

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 - www.codexalimentarius.org

Agenda Item 11

CRD06 (REV)¹
ORIGINAL LANGUAGE

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

13th Session

Yogyakarta, Indonesia, 29 April – 3 May 2019

DISCUSSION PAPER ON THE ESTABLISHMENT OF NEW MAXIMUM LEVELS FOR LEAD IN COMMODITIES ACCORDING TO A PRIORITIZATION APPROACH

Comments submitted by European Union, Kenya, Malaysia, United States, ICBA

European Union

The EU would like to comment on the fact that the prioritization methodology considers relative lead exposure against toxicological end-points, which do not include safety factors as typically applied to the establishment of health-based guidance values (such as a tolerable intake). Especially in view of the fact that JECFA stated that no safe level of lead has been identified, it would be more appropriate to consider the exposure of consumers as a criterion for prioritisation, instead of the intake, expressed as a percentage of the toxicological end-points.

In general, the EU agrees with the prioritisation criteria of exposure in line with the CCCF policy and with the proposed prioritisation list of foods, included in the discussion paper. The EU agrees to start new work on MLs for the priority food categories mentioned in paragraph 21, but would like to comment that for reasons of clarity, foods for infants and young children, should be included at the top of the priority list, instead on mentioning them in a separate paragraph.

As the category 'Sugars and confectionary, excluding cocoa' is an extremely broad category, the EU recommends to identify subcategories of products which may contribute in significant amount to lead exposure and to only start work on MLs for the relevant confectionary subcategories. Subsequently, a ML should be discussed for those identified subcategories, which may present a high lead contamination.

The EU agrees with a call for data for the food categories identified as priorities, but would like to point to some aspects relevant for the data collection for food for infants and young children:

-It is proposed to collect separate data for infant and follow-on formulae, instead of including them in the category 'ready to eat meals for infants and young children', as milk or soy based preparations could show a different lead content compared to foods prepared on the basis of fruits and vegetables. Furthermore, it would be appropriate to distinguish between products marketed as powder or as liquids.

-For herbal teas for infants and young children, a distinction needs to be made between products sold as liquids and products sold in a dry form, to be prepared by infusion or decoction.

The EU proposes to rephrase paragraph 3 of the project document in appendix 1 as follows: 'MLs for lead in the following food categories and the relevant subgroups of those food categories, taking into account the policy of the CCCF':

- Food for infants and young children
- Eggs and egg products
- Cereal flours and starch
- Sugars and confectionary, excluding cocoa
- Seafood
- Teas and herbal teas
- Cocoa and cocoa products
- Processed fish, excluding frozen and sliced'

The EU proposes to delete the different aspects, currently listed in paragraph 3, as they are covered by the term 'policy of the CCCF'.

¹ Comments of Republic of Korea have been removed and compiled in CRD23.

Kenya

Table A1. Description of food categories: Kenya proposes that: -

1. a) Tea (**from the plant *Camellia sinensis***) is categorized on its own and to include “Black, White, Green and Yellow tea”.
- b) Herbal teas to be on its own and to be referred to as ‘**infusions**’

JUSTIFICATION

Teas should only refer to products made from the plant *Camellia sinensis*. Herbal teas is confusing since in practice, these teas are not made from the plant *Camellia sinensis*, but are actually infusions of other herbs.

2. a) Inclusion of Pulses and group together with Cereals
- b) Starches should be separated and the food types to include sources other than cereals e,g tubers

JUSTIFICATION

- Pulses are consumed in large quantities and should form part of the classification.
- Starches is too general a category; need to be more specific

Malaysia

Malaysia would like to highlight that based on para 17 the food categories considered as priorities to work on new MLs for lead if the categories showed high impact of lead exposure as well as a high or intermediate impact on international trade. In Table 1, the category of “processed fish excluding frozen and sliced” falls under the low lead intake foods. It should not be listed in para 21 of the proposed prioritization list of foods. Therefore Malaysia proposes to delete the category of “processed fish excluding frozen and sliced” from para 21.

Project Document (Para 9)

Malaysia notices an editorial error for the year of 42nd Session of the Codex Alimentarius commission. It should be “2019” instead of “2018”.

Under the bullet number 3 of the work package 1, Para 9(i), the category of egg should be consistent with the food category under Para 21 of the discussion paper. It should be “Eggs and eggs products”.

United States of America

- The United States considers that the prioritization criteria and proposed prioritization list of foods are reasonable.
- The United States agrees that new work can start; however, additional consideration is needed regarding the approach for establishing MLs, i.e., whether the approach should be based on sample rejection rates or be driven by health considerations.
- The United States recommends that given the large amount of work being proposed, new work should be proposed only for the food commodities identified in Work Packages 1 and 2 in the Project Document.
- The United States supports identifying other foods that are highly consumed by children and their respective consumption through the call for data on lead in foods, rather than through a separate circular letter.
- The United States does not agree with considering individual countries’ consumption data for food categories such as seaweed and non-alcoholic beverages that do not have consumption data in the GEMS/Food Cluster Diet Consumption database. In such cases, national standards may be more appropriate.
- The United States suggests the following additions to the Project Document to reflect issues raised in the Discussion Paper:
 - For eggs, clarify whether this category includes only shell eggs or also egg products.
 - For cereal flours and starch, add the following statement, “Evaluate if an ML can be derived from the raw commodity or if separate MLs should be established based on cereal flours and starch data.”

- For teas and herbal teas, add the following statement, “Consider whether separate subcategories should be established for dried versus liquid/infused products or whether an ML should only be set for dried products based on dried products data (allowing for extrapolation to liquid/infused products).”
- For 3.f), add “and health impacts.”

