CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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**Agenda Item 8** **CX/CF 21/14/8-Add.1**

**April 2021**

**ORIGINAL LANGUAGE ONLY**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**
**CODEX COMMITTEE ON CONTAMINANTS IN FOODS**
**14th Session**
**(virtual)**
**3-7 and 13 May 2020**

# MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES

**(at Step 4)**

Comments at Step 3 submitted by Australia, Canada, Chile, Cuba, Ecuador, Egypt, European Union (EU), Iraq, Japan, United States of America (USA), FoodDrinkEurope, International Council of Beverages Associations (ICBA), International Confectionery Association (ICA), International Special Dietary Food Industries (ISDI) and Tea & Herbal Infusions Europe (THIE)

## Background

1. This document compiles comments received in response to CL 2021/13/OCS-CF issued in March 2021.

## Explanatory notes on the Annex

2. The comments are hereby compiled in the **Annex** and are presented in table format.

**COMMENTS AT STEP 3 ON MLs FOR LEAD IN CERTAIN FOOD CATEGORIES**

**ANNEX**

**GENERAL COMMENTS**

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| Australia does not have any comments on this Circular Letter. | **Australia** |
| Ecuador desea apoyar los niveles propuestos en el Apéndice I, considerando que para el caso de té de hierbas específico para lactantes y niños pequeños, debe realizarse más trabajos. | **Ecuador** |
| Egypt appreciates the work and efforts done by the EWG in drafting of this circulated document; and in this regard, Egypt would like Provide comments on: | **Egypt** |
| European Union Competence<br>European Union Vote<br>The European Union (EU) welcomes and appreciates the work on the maximum levels (MLs) for lead by the electronic Working Group chaired by Brazil.<br>The EU can agree to send the proposed MLs for final adoption, provided that sufficient agreement is reached at the CCCF14 meeting.<br>The EU can agree to the re-establishment of the electronic working group to continue working on the proposals for lead MLs for the prioritised food categories.<br>As regards the proposed actions for the individual commodities, the EU would like to present the following positions: | **EU** |
| Agree | **Iraq** |
| General Comments<br>Japan would like to thank Brazil for the work for elaborating the discussion paper on maximum levels for lead in certain food categories.<br>Japan stresses that CCCF should follow the criteria for the establishment of MLs in Food and Feed in the annex of GSCTFF (CXS 193-1995).<br>In addition, a consistent approach should be taken, referring to the discussion during the revision of the MLs for lead in the GSCTFF that had been done until the last session of the CCCF. | **Japan** |
| SUBJECT: CCCF ITEM 8. MAXIMUM LEVELS FOR LEAD IN CERTAIN FOODS – RESPONSE TO CL2021/13/OCS-CF<br>The International Confectionery Association thanks the electronic working group (EWG) Chair, Brazil, for preparing and distributing the document CX/CF 21/14/8. We appreciate the opportunity to comment on this document and support the further discussions at the Codex Committee on Contaminants in Food (CCCF) 14th session, May 3-7, and 13, 2021.<br>Our position is to support measures that respond to science-based risk, following the scientific risk assessment by JECFA, and the risk management principle that maximum levels, when necessary, should be globally reasonably achievable, following the principle of ALARA and based on sufficient global data. | **ICA** |

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| In Appendix 1, point 3., a proposed ML is listed for lead in sugar-based candies, at 0.2mg/kg. However, the data requests focused on collecting data on sugars, not on the candy products falling under the sugar-based candy listing. If MLs are best set on the ingredients that may contain lead, including managing the levels in the sugar ingredients, or spice ingredients used in spicy candy, then there would be no reason to also set an ML for the finished product. Otherwise, to determine ALARA-based MLs for sugar-based candies would require data on the various types of sugar-based candy globally that fall under this product category.<br>We thank the Committee for taking into account these considered points and look forward to further discussion at the CCCF14 session. | |
| ICBA supports the CCCF recommendations to place a footnote to the fruit juice categories specifying that the established MLs also apply to those products intended for infants and young children. Additionally, ICBA has highlighted potential areas that may require further clarification relative to the herbal teas discussion. ICBA thanks CCCF members for taking these comments into careful consideration. | **ICBA** |

**SPECIFIC COMMENTS**

**(a) Whether different rejections rates should be established for different types of products and contaminants other than the already agreed rejection rate of 5% currently being applied.**

