

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: [codex@fao.org](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

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**TO** Codex Contact Points  
Contact Points of international organizations having observer status with Codex

**FROM** Secretariat,  
Codex Alimentarius Commission,  
Joint FAO/WHO Food Standards Programme

**SUBJECT** **REQUEST FOR COMMENTS AT STEPS 3 AND 6 ON THE PROPOSED DRAFT AND DRAFT REVISED MAXIMUM LEVELS FOR LEAD IN SELECTED FRUITS AND VEGETABLES (FRESH AND PROCESSED) AND OTHER SELECTED FOOD CATEGORIES IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CODEX STAN 193-1995)**

**DEADLINE** 20 March 2017

**COMMENTS** Codex Contact Point  
The Netherlands  
Email: [info@codexalimentarius.nl](mailto:info@codexalimentarius.nl)

**Copy to:**  
Codex Secretariat  
Joint FAO/WHO Food Standards Programme  
Codex Alimentarius Commission  
E-mail: [codex@fao.org](mailto:codex@fao.org)

## BACKGROUND

1. The 6<sup>th</sup> Session of the Codex Committee on Contaminants in Foods (March 2012) agreed to establish an electronic Working Group (EWG) 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) (CODEX STAN 193-1995). The Committee also agreed to consider consolidating the MLs for canned fruit and vegetable products.<sup>1</sup>
2. The 7<sup>th</sup> Session of CCCF<sup>2</sup> (April 2013) agreed to the following:
  - a. To retain the current MLs of 0.02 mg/kg for milks, 0.2 mg/kg for cereals, and 0.05 mg/kg for juices and nectars from berries and other small fruits, ready-to-drink.
  - b. To postpone consideration of the proposed draft ML of 0.01 mg/kg for infant formula to CCCF08 to allow time for interested countries to submit additional data for analysis, with the understanding that if no additional data were made available, the Committee would consider the proposed lower ML for adoption at the 8<sup>th</sup> session.
  - c. To advance a proposed draft ML of 0.03 mg/kg for fruit juices and nectars, ready-to-drink (excluding juices from berries and other small fruits); a proposed draft ML of 0.1 mg/kg for canned fruits, including canned mixed fruits (excluding canned berry and other small fruits); and a proposed draft ML of 0.1 mg/kg for canned vegetables, including canned mixed vegetables (excluding canned brassica vegetables, canned leafy vegetables and canned legume vegetables) to the 36<sup>th</sup> Session of the Codex Alimentarius Commission for adoption at Step 5/8.

<sup>1</sup> REP12/CF, paras. 126-127

<sup>2</sup> REP13/CF, paras. 37, 39-42 and Appendix II

3. The 36<sup>th</sup> session of the Commission (July 2013) agreed to adopt the MLs for fruit juice and canned fruits and vegetables at Step 5, with the understanding that countries that had intervened to object to adoption at Step 5/8 commit to submit data to the GEMS/Food database<sup>3</sup> within a year, to allow CCCF to further consider the revision of the MLs in 2015 for submission to CAC38.<sup>4</sup>
4. The 7<sup>th</sup> session of CCCF also agreed to reestablish the EWG led by the United States of America to continue with the review of MLs for lead in fruits, vegetables, milk products and infant formula, follow-on formula and formula for special medical purposes for infants.<sup>5</sup>
5. The 8<sup>th</sup> session of CCCF (March 2014) agreed to the following:<sup>6</sup>
  - (a) To forward a draft ML for lead in infant formula and formula for special medical purposes intended for infants and follow-on formula (as consumed) at 0.01 mg/kg for adoption by the CAC37 at Step 5/8. The Commission adopted the ML of 0.01 mg/kg at Step 5/8.
  - (b) Maintain the current MLs in the GSCTFF for assorted (sub)tropical fruits, edible peel; assorted (sub)tropical fruits, inedible peel; citrus fruits; pome fruits; stone fruits; bulb vegetables; leafy vegetables; root and tuber vegetables; and secondary milk products.
  - (c) Postpone discussion of the proposed ML of 0.1 mg/kg for berries and other small fruits until CCCF09 to allow interested countries to submit new or additional data to GEMS/Food for analysis on the understanding that if no data were made available, the Committee would accept the proposed lower ML for adoption at its 9th session. The Committee noted that the proposed lower ML of 0.1 mg/kg for berries and other small fruits may be acceptable when applied to the occurrence data of this group as a whole; however, when the data are split into the individual species or varieties of berries and small fruits, the proposed reduction may be problematic for some berries such as cranberries, currants, elderberries and strawberry tree.
  - (d) Postpone discussion of the proposed MLs of 0.1 mg/kg for legume vegetables and brassica vegetables, and 0.05 mg/kg for fruiting vegetables, cucurbits, and fruiting vegetables, other than cucurbits,<sup>7</sup> for further consideration in the EWG and finalization by CCCF09. The Committee noted several comments on the need to collect more occurrence data, in particular, better distribution of data among regions.
6. The 9<sup>th</sup> Session of CCCF (March 2015) agreed to the following:<sup>8</sup>
  - (a) To forward draft MLs for fruit juices and nectars (excluding juices exclusively from berries and other small fruits and passion fruit), ready-to-drink, at 0.03 mg/kg; canned fruits (excluding berries and other small fruits) at 0.1 mg/kg; and canned vegetables (excluding canned brassica, leafy and legume vegetables) at 0.1 mg/kg to CAC38 for adoption at Step 8.
  - (b) To forward draft MLs for berries and other small fruits (excluding cranberry, currant and elderberry) at 0.1 mg/kg; cranberries at 0.2 mg/kg; currant at 0.2 mg/kg; elderberry at 0.2 mg/kg; brassica vegetables at 0.1 mg/kg; legume vegetables at 0.1 mg/kg; fruiting vegetables, cucurbits at 0.05 mg/kg; and fruiting vegetables, other than cucurbits at 0.05 mg/kg (excluding fungi and mushrooms) to CAC38 for adoption at Step 5/8.
  - (c) To recommend revocation of the following MLs by CAC38: canned grapefruit, canned mandarin oranges, canned mangoes, canned pineapples, canned fruit cocktail, canned tropical fruit salad, canned asparagus, canned carrots, canned mature processed peas, canned mushrooms, canned palmito (palm hearts) and canned sweet corn.

<sup>3</sup> Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme, [http://www.who.int/foodsafety/areas\\_work/chemical-risks/gems-food/en](http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en)

<sup>4</sup> REP13/CAC, para. 79

<sup>5</sup> REP13/CF, paras. 39-40

<sup>6</sup> REP14/CF, paras. 21-24

<sup>7</sup> Excluding fungi and mushrooms

<sup>8</sup> REP15/CF, paras. 48-51

7. The 38<sup>th</sup> Session of the Commission<sup>9</sup> (July 2015) adopted the recommendations (described in paragraph 6 above) of CCCF09.
8. The 10<sup>th</sup> session of CCCF (April 2016) agreed to the following:<sup>10</sup>
  - (a) To forward the proposed draft revised MLs for fruit juices and nectars, ready-to-drink (inclusion of passion fruit) (ML = 0.03 mg/kg); canned fruits (inclusion of canned berries and other small fruits) (ML = 0.1 mg/kg); canned vegetables (inclusion of canned leafy vegetables and canned legume vegetables) (ML = 0.1 mg/kg); jams, jellies and marmalades (revised ML = 0.1 mg/kg and inclusion of marmalades); pickled cucumbers (revised ML = 0.1 mg/kg); preserved tomatoes (revised ML = 0.05 mg/kg and deletion of the note on the adjustment of the ML to take into account the concentration of the product); table olives (revised ML = 0.4 mg/kg) for adoption by CAC39 at Step 5/8.
  - (b) To request revocation of the MLs for lead in the GSCTFF for the following food categories: canned raspberries, canned strawberries, canned green beans and canned wax beans; canned green peas; jams (fruit preserves) and jellies; pickled cucumbers; preserved tomatoes; and table olives.
  - (c) To re-establish the EWG, chaired by USA, working in English only, to continue to work on outstanding issues related to the review of MLs for lead in fruits and vegetables (fresh and processed) and other selected food categories in the GSCTFF, namely review of MLs for fruit juices and nectars that are obtained exclusively from berries and other small fruits; canned brassica vegetables; canned chestnuts and canned chestnuts puree; fungi and mushrooms; mango chutney; processed tomato concentrates and to add two new food categories, i.e., fish and pulses, for consideration by CCCF11.
9. The 39<sup>th</sup> Session of the Commission (June 2016)<sup>11</sup> adopted the MLs at Step 5/8 as proposed by CCCF with the exception of the MLs for preserved tomatoes and jams, jellies and marmalades, which would be adopted at Step 5 only on the understanding that countries that raised concerns about practicality, number of samples, and geographical representativeness would submit relevant data in order to finalize these MLs at CCCF11 (2017).
10. The United States of America, as Chair of the EWG, prepared the paper on proposed revised MLs for lead in juices and nectars from berries and other small fruits; preserved tomatoes; processed tomato concentrates; jams (fruit preserves) and jellies; mango chutney; canned chestnuts and canned chestnuts puree; canned brassica vegetables; fungi and mushrooms; pulses; and fish, with the technical assistance of the Secretariat of the Food and Agriculture Organization (FAO)/World Health Organization (WHO) Joint Expert Committee on Food Additives (JECFA).
11. The work process followed for the revision of the MLs and the analysis of the individual foods is provided in Appendix I. Besides, matters raised by some Codex members and observer organizations are described in the additional topics for consideration by the Committee as appropriate.
12. The list of countries and non-governmental organizations (NGOs) that joined the EWG can be found in Appendix II. Comments were received from the following countries/NGOs: Austria, Canada, Chile, the European Union, India, Japan, Uruguay, and the International Fruit and Vegetable Juice Association (IFU).

