CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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PPROPOSED DRAFT MAXIMUM LEVELS FOR LEAD IN SELECTED COMMODITIES IN THE GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CXS 193-1995)

(Prepared by the Electronic Working Group led by the United States of America)

Codex members and Observers wishing to submit comments at Step 6 on this draft should do so as instructed in CL 2019/07-CF available on the Codex webpage/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/.

BACKGROUND

1. CCCF06 (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) (CXS 193-1995). CCCF also agreed to consider consolidating the MLs for canned fruit and vegetable products.[1]

2. CCCF07[2] (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 CCCF08.

   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 CAC36 for adoption at Step 5/8.

3. CAC36 (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[3] within a year, to allow CCCF to further consider the revision of the MLs in 2015 for submission to CAC38.[4]

4. CCCF07 also agreed to reestablish the EWG led by the USA 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.[5]

5. CCCF08 (March 2014) agreed to the following:[6]

[1] REP12/CF, paras. 126-127
[2] REP13/CF, paras. 37, 39-42 and Appendix II
[3] Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme, http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en
[4] REP13/CAC, para. 79
[5] REP13/CF, paras. 39-40
[6] REP14/CF, paras. 21-24

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 CAC37 (2014) at Step 5/8. CAC37 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 CCCF09. 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,[7] 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. CCCF09 (March 2015) agreed to the following:[8]

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 (July 2015) 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.

7. CAC38[9] (July 2015) adopted the recommendations (described in paragraph 6 above) of CCCF09.

8. CCCF10 (April 2016) agreed to the following:[10]

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); and 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.

[7] Excluding fungi and mushrooms
[8] REP15/CF, paras. 48-51
[9] REP15/CAC, Appendices III, V
[10] REP16/CF, paras. 88-90

c. To re-establish the EWG, chaired by the 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. CAC39 (2016)[11] adopted the MLs at Step 5/8 as proposed by CCCF10 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. CCCF11 (April 2017) agreed to the following:[12]

a. To forward the proposed draft revised MLs for preserved tomatoes (ML = 0.05 mg/kg); jams, jellies and marmalades (ML = 0.4 mg/kg); canned chestnuts and canned chestnuts puree (ML = 0.05 mg/kg); and pulses (ML = 0.1 mg/kg) to CAC40 (July 2017) for adoption at Steps 8 and 5/8.

b. To forward the proposed draft revised MLs for processed tomato concentrates (ML = 0.05 mg/kg) and canned brassica vegetables (ML = 0.1 mg/kg) to CAC40 for adoption at Step 5.

c. To retain the current ML of 0.3 mg/kg for fish.

d. To retain the ML of 0.05 mg/kg for juices made exclusively from berries and other small fruits and to work on a positive list of fruits [fruit juices] that could achieve lower levels (e.g., 0.03 or 0.04 mg/kg) as more data became available.

e. To further consider an ML for farmed fungi and mushrooms (i.e., common (*Agaricus*), shiitake and oyster mushrooms) at the next session, rather than establishing a single ML of 0.6 mg/kg for the whole category of fungi and mushrooms (excluding mushroom and fungus products).

f. To request revocation of the MLs for lead in the GSCTFF for the following food categories: preserved tomatoes; jams, jellies and marmalades; canned chestnuts and canned chestnuts puree; and pulses.

g. To re-establish the EWG, chaired by the 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 grape juice (to determine if a lower ML could be established as part of the positive list to apply to juices obtained exclusively from berries and other small fruits); processed tomato concentrates; mango chutney; canned brassica vegetables; and fresh farmed mushrooms [common mushrooms (*Agaricus bisporous*), shiitake mushrooms (*Lentinula edodes*) and oyster mushrooms (*Pleurotus*)]; and to review the following new categories, i.e., salt, wine, fat spreads and blended spreads, and edible fats and oils.