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| 1a): Canada is not aware that different rejection rates have ever been applied by CCCF depending on the product or contaminant. It is consistent with other CCCF EWGs and CCCF processes to target a 5% or lower rejection rate for all food commodities and contaminants under consideration for ML elaboration. | **Canada** |
| Cuando se ha definido utilizar determinada cantidad de decimales en la posible determinación de niveles máximos, puede darse el escenario de no poder cumplir estrictamente con el 5% de rechazo máximo. Por este motivo, es pertinente considerar que si la salud del consumidor está protegida con los niveles fijados, el siguiente objetivo principal del Codex Alimentarius debe ser evitar las trabas innecesarias al comercio, por lo que se pueden considerar diferentes tasas de rechazo para cada categoría de alimento. | **Ecuador** |
| In general, the EU considers that the MLs for lead should be lowered wherever possible. A rejection rate of 5% is a good target for proposing MLs, however for each commodity also particular specificities as regards consumer groups, consumption volumes, possible mitigation measures and the available data, should be considered. | **EU** |
| As for Bullet point a. of para 12.1, Japan would like to provide the following comments:<br>While the CCCF considers the usual cut-off level of less than/equal to a 5% violation rate, the CCCF has not agreed to use a single violation rate of 5% when applying ALARA principles in establishing MLs to be health protective with a minimum negative impact on trade.<br>The ML for lead in food should be set on a case-by-case basis according to the concentration distribution of the occurrence data, taking into account the effect of exposure reduction by setting the ML, so that the violation rate under the ML is less than 5% (preferably 2-3%). Violation rates above 5% would be acceptable if the ML is not sufficient to consumer health protection. | **Japan** |
| To date, the Committee has handled ML revision and establishment on a case-by-case basis, with violation rates ranging from 0% to 5% (e.g., see mango chutney and canned chestnuts in CL 2017/23-CF). We recommend this approach be carried forward. A more extensive discussion on establishing different rejection rates for different types of products and contaminants is outside the scope of this agenda item | **USA** |
| We don’t see any reason for that. | **THIE** |

**(b) If an ML should be established for dried spices and culinary herbs or whether to use concentration factors from the fresh products and assume the same MLs for lead in leafy vegetables.**

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| 1b): Canada would support ML elaboration for dried rather than fresh spices and culinary herbs given that they are anticipated to be most commonly traded. This is supported by information in the GSTCFF (page 7):<br>"In some cases, however, there may be valid arguments to prefer expression [of an ML] on a dry weight basis... Preferably the product should be defined as it moves in trade..."<br>Dilution factors could be applied when applying the MLs for dried products to fresh products, which is sup-ported by information in the GSTCFF (page 7):<br>"When products are concentrated, dried or diluted, use of the concentration or dilution factor is generally appropriate in order to be able to obtain a primary judgment of the contaminant levels in these processed products." | **Canada** |
| Chile está de acuerdo con establecer un NM en las especias y hierbas culinarias secas y considera no aplicable utilizar los factores de concentración de los productos frescos y asumir los mismos NM de plomo en las hortalizas de hoja. Lo anterior justificado en que el consumo de una hortaliza es diferente al de una especia fresca y, por otro lado, la importancia comercial de hierbas y especias frescas es muy menor respecto de las secas, por lo que Chile se inclina a no establecer NM en estas matrices en particular. | **Chile** |
| Si la forma “seca” de las especias y hierbas culinarias es la de mayor comercio internacional, debería ser considerado la determinación de niveles máximos de manera independiente y no utilizar factores de concentración derivados de los productos secos. | **Ecuador** |
| Egypt supports the use of concentration factors from the fresh products which is the same MLs for lead in leafy vegetables. | **Egypt** |
| As for bullet point b. of para.12.1, Japan supports setting MLs for dried spices and culinary herbs but does not support using concentration factors from the fresh products for estimating ML for lead in dried spices and culi-nary herbs because drying process may affect lead contamination.<br>Japan proposes that ML for dried culinary herbs should be established based on occurrence data for lead in these products. | **Japan** |
| • The United States believes that MLs should be established in dried spices and culinary herbs based on available data, and not based on concentration factors.<br>• The United States does not agree with assuming the same MLs for lead for fresh culinary herbs as for leafy vegetables, as herbs may be cultivated differently (e.g., consumed parts may be grown closer to the ground, outer leaves are not removed before processing). MLs for fresh herbs should be based on available data.<br>• Based on industry input, the proposed MLs for dried culinary herbs; dried rhizomes, bulbs, and roots; dried bark; dried fruits and berries, dried seeds, and dried floral parts spices may be achievable, but additional data collection to ensure producer representation is also supportable.<br>• A harmonized ML of ≤1.0 mg/kg for dried fruits and berries, dried seeds, and dried floral parts spices would also be appropriate and achievable.<br>• The committee should consider how to address ground spice mixtures. | **USA** |

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| The application of a drying factor is appropriate and would also be in line with Article 20 of Regulation (EC) 396/2005, which provides the application or processing factors for pesticide residues.<br>(for HFI an average Drying Factor of 5 applies – please see also THIE Compendium of Guidelines for Herbal and Fruit Infusions (Part I, No. 4.1.): https://thie-online.eu/files/thie/docs/2018-07-17_Compendium_of_Guidelines_for_Herbal_Infusions_-_ISSUE_6.pdf) | **THIE – Tea & Herbal Infusions Europe** |

