CODEX ALIMENTARIUS COMMISSION E

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 8 **CX/CF 20/14/8-Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

14th Session
Utrecht, The Netherlands, 20 – 24 April 2020

PROPOSED DRAFT MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES

Comments at Step 3 submitted by Canada, Chile, European Union (EU), India, Iraq, Mexico, Republic of Korea, Thailand, Uganda, United States of America (USA), Zambia, International Special Dietary Food Industries (ISDI), International Organization of Spice Trade Associations (IOSTA) and International Union of Food Science and Technology (IUFOST)

NOTE: CCCF14 has been postponed to 3 – 7 May 2021. The comments compiled in this document will be made available to the EWG chaired by Brazil for further consideration and preparation of a revised version of the document for consideration by CCCF14.

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2020/21/OCS-CF issued in February 2020. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.

Explanatory notes on the appendix

2. The comments submitted through the OCS are, hereby attached as **Annex I** and are presented in table format.

ANNEX I

COMMENTS ON THE PROPOSED DRAFT MLs FOR LEAD IN CERTAIN FOOD CATEGORIES

GENERAL COMMENTS	MEMBER/OBSERVER
Canada wishes to express its appreciation to Brazil for leading the electronic Working Group (eWG) on the Proposed draft maximum levels (ML) for lead in selected commodities in the General Standard for Contaminants and Toxins in Food and Feed. Canada supports that any new MLs for lead are as low as reasonably achievable (ALARA principle). Canada has the following comments on the proposed MLs for lead in various foods at Step 4 that are presented in Appendix I. Overall, Canada suggests that further rationale be provided for some of the proposed MLs, as highlighted in their specific comments below.	**Canada**
In general, the EU considers that the MLs for lead should be lowered wherever possible. As regards the proposed actions for the individual commodities, the EU would like to present the following position as described in the section on specific comments:	**EU**
Thailand would like to thank Brazil for analyzing and preparing the proposed draft MLs for lead in selected commodities. Specifically, with respect to selected commodities, we appreciate the opportunity to provide comments on the following issues as described in the section on specific comments.	**Thailand**
Uganda is in agreement with points 6 and 7.	**Uganda**
Upon the review of the comments by different stakeholders, Zambia would like to submit its agreement with what has been provided in the proposed standard. Furthermore, inclusion of other cereal based products in the standard is supported due to the diversification of infant foods especially in developing countries. The lack of standard for these makes it difficult to regulate	**Zambia**
ISDI supports the ongoing work of the Codex Committee on Contaminants in Food in establishing Maximum Levels (MLs) for lead in different food categories. ISDI has two comments specific to share in relation to circular letter CL 2020/21/OCS-CF.	**ISDI**
IUFoST supports the establishment of these limits if they have already ben reviewed by JECFA. If this is not the case, action should be held until a JECFA review is available.	**IUFoST**