11. CAC40 (2017) adopted the proposed MLs for lead in selected processed fruits and vegetables as proposed by CCCF11.

12. CCCF12 (2018) agreed to the following:[13]

a. To advance the MLs for grape juice (ML = 0.04 mg/kg), mango chutney (ML = 0.4 mg/kg), canned brassica vegetables (ML = 0.1 mg/kg), fresh farmed mushrooms (ML = 0.3 mg/kg), salt (excluding salt from marshes, ML = 1 mg/kg), fat spreads and blended spreads (ML = 0.04 mg/kg), and edible fats and oils (ML = 0.08 mg/kg) to CAC41 for adoption at Step 5/8.

b. To propose that CAC41 revoke the existing MLs for lead in the GSCTFF for the following food categories: mango chutney, salt, fat spreads and blended spreads, and edible fats and oils in view of the adoption of revised MLs, and the ML and category for processed tomato concentrates.

c. To re-establish the EWG, chaired by the USA, working in English only, to work on MLs for wine made from grapes and for fortified wines made from grapes, harvested after the date of the establishment of the ML, and on edible offal as previously agreed (edible offal of cattle, pig, and poultry).

d. To communicate to CCEXEC that the work could be expected to be concluded at CCCF13.

[11] REP16/CAC, para. 74
[12] REP17/CF, paras. 41-89
[13] REP18/CF, paras 19-46

13. CAC41 (2018) adopted the proposed MLs for lead in selected processed fruits and vegetables and other foods as proposed by CCCF12.

14. The USA, as Chair of the EWG, prepared the paper on proposed revised MLs for lead in wine and fortified wine and edible offal of cattle, pig, and poultry 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).

15. The recommended MLs are provided in Appendix I. The work process followed for the revision of the MLs and the analysis of the individual foods is provided in Appendix II.

16. The list of countries and nongovernmental organizations (NGOs) that joined the EWG can be found in Appendix III. Comments were received from the following countries/NGOs: Australia, Canada, France, Japan, Kazakhstan, Spain, and International Organization of Vine and Wine (OIV).

APPENDIX I

RECOMMENDATIONS FOR REVISED AND NEW MAXIMUM LEVELS FOR LEAD IN SELECTED COMMODITIES IN THE GSCTFF

1. In summary, reanalysis of selected foods supports lowering the MLs for lead or establishing a new ML for lead for various foods. The EWG makes the following recommendations.

2. **Wine:**

   a. Consider revising the ML for lead in wine from 0.2 mg/kg to:

      - 0.05 mg/kg, with the ML applying to wine made from grapes harvested after the date of the establishment of the ML, or
      - 0.1 mg/kg, with the ML applying to wine made from grapes harvested after the date of the establishment of the ML.

   b. Consider establishing an ML for lead in fortified or liqueur wines of 0.15 mg/kg, for products made from grapes harvested after the date of the establishment of the ML.

3. **Edible offal:**

   a. Cattle: Consider lowering the ML for lead in edible offal of cattle from 0.5 mg/kg to 0.15 mg/kg.

   b. Pig: Consider lowering the ML for lead in edible offal of pig from 0.5 mg/kg to 0.15 mg/kg.

   c. Poultry: Consider lowering the ML for lead in edible offal of poultry from 0.5 mg/kg to 0.1 mg/kg.

APPENDIX II

SUMMARY REPORT

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

INTRODUCTION

1. 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 (JECFA73), at the request of CCCF. In the evaluation[1], 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.

2. 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,[2] as well as with an "as low as reasonably achievable approach" (ALARA) to lead in food in international trade.

WORK PROCESS

3. The Codex Secretariat requested that Codex countries, observers, and EWG members submit data on lead levels in wine and edible offal of cattle, pig, and poultry, 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 and 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.

4. For all product categories under consideration by CCCF, 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 wine, the EWG included grape-based wines, including sparkling wines, and removed honey and rice wines. This process left us with our raw dataset.

5. 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 some 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. We also reviewed the datasets for samples that were non-detects (nonquantified) with no reported LOQ. There were no samples that met this criterion, so no further exclusions were made[3].

6. The next 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[4]. 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.[5]

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[1] 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.

[2] CX/CF12/6/13, CX/CF13/7/5, CX/CF14/8/5, CX/CF15/9/5, CX/CF 16/10/7, CL 2017/23-CF, CX/CF 18/12/5

[3] The GEMS/Food database allows submission of quantified results without an LOQ. Nondetect results (nonquantified) require submission of an LOQ.

[4] As discussed in previous years, non-detects were treated as zeros in this analysis.

[5] CX/CF12/6/13, CX/CF13/7/5, CX/CF14/8/5, CX/CF15/9/5, CX/CF 16/10/7, CL 2017/23-CF, CX/CF 18/12/5. In addition, we note that the primary goal was not to attain identical achievability rates across all commodities.