**(c) If it should established a 2.0 mg/kg ML for all dried rhizomes, bulbs and roots.**

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| 1c): Canada supports turmeric being included in an ML for 'dried bulbs, rhizomes, roots spices'. A Codex ML for lead in turmeric may be help prevent and manage economic adulteration of turmeric with lead chromate.<br>The dataset upon which the ML for this category is based appears to include an adulterated sample(s) of turmeric (CX/CF 21/14/8, Table B1 (135.7 mg/kg lead)).<br>To inform an appropriate ML value for this category, Canada recommends further data analysis which excludes adulterated turmeric from the dataset, as these samples would result in inflating the lead concentration and therefore also potentially the proposed ML value. | **Canada** |
| La adulteración por cromato de plomo en la cúrcuma es una preocupación real; el incluir los datos de la cúrcuma en el análisis puede plantear la interrogante de si su aporte de plomo se debe a la presencia natural en la especia o es debido a adulteraciones. Bajo esta lógica, debería establecerse un NM de 2,0 mg/kg para todos los rizomas, bulbos y raíces secos, incluida la cúrcuma. De presentarse tasas de rechazo comercial elevadas, se puede analizar la pertinencia de fijar a futuro, un nivel máximo exclusivamente para esta especia. | **Ecuador** |
| Egypt supports establishing a 2.0 mg/kg ML for all dried rhizomes, bulbs and roots, whereas the reported limits for fresh produce are always below these values due to the presence of a large amount of water. Thus, after evaporation, the expected increase in their levels should usually be observed. | **Egypt** |
| In our opinion, a general ML of 2.0 mg/kg for all dried rhizomes, bulbs and roots is not appropriate.<br>The reasons for the presence of lead in these different products are diverse; accordingly, contamination cannot always be avoided. Establishing a general ML for all dried rhizomes, bulbs and roots would not take this fact into account appropriately. Furthermore, in several countries national MLs are already in place. Limits range from 5 mg/kg to 10 mg/kg which should be taken into consideration when fixing a ML for these products. THIE Data also confirm that a limit of a min. 5 mg/kg is practicable. | **THIE** |

**(d) To set an ML for eggs only, considering the lack of occurrence data for eggs products and because there is no harmonized definition for preserved eggs.**

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| Canada recommends that it first be determined if fresh eggs are widely traded internationally before moving forward for ML elaboration for this category. CX/CF 19/13/9 presents trade volumes for the food commodities under consideration for ML elaboration; the trade volumes for imported and exported 'eggs and egg products' were among the lowest of all foods considered. Canada questions if a significant proportion of the overall trade volume cited is comprised of 'egg products' (i.e. preserved eggs), which Canada agrees should not be pursued for ML elaboration due to the uncertainty as to how these products are defined (e.g. dried, pickled, other?). Canada therefore suggests that it first be determined if fresh eggs are widely traded internationally before moving forward for ML elaboration for this category. | **Canada** |
| Chile está de acuerdo con establecer un NM solo para los huevos, teniendo en cuenta la falta de datos de presencia de ovoproductos y que no hay una definición armonizada para los huevos conservados. | **Chile** |
| Cuba agradece el establecimiento de NM para el plomo en algunas categorías de alimentos, apoya la propuesta de considerar el establecimiento de un NM de 0,1mg/kg para huevos, azúcar refino de 0,1mg/kg. En la NC 493: 2015 en la categoría de Caramelos el NM es 0,1mg/kg.<br>No se muestra una distribución geográfica mundial equilibrada de la información, faltando regiones (América Latina y el Caribe) por presentar datos que podrían variar los resultados mostrados en el Cuadro A1 y se propone reunir más datos con respecto al estudio del NM de Pb en huevos. | **Cuba** |
| Debe fijarse sólo para huevos, siempre hay la posibilidad de ampliar los trabajos de determinación de NM a otras categorías cuando haya más datos disponibles. | **Ecuador** |
| Egypt supports set an ML for eggs only as 0.1 mg/kg. | **Egypt** |
| As for bullet point d. of para. 12.1, Japan supports setting an ML for eggs only at this stage, considering the lack of occurrence data for eggs products and because there is no harmonized definition for preserved eggs. | **Japan** |
| • The United States agrees that the lack of occurrence data for egg products and lack of a harmonized definition for preserved eggs complicate setting an ML for the category of eggs and egg products as a whole.<br>• The committee/EWG may also want to consider:<br>o Is an ML for eggs still needed if preserved eggs are removed from the category?<br>o If yes, should duck eggs be considered together with chicken eggs? | **USA** |

**(e) To set an ML for cereal-based food for infants and young children "as is" or "as consumed"**

| | |
|---|---|
| Canada does not support an ML for lead in cereal-based products for infants and young children, expressed on an 'as consumed' basis. Canada supports an ML in this category expressed on an 'as is', or dry matter basis, for the following reasons:<br>i) the ingredients used to prepare the cereal for consumption could be a potential source of lead, as suggested by the higher lead levels in cereal-based food products 'as consumed' compared to those on a dry matter basis in CX/CF 21/14/8.<br>ii) these types of products are predominantly traded in dried, not prepared, form.<br>The GSTCFF states (page 7):<br>"In some cases, however, there may be valid arguments to prefer expression [of an ML] on a dry weight basis... Preferably the product should be defined as it moves in trade..."<br>iii) the ML for DON in the same product category is expressed on a dry matter basis. | **Canada** |
| Chile está de acuerdo con establecer un NM para los alimentos a base de cereales para lactantes y niños pequeños «tal cual». Chile cree que, el establecimiento de NM para el producto «tal como se consume» podría llevar a incertidumbres legales y complicaciones a nivel de laboratorio, independiente de si el producto entregara o no información precisa sobre su forma de preparación. | **Chile** |
| As for bullet point e. of para.12.1, Japan would like to provide our view that ML for lead in cereal based products should be set to "as is" rather than "as consumed" because additional lead contamination can occur in food prep-aration process and/or "as consumed" products might be lower concentration which makes analysis more diffi-cult.<br>Current data listed in Table 8 in Appendix II of CX/CF 21/14/8 indicates that cereal based food expressed "as consumed" had higher concentration and more positive results than cereal based food expressed "as is". This is not consistent with the theoretically expected results, and further analysis of occurrence data for this category is recommended. | **Japan** |
| ISDI supports the recommendation presented in the discussion paper to establish MLs for cereal-based infant foods on a "as is" basis. | **ISDI** |

