



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

**Tenth Session  
Rotterdam, The Netherlands, 4 – 8 April 2016**

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

*Comments at Step 3 submitted by Canada, Colombia, Costa Rica, Ecuador, El Salvador, Ghana, India, Indonesia, Kenya, Republic of Korea and AU*

## CANADA

Canada thanks the United States for leading the electronic working group.

Canada was actively involved with revisions to the Codex lead maximum levels (MLs) through participation in the eWG again this year and by providing lead occurrence data in a variety of foods to the GEMS/Food database.

Canadian data for all of the food commodities under consideration, where available, readily meet the proposed MLs. Canada supports the work of the eWG to ensure that the MLs for lead are as low as reasonably achievable (ALARA) and are harmonized across food commodities for which MLs are being updated, where possible. As such, Canada agrees with the recommendations made by the electronic working group.

The postponement of the decision on a ML for lead in juices and nectars from berries and other small fruits to allow submission of new data reflects the input received from Canadian and international stakeholders in the beverage industry. The overall dataset for lead in juices and nectars from berries and other small fruits that are sold in Canada, which were submitted for consideration by the eWG, demonstrate that an ML of 0.03 mg/kg is readily achievable for these beverages as a group, although the Canadian dataset is limited for certain juices (e.g. youngberry, acai berry).

Canada is of the opinion that item 15 in the Summary and Recommendations section, that is, to consider whether further discussion is necessary to identify an acceptable minimum number of samples for revising an ML, requires further discussion. As well, the discussion should address if the minimum number of samples would apply to the broad food category to which the ML would apply (e.g. juices and nectars from berries and other small fruits) or each specific product type within the category (e.g. youngberry juice). If a minimum number of samples is required for each product type and it is not achieved, the discussion could also address if consideration could be given to utilizing, with the application of processing factors, as appropriate, available data for other forms of the food (e.g. fresh youngberries) to support the development of an ML for another type of product (e.g. youngberry juice or nectar).

## COLOMBIA

Colombia reports that concerning the document Proposed draft revision of ML for lead in a selection of fruits and vegetables in the General Standard for Contaminants and Toxin in Food and Feed (CODEX STAN 193-1995), we are not presenting our position.

This is so because our national government, through its Health and Agriculture sectors, mainly, is consolidating information about the probable occurrence of lead levels in fruit and vegetables that was submitted in 2015 through analytical reports of samples of those foods, to support the revision of proposed maximum levels or develop alternatives to these.

Thus, we ask the CCCF to slow down on this item.

**COSTA RICA**

Costa Rica appreciates the work done and has no comments to the proposal.

**ECUADOR**

Ecuador appreciates the efforts made by the United States, for the development of the Proposed Draft Revision of Maximum Levels for lead in selected fruits and vegetables in the General Standard for Contaminants and Toxins in food and feed; in that regard it wishes to express the following:

**(i) General Comments:**

Referring to paragraph 16 of the document, which states that the EWG tentatively identified approximately 20 samples as a minimum number of samples for proposing a revised ML, Ecuador would like to know on what basis this value was determined to propose the ML indicated in the document.

**(ii) Specific comment:**

- **Paragraph 33:** For jams and jellies, 100 percent of the samples in the 2016 dataset met the current Codex ML of 1 mg/kg (Table JJ-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 98 percent of samples may meet a hypothetical ML of 0.02 mg/kg. Thus, lowering the ML to the hypothetical level of 0.05 mg/kg would eliminate 1 percent of the samples in international trade and lowering the ML to 0.02 mg/kg would eliminate ~~3 percent~~ 2 percent of the samples in international trade.

**Reason:** According to Table JJ-3: "*Percentage of jams and jellies samples meeting current and hypothetical MLs: Raw dataset*", if a hypothetical ML of 0.02 mg/kg is applied, the percentage of samples to  $\leq$  the ML is 98%, therefore 2% of the samples of international trade would be eliminated, not 3%.

**EL SALVADOR**

El Salvador welcomes the document presented to the electronic working group, led by the USA.

We consider necessary further discussion in the Committee to determine a minimum number of samples, acceptable to revise a maximum level; requesting JECFA's support issuing its technical opinion regarding the sampling method.