ANALYSIS OF INDIVIDUAL FOODS

Products previously discussed by CCCF

7. **Wine**. As a reminder, at CCCF12, the Committee considered the proposed ML of 0.05 mg/kg and noted the view that when setting MLs for wine, the specific characteristics of certain types of wines should be considered, such as the fruit which was used, and whether the wine was a fortified or liqueur wine. It was also noted that the ML should only be set for wine produced from grapes harvested after the date of the modification of the ML due to the ageing period and shelf life of wine. The Committee recognized the value of gathering additional data in developing the ML to enhance geographical distribution and adopting an approach that categorized different types of grape wine clearly. Therefore, CCCF12 agreed that the EWG would continue to develop separate MLs for wine made from grapes and for fortified wines made from grapes harvested after the date of the establishment of the ML.

8. The 2019 wine (non-fortified) raw dataset consisted of 14492 results from the GEMS/Food database for samples collected and/or analyzed between 2003 and 2018. The dataset includes wine products made exclusively from grapes, including products described as table wine, red wine, white wine, rose wine, sparkling wine, dessert wine and ice wine. Products described as honey wine (mead), rice wine (sake), cooking wine, wine coolers, alcopop, vinegar, and wines made from fruits other than grapes were excluded. We excluded 39 samples with an LOQ greater than the current ML of 0.2 mg/kg to obtain the LOQ-limited dataset of 14453 samples. Table WI-1 (in the Annex) shows the breakdown by country of the 2019 raw and LOQ-limited datasets. Table WI-2 shows the mean and maximum lead levels associated with the datasets. Table WI-3 shows the number and percentage of wine samples meeting current and hypothetical MLs.

9. For wine, 100 percent of samples in the 2019 LOQ-limited dataset met the current ML of 0.2 mg/kg. In addition, 100 percent of samples may meet a hypothetical ML of 0.15 mg/kg; 99 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 95 percent of samples may meet a hypothetical ML of 0.04 mg/kg. Thus, setting an ML at the hypothetical level of 0.1 mg/kg would eliminate 1 percent of the samples in international trade, setting an ML at the hypothetical level of 0.05 mg/kg would eliminate 3 percent of the samples in international trade; and setting an ML at the hypothetical level of 0.04 mg/kg would eliminate 5 percent of the samples in international trade. Therefore, the EWG could recommend that the Committee consider lowering the ML for lead in wine to 0.05 mg/kg, for products made from grapes harvested after the date of the establishment of the ML.

10. The EWG received comments supporting MLs of 0.05 mg/kg, 0.1 mg/kg, and 0.15 mg.kg for wine. Some comments noted that although the total dataset for wine may meet a hypothetical ML of 0.05 mg/kg, individual categories of wine may not be able to achieve this lower ML. Therefore, the EWG evaluated the subcategories of wine (red, white, etc.) Table WI-4 (in the Annex) shows the percentage of wine samples by subcategory meeting hypothetical MLs of 0.05 mg/kg or 0.1 mg/kg. While most types of wine would meet the proposed ML of 0.05 mg/kg, some types of wine had a lead concentration that would approach 5 percent. Based on these observations, the EWG could recommend that the Committee consider lowering the ML for lead in wine to 0.1 mg/kg, for products made from grapes harvested after the date of the establishment of the ML.

11. At its previous session, CCCF12 agreed to retain the current ML of 0.2 mg/kg for wine pending additional data to enhance geographic distribution. Therefore, the EWG wanted to address the geographical representativeness and sample number of the new dataset. The results reported in 2018 were based on 9342 samples in the LOQ-limited dataset (submitted by Australia, Belgium, Canada, China, European Union, France, New Zealand, Singapore, Thailand, and the USA). This year's analysis consists of 14453 samples in the LOQ-limited dataset (submitted by Australia, Canada, China, European Union, Japan, New Zealand, Singapore, and the USA), reflecting an increase in sample number but a similar geographical distribution. (Thirty-one samples considered in 2018 were excluded from this year's analysis because they did not meet the extraction criteria, i.e., type of wine (only grape wine) or the timeframe (submitted to GEMS/Food after 2003)).