**(f) Whether to set an ML for lead in herbal tea specific for infant and young children or for lead in teas and herbal teas (solid, dried).**

| COMMENTS | MEMBER/OBSERVER |
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| 1f): Canada does not support ML elaboration for lead in herbal tea for infants and young children at this time. The available dataset only includes 46 samples. Furthermore, information on the ingredients, which can be quite variable for herbal teas, and format (dried, ready-to-consume) is lacking. | **Canada** |
| 1f): An ML for 'tea' is outside the scope of the current investigation and would require a separate analysis of occurrence data for tea leaves. 'Tea' is a different commodity altogether than the varied category of herbal tea, which is a mixture of herbs, spices, and/or other plant material.<br>ML elaboration for 'tea' has not undergone a prioritization exercise as have the commodities for which MLs are being proposed in CX/CF 21/14/8; prioritization would first need to be done to determine if 'tea' should be considered for ML elaboration. | **Canada** |
| Chile está de acuerdo en establecer un NM de plomo en los tés y tés de hierbas (sólidos, secos). | **Chile** |
| Debido a la sensibilidad de los niños pequeños y lactantes al plomo, debería identificarse la existencia o no de tés de hierbas destinados lactantes y niños pequeños comercializados en todo el mundo. De ser necesario, un llamado de datos específico a los países es pertinente. | **Ecuador** |
| As for bullet point f. of para. 12.1, Japan does not support setting an ML for lead in herbal tea specific for infant and young children because information on international trade was unclear and occurrence data was limited (n=46). | **Japan** |
| ICBA questions whether the data are sufficient to provide the necessary basis to set a global standard as only 46 samples were provided (see Appendix II paragraph 25 of CX/CF 21/14/8). Additionally, we ask a couple of clarifying questions to address inadvertent typos and possible inconsistencies:<br>• Relative to Table 9 in CX/CF 21/14/8, we question whether the hypothetical MLs listed for herbal teas are off by one order of magnitude (a possible typo?) – i.e., should they read 0.02, 0.03 and 0.06 mg/kg (rather than 0.2, 0.3 and 0.6 mg/kg as currently reflected in Table 9) in view of the occurrence data noted in the hundredth range?<br>• Relative to Question (f) in paragraph 12.1 that summarizes key recommendations, "Whether to set an ML for lead in herbal tea specific for infant and young children or for lead in teas and herbal teas (solid, dried),":<br>o It is not clear why the scope of the category would be expanded beyond herbal teas to include teas (proper), especially since the source materials are so different? The source material for herbal teas are herbs, spices, or other plant materials (and these represent such a varied category) as compared to teas proper which are from tea leaves. Any ML discussion for teas proper would seem to require a separate analysis of occurrence data, which was not within scope of the current investigation.<br>o Also, based on reported occurrence data of lead in 'herbal teas', it would appear as though the levels would most likely correspond to levels 'as consumed' versus on a 'solid/dried' basis as the latter tend to be in the ppm range rather than the ppb range being discussed in CX/CF 21/14/8. | **ICBA** |

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| We would like to propose to differentiation between the categories "Herbal infusions for infants and young children" and "Herbal infusions" as foodstuff for general consumption. A lack of differentiation according to these different consumer groups, for which the market also offers different products, leads to a co-mingling of foods for general consumption (= "Herbal infusions") with foods for specific groups (="Herbal infusions for infants and young children"). Such products for infants and young children as very sensitive and therefore particularly vulnerable group of consumers must meet special quality and labeling requirements (1;2) . In the consequent, these products are also labeled accordingly in practice and must be distinguished from products for general consumption. Herbal infusions as foods for general consumption are primarily targeted at consumers who are generally healthy adolescents and adults. At the time, THIE submitted a statement with corresponding date for this category, which showed that lead is present in nearly all teas (tea (Camellia sinensis) as well as herbal infusions) due to environmental factors but only partly transfers into the brew which is consumed.<br>Considering this fact as well as the international trade impact, the Codex Committee decided to downgrade the priority of the category "Teas and herbal teas" chose the following order for the further procedure for setting ML for lead (3)<br>Therefore, it would be more than consistent to establish individual/separate MLs for these different categories – "Herbal infusions for infants and young children" vs. "Teas and herbal teas"<br>(1)STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS CXS 72-1981<br>(2)REGULATION (EU) No 609/2013<br>(3) CODEX COMMITTEE ON CONTAMINANTS IN FOODS 13th Session Yogyakarta, Indonesia, 29 April – 3 May 2019 DISCUSSION PAPER | **THIE** |

