

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 5

CX/CF 23/16/5-Add.1

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

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**MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES
(AT STEPS 4 AND 7)**

Comments at Steps 3 and 6 in reply to CL 2023/18-CF

submitted by

Argentina, Canada, Chile, Cuba, Egypt, Indonesia, Iraq, Japan, Kenya, New Zealand, Peru,

Republic of Korea, Singapore, United States of America (USA),

American Herbal Products Association (AHPA),

International Commission for Uniform Methods of Sugar Analysis (ICUMSA) and

International Confectionery Association (ICA)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2023/18-CF¹ issued in February 2023. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the Annex

2. The comments submitted through the OCS are hereby annexed and presented in tabulated format.

¹ <https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>
<https://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF>

Annex**GENERAL COMMENTS**

COMMENT	MEMBER/ OBSERVER
<p>Canada would like to thank Brazil for their work on the discussion paper for the Proposed Maximum Levels for Lead in Certain Food Categories.</p> <p>Canada notes the following for further consideration with regards to approaches taken as part of the data analysis.</p> <ul style="list-style-type: none"> • LOQ limited dataset: we agree with excluding results reported as "non-detect" (ND) that have LOQ values above the ML under consideration or the p95 concentration. However, positive samples (i.e. quantified values) with higher LOQ values could still be considered in the ML achievability analysis given that an ALARA approach is being taken, where the primary concern is achievability and targeting a rejection rate of up to 5%. While it appears this approach did not impact the MLs considered for sugars significantly, this appears to be more impactful for RTE infant foods, where a significant amount of data (approximately 1600 samples) were excluded on this basis. It remains unclear what proportion of the data excluded were NDs vs. positives. Canada suggests that this should be clarified for transparency. • Substitution method: For the data analysis, it appears an UB approach was employed this year vs. a MB approach that was taken the previous year. Canada suggests that clarification be given on why a different substitution approach was used and what impact, if any, it would have on the hypothetical MLs that were derived. The potential impact could be demonstrated/substantiated by presenting the data using both options. 	Canada
Agree with no comments	Iraq
<ul style="list-style-type: none"> • The United States thanks Brazil for their work on this agenda item. • For its analysis, the EWG decided to exclude all results based on methods with LOQs greater than the 95th percentile value of the dataset (sugars) or with LOQs greater than the ML of 0.02 mg/kg at Step 5 (RTE infant meals). This approach should be considered further by the EWG on Guidance on data analysis for the development of maximum levels and improved data collection before CCCF endorses the approach for future work. 	USA

SPECIFIC COMMENTS**SUGARS (SOFT BROWN, RAW AND NON-CENTRIFUGED)**

- Consider to establish the following ML for sugar, excluding white and refined i.e. Soft brown, raw and non –centrifuged sugars

COMMENT	MEMBER/ OBSERVER
Argentina acuerda con el límite para azúcar blando moreno, en bruto y no centrifugado propuesto en el Apéndice I (0,15 mg/kg).	Argentina
<p>The comment is for Sugars (Soft Brown, Raw and Non-Centrifuged)</p> <p>Canada notes that some clarification may still be needed on the data analysis.</p> <p>However, based on the international dataset, an ML of 0.15 mg/kg lead in soft brown, raw and non-centrifuged sugars is readily achievable across all products and within the target rejection rate of up to 5%. This ML is also readily achievable for products sold in Canada.</p> <p>We agree with combining these products into a single ML, as proposed, for simplicity given similarities in their composition and manufacturing process, difficulties in their classification and low geographic representation of raw sugar. As well, the proposed ML of 0.15 mg/kg is consistent (i.e. slightly higher) with the ML of 0.1 mg/kg for white and refined sugar, which was adopted by CAC45 (2022).</p>	Canada
<p>Chile agradece la oportunidad de presentar observaciones sobre niveles máximos de plomo en determinadas categorías de alimentos.</p> <p>Al respecto, y considerando los argumentos entregados en el documento CX/CF 23/16/5, Chile quisiera comentar lo siguiente:</p> <ul style="list-style-type: none"> Respecto del azúcar blando moreno, en bruto y no centrifugado, Chile está de acuerdo con establecer un nivel máximo de 0,15 mg/kg de plomo para el conjunto de matrices sin distinción. Respecto de las comidas listas para el consumo para lactantes y niños pequeños, Chile está de acuerdo con mantener lo ya aceptado en la reunión del CCCF15, es decir, establecer un único nivel máximo de 0,02 mg/kg para toda la categoría. 	Chile
Cuba considera que en principio se manifiesta de acuerdo con el mismo y no presenta comentarios adicionales.	Cuba
Egypt agrees on the proposed limit (0.15)	Egypt
<p>Japan supports the proposed ML of 0.15 mg/kg for the following reasons:</p> <ul style="list-style-type: none"> the rejection rate of 1.6% (for the dataset excluding those data from analytical methods with high LOQs) is consistent with a range of rejection rates (generally 2-5%) accepted by CCCF; enforcing this ML would lead to 7.1% intake reduction; and establishing an ML for these products that is slightly higher than the ML of 0.10 mg/kg for refined and white sugars is acceptable as the refining process will reduce the lead concentrations in the raw materials. 	Japan
<p>Kenya supports the establishment of the proposed 0.15mg/kg ML for sugar, excluding white and refined sugar.</p> <p><u>Justification:</u> The extrapolation will cover other raw sugars mentioned that are not covered by CXS 212.</p>	Kenya