12. **Fortified or liqueur wine**. The 2019 fortified or liqueur wine raw dataset consisted of 601 results from the GEMS/Food database for samples collected and/or analyzed between 2003 and 2018. The dataset includes wine products made with added liquor, including products described as sherry, port, and vermouth, or identified as fortified or liqueur wine in GEMS/Food. We excluded 1 sample with an LOQ greater than the current ML of 0.2 mg/kg to obtain the LOQ-limited dataset of 600 samples. Table WI-1 (in the Annex) shows the breakdown by country of the 2019 raw and LOQ-limited datasets. Table WI-2 shows the mean and maximum lead levels associated with the datasets. Table WI-3 shows the number and percentage of fortified or liqueur wine samples meeting current and hypothetical MLs.

13. For fortified or liqueur wine, 100 percent of samples in the 2019 LOQ-limited dataset met the current ML of 0.2 mg/kg for wine. In addition, 98 percent of samples may meet a hypothetical ML of 0.15 mg/kg; and 94 percent of samples may meet a hypothetical ML of 0.1 mg/kg. Thus, setting an ML at the hypothetical level of 0.15 mg/kg would eliminate 2 percent of the samples in international trade, and setting an ML at the hypothetical level of 0.1 mg/kg would eliminate 6 percent of the samples in international trade. Therefore, the EWG recommends that the Committee consider establishing an ML for lead in fortified or liqueur wine of 0.15 mg/kg, for products made from grapes harvested after the date of the establishment of the ML.

New product categories under consideration by CCCF

14. **Edible Offal**. Consistent with CODEX STAN 89-1981, 98-1981, and the Codex Classification of Foods and Animal Feeds, edible offal includes products described as edible tissues and organs other than muscles (meat) and animal fat from slaughtered animals as prepared for wholesale or retail distribution. Examples include liver, kidney, tongue, heart, stomach, sweetbread (thymus gland), and brain. Products described as lungs, ears, scalp, snout, intestines and feet were excluded. Because the MLs are set on raw, primary commodities and not processed products that may contain other ingredients, we also excluded samples described as sausage, pate, headcheese, meat paste, and products that were indicated as cooked. Samples with no species identified (892 samples, i.e., samples identified only as “Edible offal, farmed animals”) were excluded from the analysis. Edible offal of cattle, pig, and poultry were evaluated as separate commodities by the EWG, consistent with the current categories in the GSCTFF.

15. **Cattle**. The 2019 raw dataset for edible offal of cattle consisted of 13196 results from the GEMS/Food database for samples collected and/or analyzed between 2003 and 2018. The dataset includes products described as brain, heart, kidney, liver, tongue, and stomach. Most of the samples in the dataset were liver (51%) and kidney (49%), with less than 1% contribution from other organs. We excluded 3 samples with an LOQ greater than the current ML of 0.5 mg/kg to obtain the LOQ-limited dataset of 13193 samples. Table CA-1 (in the Annex) shows the breakdown by country of the 2019 raw and LOQ-limited datasets. Table CA-2 shows the mean and maximum lead levels associated with the datasets. Table CA-3 shows the number and percentage of edible offal of cattle samples meeting current and hypothetical MLs.

16. For edible offal of cattle, 100 percent of samples in the 2019 LOQ-limited dataset met the current ML of 0.5 mg/kg. In addition, 98 percent of samples may meet a hypothetical ML of 0.2 mg/kg; and 96 percent of samples may meet a hypothetical ML of 0.15 mg/kg. Thus, setting an ML at the hypothetical level of 0.2 mg/kg would eliminate 2 percent of the samples in international trade, and setting an ML at the hypothetical level of 0.15 mg/kg would eliminate 4 percent of the samples in international trade. Therefore, the EWG recommends that the Committee consider lowering the ML for lead in edible offal of cattle to 0.15 mg/kg.

17. **Pig**. The 2019 raw dataset for edible offal of pig consisted of 27377 results from the GEMS/Food database for samples collected and/or analyzed between 2003 and 2018. The dataset includes products described as blood, heart, kidney, liver, and tongue. Most of the samples in the dataset were liver (50%) and kidney (50%), with less than 1% contribution from other organs. We excluded 25 samples with an LOQ greater than the current ML of 0.5 mg/kg to obtain the LOQ-limited dataset of 27352 samples. Table PI-1 (in the Annex) shows the breakdown by country of the 2019 raw and LOQ-limited datasets. Table PI-2 shows the mean and maximum lead levels associated with the datasets. Table PI-3 shows the number and percentage of edible offal of pig samples meeting current and hypothetical MLs.