#### **REQUEST FOR COMMENTS**

13. Codex members and observers are kindly invited to provide comments on the proposed draft and draft MLs for lead as indicated in paragraphs 15 - 24.
14. In providing comments, Codex members and observers are kindly invited to take into consideration the work process followed for the revision of the MLs and the analysis of individual foods as provided in Appendix I.

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<sup>9</sup> REP15/CAC, Appendices III, V

<sup>10</sup> REP16/CF, paras. 88-90

<sup>11</sup> REP16/CAC, para. 74

15. **Juices and nectars from berries and other small fruits:** Consider lowering the ML for lead in juices and nectars exclusively from berries and small fruits from 0.05 mg/kg to 0.03 mg/kg, with the exception of juices and nectars derived exclusively from currants, elderberries, raspberries, and strawberries, which should be maintained at 0.05 mg/kg.
16. **Preserved tomatoes:** Consider confirming the proposed ML for lead in preserved tomatoes of 0.05 mg/kg (currently at Step 5). Consistent with the decisions of CCCF10, the EWG also recommends deletion of the note in the GSCTFF for preserved tomatoes on the adjustment of the ML to take into account the concentration of the product.
17. **Processed tomato concentrates:** Consider lowering the ML for lead in processed tomato concentrates from 1.5 mg/kg to 0.05 mg/kg. Consistent with the decisions of CCCF10, the EWG also recommends deletion of the note in the GSCTFF for processed tomato concentrates on the adjustment of the ML to take into account the concentration of the product.
18. **Jams (fruit preserves) and jellies:** Consider revising the ML for lead in jams (fruit preserves) and jellies from 1 mg/kg (currently at Step 5 at 0.1 mg/kg) to:
  - 0.2 mg/kg, or
  - 0.5 mg/kg, or
  - If agreement cannot be reached on a revised ML, consider whether it would be preferable to revoke the current ML of 1.0 mg/kg for jams and jellies than to retain an ML of 1.0 mg/kg that is inconsistent with other MLs for lead in the GSCTFF.
19. **Mango chutney:** Consider lowering the ML for lead in mango chutney from 1 mg/kg to:
  - 0.1 mg/kg, which is 100 percent achievable but based on 34 samples, or
  - combine with jams (fruit preserves) and jellies at 0.2 mg/kg or 0.5 mg/kg, or
  - If agreement cannot be reached on a revised ML, consider whether it would be preferable to revoke the current ML of 1.0 mg/kg for mango chutney than to retain an ML of 1.0 mg/kg that is inconsistent with other MLs for lead in the GSCTFF.
20. **Canned chestnuts and chestnuts puree:** Consider lowering the ML for lead in canned chestnuts and chestnuts puree from 1 mg/kg to:
  - 0.05 mg/kg, which is 100 percent achievable, but based on 36 samples, or
  - combine with canned fruits at 0.1 mg/kg, or
  - If agreement cannot be reached on a revised ML, consider whether it would be preferable to revoke the current ML of 1.0 mg/kg for canned chestnuts and canned chestnuts puree than to retain an ML of 1.0 mg/kg that is inconsistent with other MLs for lead in the GSCTFF.
21. **Canned brassica vegetables:** Consider extending the current ML of 0.1 mg/kg lead in canned vegetables to canned brassica vegetables.
22. **Fungi and mushrooms:** Consider establishing an ML for lead in fungi and mushrooms (excluding mushroom and fungus products) of 0.6 mg/kg.
23. **Pulses:** Consider lowering the ML from 0.2 mg/kg to 0.1 mg/kg.
24. **Fish:** Maintain the current ML for lead in fish of 0.3 mg/kg.

## APPENDIX I SUMMARY REPORT

### (For information by Codex Members and Observers when considering the revised proposed MLs)

#### I INTRODUCTION

25. As a reminder, this work was undertaken in response to the new toxicological evaluation of lead in food conducted by JECFA at its 73<sup>rd</sup> meeting, at the request of CCCF. In the evaluation,<sup>1</sup> 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.
26. 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 previously,<sup>2</sup> as well as with an “as low as reasonably achievable approach” (ALARA) to lead in food in international trade.

#### WORK PROCESS

27. The Codex Secretariat requested that Codex countries, observers, and EWG members submit data on lead levels in juices and nectars from berries and other small fruits; preserved tomatoes; processed tomato concentrates; jams (fruit preserves) and jellies; mango chutney; canned chestnuts and canned chestnuts puree; canned brassica vegetables; fungi and mushrooms; pulses; and fish, preferably from the past 10 years, to the WHO GEMS/Food database. The collection and initial categorization of data were performed by the JECFA Secretariat, in consultation with the EWG, and based on the GEMS/Food database. Analysis of results and decisions about which data were excluded, how data should be presented, and what recommendations should be included were made by the EWG.
28. For products previously discussed by CCCF (juices and nectars from berries and other small fruits; preserved tomatoes; processed tomato concentrates; jams (fruit preserves) and jellies; mango chutney; canned chestnuts and canned chestnuts puree; and canned brassica vegetables), the EWG extracted data submitted since the extraction for last year’s report, and combined the new data with the dataset used in last year’s report. For the three remaining product categories under consideration by CCCF (fish, pulses, and fungi and mushrooms), the EWG extracted data from the GEMS/Food database covering approximately the last 15 years. The first step in analysis of the data was to remove data from the initial extractions that did not meet basic criteria. For example, for fungi and mushrooms, the EWG included uncooked fungi and mushrooms, and removed canned and dried fungi. This process left us with our raw dataset.
29. The second step was to prepare a second dataset based on the limit of quantitation (LOQ) of the analytical method associated with each sample (LOQ-limited dataset). The EWG 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 non-detects (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 category, the EWG prepared a second dataset excluding all results obtained with a method with an LOQ higher than the ML. The EWG also excluded samples that were entered in the GEMS/Food database without an LOQ, as the EWG could not evaluate whether these samples met the LOQ criteria. Since the EWG 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.

<sup>1</sup> 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.

<sup>2</sup> CX/CF12/6/13, CX/CF13/7/5, CX/CF14/8/5, CX/CF15/9/5, CX/CF 16/10/7

30. 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 and to make recommendations based on those percentages. The EWG 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 in general, our approach has been to recommend reductions in MLs when the percentage of excluded samples was less than 5 percent.<sup>3</sup> In cases where the Committee had previously identified potential MLs for consideration (e.g., 0.05 mg/kg for preserved tomatoes), the EWG considered the MLs previously identified by the Committee, rather than proposing new MLs. Likewise, in cases where the Committee had previously identified MLs for broad groupings (e.g., fruit juice), but excluded certain subsets (e.g., juice from berries and small fruits), the EWG focused on whether data supported extending the previously identified MLs to the subsets that had been excluded by the Committee.
31. 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, the EWG 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, the EWG replaced NDs with zeros.

### **ANALYSIS OF INDIVIDUAL FOODS**

#### Products previously discussed by CCCF

32. **Juices and nectars from berries and other small fruits.** At CCCF10, the Committee agreed to postpone the decision on juices and nectars from berries and other small fruits to allow submission of more data for consideration by CCCF11 on whether the ML of 0.03 mg/kg for fruit juices and nectars, ready-to-drink could apply or whether a higher separate ML of 0.04 mg/kg for this subset category should apply and to take a decision at CCCF11. The 2017 raw dataset for juices and nectars from berries and other small fruits consisted of 1132 results from the GEMS/Food database for samples collected and/or analyzed between 2000 and 2016. The EWG included juices and nectars exclusively from berries and other small fruits that were either not concentrated or were reconstituted to the original juice concentration (ready-to-drink). The EWG excluded 15 samples with an LOQ > the current ML of 0.05 mg/kg and 146 samples with no reported LOQ to obtain the 2017 LOQ-limited set of 971 samples. Table BF-1 (in the Annex) shows the breakdown by country of the 2017 raw and LOQ-limited datasets. Table BF-2 shows the mean and maximum lead levels associated with both datasets. Finally, Table BF-3 shows the percentage of samples of juices and nectars from berries and other small fruits meeting current and hypothetical MLs.
33. For juices and nectars from berries and other small fruits, 97 percent of the samples in the 2017 LOQ-limited dataset met the current ML of 0.05 mg/kg (Table BF-3). This table also indicates that 97 percent of samples may meet a hypothetical ML of 0.04 mg/kg and 95 percent of samples may meet a hypothetical ML of 0.03 mg/kg.<sup>4</sup>
34. During both CCCF09 and CCCF10, the EWG addressed questions about whether certain subsets of berries and other small fruits, such as cranberries and currants, or juices and nectars made from such fruits, would have difficulty meeting proposed revised MLs, even if proposed lower MLs may be acceptable when applied to the occurrence data of these groups as a whole. Consistent with this approach, the EWG examined individual fruit juices in the juices from berries and other small fruits category and evaluated the number of samples that would meet a proposed ML of 0.04 mg/kg or 0.03 mg/kg. Table BF-4 shows the number and percent of each type of juice in the 2017 LOQ-limited dataset, as well as the number and percentage of samples ≤ 0.03 mg/kg and ≤ 0.04 mg/kg for each type of juice. The percentage of samples ≤ 0.03 mg/kg was 96 percent or greater for each type of fruit juice except for currant juice (92%), elderberry juice (50%), raspberry juice (94%), and strawberry juice (88%). The percentage of samples ≤ 0.04 mg/kg was 96 percent or greater for each type of fruit juice except for currant juice (94%), raspberry juice (94%), and strawberry juice (90%). With all four juices removed, 99 percent of the remaining juices could meet the 0.03 mg/kg level and 0.04 mg/kg level.

