

CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of
the United Nations



World Health
Organization

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TO: Codex Contact Points
Interested International Organizations

FROM: Secretariat, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
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SUBJECT: Request for data on lead in fruit juices and nectars, ready-to-drink;
canned fruits and canned vegetables¹

DEADLINE: 31 July 2014

BACKGROUND

1. The 7th Session of the Committee on Contaminants in Food (April 2013) agreed to advance the proposed draft ML of 0.03 mg/kg for fruit juices and nectars, ready-to-drink (excluding juices from berries and other small fruits); the proposed draft ML of 0.1 mg/kg for canned fruits, including canned mixed fruits (excluding canned berry and other small fruits); and the 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 36th Session of the Commission for adoption at Step 5/8. The main points of the discussion are highlighted below for easy of reference.

2. The 73rd JECFA Meeting had withdrawn the PTWI (provisional tolerable weekly Intake) of 25 µg/kg bw and concluded that it was not possible to establish a new PTWI that would be considered health protective. As no safe levels were identified by JECFA, the focus of the review was to assess the occurrence data of lead in the selected commodities to determine what percentage of samples could meet the revised MLs thus the proposals were not based on levels of exposure or consumption. Occurrence data were taken from the GEMS/Food Database and that the samples used to work on the proposals were based on LOQ-limited dataset that met the current and revised (lower) MLs.

3. The Committee had a general exchange of views on the approach used to derive the revised MLs. Several delegations questioned the lack of geographic representative data to justify the proposals for revised (lower) global MLs; the basis for the selection and the inconsistent application of the cut-off value to define the percentage of samples that would be eliminated from international trade and so to derive the revised (lower) MLs; the need for an adequate exposure assessment to determine which food categories contributed the most to the overall lead intake in different regions to determine whether the current ML was still health protective (especially for vulnerable groups such as infants and young children) even though lower levels might be technologically achievable before they could be finalized by the Committee. Other delegations recalled that lack of geographic distributed data was a recurring issue when discussing the establishment of MLs for contaminants and in this regard, countries were repeatedly invited to submit relevant data to GEMS/Foods; that the LOQ-based criteria should be applied on a commodity basis rather than generally applied to commodities; and that, if lower MLs were achievable while not being unnecessarily trade restrictive as shown in the working document, they would assist in reducing the dietary intake of lead by consumers especially the vulnerable groups, taking into account the withdrawal of the PTWI by JECFA.

4. The JECFA Secretariat informed the Committee that a large number of analytical data were considered in the JECFA re-evaluation of lead, in total over 110,000 data points from all regions of the world except Africa.

5. The Committee agreed with a revised ML of 0.03 mg/kg for fruit juices and nectars, ready-to-drink. It further agreed to assign a higher ML of 0.05 mg/kg to juices and nectars from berries and other small fruits since these type of fruits had a higher concentration of lead as shown by the higher ML allocated to this group of fruits in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995)². The Committee noted that in future, there might be a need for different MLs for fruit juices depending on the outcome of discussions on the ML for lead in fruit.

¹ Reports of Codex meetings are available on the Codex website: <http://www.codexalimentarius.org/> by clicking on "Meetings and Reports", 2013.

² Codex standards and related texts are available on the Codex website: <http://www.codexalimentarius.org/> by clicking on "Standards".

6. The Committee agreed to consolidate the MLs for the individual canned fruits and vegetables and to assign a revised ML of 0.1 mg/kg for canned fruits and canned vegetables and canned mixed fruits and vegetables with the exclusion of canned berries and small fruits (see fruit juices). As to whether the ML would apply to the solid foods in the can, the packing liquid, or the composite of the solids and liquid, the Committee agreed that the MLs applied to the product as consumed. The Committee further agreed to exclude brassica, leafy and legume vegetables as the corresponding raw vegetables had higher MLs as shown in the GSCTFF.³

7. The 36th Session of the Codex Alimentarius Commission (July 2013) noted that there was wide support for further work on the MLs and the views expressed on the need to consider more geographically representative data. The Commission agreed to adopt the MLs at Step 5 with the understanding that countries would submit data to GEMS/Food database within a year, to allow CCCF to further consider the revision of the MLs in 2015 for submission to the 38th Session of the Commission. The main points of the discussion are highlighted below to ease the reference.