18. For edible offal of pig, 99 percent of samples in the 2019 LOQ-limited dataset met the current ML of 0.5 mg/kg. In addition, 98 percent of samples may meet a hypothetical ML of 0.2 mg/kg; 97 percent of samples may meet a hypothetical ML of 0.15 mg/kg; and 95 percent of samples may meet a hypothetical ML of 0.1 mg/kg. Thus, setting an ML at the hypothetical level of 0.2 mg/kg would eliminate 2 percent of the samples in international trade, setting an ML at the hypothetical level of 0.15 mg/kg would eliminate 3 percent of the samples in international trade, and setting an ML at the hypothetical level of 0.1 mg/kg would eliminate 5 percent of the samples in international trade. Therefore, the EWG recommends that the Committee consider lowering the ML for lead in edible offal of pig to 0.15 mg/kg.

19. **Poultry**. The 2019 raw dataset for edible offal of poultry consisted of 9090 results from the GEMS/Food database for samples collected and/or analyzed between 2003 and 2018. The dataset includes products described as heart, kidney, liver, gizzard (stomach), and thymus. Most of the samples in the dataset were liver (74%) and kidney (16%) with approximately 10% contribution from other organs. We excluded 1 sample with an LOQ greater than the current ML of 0.5 mg/kg to obtain the LOQ-limited dataset of 9089 samples. Table PO-1 (in the Annex) shows the breakdown by country of the 2019 raw and LOQ-limited datasets. Table PO-2 shows the mean and maximum lead levels associated with the datasets. Table PO-3 shows the number and percentage of edible offal of poultry samples meeting current and hypothetical MLs.

20. For edible offal of poultry, 100 percent of samples in the 2019 LOQ-limited dataset met the current ML of 0.5 mg/kg. In addition, 99 percent of samples may meet a hypothetical ML of 0.2 mg/kg or 0.15 mg/kg; 98 percent of samples may meet a hypothetical ML of 0.1 mg/kg; and 95 percent of samples may meet a hypothetical ML of 0.05 mg/kg. Thus, setting an ML at the hypothetical level of 0.2 mg/kg or 0.15 mg/kg would eliminate 1 percent of the samples in international trade, setting an ML at the hypothetical level of 0.1 mg/kg would eliminate 2 percent of the samples in international trade, and setting an ML at the hypothetical level of 0.05 mg/kg would eliminate 5 percent of the samples in international trade. Therefore, the EWG recommends that the Committee consider lowering the ML for lead in edible offal of poultry to 0.1 mg/kg.

ADDITIONAL TOPICS

21. Canada commented that the proposed ML for wine may not be achievable for Canadian “dessert wines” considered alone. Because the term “dessert wines” is ambiguous and can include both wines and fortified wines, the EWG does not recommend creation of a “dessert wines” subcategory.

PROPOSED DRAFT REVISION OF MAXIMUM LEVELS FOR LEAD IN SELECTED FOOD CATEGORIES (FRESH AND PROCESSED) IN THE *GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED* (CODEX STAN 193-1995)

(Prepared by the Electronic Working Group chaired by the United States of America)

Annex I: Tables

Table WI-1: Wine and fortified or liqueur wine: Data contribution by country to raw and LOQ-limited datasets

Country*	Wine		Fortified or liqueur wine	
	Raw dataset	LOQ-limited dataset	Raw dataset	LOQ-limited dataset
Australia	16	16	0	0
Canada	5419	5419	538	538
China	4	4	0	0
European Union	5744	5743	33	32
Japan	206	206	14	14
New Zealand	16	16	0	0
Singapore	48	10	0	0
USA	3039	3039	16	16
Grand Total	**14492**	**14453**	**601**	**600**

***** Geographical distribution is based on the country which submitted the data to GEMS/Food. Information indicating the wine producer or country of origin for the wine was generally unavailable from GEMS/Food.