<sup>3</sup> CX/CF12/6/13, CX/CF13/7/5, CX/CF14/8/5, CX/CF15/9/5, CX/CF 16/10/7. In addition, the EWG notes that the primary goal was not to attain identical achievability rates across all commodities.

<sup>4</sup> Because a large number of juice and nectar samples were excluded for not reporting an LOQ, the EWG also considered whether retaining these samples (6 of which had results greater than 0.05 mg/kg) would change the results. Similar results (97 percent at 0.05 mg/kg, 96 percent at 0.04 mg/kg, and 94 percent at 0.03 mg/kg) were obtained with the revised sample set.

Thus, for juices and nectars from berries and small fruits other than currants, elderberries, raspberries, and strawberries, lowering the ML to the proposed levels of 0.03 mg/kg or 0.04 mg/kg would eliminate 1 percent of the samples in international trade. Therefore, the EWG recommends extending the current ML of 0.03 mg/kg for juices and nectars to juices and nectars exclusively from berries and other small fruits, with the exception of juices and nectars derived exclusively from currants, elderberries, raspberries, and strawberries, which should be maintained at 0.05 mg/kg.

35. At CCCF10,<sup>5</sup> the EWG noted that several types of fruit juice were represented by 3 or fewer samples each. Although the overall number of samples increased from 658 samples in the 2016 LOQ-limited set to 971 in the 2017 LOQ-limited set, the juice categories with 3 or fewer samples in 2016 (blackberry, chokeberry, elderberry, field berry, mulberry, and youngberry) did not change significantly. Without specific evidence that these juices cannot meet the proposed 0.03 mg/kg ML, the EWG recommends that blackberry, chokeberry, field berry, mulberry, and youngberry be included in the category of juices and nectars with an ML of 0.03 mg/kg (see also Additional Topics).
36. **Preserved tomatoes.** The 2017 preserved tomatoes raw dataset consisted of 142 results from the GEMS/Food database for samples collected and/or analyzed between 2000 and 2016. Consistent with the Standard for Preserved Tomatoes (CODEX STAN 13-1981), the dataset includes canned products described as tomatoes, whole tomatoes, diced tomatoes, crushed tomatoes, chopped tomatoes, strained tomatoes, etc. Samples described as tomato sauce, tomato powder, and ketchup (catsup) were excluded from analysis. In 2016, CCCF10 forwarded an ML for preserved tomatoes of 0.05 mg/kg to CAC39 for adoption at Step 5/8. Because the CAC39 did not adopt the revised ML in 2016, the EWG evaluated the data at the current ML of 1 mg/kg. No LOQs associated with the results exceeded the ML, therefore, no further exclusions were made and there is only one dataset for preserved tomatoes. Table PT-1 (in the Annex) shows the breakdown by country of the 2017 raw dataset. Table PT-2 shows the mean and maximum lead levels associated with the raw dataset. Table PT-3 shows the percentage of preserved tomatoes samples meeting current and hypothetical MLs.
37. For preserved tomatoes, 100 percent of the samples in the 2017 raw dataset met the current ML of 1 mg/kg (Table PT-3). This table also indicates that 100 percent of samples may meet a hypothetical ML of 0.1 mg/kg, 99 percent of samples may meet a hypothetical ML of 0.05 mg/kg, and 96 percent of samples may meet a hypothetical ML of 0.02 mg/kg. Lowering the ML to the previously proposed level of 0.05 mg/kg would eliminate 1 percent of the samples in international trade. Therefore, the EWG again recommends lowering the ML for lead in preserved tomatoes to 0.05 mg/kg. Consistent with the decisions of CCCF10, the EWG also recommends deletion of the note in the GSCTFF for preserved tomatoes on the adjustment of the ML to take into account the concentration of the product.
38. At CAC39, some delegations were in favor of adopting the proposed ML of 0.05 mg/kg for preserved tomatoes at Step 5 only, for reasons including practicality, number of samples, and geographical representativeness. CAC adopted the revised ML at Step 5 only, on the understanding that countries that expressed concern at CAC would submit relevant data in order to finalize the ML at CCCF11 (2017). Because of these concerns, the EWG wanted to address the geographical representativeness and sample number of the new dataset. The results reported in 2016 were based on 82 samples in the raw dataset (from Australia, Canada, China, Japan, and the USA). This year's analysis consists of 142 samples in the 2017 raw dataset (from Australia, Brazil, Canada, China, Japan, New Zealand, Singapore, Thailand, the USA, and Uruguay), reflecting an increase in both sample number and geographical distribution.
39. **Processed tomato concentrates.** The 2017 processed tomato concentrates raw dataset consisted of 60 results from the GEMS/Food database for samples collected and/or analyzed between 2006 and 2016. Consistent with the Standard for Processed Tomato Concentrates (CODEX STAN 57-1981), the dataset includes products described as tomato pastes and purees. Samples described as tomato sauce, tomato powder, and ketchup (catsup) were excluded from analysis. No LOQs associated with the results exceeded the current ML of 1.5 mg/kg, therefore, no further exclusions were made and there is only one dataset for processed tomato concentrates. Table TC-1 (in the Annex) shows the breakdown by country of the 2017 raw dataset. Table TC-2 shows the mean and maximum lead levels associated with the dataset. Table TC-3 shows the percentage of processed tomato concentrates samples meeting current and hypothetical MLs.
40. For tomato concentrates, 100 percent of the samples in the 2017 dataset met the current ML of 1.5 mg/kg (Table TC-3). This table also indicates that 100 percent of samples may meet a hypothetical ML of 0.1 mg/kg, 97 percent of samples may meet a hypothetical ML of 0.05 mg/kg, and 93 percent of samples may meet a hypothetical ML of 0.03 mg/kg.

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<sup>5</sup> CX/CF16/10/7

Thus, lowering the ML to the hypothetical level of 0.05 mg/kg would eliminate 3 percent of the samples in international trade. Therefore, the EWG recommends lowering the ML for lead in processed tomato concentrates to 0.05 mg/kg. Consistent with the decisions of CCCF10, the EWG also recommends deletion of the note in the GSCTFF for processed tomato concentrates on the adjustment of the ML to take into account the concentration of the product.

41. At CCCF10, some delegations commented that the number of samples available was not sufficient to carry out a statistical analysis of the worldwide production and that an increased number of samples would give a more realistic idea of the violation rates and their impact on international trade. The Committee agreed to retain the ML of 1.5 mg/kg for processed tomato concentrates pending additional data and to take a decision at CCCF11. Because of these concerns, the EWG wanted to address the geographical representativeness and sample number of the new dataset. The results reported in 2016 were based on 21 samples in the raw dataset (from Argentina, Canada, China, European Union, and Singapore). This year's analysis consists of 60 samples in the raw dataset (from Argentina, Brazil, Canada, China, European Union, Singapore, Thailand, and the USA), reflecting an increase in both sample number and geographical distribution.
42. **Jams (fruit preserves) and jellies.** The 2017 jams (fruit preserves) and jellies raw dataset consisted of 366 results from the GEMS/Food database for samples collected and/or analyzed between 2009 and 2016. Consistent with the Standard for Jams, Jellies and Marmalades (CODEX STAN 296-2009), the dataset includes products described as jams, preserves, jellies, and fruit spreads. Marmalades were included, since the Committee confirmed in 2016 that citrus and non-citrus marmalades were covered by CODEX STAN 296-2009.<sup>6</sup> Any reduced/low sugar products or products where sugars had been whole or partially replaced by food additive sweeteners were excluded from the dataset. In 2016, CCCF10 forwarded an ML for jams (fruit preserves) and jellies of 1 mg/kg to CAC39 for adoption at Step 5/8. Because CAC39 did not adopt the revised ML in 2016, the EWG evaluated the data at the current ML of 1 mg/kg. No LOQs associated with the results exceeded the ML, therefore, no further exclusions were made and there is only one dataset for jams (fruit preserves) and jellies. Table JJ-1 (in the Annex) shows the breakdown by country of the 2017 raw dataset. Table JJ-2 shows the mean and maximum lead levels associated with the dataset. Table JJ-3 shows the percentage of jams (fruit preserves) and jellies samples meeting current and hypothetical MLs.
43. For jams (fruit preserves) and jellies, 99 percent of the 2017 raw dataset met the current ML of 1 mg/kg (Table JJ-3). This table also indicates that 96 percent of samples may meet a hypothetical ML of 0.3 mg/kg or 0.2 mg/kg, and 94 percent of samples may meet a hypothetical ML of 0.1 mg/kg. Thus, lowering the ML to the proposed level of 0.1 mg/kg would eliminate 6 percent of the samples in international trade and lowering the ML to the hypothetical level of 0.2 mg/kg would eliminate 4 percent of the samples in international trade. Based on this evaluation, the EWG's initial recommendation was to revise the ML for lead in jams (fruit preserves) and jellies, including marmalades, to 0.2 mg/kg.
44. At CAC39, some delegations were in favor of adopting the proposed ML of 0.1 mg/kg for jams (fruit preserves) and jellies at Step 5 only, for reasons including practicality, number of samples, and geographical representativeness. CAC39 adopted the revised ML at Step 5 only, with the understanding that countries that expressed concern at CAC39 would submit relevant data in order to finalize the ML at CCCF11 (2017). Because of these concerns, the EWG wanted to address the geographical representativeness and sample number of the new dataset. The results reported in 2016 were based on 239 samples in the raw dataset (from Canada, New Zealand, and the USA). This year's analysis consists of 366 samples in the 2017 raw dataset (from Argentina, Canada, India, Indonesia, New Zealand, Thailand, and the USA), reflecting an increase in both sample number and geographical distribution. Also, although 238 of the 2017 samples are from Canada, the majority of these (172) are listed as imported in the GEMS/Food database. This would suggest that the Canadian samples represent a wider geographical distribution than implied by Table JJ-1.
45. In January 2017, India submitted 98 new jams, jellies, and marmalades results to the GEMS/Food database and requested the data be considered by the EWG for CCCF11. The January 2017 dataset had more high-lead values than the data submitted by India in 2016 (Table JJ-1); i.e., lead values in the January 2017 dataset ranged from non-detect<sup>7</sup> to 0.76 mg/kg, with 30 of 98 samples > 0.25 mg/kg, while lead values reported in 2016 ranged from non-detect<sup>8</sup> to 1.34 mg/kg, with only 2 of 52 samples > 0.25 mg/kg.