**Proposed MLs for the prioritized categories and which ones could be advanced to the Codex Alimentarius Commission for final adoption or be returned to the Electronic Working Group for further consideration**

**ML of 0.1 mg/kg for eggs.**

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| Eggs, ML0.1 mg/kg: Canada does not support establishing an ML of 0.1 mg/kg for lead in eggs (fresh chicken and duck eggs). If an ML for fresh eggs moves forward for consideration, Canada suggests that an ML of 0.03 mg/kg would be appropriate to propose for fresh chicken eggs only, given that this ML would be ALARA and within the target rejection rate (4% rejection rate).<br>Canada does not support including duck eggs in a proposed ML for fresh (chicken) eggs due to limited data (n=64), different apparent lead levels in duck versus chicken eggs, and because of the questionable volume of fresh duck eggs in international trade. | **Canada** |
| Chile está de acuerdo con los valores propuestos por el GTE para huevos de 0,1 mg/kg, y de no establecer un NM para huevos en conserva. | **Chile** |
| For eggs the EU considers that in view of the lower concentration of lead in chicken eggs, compared to duck eggs, and in view of the higher consumption of chicken eggs, it would be appropriate to set separate MLs for chicken eggs and duck eggs.<br>- For chicken eggs, taking into account the occurrence data for the global data set, there is margin to set an ML of 0.04 mg/kg, which is closer to a 5% rejection rate.<br>- For duck eggs the proposed ML of 0.1 mg/kg can be supported by the EU.<br>Considering the lack of occurrence data for egg products, the EU agrees to set an ML for eggs only. For egg products, the ML for eggs should be applied, taking into account an appropriate processing factor. | **EU** |
| Japan supports the proposed draft ML of 0.1 mg/kg because Table 1 in Appendix II of CX/CF 21/14/8 indicates it had significant impact on intake reduction of lead from eggs (27% reduction) compared with the current situation with no codex ML while the proportion of rejected eggs from the world market would be minimized (0.3%). | **Japan** |

**MLs for culinary herbs and spices:**

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| Culinary herbs (fresh leaves); Include in ML for lead in leafy vegetables: Canada does not support applying the existing ML for lead in leafy vegetables (0.2 mg/kg) to 'culinary herbs (fresh leaves)'. Some of the "culinary herbs (fresh leaves)" are not 'leafy' in structure (e.g. lemon grass, rosemary). Furthermore, it's recommended that MLs are elaborated for dried herbs, which are those most commonly traded. | **Canada** |
| Culinary herbs (dried leaves or mixed herbs), ML 2.0 mg/kg: Canada does not support the proposed ML of 2 mg/kg in dried culinary herbs. No rationale is provided as to why an ML of 2.0 mg/kg is proposed (1.7% rejection rate) when lower MLs would still have rejection rates of 5% or less, and would therefore be considered ALARA.<br>Canada would support an ML of 1.5 mg/kg (3.6% rejection rate). | |
| Dried bulbs, rhizomes, roots spices, ML 2.0 mg/kg: Canada recommends further data analysis which excludes adulterated turmeric from the dataset, and using this reanalyzed dataset for ML elaboration. The dataset upon which the ML for this category is based includes what appears to be an adulterated sample(s) of turmeric (CX/CF 21/14/8, Table B1 (135.7 mg/kg lead)), which would skew the overall lead concentrations upwards. | |
| Bark, ML 2.0 mg/kg: Canada supports an ML of 2.0 mg/kg lead in bark (rejection rate 4.7%). | |
| Dried fruits and berries spices, ML 0.6 mg/kg: Canada support an ML of 0.6 mg/kg lead in dried fruits and berries spices (rejection rate 4.4%). | |
| Dried seeds spices, ML 0.6 mg/kg: Canada suggests that the rejection rate associated with an ML of 0.5 mg/kg be presented for consideration (rejection rate not shown in CX/CF 21/14/8,) for lead in dried seeds spices as it may be within the target rejection rate and more consistent with the ALARA principle than that of 0.6 mg/kg (3.0% rejection rate) which is proposed. | |
| Dried floral parts spices, ML 0.7 mg/kg: Canada would like to inquire if data for all of the different spices made from floral parts (cloves, saffron, chamomile flower) are available in GEMS/Food and therefore informed this ML proposal. Canada recommends that data for individual spices be presented before ML elaboration progresses. | |
| Canada recommends that information and data analysis be presented for each of the various spices in each spice category for which occurrence data are available in GEMS/Food. As presented in CX/CF 21/14/8, data analysis is only presented for all spices, combined, in each spice category, and no information is presented regarding if data are available for all spices in each category. | |
| *Hierbas culinarias: Chile está de acuerdo con el valor propuesto por el GTE de 2,0 mg/kg para hojas secas o mezclas de hierbas secas, en el entendido que se incluiría un listado que detalle a qué hierbas aplica en el campo Notas/Observaciones del CXS/193, y está de acuerdo en no establecer un NM para hierbas frescas.<br>* Especias culinarias: Chile está de acuerdo con los valores propuestos por el GTE para todas las categorías secas establecidas, en el entendido que se incluiría un listado de a que especias aplica en el campo Notas/Observaciones del CXS/193, y está de acuerdo en no establecer un NM para especias frescas | **Chile** |

