samples with an LOQ > 0.2 mg/kg to obtain the LOQ-limited set of 9080 samples. Tables CL-1 and CL-2 show the breakdown by country of the raw dataset and the LOQ-limited dataset.

30. Our next step was statistical analysis of the datasets. Table CL-3 shows the mean and maximum lead levels associated with the cereal datasets. Table CL-4 shows the percentage of cereal samples meeting current and hypothetical lower MLs for the LOQ-limited dataset.

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[10] CX/CF 12/6/13

[11] Japan has noted that a number of MLs currently listed in Schedule I of the GSCTFF (amended in 2010) have been revoked, although the GSCTFF document on the Codex website has not been updated. The revoked standards are canned grapefruit, canned oranges, canned asparagus, canned carrots, canned green beans and canned wax beans, canned green peas, canned mature processed peas, canned palmito, and canned sweet corn.

[12] Jams and jellies, chutney, table olives, pickled cucumbers, and processed tomato concentrates were not included in this analysis.

[13] Processed cereal products included products described as bran, breakfast cereal, cereal bars, cooked grains, corn chips, flakes, flour, germ, grits, meal, milling products, pasta, puffed or popped grains, and starch.

31. For cereals, 97 percent of the samples in the LOQ-limited dataset (i.e., results obtained with a method with an LOQ ≤ 0.2 mg/kg) met the current Codex ML of 0.2 mg/kg (Table CL-4). This table also indicates that 92.0 percent of samples may meet a hypothetical ML of 0.1 mg/kg, 83 percent of samples may meet a hypothetical ML of 0.05 mg/kg, and 75 percent of samples may meet a hypothetical ML of 0.03 mg/kg. Thus, lowering the ML to the hypothetical level of 0.1 mg/kg would eliminate approximately 8 percent of the samples in international trade, lowering the ML to the hypothetical level of 0.05 mg/kg would eliminate approximately 17 percent of the samples in international trade, and lowering the ML to the hypothetical level of 0.03 mg/kg would eliminate 25 percent of samples in international trade. These results suggest that it will be difficult to lower the ML for all cereals. One possibility that could be considered in the future is whether certain cereal grains have uniquely high lead levels and whether more than one ML should be considered for cereal grains in the future. The current terms of reference do not cover proposing new MLs.

ADDITIONAL TOPICS

32. One member of the working group noted that lowering the MLs for only certain foods, and only when it impacts a certain percentage of the market, would help eliminate a portion of products with higher lead content and help reduce exposure, but may not have a significant effect on overall lead intake. One option would be to request JECFA to perform an intake assessment to determine which food categories contribute the most to the overall lead intake in children and to determine the potential benefit of lowering the corresponding MLs even further, and potentially to consider reductions that would affect more than a small percentage of the market. We are including this comment for consideration by the Committee.

33. Additional comments about fruit juices that have not been addressed elsewhere in this paper include: (a) Data do not represent all producing areas and (b) The choice of percentage cut-off value was arbitrary. Regarding (a), the WG notes that representation by all producing areas is dependent on submission of data by member countries. Regarding (b), the WG attempted to choose a percentage value that would be consistent with current occurrence data and would provide some reduction in lead levels, but without having too significant an impact on international trade. There was no specific rule to identify the appropriate cut-off value, but the values chosen in this paper were less than 5 percent. Further discussion by the Committee may be needed on the issue of cut-off values.

34. The WG also received a comment about infant formula stating that the fact that the infant formula samples contained a lower lead level than the current Codex ML is not a scientific justification for lowering the ML, and that the proposed revision does not provide evidence of increased safety. However, other comments were supportive of the approach of using occurrence data as a basis for proposing revised MLs.

SUMMARY AND RECOMMENDATIONS

35. In summary, analysis of the submitted occurrence data shows that it may be possible to lower MLs for lead in the GSCTFF for some foods, but that lowering MLs for other foods would be more challenging. The WG makes the following recommendations.