SPECIFIC COMMENTS	
Section/paragraph	**Member /Observer**
Eggs and preserved eggs: Canada does not object to the proposed MLs for lead of 0.1 mg/kg for eggs (fresh) and 1.5 mg/kg or 2 mg/kg for preserved eggs. However, given the higher lead concentrations in preserved eggs relative to fresh eggs, it seems that preserved eggs may be dehydrated/dried, powdered eggs, although raw (liquid) eggs can also be sold in a preserved form. Further, there are 4 samples listed as dried eggs (whole, yolk, and white) in Annex I, Table A1. Defining the 'preserved egg' category would be useful, which could include confirming with the three countries that submitted data for this commodity that the food products are comparable. Depending on how preserved eggs relate to fresh eggs (e.g. if there is a concentration or processing factor) will help determine if an ML of 1.5 mg/kg or 2 mg/kg would be most appropriate and if proportionality between the respective MLs for fresh and preserved eggs should be considered. **Culinary herbs and spices** **Fresh and dried culinary herbs / rhizomes, bulbs and roots:** The concept of proportionality could also be considered in the cases of fresh and dried culinary herbs as well as fresh and dried rhizomes, bulbs, and roots. A discussion of the concentration factors between the fresh and dried commodities will help determine if proportionality between the respective MLs for fresh and dried commodities should be considered and would help guide the ML proposals. Canada supports the proposed ML of 0.2 mg/kg lead in fresh culinary herbs, resulting in a 2.6% rejection rate. A single ML of 2 mg/kg (rejection rate of 1.9%) was proposed in dried culinary herbs. MLs of 1.5 mg/kg (rejection rate of 3.9%) and 1 mg/kg (rejection rate 4.5%) for dried culinary herbs would have rejection rates <5% and these lower MLs would be more consistent with the ALARA principle. Canada suggests that further consideration may be warranted for fresh and dried culinary herbs taking into consideration both the ALARA principle and proportionality of the fresh and dried products. The proposed MLs of 2.5 mg/kg (rejection rate of 4.3%) and 0.8 mg/kg (rejection rate of 4.8%) in fresh and dried, respectively, rhizomes, bulbs and roots are reasonable and consistent with the ALARA principle. However, Canada suggests that the proportionality between the MLs for fresh and dried products should considered as part of the ML elaboration process. **Fruits and berries**: The proposed MLs of 0.6 mg/kg (rejection rate of 4.5%) in fruits and berries is reasonable and consistent with the ALARA principle. **Bark**: If a rejection rate of 5% or lower is targeted for bark (cinnamon), an appropriate ML would be 4 mg/kg (rejection rage 4.8%), rather than the proposed ML of 3 m/kg (rejection rate 6.6%). **Floral parts**: As only 30 samples are available for floral parts (cloves and saffron), a larger dataset may demonstrate more consistency between hypothetical MLs as well as lower rejection rates at certain hypothetical ML values. It is suggested that a call for data be initiated to augment the dataset for this food group prior to ML elaboration. **Seeds**: The proposed ML of 0.9 mg/kg (rejection rate of 4.9%) in spices in the form of seeds (e.g. coriander, cumin) is reasonable and consistent with the ALARA principle. **Cereal based food for infants and young children** **Sugars and confectionery** Canada supports that consideration of MLs for lead in food for infants and young children as well as sugar and confectionery be continued next year in order to utilise the most recent (2019) data. A proposed ML for lead in lead in cereal based food for infants and young children could be expressed on a 'dry matter' basis, rather than an 'as consumed' basis, similar to the ML for deoxynivalenol (DON) in cereal-based foods for infants and young children in the GSTCCFF. This ML for DON is the only ML for cereal-based foods for infants and young children currently in the GSTCFF. Editorial comments: Table 2 (row 5, column 2): "Cumin, anise seed, fenugreek, chili seed, funnel fennel seeds, coriander seed, dill seed, cardamom, mustard, nutmeg"	**Canada**
Chile welcomes the opportunity to provide comments on the draft Maximum Levels of lead in some products. Chile reviewed the recommendations in this circular letter and has the following comments to make:	**Chile**