We support in general the ML for lead proposed by the electronic working group, for: berries and other small fruits juices and nectars; passion fruit juice and nectar; canned berries and other small fruits; canned vegetables; canned leaf vegetables; canned brassica vegetables; jams (canned fruit) and jellies; mango chutney; canned chestnuts and canned chestnuts puree; pickled cucumbers (cucumber pickles); canned tomatoes; processed tomato concentrates; table olives; fresh fungi and mushrooms.

**GHANA**

**Position 1:** We do not support the lowering of maximum levels of lead in the selected fruits and vegetables. However, we support the postponement of the revision of MLs of lead in juices and nectars, canned chestnuts and canned chestnut purees, mango chutney and canned brassica vegetables subject to submission of new or additional data.

**Rationale:** We agree with the principle that where adverse public health effect of a contaminant can be substantiated, a risk management measure (in this case lowering of ML) can be applied as a means of reducing public health risk. The approach for establishing such MLs is well defined in the criteria for the establishment of maximum levels in food and feed (GSCTFF). The GSCTFF provides that "integrated toxicological expert advice regarding a safe/tolerable intake level of a contaminant is essential when decisions about maximum levels in foods are considered. A recommendation from the Joint FAO/WHO Expert Committee on Food Additives (JECFA) regarding the maximum allowable or tolerable intake, based on a full evaluation of an adequate toxicological database, should be the main basis for decisions by Codex members". Currently, JECFA has not identified a toxicological reference value for lead in food following the withdrawal of PTWI of 25  $\mu\text{g}/\text{kg}$  bw.

We note with concern that exposure or consumption rates was not factored into the revision of MLs for lead. Only occurrence data was used to derive the MLs for lead. Moreover, the occurrence data had narrow geographical representation and limited sample size for several food categories. We are therefore concerned that the proposed ML may lack the expected high level of statistical confidence. In our view, the approach used for proposing the MLs for lead does not reflect and support the objective of revising MLs which is to protect the health of consumers worldwide. There is the need for more data from all geographical representation and further discussion on the approach for the revision including the acceptable minimum number of samples for revision of MLs.

**INDIA****General comments:**

1. India appreciates the work initiated by the EWG. The recommendations of the EWG on the following commodities for the revision of MLs of lead are acceptable to India:
  1. Juices and nectars from berries and other small fruits
  2. Passion fruits and nectar
  3. Canned berries and other small fruits
  4. Canned leafy vegetables
  5. Canned legume vegetables
  6. Canned brassica vegetables
  7. Canned chestnuts and chestnut puree
  8. Pickled cucumber (cucumber pickles)
  9. Table olives
2. However, India has comments on the other commodities as follows:

**2.1 Jam (fruit preserves) and jellies:**

India does not support the lowering of ML from 1mg/kg to 0.1 mg/kg at this stage keeping in view the data limitations as majority of the samples were from one country (also agreed by EWG). Further, data from producing countries need to be taken into consideration to have holistic approach in lowering the ML. However, India supports to include marmalades in this category as the product nature of marmalades is similar to Jams and jellies and TSS level for final products is same (65-68%).

**2.2 Mango Chutney:**

India supports the recommendation of EWG to maintain the current ML of 1.0 mg/kg due to limited data availability and to allow submission for new data on mango chutney to consider decision in next session, if possible. India is willing to generate data on MLs of lead in Mango Chutney and submit to GEMS data base. However, India does not support recommendation of EWG to combine mango chutney with jams and jellies in GSCTFF merely on the grounds that they have similar fruit contents. The ingredients of mango chutney are different from jams and jellies, as spices, vinegar, salt etc are added to Mango chutney.

**2.3 Processed tomato concentrates:**

India does not support the recommendation of EWG for lowering the ML from 1mg/kg to 0.05 mg/kg on the basis of such limited dataset of 21 samples (majority of being from one continent). Data from producing countries need to be considered before any decision is taken. Therefore, India requests committee that decision to lower ML may be kept on hold, unless until sufficient geographically representative data is available.

**2.4 Fungi and mushrooms:**

Indian does not support the recommendation of EWG for establishing an ML of 0.3mg/kg due to following reasons:

- As agreed by EWG under para 10, the focus of the paper is to review existing MLs based on occurrence data, the same approach may not be ideal for establishing a new ML.
- EWG excluded fungi and mushroom from the category of fruiting vegetables which means that same approach as used for fruiting vegetables may not be applicable primarily because consumption pattern of this product category is totally different.