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| For culinary herbs, the EU prefers to establish separate MLs for the dried herbs and the fresh herbs.<br>For culinary herbs (fresh leaves), the EU has data available, which indicate that for specific herbs such as oregano and thyme the proposed ML of 0.3 mg/kg would be too low. Therefore the EU is of the opinion that the data for individual species of herbs should be analysed, before an ML for the entire category of fresh culinary herbs can be considered.<br>For culinary herbs (dried leaves or mixed herbs), the EU can support the proposed ML of 2.0 mg/kg.<br>For spices the EU considers that for most spices it is sufficient to establish an ML for the dried spices. However for some spices, which are also consumed fresh, it might be useful to also establish an ML for the fresh product: e.g. for fresh ginger and fresh turmeric.<br>For fruit and berry spices the EU can support the proposed ML of 0.6 mg/kg.<br>For dried bulb, rhizome and root spices the EU considers that it should be avoided that samples of turmeric, which were fraudulently coloured with lead chromate, would influence the conclusions on an appropriate ML for this group. For this reason and also because the EU data show that the concentrations of lead in non-coloured turmeric are lower than in other root and rhizome spices, the EU prefers to consider the data set for dried rhizomes, bulbs and roots, excluding turmeric, to set an ML for the entire category of rhizome, bulb and root dried spices. Taking into account this data set, there is margin to set an ML, which is lower than the proposed ML of 2.0 mg/kg. The EU would be in favour of an ML of 1.5 mg/kg, which would lead to a 5.2% 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.<br>For bark spices the EU can support the proposed ML of 2.0 mg/kg.<br>For dried floral part spices the EU can support the proposed ML of 0.7 mg/kg.<br>For dried seed spices the EU wonders why in CX/CF 20/14/8 371 samples were included and in CX/CF 21/14/8 only 302 samples were available? The EU can support the proposed ML of 0.6 mg/kg. | **EU** |
| As for culinary herbs of fresh leaves, Japan does not support including these products in ML for lead in leafy vegetables because herbs have a different growing environment and consumption pattern than leafy vegetables. In addition, separate groups are established for herbs (Group 027) and leafy vegetables (Group 013) in the Codex classification of Food and Feed (CXM4-1989).<br>Japan proposes that ML for fresh culinary herbs should be established based on occurrence data for lead in these products.<br>As for dried culinary herbs, dried bulbs, rhizomes and roots, and dried bark, Japan supports the proposed draft MLs of 2.0 mg/kg but also can accept a slightly higher ML than 2.0 mg/kg such as 3.0 mg/kg because Table 5 in Appendix II of CX/CF 21/14/8 indicates that estimated rejection rate for dried bulbs, rhizomes and roots and dried bark with draft ML of 2.0 mg/kg were slightly high (5.7% and 4.7%, respectively) while intake reduction rates were comparable for a slightly higher ML.<br>In addition, since the current MLs for lead listed in the GSCTFF are all set in single digits, we believe it is preferable to use 2 mg/kg instead of 2.0 mg/kg for consistency.<br>As for dried fruits and berries, Japan supports 1.0 mg/kg instead of the proposed draft of 0.6 mg/kg because Table 5 in Appendix II of CX/CF 21/14/8 indicates that the violation rate of 4.4% at 0.6 mg/kg was slightly high while the violation rate of 1.4% at 1.0 mg/kg would have minimal economic impact and have significant impact on intake reduction of 34.5%.<br>In addition, since the current MLs for lead listed in the GSCTFF are all set in single digits, we believe it is preferable to use 1 mg/kg instead of 1.0 mg/kg for consistency.<br>As for dried seed spices and dried floral parts spices, Japan supports the proposed draft MLs of 0.6 mg/kg and 0.7 mg/kg, respectively. | **Japan** |

**MLs for sugars and sugar-based candies**

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| White and refined sugar: White sugar' and 'refined sugar' should be defined. | **Canada** |
| White and refined sugar, ML 0.1 mg/kg: Canada does not support an ML of 0.1 mg/kg in white and refined sugar. An ML between 0.1 mg/kg (rejection rate 1.1%) and 0.05 mg/kg (rejection rate 5.7%) may be considered ALARA. Canada recommends that additional, lower, ML values be considered between 0.05 and 0.09 mg/kg. | |
| Raw and Brown sugar: 'Raw sugar' and 'brown sugar' should be defined. | |
| Raw and brown sugar, ML 0.2 mg/kg: Canada does not support the ML proposed for raw and brown sugar. Achievability with an ML value of 0.2 mg/kg for raw and brown sugar is not presented in CX/CF 21/14/8, therefore it is difficult to comment on this proposed ML value.<br>The lead concentrations in raw and brown sugar are notably different (mean lead level in brown sugar is nearly double that of raw sugar), such that MLs could be considered separately for these commodities. Alter-natively, raw sugar could be considered for inclusion with white sugar as the lead profiles in these types of sugar is more comparable, however different consumption patterns of these 2 products may make this impractical. | |
| Syrup and molasses, ML 0.1 mg/kg: Canada supports an ML value of 0.1 mg/kg in syrup and molasses (3.6% rejection rate). | |
| Honey, ML 0.1 mg/kg or ML 0.05 mg/kg: Canada supports an ML value of 0.05 mg/kg lead in honey (rejection rate 4.2%). | |
| Sugar-based candies, ML 0.2 mg/kg: Canada does not support an ML of 0.2 mg/kg in sugar-based candies. Based on the information presented in CX/CF 21/14/8, an ML of 0.1 mg/kg (5.2% rejection rate) may be considered ALARA rather than an ML of 0.2 mg/kg (rejection rate 1.1%). Canada recommends that additional, lower, ML values around 0.1 mg/kg be considered. | |
| Egypt supports ML for Honey as 0.1 mg/kg. | **Egypt** |
| For white and refined sugar the EU can support the proposed ML of 0.1 mg/kg.<br>For raw and brown sugar the EU can support the proposed ML of 0.2 mg/kg.<br>For honey the EU believes that there is margin to propose a lower ML of 0.05 mg/kg, which would correspond to a global rejection rate of 4.2%.<br>For syrups and molasses the EU can support the proposed ML of 0.1 mg/kg.<br>For sugar-based candies the EU believes that there is margin to propose a lower ML of 0.1 mg/kg, which would correspond to a global rejection rate of 5.2%. As in sugar-based candies typically refined sugar is used, there seems to be no need to set an ML, which is higher than the one for refined sugars. | **EU** |