8. Several delegations did not support adoption at Step 5/8 of the proposed draft MLs for lead in fruit juices, canned fruits and canned vegetables as they had concerns with the approach taken to derive the revised MLs; the lack of geographically representative data, especially from producer-countries; and the need for an adequate exposure assessment to determine which food categories contributed the most to the overall lead intake in different regions. These delegations expressed the view that setting MLs, when a complete exposure assessment was not possible, should be based on scientific evidence, on the ALARA Principle (as low as reasonably achievable) and should not create problems in international trade. A further concern was that the proposed lower MLs would require more sensitive methods of analysis. It was therefore proposed that the draft MLs be adopted at Step 5 with a request for CCCF to further analyze additional data.

9. The JECFA Secretariat explained that JECFA at its 73rd meeting undertook an updated risk assessment, taking all new data into account. An extensive exposure assessment was undertaken, mainly taking national estimates and international data into account. Based on the dose-response analysis from human studies, JECFA estimated that the previously established PTWI of 25µg/kg bw is associated with a measurable health impact in children and in adults. JECFA therefore concluded that the PTWI could no longer be considered health protective, and it was withdrawn. Since no threshold for these effects could be determined, no new PTWI was established. The Secretariat also explained that the focus of the review, undertaken by the CCCF electronic working group, was to assess the occurrence data of lead in the selected commodities to determine what percentage of samples could meet the revised MLs. This was in accordance with general procedures used in cases where no safe exposure level could be determined. It was further explained that occurrence data were taken from the GEMS/Food Database, in total, over 110 000 data points from all regions of the world, except Africa. It was also explained that while data might not have originated from producer-countries, because the products of concern were widely traded internationally, the data from importing countries reflected the occurrence of lead in products also from producer countries. It was further noted that limited data from the country raising concern with the MLs had been used in the work to revise the MLs and that it had been shown that only a small number would fail compliance with the proposed draft MLs. In addition, it was noted that JECFA had completed its work on risk assessment of lead, including a full exposure assessment, and that no further work in this regard was required.

10. It was noted that tinned vegetables and non-tinned vegetables should have a harmonized ML as lead should no longer be used in the production of cans for foods and thus no longer affected the lead levels.⁴

Request for data

11. In view of the decision of the Commission, comments will not be requested at Step 6 on the draft MLs for lead in fruit juices and nectars, ready-to-drink; canned fruits and canned vegetables until further data has been submitted (see para. 7).

12. Codex members and observers are invited to submit data on lead levels in fruit juices and nectars, ready-to-drink; canned fruits and canned vegetables to GEMS/Food database preferably for the past 10 years. Information on how to submit data can be found on the WHO website at <http://www.who.int/foodsafety/chem/gems/en/index.html>. Please read the "GEMS/Food Database Manual" before attempting to submit data to GEMS. To submit data an account is needed. Instructions on creating an account are found on page 2 of the manual. For technical questions about submitting data to GEMS, please contact Philippe Verger at WHO (<mailto:vergerp@who.int>) with a copy to Lauren Robin (<mailto:lauren.robin@fda.hhs.gov>).

13. Data that were already submitted do not need to be resubmitted. Data that were submitted to JECFA for the 2010 lead risk assessment also do not need to be resubmitted.

14. When submitting data to the GEMS/Food database for this work, please:

- Provide complete information on the LOQ and LOD of analytical methods.

³ REP13/CF, paras. 23-43, Appendix II.

⁴ REP13/CAC, paras. 73-79, Appendix IV.

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

15. Codex members and observers are also invited to actively participate in the electronic work group on lead chaired by the United States of America that is currently working on the review of the MLs for fruits and vegetables in the GSCTFF (see para. 5) as this may impact on the final revision of the MLs for the derived products e.g. fruit juices, canned fruits, canned vegetables, etc. by contacting the Chair of the EWG Lauren Robin (see e-mail above).