India is of considered opinion that more comprehensive recent data with proper geographical representation should be available before the committee considers to establish ML for edible fungi and mushrooms.

**2.5 Additional Topic:**

India feels that discussion is necessary to identify an acceptable minimum number of samples for revising any ML because revision of ML based on limited dataset may be sometime trade restrictive. Further, India feels along with minimum number of samples the criteria of global geographical representation, producing countries etc. should also be duly considered while decisions on revision of MLs.

**INDONESIA**

Indonesia welcomes and appreciates the work performed by the electronic Working Group under the lead of United States of Amerika on Proposed draft revision of maximum levels for lead in selected fruits and vegetables (fresh and processed) in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995). The followings are Indonesia comments:

No	products	proposals	Indonesia comments
1	Juices and nectars from berries and other small fruits	Postpone the decision on juices and nectars from berries and other small fruits to allow submission of new data; consider MLs of 0.03 mg/kg and 0.04 mg/kg in 2017.	Indonesia agrees with proposal
3	Canned berries and other small fruits	Consider including in the canned fruits category with an ML of 0.1 mg/kg. Revoke the standards in the GSCTFF for canned raspberries and canned strawberries.	Indonesia agrees with proposal
5	Canned legume vegetables	Consider including in the canned vegetables category with an ML of 0.1 mg/kg. Revoke the standards in the GSCTFF for canned green beans and canned wax beans and canned green peas.	Indonesia agrees with proposal
6	Canned brassica vegetables	Maintain the note in the GSCTFF excluding canned brassica vegetables from the ML for canned vegetables, pending new data.	Indonesia agrees with proposal
7	Jams (fruit preserves) and jellies	Consider lowering the ML from 1 mg/kg to 0.1 mg/kg.  Reconsider whether marmalades should be included in this category	Indonesia agrees with proposal.  Indonesia considers that marmalades should be included in this category
8	Mango chutney	Maintain the current ML of 1.0 mg/kg, pending new data. If insufficient data are available to consider mango chutney as a unique category in 2017, combine mango chutney with jams and jellies in the GSCTFF.	Indonesia agrees with proposal
9	Canned chestnuts and chestnut puree	Maintain the current ML of 1 mg/kg, pending new data. If insufficient data are available to consider canned chestnuts and chestnut puree as a unique category in 2017, combine canned chestnuts and chestnut puree with canned fruits in the GSCTFF.	Indonesia agrees with proposal
11	Preserved tomatoes	Consider lowering the ML from 1 mg/kg to 0.05 mg/kg.	Indonesia agrees with proposal
12	Processed tomato concentrates	Consider lowering the ML from 1.5 mg/kg to 0.05 mg/kg.	Indonesia agrees with proposal
13	Table olives	Consider lowering the ML from 1 mg/kg to 0.4 mg/kg. Reevaluate table olives in the future when more data are available	Indonesia agrees with proposal

**KENYA****COMMENT:**

We would like to make our comments as follows for number 7 and 15 under the “summary and Recommendation” given in the document:

1. We generally accept the proposed limits of Lead so far awaiting for data submission from member countries to set the limits however we would propose the following.

**7: Jams (fruit preserves) and jellies:** Consider lowering the ML from 1 mg/kg to 0.1 mg/kg. Reconsider whether marmalades should be included in this category.

**COMMENT**

*If there is no sufficient data by 2017, mango chutney will be in a separate category then marmalades should be included in that separate category.*

**JUSTIFICATION**

*This is because peels are used in both products during processing.*

**15.** Consider whether further discussion is necessary to identify an acceptable minimum number of samples for revising an ML.

**SPECIFIC COMMENT**

*We have observed that further discussion is necessary to identify an acceptable minimum number of samples for revising an ML.*

**REPUBLIC OF KOREA**

According to Chapter 6. Dietary Exposure Assessment of Chemicals in Food in ‘Principles and Methods for the Risk Assessment of Chemical in Food,’ data generated through surveillance or monitoring of individual food commodities are usually 30-50 or more. Therefore, the minimum number of samples, 20 samples, proposed by EWG may not be appropriate.