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<sup>6</sup>REP16/CF

<sup>7</sup> LOQ = 0.02 mg/kg

<sup>8</sup> LOQ = 0.25 mg/kg



With the January 2017 data included in the analysis, lowering the ML to the hypothetical level of 0.5 mg/kg would eliminate 3 percent of the samples in international trade and lowering the ML to the hypothetical level of 0.4 mg/kg would eliminate 5 percent of the samples in international trade. Based on its new data, India suggested lowering the current ML of 1.0 mg/kg to 0.5 mg/kg, rather than 0.2 mg/kg.

46. Other members of the EWG, while not having viewed the January 2017 data, concurred with the original recommendation for 0.2 mg/kg, which takes into account data submitted in 2016<sup>9</sup>. Also, the EWG note that the ML of 0.2 mg/kg is consistent with the MLs of 0.1-0.2 mg/kg for various fruits and canned fruits in the GSCTFF. If elevated lead levels are due to sources other than fruit, these may be addressed by Codex Code of Practice for the Prevention and Reduction of Lead Contamination in Foods (CAC/RCP 56-2004), which suggests strategies for mitigation of lead in finished products, including food ingredients, processing and production, and the use of packaging and storage products.
47. In light of the new data, the EWG suggests the Committee consider the following recommendations:
  - Adopt the revised ML of 0.2 mg/kg based on data submitted in 2016.
  - Adopt the revised ML of 0.5 mg/kg proposed by India based on inclusion of the January 2017 dataset.
  - If agreement cannot be reached on a revised ML, consider whether it would be preferable to revoke the current ML of 1.0 mg/kg for jams and jellies than to retain an ML of 1.0 mg/kg that is inconsistent with other MLs for lead in the GSCTFF.
48. **Mango chutney.** The 2017 mango chutney raw dataset consisted of 34 results from the GEMS/Food database for samples collected and/or analyzed between 2006 and 2016. Consistent with the Standard for Mango Chutney (CODEX-STAN 160-1987), the dataset includes products described as mango chutney and excluded one product described as mango jam. No LOQs associated with the results exceeded the current ML of 1 mg/kg; therefore, no further exclusions were made and there is only one dataset for mango chutney. Table MC-1 (in the Annex) shows the breakdown by country of the 2017 raw dataset. Table MC-2 shows the mean and maximum lead levels associated with the dataset. Table MC-3 shows the number and percentage of mango chutney samples meeting current and hypothetical MLs.
49. For mango chutney, 100 percent of the samples in the 2017 raw dataset met the current ML of 1 mg/kg (Table MC-3). This table also indicates that 100 percent of samples may meet hypothetical MLs of 0.2 and 0.1 mg/kg, and 94 percent of samples may meet a hypothetical ML of 0.05 mg/kg. Thus, lowering the ML to the hypothetical level of 0.1 mg/kg would eliminate 0 percent of the samples in international trade and lowering the ML to the hypothetical level of 0.05 mg/kg would eliminate 6 percent of the samples in international trade. Based on these results, the EWG could recommend maintaining the category of mango chutney and lowering the ML for lead in mango chutney to 0.1 mg/kg.
50. However, CCCF10 also agreed that the EWG would consider combining mango chutney with the broad category of jams, jellies, and marmalades, if insufficient data<sup>10</sup> were available to consider mango chutneys as an individual category in 2017. The Chair urged those member countries interested in keeping mango chutney as a stand-alone category to submit data to the GEMS/Food database for consideration by the EWG. The 2017 dataset of 34 samples represents an increase of 30 samples over the 2016 dataset, with data representing manufacture by at least 5 countries, including Canada, India, Jamaica, the United Kingdom, and the United States, based on label information. Therefore, EWG members were asked to consider whether mango chutney should be combined with jams and jellies or maintained as a stand-alone category. Two countries responded that mango chutney could be combined with jams and jellies, and two countries preferred to retain mango chutney as a stand-alone category on technical grounds. One country that supported combining mango chutneys with jams and jellies preferred that the minimum number of samples for a stand-alone category be 50 or 60.
51. In light of this discussion, the EWG suggests the Committee consider the following recommendations:

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<sup>9</sup> The call for data requested data by September 16, 2016.

<sup>10</sup> In response to a comment that that this food category could not be combined with that of jams, jellies and marmalades, the Committee also requested technical justification and/or a justification from the point of view of risk assessment be provided to the EWG that mango chutney could not be combined with that of jams, jellies and marmalades.

- Retain mango chutney as a stand-alone category with an ML of 0.1 mg/kg, which is 100 percent achievable, but based on 34 samples.
  - Combine mango chutney with the category of jams and jellies with an ML of 0.2 mg/kg or 0.5 mg/kg, depending on the outcome of the discussion on jams and jellies.
  - If agreement cannot be reached on a revised ML, consider whether it would be preferable to revoke the current ML of 1.0 mg/kg for mango chutney than to retain an ML of 1.0 mg/kg that is inconsistent with other MLs for lead in the GSCTFF.
52. **Canned chestnuts and canned chestnuts purees.** The 2017 canned chestnuts and canned chestnuts puree raw dataset consisted of 36 results from the GEMS/Food database for samples collected and/or analyzed between 2006 and 2016. Consistent with the Standard for Canned chestnuts and Canned Chestnuts Purees (CODEX STAN 145-1985), the dataset includes products described as canned chestnuts, chestnuts creams, and chestnuts purees. Dried chestnuts and chestnuts that appeared to be non-canned were excluded. No results exceeded the current ML of 1 mg/kg and no LOQs associated with the results exceeded 1 mg/kg. Therefore, no further exclusions were made and there is only one dataset for canned chestnuts. Table CC-1 (in the Annex) shows the breakdown by country of the 2017 raw dataset. Table CC-2 shows the mean and maximum lead levels associated with the dataset. Table CC-3 shows the number and percentage of canned chestnuts samples meeting current and hypothetical MLs.
53. For canned chestnuts and canned chestnuts purees, 100 percent of the samples in the 2017 dataset met the current ML of 1 mg/kg (Table CC-3). This table also indicates that 100 percent of the samples would meet a hypothetical ML of 0.1 mg/kg and 0.05 mg/kg, and that 97 percent of samples would meet a hypothetical ML of 0.01 mg/kg. Thus, lowering the ML to the hypothetical level of 0.1 or 0.05 mg/kg would eliminate 0 percent of the samples in international trade and lowering the ML to the hypothetical level of 0.01 mg/kg would eliminate 3 percent of the samples in international trade. Based on these results, the EWG could recommend maintaining the category of canned chestnuts and lowering the ML for lead in canned chestnuts to 0.05 mg/kg or lower.
54. However, CCCF10 also agreed that if insufficient data were available to consider canned chestnuts and canned chestnuts puree as a stand-alone category in 2017, the EWG would consider combining canned chestnuts and canned chestnuts puree with canned fruits. The 2017 dataset of 36 samples represents an increase of 25 samples over the 2016 dataset, with new data representing manufacture by 5 additional countries, including samples produced in France, Italy, Romania, Spain, and Turkey, based on label information. Therefore, EWG members were asked to consider whether canned chestnuts should be combined with canned fruits or maintained as a stand-alone category. Two countries responded that canned chestnuts are not technically classified as fruits<sup>11</sup>, so they should be retained as a stand-alone category. However, these countries could also support an ML of 0.1 mg/kg (the same as canned fruits) or lower (0.05 mg/kg or 0.01 mg/kg). One country supported combining canned chestnuts with canned fruits (0.1 mg/kg), but also could support a stand-alone category with an ML of 0.05 mg/kg or 0.01 mg/kg.
55. The EWG suggests the Committee consider the following recommendations:
- Retain canned chestnuts and canned chestnuts puree as a stand-alone category with an ML of 0.05 mg/kg, which is 100 percent achievable, but based on 36 samples.
  - Combine canned chestnuts and canned chestnuts puree with the category of canned fruits with the ML of 0.1 mg/kg.
  - If agreement cannot be reached on a revised ML, consider whether it would be preferable to revoke the current ML of 1.0 mg/kg for canned chestnuts and canned chestnuts puree than to retain an ML of 1.0 mg/kg that is inconsistent with other MLs for lead in the GSCTFF.
56. **Canned brassica vegetables.** CCCF10 noted that current data (5 samples) were not sufficient to support extending the ML for canned vegetables (ML = 0.1 mg/kg) to the subset of canned brassica vegetables. As current canning processes no longer give rise to dramatic increases in lead content of canned products, a proposal was made to align the ML for the canned products to the ML for the corresponding fresh products. It was, however, noted that before deriving MLs for processed products from the corresponding fresh produce, it would be preferential to gather additional data for the canned product itself. Subsequently alternative ways to derive an ML for this subset food category could be explored. The Committee agreed to keep the note excluding canned brassica vegetables from the broad category of canned vegetables pending additional data and to take a decision at CCCF11.