SPECIFIC COMMENTS	
Section/paragraph	**Member /Observer**
Eggs: Chile agrees with the values proposed by the EWG for eggs, and preserved eggs. **Culinary herbs and spices**: Chile agrees with the values proposed by the EWG for spices and culinary herbs, nonetheless, it believes that it is necessary to specify to which spices/herbs they will apply. **Cereal based food for infants and young children** **Sugars and confectionery** Chile agrees with postponing until next year the establishment of maximum levels in foods for infants and young children, and in sugar and confectionery products, in light of the inconsistencies identified in the lead data in these food matrices.	
Culinary herbs and spices: India does not support the proposed MLs for Spices and Culinary Herbs. It is observed that many spice producing countries have not submitted the data and, hence, the data considered for the proposing these MLs is neither sufficient nor representing the actual spice producing countries, geographically. India, being lead producer of spices and condiments, wishes to submit fresh data for all categories of spices and culinary herbs before establishing MLs. Therefore, the limits maybe reworked/ revised after collecting more data from primary producer countries and analyzing the same. The data submitted by India recently also does not support the proposed levels for Rhizomes, bulbs and roots; fruits and berries. Further, data pertaining to other category is not significant enough to drive any conclusion. Therefore, we wish to generate more data on other categories as well.	**India**
We agree with proposed draft of maximum levels for Lead for selected food categories without any comments.	**Iraq**
Fresh eggs: For eggs the EU considers that, taking into account the occurrence data for the global data set, there is margin to set an ML, which is lower than the proposed ML of 0.1 mg/kg. The EU would be in favour of an ML of 0.05 mg/kg, which is closer to a 5% rejection rate for the global data set. **Preserved eggs**: For preserved eggs the EU does not support the establishment of an ML. It is not clear which products are included in this category. As this category does not include dried egg products, it is not clear why the occurrence data are much higher than for regular eggs and what the source of contamination is. **Fresh culinary herbs**: For fresh culinary herbs the EU can support the proposed ML of 0.2 mg/kg. **Dried culinary herbs**: For dried culinary herbs the EU can support the proposed ML of 2.0 mg/kg. **Spices** **Fruits and berries**: For fruit and berry spices the EU can support the proposed ML of 0.6 mg/kg. **Dried rhizones, bulbs and roots**: For rhizome, bulb and root dried spices the EU considers that, taking into account the occurrence data for the global data set, there is margin to set an ML, which is lower than the proposed ML of 2.5 mg/kg. The EU would be in favour of an ML of 1.5 mg/kg, which would lead to a 6% rejection rate for the global data set. Especially in view of the known adulteration practices of colouring turmeric with lead chromate, it is important to set an ML, which is low enough to allow enforcement action against those practices. **Fresh rhizomes, bulbs and roots**: For rhizome, bulb and root fresh spices the EU can support the proposed ML of 0.8 mg/kg. **Bark**: For bark spices the EU would like to introduce a reservation against the proposed ML of 3.0 mg/kg, as the data provided by EU stakeholders would support a lower ML of 2.0 mg/kg. **Floral parts**: For floral part spices the EU can support the proposed ML of 1.0 mg/kg. **Seeds**: For seed spices the EU can support the proposed ML of 0.9 mg/kg. **Cereal based food for infants and young children /** **Sugars and confectionery** The EU can agree to postpone the establishment of MLs for lead in food for infants and young children and sugar and confectionary until next year. The EU would prefer the establishment of MLs for cereal-based products for infants and young children 'as sold' instead of 'as consumed', because this would facilitate enforcement in case no clear preparation instruction would be indicated on the product label.	**EU**