1) **Fruit juice**: Revise the ML to 0.03 mg/kg. Consider whether fruit juices should be analyzed separately in future work and whether more than one ML should be considered for fruit juices.
2) **Milk**: Maintain the current ML of 0.02 mg/kg.
3) **Infant formula**: Revise the ML to 0.01 mg/kg. Consider whether to add a note in the note/remarks column in the GSCTFF that the ML also applies to powdered formula with a dilution factor.
4) **Canned fruits and vegetables**: Consolidate the MLs for canned fruits and for canned vegetables and establish MLs of 0.1 mg/kg. Consider whether the revised MLs in the GSCTFF should simply apply to all canned fruits and vegetables or whether detailed scope requirements need to be included.[14,15]
5) **Cereals**: Maintain the current ML of 0.2 mg/kg. Consider whether more than one ML should be considered for cereal grains in the future, which would require reanalysis of cereal data by grain type.
6) Where lower MLs are proposed, refer the proposed MLs to CCMAS for consideration of whether methodology supports the lower MLs.
7) For next year, proceed with analysis of fruits, milk products, and vegetables. Analysis of fruits and vegetables is particularly important if CCCF adopts the proposed ML of 0.1 mg/kg for canned fruits and vegetables, since some non-canned fruits and vegetables have MLs > 0.1 mg/kg (e.g., brassica vegetables and berries).

[14] For example, the scope for tin in canned vegetables in the GSCTFF is as follows: "The scope of the Standard includes canned asparagus, canned carrots, canned green peas, canned green beans and wax beans, canned mature processed peas, canned palmito, canned sweet corn and canned baby corn offered for direct consumption, including for catering purposes or for repacking if required."

[15] The Committee may also want to consider whether the GSCTFF should include a statement of whether the canned food standards apply to the solid foods in the can, the packing liquid, or a composite of the solids and liquid.

36. The GEMS/Food database is an invaluable resource for this type of work. For maximum usefulness, the WG recommends that countries submitting data to the GEMS/Food database:

- Provide complete information on LOQ and LOD of analytical methods.
- Provide information in the “Local Food Identifier” or “Notes” fields of the database to allow more specific identification of samples, e.g., Is a food canned or jarred? Is it a finished product or a raw grain?
- Provide information on “State of Food Analyzed,” e.g., cooked or raw.

Appendix 1: Tables[16]

Table FJ-1: Fruit juice: Data contribution by country to raw dataset

Country	Total
Argentina	1
Australia	2
Canada	33
China	118
European Union	1835
Japan	43
New Zealand	25
Singapore	62
Thailand	74
USA	873
Grand Total	3066

Table FJ-2: Fruit juice: Data contribution by country to LOQ-limited dataset

Country	Total
Argentina	1
Australia	1
Canada	3
China	118
European Union	1623
Japan	43
New Zealand	24
Thailand	29
USA	861
Grand Total	2703

Table FJ-3: Fruit juice: Mean and maximum for all fruit juice datasets

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.0064	0.69
LOQ-limited dataset	0.0058	0.371

Table FJ-4: Percentage of fruit juice samples meeting current and hypothetical MLs: LOQ-limited dataset

Current and hypothetical MLs	Percentage of samples ≤ MLs
0.05	99
0.04*	98
0.03	96
0.02	92

*Hypothetical MLs shown in italics

[16] Some countries submitted aggregated data corresponding to single analytical results obtained by pooling several individual samples. For the LOQ-limited datasets, only 22 aggregated samples remained from 6 countries (Singapore, USA, Japan, Australia, New Zealand, Argentina). By definition, pooling samples decreases the apparent variability, however, for the current analysis it is unlikely that the pooled samples have a significant impact.

Table M-1: Milk: Data contribution by country to raw dataset

Country	Total
Australia	3
Canada	31
China	1245
European Union	4043
New Zealand	26
Singapore	266
USA	255
Grand Total	5869

Table M-2: Milk: Data contribution by country to LOQ-limited dataset

Country	Total
Australia	3
China	833
European Union	3864
New Zealand	26
USA	100
Grand Total	4826

Table M-3: Milk: Mean and maximum for all milk datasets

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.0058	0.52
LOQ-limited dataset	0.0052	0.52

Table M-4: Percentage of milk samples meeting current and hypothetical MLs: LOQ-limited dataset

Current and hypothetical MLs	Percentage of samples ≤ MLs
0.02	94
0.015	90
0.01	85

*Hypothetical MLs shown in italics

Table IF-1: Infant formula: Data contribution by country to raw dataset

Country	Total
Canada	16
New Zealand	8
Singapore	21
USA	130
Grand Total	175

Table IF-2: Infant formula: Data contribution by country to LOQ-limited dataset

Country	Total
New Zealand	8
USA	130
Grand Total	138

Table IF-3: Infant formula: Mean and maximum for infant formula datasets

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.001	0.011
LOQ-limited dataset	0.001	0.011

Table IF-4: Percentage of infant formula samples meeting current and hypothetical MLs: LOQ-limited dataset