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<sup>11</sup> CAC/MISC-4

57. The 2017 canned brassica raw dataset consisted of 16 results from the GEMS/Food database for samples collected and/or analyzed between 2008 and 2016, with five samples of canned pickled cabbage, ten samples of sauerkraut and one sample of canned pachranga (turnip cauliflower mix). No samples exceeded the current ML of 1 mg/kg; therefore, no further exclusions were made and there is only one dataset for canned brassica vegetables. Table CB-1 (in the Annex) shows the breakdown by country of the 2017 raw dataset. Table CB-2 shows the mean and maximum lead levels associated with the dataset. Finally, Table CB-3 shows the percentage of canned brassica samples meeting current and hypothetical MLs.
58. For canned brassica, 100 percent of the samples in the 2017 dataset met the current ML of 1 mg/kg (Table CB-3). This table also indicates that 100 percent of samples would meet a hypothetical ML of 0.6 mg/kg and 94 percent of samples would meet a hypothetical ML of 0.4 mg/kg and 0.1 mg/kg. Thus, lowering the ML to the hypothetical level of 0.6 mg/kg would eliminate 0 percent of samples in international trade and lowering the ML to the hypothetical level of 0.4 mg/kg or 0.1 mg/kg would eliminate 6 percent of the samples in international trade. Based on these results, the EWG could recommend maintaining the category of canned brassica and keeping the current ML of 1 mg/kg. However, the EWG note that this determination is based on one sample at 0.5 mg/kg (all other samples had lead levels less than 0.1 mg/kg).
59. CCCF10 agreed to consider alternative ways to derive an ML for the canned brassica subset of vegetables in 2016 if sufficient data were not available. The 2017 dataset of 16 samples represents an increase of 11 samples over the 2016 dataset, with data contributed by Japan, Thailand, and the United States. However, the dataset is still small. As all of the additional samples since 2016 were provided by one country, specifically to increase the number of samples available for this paper, the EWG cannot plan on receiving additional data on canned brassica vegetables in the near future. As noted above, with the exception of one canned cabbage sample at 0.5 mg/kg lead, all the canned brassica samples contained less than 0.1 mg/kg of lead, which is consistent with the ML for fresh brassica vegetables (0.1 mg/kg) and canned vegetables (0.1 mg/kg), as well as the ML for fresh leafy vegetables (0.3 mg/kg). Since the committee agreed to consider alternative approaches in 2017 for subsets lacking sufficient data, the EWG was asked to consider whether the current ML of 0.1 mg/kg for canned vegetables should be extended to canned brassica vegetables. The three countries that responded on this point agreed with the proposed approach. Therefore, the EWG recommends extending the current ML of 0.1 mg/kg lead for canned vegetables to canned brassica vegetables.

New product categories under consideration by CCCF

60. **Fungi and mushrooms.** The current version of the GSCTFF (CODEX STAN 193-1995, 2016 amendment) excludes fungi and mushrooms from the 0.05 mg/kg standard for lead in fruiting vegetables. A previous version (2011 amendment) excluded mushrooms, but not fungi. In 2014 and 2015, at CCCF08 and CCCF09, the EWG excluded all fungi and edible mushrooms from the analysis of fruiting vegetables, other than cucurbits. In 2015, CCCF09 noted that in view of the exclusion of fungi and mushrooms from the ML for fruiting vegetables, other than cucurbits, MLs for these commodities would be considered by the EWG. In 2016, CCCF10 agreed to consider the setting of MLs for mushrooms and different species/group of species of fungi if appropriate and feasible at CCCF11.
61. The 2017 fungi and mushroom raw dataset consisted of 2148 results from the GEMS/Food database for samples collected and/or analyzed between 1998 and 2016. Consistent with the Standard for Edible Fungi and Fungus Products (CODEX STAN 38-1981), the dataset consists of fresh edible fungi. Although the standard specifically excludes canned, cultivated *Agaricus* mushrooms, the EWG excluded all canned fungi and mushrooms as they were considered in the analysis of canned vegetables in 2015. The EWG also excluded "fungus products," including dried fungus, since CCCF09 did not specify "fungus products" when it requested evaluation of "fungi and mushrooms," and since, in general, MLs are set for primary products. The EWG did not prepare an LOQ-limited set based on ML, since there is no existing ML for fungi and mushrooms.<sup>12</sup> However, the EWG excluded 10 products with no reported LOQ to obtain the 2017 LOQ-limited dataset of 2138 samples. Table FM-1 (in the Annex) shows the breakdown by country of the 2017 raw and LOQ-limited datasets for fresh fungi and mushrooms. Table FM-2 shows the mean and maximum lead levels associated with the datasets. Table FM-3 shows the percentage of fungi and mushroom samples meeting current and hypothetical MLs.

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<sup>12</sup> CX/CF16/10/7, par. 51

62. For fresh fungi and mushrooms, 98 percent of samples in the 2017 LOQ-limited dataset may meet a hypothetical ML of 1 mg/kg, 96 percent of samples may meet a hypothetical ML of 0.6 mg/kg, and 95 percent of samples may meet a hypothetical ML of 0.5 mg/kg. Thus, setting an ML at the hypothetical level of 1 mg/kg would eliminate 2 percent of the samples in international trade, setting an ML at the hypothetical level of 0.6 mg/kg would eliminate 4 percent of the samples in international trade, and setting an ML at the hypothetical level of 0.5 mg/kg would eliminate 5 percent of the samples in international trade. The EWG recommends that the Committee consider establishing an ML for lead in fresh fungi and mushrooms (excluding mushroom and fungus products) of 0.6 mg/kg.
63. The Committee also may want to consider whether it would be appropriate to establish an ML for dried fungi and mushrooms or note that countries may wish to consider use of a concentration factor.<sup>13</sup> A similar analysis of dried samples showed that dried fungi and mushrooms have higher lead levels, e.g., a mean of 0.33 mg/kg and a maximum of 18.48 mg/kg for dried fungi and mushrooms versus a mean of 0.14 mg/kg and a maximum of 5.20 mg/kg for fresh fungi and mushrooms. Only 89 percent of dried fungi and mushrooms had lead levels below the ML of 0.6 mg/kg proposed for fresh fungi and mushrooms.
64. **Pulses.** The 2017 pulses raw dataset consisted of 3526 results from the GEMS/Food database for samples collected and/or analyzed between 1995 and 2016. Consistent with the Standard for Certain Pulses (CODEX STAN 171-1989), the dataset includes products described as dry seeds of leguminous plants that may be whole, shelled, or split. The EWG included 740 samples (mung, kidney, cowpea, red bean, soybean, lentil, and broad bean) that appeared to have been misclassified in the GEMS/Food database as legumes rather than pulses. The EWG excluded products that were cooked, canned, sprouted, or combined with other components, immature seeds, and fresh legumes (legume vegetables) expressly indicated as belonging to Group 014 in the Codex Classification of Foods and Animal Feeds.<sup>14</sup> The EWG excluded 52 samples with an LOQ > the current Codex standard of 0.2 mg/kg and one sample with no reported LOQ to obtain the 2017 LOQ-limited dataset of 3473 samples. Table PU-1 (in the Annex) shows the breakdown by country of the 2017 raw and LOQ-limited datasets. Table PU-2 shows the mean and maximum lead levels associated with the datasets. Table PU-3 shows the percentage of pulse samples meeting current and hypothetical MLs.
65. For pulses, 99 percent of the samples in the 2017 LOQ-limited dataset met the current ML of 0.2 mg/kg (Table PU-3). The table also indicates that 97 percent of samples may meet a hypothetical ML of 0.1 mg/kg and 91 percent of samples may meet a hypothetical ML of 0.05 mg/kg. Thus, lowering the ML to the hypothetical level of 0.1 mg/kg would eliminate 3 percent of the samples in international trade and lowering the ML to the hypothetical level of 0.05 mg/kg would eliminate 9 percent of the samples in international trade. Therefore, the EWG recommends lowering the ML for lead in pulses to 0.1 mg/kg.
66. **Fish.** The 2017 fish raw dataset consisted of 6469 results from the GEMS/Food database for samples collected and/or analyzed between 1995 and 2016. The dataset includes fish from Type 8, Groups 040, 041, and 042, as defined by the Codex Classification of Foods and Animal Feeds; which are fresh water, marine, and diadromous fish, respectively. The EWG excluded aquatic animals classified outside of these specific groups. Products that were fresh and frozen, either whole or cut into filets, were included; while smoked, dried, canned, and otherwise cooked products were excluded from the analysis. The EWG excluded 12 samples with an LOQ > the current Codex standard of 0.3 mg/kg and 734 samples with no LOQ to obtain the 2017 LOQ-limited dataset of 5723 samples. Table FI-1 (in the Annex) shows the breakdown by country of the 2017 raw and LOQ-limited datasets. Table FI-2 shows the mean and maximum lead levels associated with the datasets. Table FI-3 shows the percentage of fish samples meeting current and hypothetical MLs.
67. For fish, 97 percent of the samples in the 2017 LOQ-limited dataset met the current ML of 0.3 mg/kg (Table FI-3). The table also indicates that 95 percent of samples may meet a hypothetical ML of 0.2 mg/kg and 89 percent of samples may meet a hypothetical ML of 0.1 mg/kg. Thus, lowering the ML to the hypothetical level of 0.2 mg/kg would eliminate 5 percent of the samples in international trade. The EWG recommends maintaining the current ML for lead in fish of 0.3 mg/kg.