SPECIFIC COMMENTS	
Section/paragraph	**Member /Observer**
Furthermore, the method of preparation is not always straightforward and may be highly variable depending on the types and amounts of additional ingredients used for the final home preparation and depending on possible different options for the preparation of the ready-to-eat food. No standardized procedures for preparation of different cereal-based baby foods exist and it would also not be realistic to establish such standardized procedures. Therefore, the establishment of MLs for the product 'as consumed' might lead to legal uncertainties and complexities in official food laboratories as well as in law enforcement, regardless of whether or not precise information on the product preparation is available. As occurrence data are gathered for these commoditizes 'as sold', it would be logic to also set MLs on an 'as sold' basis. Also for other foods for infants and young children, for example herbal teas, it should be taken into account that further preparation before consumption is required. Therefore, it should be specified for each category of food for infants and young children that the ML applies to the product 'as sold'.	
Preserved eggs: Establish an ML of 1.5 ~~or 2~~ mg/kg for preserved eggs. Have a default value to avoid confusion with the ML.	**Mexico**
Eggs: Republic of Korea supports the establishment of ML for eggs. **Culinary herbs and spices**: We would like to provide following suggestion about classification (herbs, spices). It is difficult to apply because the suggested categories are too specific, so the category should be modified to become more simple. For example: Fresh culinary herbs / Dried culinary herbs / Spices [Fruits and berries, Rhizomes, bulbs and roots (dried), Rhizomes, bulbs and roots (fresh), Bark, Floral part, seed] → Herbs / Spices, fruit or berry / Spices, seeds / Spices, root, rhizome / Other spices	**Republic of Korea**
Fresh eggs: We would like to seek clarification for data of duck eggs. According to the data on the first draft circulated via EWG, we note that the data of duck eggs on the EWG draft and CX/CF 20/14/8 show a significant difference. Refer to the CX/CF 20/14/8, we consider that it is necessary to further call for duck egg data. Thailand does not oppose the establishment of ML for lead in chicken eggs due to sufficient data; however, it is recommended to include the data of intake reduction for considering. More important, we do not agree to set up the ML for lead in fresh eggs by combining the data of chicken eggs and duck eggs. It is obviously shown that there is a significant difference between both data. In fact, duck eggs have higher lead levels than chicken eggs. We, therefore, suggest postponing the consideration on establishing an ML for lead in duck eggs until sufficient data is available. **Preserved eggs**: Regarding to the proposed ML for lead in preserved eggs, we suggest elevating the MLs which cover the sample rejection rate between 2% and 5%. We suggest that the analyzing for ML should contain the value of intake reduction for each individual proposed MLs for lead. We believe that preserved eggs are not mainly consumed; therefore, the consumption data of preserved eggs could be very low. Thus, the proposed MLs as 1.5 mg/kg or 2.0 mg/kg with the high rejection rate may not be appropriate for preserved eggs. We propose that the hypothetical MLs should be proposed in the higher level such as 3.0 mg/kg with their intake reductions for concrete consideration. **Fresh culinary herbs**: According to the data shown in Table A2 of CX/CF 20/14/8, there are only 2 countries, Canada and the United States of America, which submitted the data. Thus, we are of the view that the data of fresh herbs is not worldwide. Also, the proposed MLs are not aligned with the existing ML for lead in leafy vegetables established in GSCTFF as 0.3 mg/kg. Hence, we suggest that the Committee consider whether the data should be recalled and re-establishment of ML for lead in fresh herbs with sufficient available data in the next year. **Dried culinary herbs**: Thailand supports the establishment of ML for lead in dried herbs at 2.0 mg/kg which has appropriate intake reduction rate of 41.14% and sample rejection rate of 1.9%. **Spices**: Principally, we believe that spices have a very low consumption pattern; therefore, the proposed MLs with high percentage of sample rejection rate may be an inappropriate level. Consequently, we propose that the new hypothetical MLs should be analyzed to cover the sample rejection rate between 2% and 5%. **Fruit and berries**: Thailand opposes the establishment of ML for lead in fruits and berries at 0.6 mg/kg with sample rejection rate of 4.5%. Therefore, we propose the ML should be higher to 0.8 mg/kg or 1.0 mg/kg which has more appropriate intake reduction rate and sample rejection rate. **Dried rhizomes, bulbs and roots**: Thailand opposes the establishment of ML for lead in dried rhizomes, bulbs and roots spices at 2.5 mg/kg. We suggest that the proposed ML for lead in this food category should be higher to cover sample rejection rate of 2%.	**Thailand**

SPECIFIC COMMENTS	
Section/paragraph	**Member /Observer**
Fresh rhizomes, bulbs and roots: Thailand opposes the establishment of ML for lead in fresh rhizomes, bulbs and roots spices at 0.8 mg/kg with sample rejection rate of 4.8%. Therefore, we propose the ML should be at 1.0 mg/kg which has more appropriate sample rejection rate as 1.6%. **Barks**: Thailand opposes the establishment of ML for lead in barks at 3.0 mg/kg. We consider that the proposed ML for lead in this food category should cover sample rejection rate between 2% and 5%. **Floral parts**: Thailand supports the establishment of ML for lead in floral parts at 1.0 mg/kg which has an appropriate sample rejection rate of 2.7%. **Seeds**: Thailand opposes the establishment of ML for lead in seeds at 0.9 mg/kg with sample rejection rate of 4.9%. Therefore, we propose the ML should be at 1.0 mg/kg which has more appropriate sample rejection rate of 2.9%. **Cereal based food for infants and young children**: We do not object to postpone the consideration on the establishment of ML for lead in this category. Also, we have no objection to express the ML with "as consumed" in order to in consistent with other food categories established in GSCTFF. **Sugars and confectionery**: We do not object to postpone the consideration on the establishment of ML for lead in this category. However, we are of the view that each type of sugars should be clearly classified. In addition, for clarification about our submitted data for raw sugar to GEMS/Food in 2019, we would like to ask the EWG to confirm whether our submitted data will be used for the next year.	