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| Japan proposes that the commodity name of sugars should be harmonized with the Standard for sugars (CXS 212-1999) in order to clarify the scope of the commodity to which the ML applies and to keep consistency of terminology within Codex.<br>Japan would like to point out that the violation rate and intake reduction rate of 0.2 mg/kg for raw sugar and brown sugar are not listed in Table 6 in Appendix II of CX/CF 21/14/8. This information is important for the discussion of the proposed draft ML and should be included.<br>Japan suggests further work for sugar products in order to define commodities to which MLs apply and to reevaluate the occurrence data according to the defined commodities.<br>Japan supports the proposed draft ML of 0.2 mg/kg for sugar-based candies at this stage but also suggests that it be finalized after MLs for sugars as ingredients in candies are set.<br>As for honey, Japan can support the ML of 0.1 mg/kg rather than 0.05 mg/kg because Table 6 in Appendix II of CX/CF 21/14/8 indicates these levels had similar intake reduction rate and 0.1 mg/kg had lower violation rate than 0.05 mg/kg. | **Japan** |
| • The United States can support an ML of 0.1 mg/kg for sugar-based candy intended for young children.<br>• Multiple food categories under sugars are presented in Table C1, and they appear to have different mean and 95th percentile values. Separately, the category “syrup and molasses” may conflate different food types (molasses, agave syrup, corn syrup, maple syrup) without identifying possible different ML needs. We suggest more work to refine this category and identify specific food types where an ML would be beneficial. | **USA** |
| The draft proposes a ML for lead in sugar-based candies at 0.2mg/kg. However, we would like to note that the EWG focused on collecting data on sugars, not on the candy products falling under the sugar-based candy list in the table. If the EWG determined that MLs are best set on the ingredients that may contain lead, including managing the levels in the sugar ingredients, or spice ingredients used in spicy candy, then there would be no reason to also set an ML for the finished product. Otherwise, to determine ALARA-based MLs for sugar-based candies would require data on the various types of candy falling under this product category. | **FoodDrinkEurope** |
| In Appendix 1, point 3., a proposed ML is listed for lead in sugar-based candies, at 0.2mg/kg. However, the data requests focused on collecting data on sugars, not on the candy products falling under the sugar-based candy listing. If MLs are best set on the ingredients that may contain lead, including managing the levels in the sugar ingredients, or spice ingredients used in spicy candy, then there would be no reason to also set an ML for the finished product. Otherwise, to determine ALARA-based MLs for sugar-based candies would require data on the various types of sugar-based candy globally that fall under this product category. | **ICA** |

**Taking into account the similarity between the proposed MLs for lead in fruit juices for infants and young children and the MLs already established in the *General Standard for Contaminants in Food and Feed* (CXS 193-1995) for fruit juices, the Committee should consider to change the fruit juice categories names already established in CXS 193 for: fruit juices including for infants and young children;**

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| Canada recommends that further data and data analysis is needed before fruit juices for infants and young children are added to the MLs already established for various fruit juice categories in the GSTCFF.<br>The data analysis provided in CX/CF 21/14/8 does not support including fruit juice for infants and young children in the MLs for lead in fruit juice, fruit juice from berries and other small fruits, and grape juice that are already in the GSTCFF. Higher relative lead levels were not observed in the juices from berries and other small fruits in the dataset presented for infants, and no data were presented specifically for infant grape juice. | **Canada** |
| Does not need to be underlined. | **Canada** |
| Japan can support changing the “fruit juice” categories name for lead in GSCTFF to “fruit juices including for infants and young children”. | **Japan** |
| ICBA supports the eWG recommendation to include a footnote for fruit juices relative to lead (Pb) MLs – as suggested in paragraph 24 of Appendix II – to help clarify that the established MLs not only apply to the general population but also infants and young children (although the absence of a footnote should suggest same from our perspective). | **ICBA** |