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<sup>13</sup> The GSCTFF states that: When contaminant levels are consistently different in processed products related to the primary products from which they are derived, and sufficient information is available about the contamination pattern, it may be appropriate to establish separate maximum levels for these processed products. This also applies when contamination may occur during processing. In general however, 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. When these factors are sufficiently known, they should be mentioned in the suffix to the maximum level following the format of list of MLs as defined in Annex II.

<sup>14</sup> CAC/MISC-4

**ADDITIONAL TOPICS**

68. On the issue of canned brassica vegetables, Japan noted that the ML for fresh Brassica vegetables in the GSCTFF does not apply to kale, and it may be necessary to exclude canned kales from the ML for lead in canned vegetables.
69. Regarding dried fungi and mushrooms, Canada noted that if the EWG were to consider a concentration factor for fresh versus dried mushrooms, it should be developed based on, if possible, matched samples.
70. Canada noted that for several commodities with limited samples (canned brassica, subsets of juices from a specific berry type), the Committee could consider maintaining a call for data for a predetermined/specific period of time, and then, if no additional data are received within the predetermined number of years, the commodity could move to the lower ML. However, for both these categories, the Committee previously agreed to review data for a second year and finalize MLs in 2017.
71. IFU commented that juices with limited data (e.g., aronia, chokeberry, mulberry, and blackberry) should be retained at an ML of 0.05 mg/kg until data are available to prove otherwise. Alternatively, Japan commented that elderberry juice, having only two samples, should be included under the 0.03 mg/kg ML, and recalled the approach taken at the 9<sup>th</sup> CCCF to include all juice subtypes (other than juices exclusively from berries and small fruits) under the 0.03 mg/kg ML. Based on these comments, the EWG did not change the recommendations in the paper; however, the Committee may want to consider the issue of elderberry juice further at the plenary.

## ANNEX

## TABLES

**TABLE BF-1: JUICES AND NECTARS FROM BERRIES AND OTHER SMALL FRUITS: DATA CONTRIBUTION BY COUNTRY TO 2017 RAW AND LOQ-LIMITED DATASETS**

Country	Number of Samples – raw dataset	Number of Samples – LOQ-limited dataset
Austria	45	12
Belgium	263	263
Canada	198	163
China	2	2
Denmark	2	2
European Union	8	8
France	10	6
Germany	26	2
Hungary	2	1
India	3	2
Italy	338	292
Japan	31	31
Poland	2	2
Romania	17	14
Singapore	9	0
Slovakia	2	1
Spain	1	0
Thailand	17	17
USA	156	153
<b>Total</b>	<b>1132</b>	<b>971</b>

**TABLE BF-2: JUICES AND NECTARS FROM BERRIES AND OTHER SMALL FRUITS: MEAN AND MAXIMUM FOR 2017 DATASETS**

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.012	0.206
LOQ-limited dataset	0.011	0.206

**TABLE BF-3: PERCENTAGE OF JUICES AND NECTARS FROM BERRIES AND OTHER SMALL FRUITS MEETING CURRENT AND HYPOTHETICAL MLS: LOQ-LIMITED DATASET**

Current and hypothetical MLs (mg/kg)	Samples ≤ MLs	
	Number	Percentage
0.05	943	97%
<i>0.04*</i>	937	97%
<i>0.03</i>	922	95%
<i>0.02</i>	842	87%

\*HYPOTHETICAL MLS SHOWN IN ITALICS

**TABLE BF-4: JUICES AND NECTARS FROM BERRIES AND OTHER SMALL FRUITS:  
DATA CONTRIBUTION BY TYPE OF FRUIT TO 2017 LOQ-LIMITED DATASET**

JUICE TYPE	NUMBER			PERCENTAGE		
	TOTAL	≤ 0.03 MG/KG	≤ 0.04 MG/KG	TOTAL	≤ 0.03 MG/KG	≤ 0.04 MG/KG
Blackberry	3	3	3	0.3%	100%	100%
Blueberry	23	22	22	2.4%	96%	96%
Chokeberry	1	1	1	0.1%	100%	100%
Cranberry	40	39	39	4.1%	98%	98%
Currant	49	45	46	5.1%	92%	94%
Elderberry	2	1	2	0.2%	50%	100%
Field berry	1	1	1	0.1%	100%	100%
Grape	632	606	617	65.0%	96%	98%
Mix (blend)**	66	65	65	6.8%	98%	98%
Mulberry	1	1	1	0.1%	100%	100%
Raspberry	53	50	50	5.5%	94%	94%
Strawberry	99	87	89	10.3%	88%	90%
Youngberry	1	1	1	0.1%	100%	100%
<b>Total</b>	<b>971</b>	<b>922</b>	<b>937</b>	<b>100.0%</b>	<b>95%</b>	<b>96%</b>

\*\*Contains 100 percent juice from a variety of berries and small fruits

**TABLE PT-1: PRESERVED TOMATOES: DATA CONTRIBUTION BY COUNTRY TO 2017 RAW DATASET**

Country	Number of Samples
Australia	4
Brazil	1
Canada	28
China	10
Japan	34
New Zealand	4
Singapore	2
Thailand	20
USA	33
Uruguay	6
<b>Total</b>	<b>142</b>

**TABLE PT-2: PRESERVED TOMATOES: MEAN AND MAXIMUM FOR 2017 DATASET**

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.005	0.080

**TABLE PT-3: PERCENTAGE OF PRESERVED TOMATOES SAMPLES MEETING CURRENT AND HYPOTHETICAL MLS: RAW DATASET**

Current and hypothetical MLs (mg/kg)	Samples $\leq$ MLs	
	Number	Percentage
1	142	100%
<i>0.1*</i>	142	100%
<i>0.05</i>	141	99%
<i>0.02</i>	137	96%

\*HYPOTHETICAL MLS SHOWN IN ITALICS

**TABLE TC-1: PROCESSED TOMATO CONCENTRATES: DATA CONTRIBUTION BY COUNTRY TO 2017 RAW DATASET**

Country	Number of Samples
Argentina	1
Brazil	6
Canada	4
China	1
European Union	15
Singapore	3
Thailand	4
USA	26
<b>Total</b>	<b>60</b>

**TABLE TC-2: PROCESSED TOMATO CONCENTRATES: MEAN AND MAXIMUM FOR 2017 DATASET**

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.007	0.060

**TABLE TC-3: PERCENTAGE OF PROCESSED TOMATO CONCENTRATES SAMPLES MEETING CURRENT AND HYPOTHETICAL MLS: RAW DATASET**

Current and hypothetical MLs (mg/kg)	SAMPLES $\leq$ MLS	
	Number	Percentage
1.5	60	100%
<i>0.1*</i>	60	100%
<i>0.05</i>	58	97%
<i>0.03</i>	56	93%

\*HYPOTHETICAL MLS SHOWN IN ITALICS



**TABLE JJ-1: JAMS (FRUIT PRESERVES) AND JELLIES: DATA CONTRIBUTION BY COUNTRY TO 2017 RAW DATASET**

Country	Number of samples
Argentina	1
Canada	238
India	52
Indonesia	19
New Zealand	8
Thailand	40
USA	8
<b>Total</b>	<b>366</b>

**TABLE JJ-2: JAMS (FRUIT PRESERVES) AND JELLIES: MEAN AND MAXIMUM FOR 2017 DATASET**

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.035	1.49

**TABLE JJ-3: PERCENTAGE OF JAMS (FRUIT PRESERVES) AND JELLIES SAMPLES MEETING CURRENT AND HYPOTHETICAL MLS: RAW DATASET**

Current and hypothetical MLs (mg/kg)	Samples ≤ MLs	
	Number	Percentage
1	362	99%
<i>0.3*</i>	353	96%
<i>0.2</i>	350	96%
<i>0.1</i>	345	94%

\*HYPOTHETICAL MLS SHOWN IN ITALICS

**TABLE MC-1: MANGO CHUTNEY: DATA CONTRIBUTION BY COUNTRY TO 2017 RAW DATASET**

Country	Number of Samples
Canada	1
China	3
USA	30
<b>Total</b>	<b>34</b>

**TABLE MC-2: MANGO CHUTNEY: MEAN AND MAXIMUM FOR 2017 DATASET**

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.018	0.057

**TABLE MC-3: PERCENTAGE OF MANGO CHUTNEY SAMPLES MEETING CURRENT AND HYPOTHETICAL MLS: RAW DATASET**

Current and hypothetical MLs (mg/kg)	SAMPLES ≤ MLS	
	Number	Percentage
1	34	100%
<i>0.2*</i>	34	100%
<i>0.1</i>	34	100%
<i>0.05</i>	32	94%