Eggs
• The United States potentially would not object to the proposed ML of 0.1 mg/kg for eggs but is reviewing data to confirm this position for the next session.
• The United States questions whether an ML for preserved eggs is needed, given that most samples are from China and Singapore. Preserved eggs may not be an important commodity in international trade.
Culinary herbs and spices
• Based on input from producers, the United States believes that the proposed MLs for dried culinary herbs; dried rhizomes, bulbs, and roots; dried bark; and dried floral parts are achievable; and that, for the categories "fruits and berries" and "seed," MLs of 1.0 mg/kg would be achievable.
• The United States has some concerns with the proposed MLs of 3.0 mg/kg for bark (e.g., cinnamon), and 2.5 mg/kg for dried rhizomes, bulbs, and roots (e.g., turmeric) on a health basis.
• The United States is currently reviewing additional data to refine positions on the proposed MLs for spices, dried culinary herbs, and fresh culinary herbs.
• The United States suggests consideration of an ML for spice mixes, particularly for ground spice mixes.
Cereal based food for infants and young children
• The United States agrees with further review of the MLs for lead in food for infants and young children.
Cereals: MLs for cereal-based products for infants and young children should be based on an "as is"/dry basis, comparable to deoxynivalenol MLs for cereal-based foods for infants and young children. Lead concentrations measured on an "as consumed" basis will vary depending on preparation method.
Sugars and confectionery
• The United States agrees with further review of the MLs for lead in sugars and confectionery.
Other categories
• We also have specific comments on the following categories:
  • Fruit juice: An ML may not be needed. Data on lead in fruit juice for infants and young children were included in the recent reassessment of existing lead MLs, and these products are covered by the revised MLs in the GSCTFF.
  • Herbal teas: An ML may not be needed. Herbal tea for infants and young children appears to be a regionally consumed food, based on the small number of data available from only one region.
	USA

SPECIFIC COMMENTS	
Section/paragraph	**Member /Observer**
• Dairy products: It may be possible to consolidate the dairy product subcategories for infants and young children. If there are still not enough data or if consolidation is not appropriate, these foods may not be important in international trade, and establishing MLs may not be needed.	
Spices: IOSTA requests that the discussion regarding MLs in spices be placed on hold until further study is done, additional data is generated, and also to give sufficient time to producing countries to implement the code of practice for prevention of lead contamination,	**IOSTA**
Cereal based food for infants and young children **Sugars and confectionery** ISDI supports the recommendation to postpone recommendations for MLs for lead in food for infant and young children and sugar and confectionary and extract to allow more time to address inconsistencies that were identified in the data. ISDI further suggests that generation of ML proposals may benefit from waiting for the outcome of the Electronic Working Group on "General Guidance on Data Analysis for Development of Maximum Levels" being chaired by the EU, Japan, The Netherlands, and The USA. The outcome of this related work may be very useful in guiding this discussion. ISDI supports the recommendation presented in the discussion paper to establish MLs for cereal-based infant foods "as consumed", consistent with how the MLs for infant formulae have been established. As the MLs for food products are based on the concentrations of contaminants present in those foods, as they are consumed, expressing the MLs "as consumed" provides the best link between the risk assessment and product concentration. While we recognize that expressing MLs "as is" may be the most simple approach from an enforcement perspective, these products all include instructions for preparation that make conversion of values measured "as is" to concentrations "as consumed" a very straightforward mathematical conversion.	**ISDI**