ICBA

ICBA supports the 73rd JECFA meeting conclusions that measures taken to reduce global dietary exposure to lead should be commensurate with the level of risk reduction internationally, by identifying primary contributing sources that would benefit from such reductions.

During the electronic working group, ICBA raised data quality concerns which – if addressed – would require trimming of the existing GEMS dataset before a reanalysis is undertaken to identify appropriate maximum limits (MLs).

Concern A. Quality Assurance/Quality Control of submitted occurrence data

ICBA questions the quality of the submitted data and seeks to understand what kind of quality assurance and quality control measures are in place to review submissions. While Brazil did remove data that ‘did not comply with basic criteria ... such as incomplete information, aggregated data, results on dry matter basis and data without limit of quantitation (LOQ) reported,’ some entries reflected in the GEMS dataset seem exaggerated and to be highly unlikely occurrences.

Dataset Refinement

To ensure a more appropriate and refined dataset is the basis for prioritization, ICBA suggests applying the following steps to remove questionable data points:

Step 1: "Trim" dataset to exclude all non-detects with limit of detection (LOD) > 25 ppb.

Rationale 1: Any analytical methodology with LOD greater than 25 ppb is unreasonable in view of current technological capabilities with LODs as low as 1 ppb in some cases. A 25 ppb LOD threshold was chosen based on the LOD that offered a ‘natural break’ in the LOD distributions for samples with measured levels of Pb. Reported LODs from 0.02 µg/kg to 5.0 mg/kg and Limit of Quantitation (LOQ) from 0.05 µg/kg to 16.7 mg/kg are far too large a range to accurately analyze the dataset.

Step 2: Remove “outliers”, i.e., entries exceeding ‘75th percentile + 1.5*Interquartile range (IQR)’.

Rationale 2: A statistical evaluation of the raw dataset can ensure that the analysis is not skewed by questionable data. The formula proposed – i.e., ‘75th percentile + 1.5*Interquartile range (IQR)’ – is a standard approach to identify outliers used in statistical summaries, particularly for box and whiskers plots. /

Step 3: Place a value of ½ LOD for non-detects (already addressed in paragraph 25 of the discussion draft).

Rationale 3: A value of ½ LOD for non-detects is a standard approach used by regulatory agencies and ensures non-detects are not given a value of ‘0’.

Data Submission Verification

ICBA questions whether the data submitters for the ‘teas and herbal teas’ category selected the appropriate units (i.e., µg/kg versus mg/kg) or basis (on dry matter versus as consumed) for reporting. Many of the entries reflected for this commodity would appear to be on a dry basis unfortunately, typically reported as mg/kg. Thus, transference of the lead from the dried tea leaf to the finished brewed tea as consumed would need to be accounted for as the dried tea leaf per se is not consumed.

Research has found lead to be present at very low levels in tea leaf, with transference to the brewed tea after steeping ranging from 0 to 20 percent. / Brewing transference rates and the low likelihood of surface lead minimize the amount of lead in the typical cup of tea. While the U.S. Environmental Protection Agency (EPA) has not adopted a Maximum Contaminant Level (MCL) for lead in drinking water due to lack of feasibility and primarily relies on a “treatment approach” to achieve the objective of reducing exposures to lead, / the U.S. EPA has set an “action level” for lead in drinking water of 15 ppb considered to be “feasible for public water systems to attain by such measures as adjusting the physical characteristics of the water (pH, hardness) which affect the corrosivity of the water.” /

Concern B. Reasonableness of consumption data

Some of the daily consumption amount for commodities seem unreasonable based on available national data.

For example, reviewing daily consumption amounts across GEMS/Food cluster diets in Appendix III Table X1 of the discussion draft for 'spices and aromatic herbs', the two highest consuming clusters identified were G15 (36.73 g/day) and G09 (33.68 g/day) with a mean of 17.3 g/day. One teaspoon of spices may contain 2-5 g, depending on the spice. The above numbers would suggest per capita intake of spices as high as 7 - 18 teaspoons. Does a single person in any one country consume 18 teaspoons of spice every day? Amounts reported for herbs – having a lower density to spices – likewise would erroneously suggest that 36 'tablespoons' of herbs are consumed daily per capita. In either scenario, the amounts reportedly consumed on a daily per capita basis seem unrealistic. Typical consumption amounts are a fraction of what has been reported in the GEMS cluster diets, even in high consuming markets such as India where most spices consumed were below 1 g per serving. //

Similarly, we question the consumption values reported for 'sugar and confectionary excluding cocoa'. Are the reported daily amounts consumed on a sugar commodity basis or a whole finished product basis?

The U.S. Food Commodity Intake Database (FCID) is based on the U.S. National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA) food intake and FCID recipes to estimate food commodity consumption for the purposes of pesticide dietary exposure assessment. / Leveraging the FCID calculator and selecting either sugarbeet or sugarcane for children/adolescents (< 17 yrs) or adults (>18 yrs) or the general population (all ages), the 'eaters only' intake amounts are reflected in the below distribution:

The reported amounts consumed daily for sugar from sugarbeet or sugar cane at the 95th percentile were 46 g/d or 62 g/d, respectively, and at the median, 11 g/day or 14 g/day. These reported amounts do not align with the amounts reported in Appendix III Table X1 of the discussion draft for the highest consuming clusters (i.e., 245 g/d for the G6 cluster or 237 g/d for the G11 cluster) or even for the G10 cluster of which USA is a part (i.e., 194.91 g/d).

Finally, dried tea leaves are not consumed as such but rather steeped and brewed prior to consumption. Amounts reported in GEMS/Foods would appear to reflect dried amounts rather than finished brewed tea. A maximum transference of 20 percent of lead from dried tea leaf to the brewed tea would have to be factored into these calculations.