Table WI-2: Wine: Mean and maximum for 2019 raw and LOQ-limited datasets

	Raw dataset		LOQ-limited dataset	
Dataset	Mean (mg/kg)	Maximum (mg/kg)	Mean (mg/kg)	Maximum (mg/kg)
Wine	0.012	5.80	0.012	5.80
Fortified or liqueur wine	0.037	0.565	0.037	0.565

Table WI-3: Percentage of wine and fortified or liqueur wine samples meeting hypothetical MLs: LOQ-limited datasets

Current and hypothetical MLs (mg/kg)	Samples ≤ MLs			
	Wine		Fortified or liqueur wine	
	Number	Percentage	Number	Percentage
0.2	14434	100%	598	100%
*0.15**	14403	100%	590	98%
0.1	14321	99%	563	94%
0.05	14014	97%	467	78%
0.04	13813	95%	402	67%

*Hypothetical MLs shown in italics

Table WI-4: Percentage of wine samples by subcategory meeting hypothetical MLs of 0.05 mg/kg or 0.1 mg/kg

Wine subcategory	Total number of samples	Samples ≤ 0.05 mg/kg		Samples ≤ 0.1 mg/kg	
		Number	Percentage	Number	Percentage
Dessert*	72	64	89%	69	96%
Formulated	71	71	100%	71	100%
Ice	449	443	99%	444	99%
Miscellaneous**	3556	3473	98%	3533	99%
Red	4803	4645	97%	4757	99%
Rose	152	151	99%	152	100%
Sparkling	1633	1618	99%	1630	100%
White	3717	3549	95%	3665	99%
Grand Total	**14453**	14014	97%	14315	99%

*The term “dessert wines” is ambiguous and can include both wines and fortified wines.

**“Miscellaneous” samples were described in GEMS/Food simply as “wine” and a subcategory for these could not be determined from the database.

Table CA-1: Edible offal of cattle: Data contribution by country to 2019 raw and LOQ-limited datasets

Country	Raw dataset	LOQ-limited dataset
Brazil	2899	2899
European Union	10098	10095
USA	199	199
Grand Total	**13196**	**13193**

Table CA-2: Edible offal of cattle: Mean and maximum for 2019 raw and LOQ-limited datasets

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.121	113.6
LOQ-limited dataset	0.121	113.6

Table CA-3: Percentage of edible offal of cattle samples meeting hypothetical MLs: LOQ-limited dataset

Current and hypothetical MLs (mg/kg)	Samples ≤ MLs	
	Number	Percentage
0.5	13150	100%
*0.2**	12879	98%
0.15	12640	96%
0.1	11981	91%

*Hypothetical MLs shown in italics

Table PI-1: Edible offal of pig: Data contribution by country to 2019 raw and LOQ-limited datasets

Country	Raw dataset	LOQ-limited dataset
Brazil	1883	1883
China	2596	2596
European Union	22399	22374
USA	499	499
Grand Total	**27377**	**27352**

Table PI-2: Edible offal of pig: Mean and maximum for 2019 raw and LOQ-limited datasets

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.023	6.55
LOQ-limited dataset	0.023	6.55

Table PI-3: Percentage of edible offal of pig samples meeting hypothetical MLs: LOQ-limited dataset

Current and hypothetical MLs (mg/kg)	Samples ≤ MLs	
	Number	Percentage
0.5	27209	99%
*0.2**	26767	98%
0.15	26467	97%
0.1	25978	95%

*Hypothetical MLs shown in italics

Table PO-1: Edible offal of poultry: Data contribution by country to 2019 raw and LOQ-limited datasets

Country	Raw dataset	LOQ-limited dataset
Brazil	2360	2360
European Union	6566	6565
USA	164	164
Grand Total	**9090**	**9089**

Table PO-2: Edible offal of poultry: Mean and maximum for 2019 LOQ-limited dataset

Dataset	Mean (mg/kg)	Maximum (mg/kg)
Raw dataset	0.009	7.130
LOQ-limited dataset	0.009	7.130

Table PO-3: Percentage of edible offal of poultry samples meeting hypothetical MLs: LOQ-limited dataset

Current and hypothetical MLs (mg/kg)	Samples ≤ MLs	
	Number	Percentage
0.5	9087	100%
*0.2**	9042	99%
0.15	8999	99%
0.1	8875	98%
0.05	8595	95%

*Hypothetical MLs shown in italics

APPENDIX III

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