\*HYPOTHETICAL MLS SHOWN IN ITALICS

**TABLE CC-1: CANNED CHESTNUTS AND CANNED CHESTNUTS PUREES:  
DATA CONTRIBUTION BY COUNTRY TO 2017 RAW DATASET**

Country	Number of Samples
Canada	1
China	7
European Union	1
Thailand	2
USA	25
<b>Total</b>	<b>36</b>

**TABLE CC-2: CANNED CHESTNUTS AND CANNED CHESTNUTS PUREES:  
MEAN AND MAXIMUM FOR 2017 DATASET**

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.002	0.020

**TABLE CC-3: PERCENTAGE OF CANNED CHESTNUTS AND CANNED CHESTNUTS PUREES  
SAMPLES MEETING CURRENT AND HYPOTHETICAL MLS: RAW DATASET**

Current and hypothetical MLS (mg/kg)	SAMPLES ≤ MLS	
	Number	Percentage
1	36	100%
<i>0.1*</i>	36	100%
<i>0.05</i>	36	100%
<i>0.01</i>	35	97%

\*HYPOTHETICAL MLS SHOWN IN ITALICS

**TABLE CB-1: CANNED BRASSICA VEGETABLES:  
DATA CONTRIBUTION BY COUNTRY TO 2017 RAW DATASET**

Country	Number of samples
Japan	1
Thailand	3
USA	12
<b>Total</b>	<b>16</b>

**TABLE CB-2: CANNED BRASSICA VEGETABLES:  
MEAN AND MAXIMUM FOR 2017 DATASET**

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.042	0.50

**TABLE CB-3: PERCENTAGE OF CANNED BRASSICA VEGETABLES SAMPLES MEETING CURRENT  
AND HYPOTHETICAL MLS: RAW DATASET**

Current and hypothetical MLS (mg/kg)	Samples ≤ MLS	
	Number	Percentage
1	16	100%
<i>0.6*</i>	16	100%
<i>0.4</i>	15	94%
<i>0.1</i>	15	94%

\*HYPOTHETICAL MLS SHOWN IN ITALICS

**TABLE FM-1: FUNGI AND MUSHROOMS: DATA CONTRIBUTION BY COUNTRY TO 2017 RAW AND LOQ-LIMITED DATASETS**

Country	Number of samples – raw dataset	Number of samples – LOQ-limited dataset
Australia	50	50
Canada	86	76
China	1586	1586
France	8	8
India	10	10
Japan	160	160
New Zealand	9	9
Singapore	82	82
Slovakia	8	8
Thailand	86	86
USA	63	63
<b>Total</b>	<b>2148</b>	<b>2138</b>

**TABLE FM-2: FUNGI AND MUSHROOMS: MEAN AND MAXIMUM FOR 2017 RAW AND LOQ-LIMITED DATASETS**

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.14	5.20
LOQ-limited dataset	0.14	5.20

**TABLE FM-3: PERCENTAGE OF FUNGI AND MUSHROOM SAMPLES MEETING HYPOTHETICAL MLS: LOQ-LIMITED DATASET**

Hypothetical MLs (mg/kg)	Samples ≤ MLs	
	Number	Percentage
<i>1*</i>	2099	98%
<i>0.6</i>	2054	96%
<i>0.5</i>	2037	95%

\*HYPOTHETICAL MLS SHOWN IN ITALICS

**TABLE PU-1: PULSES: DATA CONTRIBUTION BY COUNTRY TO 2017 RAW AND LOQ-LIMITED DATASETS**

Country	Number of samples – raw dataset	Number of samples – LOQ-limited dataset
Argentina	1	1
Australia	9	9
Brazil	12	12
Canada	1636	1636
China	85	85
Germany	1	1
Japan	309	309
Nigeria	1	1
Korea	983	983
Singapore	53	0
Slovakia	41	41
Thailand	389	389
USA	6	6
<b>Total</b>	<b>3526</b>	<b>3473</b>

**TABLE PU-2: PULSES: MEAN AND MAXIMUM FOR 2017 RAW AND LOQ-LIMITED DATASETS**

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.018	0.600
LOQ-limited dataset	0.017	0.600

**TABLE PU-3: PERCENTAGE OF PULSES SAMPLES MEETING CURRENT AND HYPOTHETICAL MLS: LOQ-LIMITED DATASET**

Current and hypothetical MLs (mg/kg)	Samples ≤ MLs	
	Number	Percentage
0.2	3433	99%
<i>0.1*</i>	3358	97%
<i>0.05</i>	3151	91%

\*HYPOTHETICAL MLS SHOWN IN ITALICS

**TABLE FI-1: FISH: DATA CONTRIBUTION BY COUNTRY TO 2017 RAW AND LOQ-LIMITED DATASETS**

Country	Number of samples – raw dataset	Number of samples – LOQ-limited dataset
Canada	393	389
China	1853	1853
France	1341	612
Japan	44	44
Lithuania	2	2
New Zealand	108	108
Nigeria	1	1
Singapore	5	4
Slovakia	175	175
Thailand	1865	1862
USA	682	673
<b>Total</b>	<b>6469</b>	<b>5723</b>

**TABLE FI-2: FISH: MEAN AND MAXIMUM FOR 2017 RAW AND LOQ-LIMITED DATASETS**

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.042	10.31
LOQ-limited dataset	0.043	10.31

**TABLE FI-3: PERCENTAGE OF FISH SAMPLES MEETING CURRENT AND HYPOTHETICAL MLS: LOQ-LIMITED DATASET**

Current and hypothetical MLs (mg/kg)	Samples ≤ MLs	
	Number	Percentage
0.3	5566	97%
<i>0.2*</i>	5442	95%
<i>0.1</i>	5105	89%

\*HYPOTHETICAL MLS SHOWN IN ITALICS

**APPENDIX II****List of Participants****Chair****United States of America**

Lauren Posnick Robin  
 Chief, Plant Products Branch  
 Office of Food Safety  
 U.S. Food and Drug Administration  
 HFS-317  
 5100 Campus Drive  
 College Park, MD 20740  
 Tel: 240-402-1639  
 E-mail: lauren.robin@fda.hhs.gov

**Australia**

Ms. Leigh Henderson  
 Section Manager, Product Safety Standards  
 AUSTRALIA  
[Leigh.henderson@foodstandards.govt.nz](mailto:Leigh.henderson@foodstandards.govt.nz)

Codex contact point, Australia:  
[codex.contact@agriculture.gov.au](mailto:codex.contact@agriculture.gov.au)

**Austria**

Dr. Daniela Hofstädter  
 Scientific Expert  
 Austrian Agency for Health and Food Safety  
 Risk Assessment, Data and Statistics  
 Spargelfeldstr. 191  
 A-1220 Vienna, Austria  
 Tel.: +43 (0) 5 05 55 / 25703  
[Daniela.hofstaedter@ages.at](mailto:Daniela.hofstaedter@ages.at)

**Brazil**

Mrs. Ligia Lindner Schreiner  
 Health Regulation Expert  
 Brazilian Health Regulatory Agency  
 e-mail: [ligia.schreiner@anvisa.gov.br](mailto:ligia.schreiner@anvisa.gov.br)

**Canada**

Stephanie Glanville  
 Scientific Evaluator, Food Contaminants Section  
 Bureau of Chemical Safety, Health Products and Food  
 Branch  
 Health Canada  
[Stephanie.Glanville@hc-sc.gc.ca](mailto:Stephanie.Glanville@hc-sc.gc.ca)

Elizabeth Elliott  
 Head, Food Contaminants Section  
 Bureau of Chemical Safety, Health Products and Food  
 Branch  
 Health Canada  
[Elizabeth.Elliott@hc-sc.gc.ca](mailto:Elizabeth.Elliott@hc-sc.gc.ca)

**Chile**

Ms. Lorena Delgado Rivera  
 Chilean Coordinator of CCCF  
 Institute of Public Health, Chile  
 +56225755493  
[ldelgado@ispch.cl](mailto:ldelgado@ispch.cl)

**Costa Rica**

Mr. Johan Molina Delgado  
 Coordinador Laboratorio Calidad de Aguas  
 Centro de Investigación en Contaminación Ambiental  
 (CICA)  
 Teléfono: 2511-8304  
 Correo electrónico: [johan.molina@ucr.ac.cr](mailto:johan.molina@ucr.ac.cr),  
[aguas.cica@ucr.ac.cr](mailto:aguas.cica@ucr.ac.cr)

Lic. María Elena Aguilar Solano  
 Ministerio de Salud  
 Dirección de Regulación de Productos de Interés  
 Sanitario, Unidad de Normalización y Control  
 Tel: (506) 2233-6922  
 Fax: (506) 2255-4512  
[maria.aguilar@misalud.go.cr](mailto:maria.aguilar@misalud.go.cr)

Ing. Amanda Lasso Cruz  
 Licensed Food Technologist  
 Department of Codex  
 Ministry of Economy, Trade and Industry  
 COSTA RICA  
 Tel: (506) 2549-1434  
 Fax: +506 22912015  
[alasso@meic.go.cr](mailto:alasso@meic.go.cr)

**European Union**

Mr. Frank Swartenbroux  
 European Commission  
 Health and Consumers Directorate-General  
 Tel.: ++32 229-93854  
[frank.swartenbroux@ec.europa.eu](mailto:frank.swartenbroux@ec.europa.eu)