**MLs for food for infants and young children:**

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| Cereal-based products, expressed as consumed ML 0.04 mg/kg: Canada does not support an ML of 0.04 mg/kg lead in cereal-based products for infants and young children, expressed on an as consumed basis. Canada would support ML elaboration for this product category that is expressed on a dry matter basis. | **Canada** |
| Herbal tea ML 0.6 mg/kg: Canada does not support ML elaboration for herbal tea at this time. The sample size for this category is low, information on the specific ingredients in the teas is lacking as is information on the format of the teas for which data are submitted (e.g. brewed, dried). | |
| Ready-to-eat meals ML 0.03 mg/kg: Canada supports an ML of 0.03 mg/kg lead in all types of ready-to-eat meals for infants and young children (2.8% rejection rate). | |
| Does not need to be underlined. | |
| Egypt supports set an ML for cereal-based food for infants and young children " as sold" and agree with the following ML as it is. | **Egypt** |
| 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. 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.<br>Normally in products expressed 'as consumed', lower concentrations of lead would be expected, as these products are reconstituted in some cases. As the data show an opposite trend, the reasons for this should be investigated. The EU prefers an ML for the products expressed 'as is'.<br>On the basis of the global data set for cereal-based food expressed 'as is' and in view of the need to protect the young and more vulnerable consumer groups, an ML of 0.02 mg/kg for cereal-based products for infants and young children expressed 'as is' would be appropriate, as this corresponds to a rejection rate of 2.6-3%. A recent data collection and stakeholder consultation in the EU has shown that this ML is achievable through a careful sourcing of the raw materials.<br>For fruit juice for infants and young children the EU does not agree to apply the Codex MLs for fruit juices by adding a note that they also apply to these juices for infants and young children. A lower ML of 0.02 mg/kg is achievable, taking into account the EU data and the rejection rate of 3.1% for the global data set. It is possible to set a lower ML for fruit juices for infants and young children compared to the regular juices, through careful sourcing of the raw materials. A lower ML is needed to protect this vulnerable consumer group from the adverse effects of lead exposure.<br>For herbal teas the EU prefers to establish a separate ML for herbal teas for infants. and young children as through a careful sourcing of raw materials it is possible to reduce the lead concentrations in these products, which is important for reducing the exposure of these young consumers. | **EU** |

| COMMENTS | MEMBER/OBSERVER |
|---|---|
| For herbal teas, which are not intended for infants and young children, the MLs for dried spices and dried culinary herbs can be applied, taking into account the composition of the tea, so a separate ML for these teas is not strictly necessary. However the EU could also agree to the establishment of a separate ML for herbal teas, which are not intended for infants and young children. In such case more data need to be collected on teas to be prepared by infusion or decoction, in order to determine what the appropriate ML would be.<br>For herbal teas for infants and young children the Codex data do not allow to distinguish whether the products were ready to drink or to be prepared by infusion or decoction. In view of the different lead concentrations in those categories, the data should not be merged. On the basis of its available data, the EU is of the opinion that an ML of 0.5 mg/kg is achievable for herbal teas for infants and young children to be prepared by infusion or decoction. An ML of 0.02 mg/kg is appropriate for herbal teas for infants and young children marketed as liquids.<br>For ready-to-eat meals for infants and young children the EU can support the proposed ML of 0.03 mg/kg. | |
| As for ready-to-eat meals, Japan supports the proposed draft ML of 0.03 mg/kg. | **Japan** |
| • Based on a preliminary analysis, the United States can support the proposed MLs for infant cereals (as dried), but more clarity is needed on what foods fall in this category. Further consideration in the EWG for CCCF15 would be appropriate.<br>o The United States considers that lead concentrations measured on an "as consumed" basis will vary depending on preparation method; therefore, MLs for infant cereals for infants and young children should be based on an "as is"/dry basis, as was done for deoxynivalenol in infant cereal. Infant cereal may be diluted to any desired concentration by multiple beverages, while infant formula is diluted by water at a specified ratio.<br>• Ready-to-eat meals:<br>o We suggest further work in the EWG to define this category and the data sources used to support the proposed ML (e.g., is the ML/are the data used limited to jarred foods and purees or do they include a variety of multi-ingredient meals marketed for toddlers?).<br>• For root-vegetable based foods such as jarred sweet potatoes and carrots, specific data may be needed to determine what MLs are achievable and appropriate.<br>• The United States considers that an ML may not be needed for herbal tea for infants and young children. Herbal tea for infants and young children appears to be a regionally consumed food, based on the small number of data submissions, available from only one region.<br>o Development of an ML for the combined category of teas (dried)/herbal teas (dried) is not appropriate without additional analysis as the source material used in these two types of beverages is different. An analysis of tea leaves would require a separate assessment that was not addressed within the scope of the present work.<br>• The United States supports adding a note to the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) for lead in fruit juices, indicating that this standard is applicable to all juices, including juices for infants and young children. | **USA** |
| As referenced in the answer to question e, ISDI supports defining the limit for lead in cereal-based foods for infants and young children "as is". ISDI notes that this may require adjustment to the proposed ML, depending on whether the source of the data used to generate this value came from samples analyzed and presented were from products "as is" or whether they were adjusted to "as consumed". | **ISDI** |