Current and hypothetical MLs	Percentage of samples ≤ MLs
0.02	100
0.01*	99
0.005	95
0.003	92

*Hypothetical MLs shown in italics

Table IF-5: Infant formula results other than nondetects from the LOQ-limited dataset

Results (mg/kg)
0.0014
0.0016
0.0017
0.0040
0.0040
0.0050
0.0060
0.0070
0.0080
0.0100
0.0110

Table IF-6: Percentage of powdered infant formula samples meeting current and hypothetical MLs for ready to feed formula: LOQ-limited dataset

Current and hypothetical MLs	Percentage of samples ≤ MLs
0.02	100**
0.01*	100
0.005	100
0.003	100

*Hypothetical MLs shown in italics

**Assumes a 1:8 dilution of reported results for powdered samples.

Table C-1: Canned fruit types included in canned fruit category

Canned fruit type*	Number of results
Apple	6
Apricot	43
Assorted subtropical fruits	65
Cherries	5
Fruit and fruit products (NES)	142
Grapes	2
Jackfruit	2
Litchi	15
Longan	6
Mandarin and mandarin-like hybrid	58
Mango	7
Orange, sweet, sour and orange-like hybrid	31
Papaya	1
Peach	171
Pear	149
Pineapple	213
Rambutan	4
Strawberry	1
Total	921

*Based on WHO food identifiers. NES is “not elsewhere specified”. “Assorted subtropical fruits” includes canned fruit cocktails and canned fruit salads.

Table C-2: Canned vegetable types included in canned vegetable category

Canned fruit type*	Number of results
Artichoke globe	2
Asparagus	30
Bamboo shoots	13
Beetroot	37
Bulb vegetables	3
Cabbage, head	3
Carrot	4
Chestnuts	2
Fungi, edible (not including mushrooms)	1
Mushrooms	79
Mustard greens	2
Palm hearts	5
Peas (green pods & immature seeds)	6
Peppers, chili	10
Peppers, sweet (including pimento)	2
Pumpkins	1
Sugar beet	3
Sweet corn (cob)	7
Sweet corn (kernels)	87
Sweet potato	36
Tomato	49
Vegetables and vegetable products (NES)	13
Total	395

*Based on WHO food identifiers. NES is "not elsewhere specified" and may include canned bean sprouts, mixed vegetables, canned water chestnuts, canned green jackfruit, canned baby corn, and canned pickled ginger.

Table C-3: Canned fruit: Data contribution by country

Country	Total
Argentina	3
Australia	1
Canada	5
European Union	245
Japan	88
New Zealand	8
Thailand	51
USA	520
Grand Total	921

Table C-4: Canned fruits: Mean and maximum for canned fruits dataset

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.015	0.23

Table C-5: Percentage of canned fruit samples meeting current and hypothetical MLs

Current and hypothetical MLs	Percentage of samples ≤ MLs
1.0	100
0.5*	100
0.1	98
0.05	95
0.02	76

*Hypothetical MLs shown in italics

Table C-6: Canned vegetables: Data contribution by country

Country	Total
Australia	2
Japan	126
Singapore	7
Thailand	43
USA	217
Grand Total	395

Table C-7: Canned vegetables: Mean and maximum for canned vegetables dataset

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.0087	0.44

Table C-8: Percentage of canned vegetable samples meeting current and hypothetical MLs

Current and hypothetical MLs	Percentage of samples ≤ MLs
1.0	100
0.5*	100
0.1	99
0.05	96
0.02	89

*Hypothetical MLs shown in italics

Table CL-1: Cereals: Data contribution by country to raw dataset

Country	Total
Argentina	2
Australia	1
Canada	32
China	2107
European Union	4727
Japan	1804
Mali	99
New Zealand	3
Singapore	276
Thailand	157
USA	157
Grand Total	9365

Table CL-2: Cereals: Data contribution by country to LOQ-limited dataset

Country	Total
Argentina	2
Australia	1
China	2086
European Union	4681
Japan	1804
Mali	99
New Zealand	3
Singapore	95
Thailand	157
USA	152
Grand Total	9080

Table CL-3: Cereals: Mean and maximum for cereal datasets

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.065	23.62
LOQ-limited dataset	0.064	23.62

Table CL-4: Percentage of cereal samples meeting current and hypothetical MLs

Current and hypothetical MLs	Percentage of samples ≤ MLs
0.2	97
0.1*	92
0.05	83
0.03	75

*Hypothetical MLs shown in italics

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