Codex Contact Poin, EU: [Sante-codex@ec.europa.eu](mailto:Sante-codex@ec.europa.eu)

**Germany**

Ms. Klara Jirzik  
 Food Chemist  
 Federal Office of Consumer Protection and Food Safety  
 (BVL)  
 Unit 101  
 Mauerstr. 39 - 42  
 D-10117 Berlin  
 Tel: +49 30 18444 10128  
 Fax: +49 30 18444 89999  
 klara.jirzik@bvl.bund.de

**India**

Mr. R.M. Mandlik  
 Deputy Director (Tech.)  
 Export Inspection Council of India  
 tech1@eicindia.gov.in

Mr. Gadadhar Chandrasekar  
 Specialist-Regulatory  
 Nestle R&D Centre India Pvt. Ltd  
 Gadadhar.Chandrasekar@RD.nestle.com

Codex Contact Point, India: codex-india@nic.in

**Indonesia**

Mrs. Elin Herlina  
 Director of Food Product Standardization  
 National Agency of Drug and Food Control, Indonesia  
 codexbpom@yahoo.com, ewg.indonesia@gmail.com

**Israel**

Ziva Hamama  
 Food Control Service, Israel  
 ziva.elishov@moh.health.gov.il

**Japan**

Dr. Yukiko Yamada  
 Guest Scholar  
 National Institute of Health Sciences  
 codexj@mhlw.go.jp

Ms. Mao Yanagisawa  
 Technical officer  
 Standards and Evaluation Division, Department of  
 Environmental Health and Food Safety  
 Ministry of Health, Labour and Welfare  
 codexj@mhlw.go.jp

Mr. Tetsuo Urushiyama  
 Associate Director, Scientific adviser  
 Plant Products Safety Division, Food safety and  
 Consumer Affairs Bureau  
 Ministry of Agriculture, Forestry and Fisheries  
 tetsuo\_urushiyama530@maff.go.jp

**Korea**

Ministry of Food and Drug Safety (MFDS)  
 Republic of Korea  
 codexkorea@korea.kr

Miok, Eom  
 Senior Scientific officer  
 Livestock Products Standard Division, Ministry of Food  
 and Drug Safety (MFDS)  
 miokeom@korea.kr

Seong-ju, Kim  
 Scientific officer  
 Livestock Products Standard Division, Ministry of Food  
 and Drug Safety (MFDS)  
 foodeng78@korea.kr

So-young, Yune  
 Scientific officer  
 Livestock Products Standard Division, Ministry of Food  
 and Drug Safety (MFDS)  
 biosyyune@korea.kr

Min, Yoo  
 Codex researcher  
 Food Standard Division, Ministry of Food and Drug  
 Safety (MFDS)  
 minyoo83@korea.kr

**Malaysia**

Ms. Raizawanis Abdul Rahman  
 Chief Assistant Director  
 Food Safety and Quality Division  
 Ministry of Health Malaysia  
 Tel.: +603 8885 0797 ext. 4271  
 Fax: +603 8885 0790  
 raizawanis@moh.gov.my

Ms. Rabia'atuladabiah Hashim  
 Senior Assistant Director  
 Food Safety and Quality Division  
 Ministry of Health Malaysia  
 Tel.: +603 8885 0797 ext. 4062  
 Fax: +603 8885 0790  
 adabiah@moh.gov.my

Codex Contact Point, Malaysia:  
 ccp\_malaysia@moh.gov.my

**Mexico**

Jessica Gutiérrez Zavala  
 Dirección Ejecutiva de Operación Internacional  
 Comisión Federal para la Protección Contra Riesgos  
 Sanitarios (COFEPRIS)  
 MÉXICO  
 jgutierrez@cofepris.gob.mx

Luis Atzin Rocha Lugo  
 Dirección Ejecutiva de Operación Internacional  
 Comisión Federal para la Protección Contra Riesgos  
 Sanitarios (COFEPRIS)  
 MÉXICO  
 lrocha@cofepris.gob.mx

Codex Contact Point, Mexico:  
 codex@cofepris.gob.mx, [codexmex@economia.gob.mx](mailto:codexmex@economia.gob.mx)

**Morocco**

Mr. Zerouali Elhassane  
 Laboratory Manager  
 Autonomous Establishment of Export Control and  
 Coordination (EACCE)  
 zerouali@eacce.org.ma  
 hassane\_zerouali@yahoo.fr

MESSAOUDI Bouchra  
 Secrétariat du point de contact Codex- Maroc  
 Cadre au Service de Normalisation et du Codex  
 Alimentarius  
 Division de la Normalisation et du Codex Alimentarius  
 et des Questions SPS  
 Office National de la Sécurité Sanitaire Des Produits  
 Alimentaires (ONSSA)  
 Tel: 05 37 67 65 90  
 bouchring@yahoo.fr

#### **Netherlands**

Ms. Ana Vilorio  
 Senior Policy Officer Ministry of Health, Welfare and  
 Sport Nutrition  
 Health Protection and Prevention Department  
 P.O. Box 20350  
 2500 EJ The Hague, Netherlands  
 Tel: +31 70 3406482  
 ai.viloria@minvws.nl

Ms. Astrid Bulder  
 Senior Risk Assessor  
 National Institute for Public Health and the Environment  
 (RIVM)  
 Centre for Nutrition, Prevention and Health Services  
 (VPZ)  
 P.O. Box 1  
 3720 BA Bilthoven, Netherlands  
 Tel: +31 30 274 7048  
 astrid.bulder@rivm.nl

#### **Nigeria**

Mrs. Omolara Okunlola, Ph.D  
 Deputy Director  
 Standards Organisation of Nigeria  
 florence.arin@gmail.com  
 Tel: + 234 (0) 8023590639

Codex Contact Point,  
 Nigeria: codexsecretariat@son.gov.ng,  
 megesciatt@yahoo.com

#### **New Zealand**

John Reeve  
 Principle Adviser Toxicology  
 Ministry for Primary Industries, New Zealand  
 john.reeve@mpi.govt.nz

#### **Sudan**

Sawsan osman Abd Alrazig  
 Head of Food Department  
 National Chemicals Laboratories  
 Federal Ministry of Health, Sudan  
 sawsan\_balla@yahoo.com, almohalb2008@gmail.com

#### **Thailand**

Mrs. Chutiwan Jatupornpong  
 Standards officer, Office of Standard Development,  
 National Bureau of Agricultural Commodity and Food  
 Standards,  
 50 Phaholyothin Road, Ladyao, Chatuchak,  
 Bangkok 10900 Thailand  
 Tel: (+662) 561 2277  
 Fax: (+662) 561 3357, (+662) 561 3373  
 chutiwan9@hotmail.com

Codex contact point, Thailand: codex@acfs.go.th

#### **United States of America**

Lauren Posnick Robin  
 U.S. Delegate, CCCF  
 Chief, Plant Products Branch, Office of Food Safety  
 U.S. Food and Drug Administration  
 5001 Campus Drive  
 College Park, MD 20740  
 Tel: 240-402-1639  
 lauren.robin@fda.hhs.gov

Henry Kim  
 Senior Policy Analyst  
 Office of Food Safety  
 U.S. Food and Drug Administration  
 5001 Campus Drive  
 College Park, MD 20740  
 Tel: 240-402-2023  
 henry.kim@fda.hhs.gov

Sara McGrath  
 Chemist  
 Office of Regulatory Science  
 U.S. Food and Drug Administration  
 5001 Campus Drive  
 College Park, MD 20740  
 Tel: 240-402-2997  
 sara.mcgrath@fda.hhs.gov

#### **Uruguay**

Raquel Huertas  
 Laboratorio Tecnológico del Uruguay  
 rhuertas@latu.org.uy

Codex contact point, Uruguay: Codex@latu.org.uy

#### **WHO (JECFA)**

Philippe Jean-Paul Verger  
 Department of Food Safety and Zoonoses  
 World Health Organization  
 Avenue Appia  
 1211 Geneva 27, Switzerland  
 Tel: +41 22 791 3569  
 Fax: +41 22 791 4848  
 vergerp@who.int

#### **FoodDrinkEurope**

Beate Kettlitz  
 b.kettlitz@fooddrinkeurope.eu

Eion Keane  
 Manager, Food Policy, Science and R&D  
 Food Drink Europe  
 Avenue des Nerviens 9-31  
 1040 Bruxelles, Belgium  
 Tel. 32 2 5008756  
 e.keane@fooddrinkeurope.eu

#### **Food Industry Asia (FIA)**

Ms. Jiang Yifan  
 Regional Regulatory Affairs Manager  
 codex@foodindustry.asia



**International Council of Grocery Manufacturers****Associations (ICGMA)**

René Viñas, MS, PhD  
ICGMA Delegate to CCCF  
International Council of Grocery Manufacturers  
Associations  
1350 I Street, NW, Suite 300, Washington DC, 20005  
Tel: 202-639-5972; Mobile: 830-352-5583  
Fax: 202-639-5991  
RVinas@gmaonline.org

**Institute of Food Technologists (IFT)**

Dr. James R. Coughlin  
President & Founder  
Coughlin & Associates  
Tel: 949-916-6217  
jrcoughlin@cox.net

**International Fruit & Vegetable Juice Association  
(IFU)**

John Collins  
Executive Director  
International Fruit & Vegetable Juice Association (IFU)  
Land line Tel: +44 1934 627844  
Mobile Tel: +44 7850 910989  
john@ifu-fruitjuice.com