**AFRICAN UNION (AU)**

**Position 1: AU** does not support the lowering of maximum levels of lead in the selected fruits and vegetables without data from Africa.

**Position 2: AU** supports the postponement of the revision of MLs of lead in juices and nectars, canned chestnuts and canned chestnut purees, mango chutney and canned brassica vegetables pending new data and also SUPPORT further discussion to identify acceptable minimum number of samples for revising MLs.

**Issue & Rationale:** As a reminder, the work on revision of MLs started as a response to new toxicological evaluation of lead in food conducted by JECFA at its 73<sup>rd</sup> meeting. The study revealed that exposure to lead is associated with various neurodevelopmental effects making fetuses, infants and children most sensitive to lead poisoning. In order to protect these susceptible groups, it was agreed at the 6th session of CCCF in 2012 that 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) be revised. The Committee also agreed to consider consolidating the MLs for canned fruit and vegetable products.

Subsequently, the 7th and 8th sessions retained MLs in the commodities but demanded for the revision of MLs for lead in fruit juice and nectars, canned fruits and vegetables, berries and small fruits, legume vegetables, brassica vegetables, fruiting vegetables (cucurbits) and fruiting vegetables (other than cucurbits) for consideration at the 9th session.

In preparing the document for CCCF 9, the EWG proposed MLs that will provide the highest level of reduction in lead level without having too significant adverse impact on international trade. The recommended MLs were not based on exposure or consumption rates. The following were the recommended MLs: 0.03mg/kg for fruit juices and nectars, ready-to-drink (excluding juices from berries and other small fruits); 0.1mg/kg for canned fruits (excluding berries and other small fruits) and canned vegetables (excluding canned brassica, leafy, and legume vegetables): and 0.1mg/kg for Berries and other small fruits. Others include 0.1mg/kg for both legume and brassica vegetables and 0.05mg/kg for both fruiting vegetables cucurbits and other than cucurbits excluding mushroom and fungi.

In spite of Africa’s objection to the adoption of the MLs which was hinged on the fact that the MLs were derived from occurrence data with no data from Africa, the 9th session of CCCF recommended and the 38th CAC session adopted the above MLs.

The committee also agreed to re-establish the EWG to continue the work on outstanding issues related to the review of MLs for Lead in fruits and vegetable in the GSCTFF. Using the same method the EWG in preparing the current document proposed MLs that will have the least adverse effect on international trade using occurrence data. The recommendations of the Group are, lower MLs of canned berries and small fruit, canned leafy vegetables, canned legume vegetables, jams and jellies and prickled cucumber to 0.1mg/kg. The MLs of passion fruits and nectars (0.4mg/kg), preserved tomatoes (0.05mg/kg), tomatoes concentrates (0.05mg/kg), table olives (0.4mg/kg) and fungi and mushroom (0.3mg/kg) were also lowered. However, the revision of MLs for juices and nectars, canned chestnuts and canned chestnut purees was postponed to 2017 pending new data. Also, because the LOQ limit set of data used for proposed MLs for canned berries and small fruits (24), canned leafy vegetables (19), canned chestnuts and canned chestnut purees (11), canned brassica vegetables (5) and tomatoes concentrates (21) were few, the EWG is recommending discussion to identify acceptable minimum data for revising MLs.

The proposed MLs were derived from occurrence data and set such that they will provide the highest level of reduction in lead level without having to significantly impact on international trade. The recommended MLs were not based on exposure or consumption rates. The reason for setting MLs is to protect the health of the consumer worldwide but when lead occurrence data used to revise MLs have narrow geographical representation then the objective of setting world standards is defective. No data from Africa was used in proposing these limits.

The LOQ limit set of data used for proposed MLs for canned berries and small fruits (24), canned leafy vegetables (19), canned chestnuts and canned chestnut purees (11), canned brassica vegetables (5) and tomatoes concentrates (21) were quite few and limited to Europe, USA, Canada and in most cases one or two countries in Asia. About 24 samples or less from few countries is too few and lack geographical spread to propose acceptable limits with high statistical confidence for the world. This necessitates for more data from all continents and further discussion on the acceptable minimum number of samples for revision of MLs. We therefore recommend that the acceptable minimum sample size should be 20 from each continent.