COMMENT	MEMBER/ OBSERVER
<p>New Zealand would like to thank the EWG Chair for the work on MLs for lead in certain food categories.</p> <ul style="list-style-type: none"> New Zealand would like to note that a ML of 0.10 mg/kg for raw cane sugar is below the rejection rate of 5%, and would like to propose a ML for raw cane sugar of 0.1 mg/kg, in line with the agreed MLs for lead in white and refined sugar at CCCF15. New Zealand would like to note the effect of the proposed ML for lead in non-centrifuged sugars, sample rejection 0% and intake reduction 0%, however New Zealand does support establishing a ML for lead in non-centrifuged sugars. 	New Zealand
<p>El Perú desea agradecer a la Secretaría de la Comisión del Codex Alimentarius, Programa Conjunto FAO/OMS sobre Normas Alimentarias, respecto a la solicitud de observaciones sobre niveles máximos de plomo en determinadas categorías de alimentos.</p> <p>En esta ocasión, el Perú apoya los niveles máximos de plomo propuestos para las siguientes categorías: Sin</p>	Peru
<p>Singapore supports the proposed ML of 0.15 mg/kg for soft brown, raw and non-centrifuged sugars as these MLs have been proposed in accordance with the ALARA principle. Geographically representative data has been considered, and substantial reduction in dietary exposures have also been demonstrated at the proposed MLs.</p>	Singapore
<ul style="list-style-type: none"> The United States thanks Brazil for their work on this agenda item. The United States supports a single ML for soft brown, raw, and non-centrifuged (non-centrifugal) sugars given similarities in their composition (i.e., less refined sugars). The United States can support the proposed ML of 0.15 mg/kg for soft brown, raw, and non-centrifuged (non-centrifugal) sugars, reflecting a sample rejection rate of 1.6% and an intake reduction of lead of 7.1%. <ul style="list-style-type: none"> The term “non-centrifuged” sugars should be changed to non-centrifugal to reflect the English translation. See: https://stats.fao.org/classifications/FCL/0163.html The United States questions whether mascavo should be included in the Notes/Remarks section, given that mascavo is not a common name for panela and no data on mascavo were reported in GEMS/Foods. 	USA
<p>The International Confectionery Association appreciates the opportunity to comment on the Codex circular letter CL 2023/18-CF related to maximum levels (MLs) for lead in certain food categories. ICA’s comments are limited to the proposed MLs for various sugars in the table below, as part of Appendix I in the proposed final discussion paper.</p> <p>ICA supports the approach of combining maximum levels for various sugars - soft brown, raw, and non-centrifuged sugars. In addition to ensuring that the MLs established for lead in various food categories, including sugars, serve to protect public health, they must also be economically achievable and realistic to facilitate international trade and to provide a single harmonized standard to simplify the complicated global compliance challenges.</p> <p>We thank the Committee for considering our position and look forward to further discussion at the CCCF session.</p>	ICA
<p>The current proposed ICUMSA definition for brown sugar is:</p>	ICUMSA

COMMENT	MEMBER/ OBSERVER
<p>"Brown sugar is either a partially refined soft sugar consisting of sugar (sucrose) crystals with some residual molasses content or it is produced by the addition of molasses to refined white sugar. Brown sugar must contain at least 88% of sucrose plus invert sugar and may contain up to 10% molasses by weight (Codex Stan 212-1999, Amendment 2001)"</p> <p>The current proposed ICUMSA definition for raw sugar is:</p> <p>"Raw Sugar may be generally described as the crystalline product of sugar manufacturing before refining. Raw sugar may be described as sugar of the standard quality with a yield of white sugar of 92 % (Regulation EU No. 1308/2013). Raw cane sugar is described as partly purified sucrose with a sulphur dioxide content \leq 20 mg/kg , which is crystallised from partially purified cane juice, without purification, but which does not preclude centrifugation or drying, and which is characterised by sucrose crystals covered with a film of cane molasses (CODEX STAN 212-1999, Amendment 2001). The ICUMSA methods do not generally specify (but should) a type or quality for Raw Sugar (relative to the definition above) and many of the methods have been validated for raw cane sugar with no information about the performance of the method for other types of raw sugar. Please check the respective (abstract) of the Method for the quality criteria to ensure it is suitable for the intended use."</p> <p>Therefore, non-centrifuged sugars are to be considered as either brown or raw sugars. Panela is effectively a raw sugar while muscavado is a brown sugar.</p>	

READY-TO-EAT MEALS FOR INFANTS AND YOUNG CHILDREN

- Consider to establish a single ML of 0.02 mg/kg for the whole category of ready-to-eat meals for infants and young children as proposed by CCCF15 and adopted at Step 5 by CAC44 in 2022 (For comments at Step 6)
- Consider either to establish a single ML of 0.03 mg/kg for the whole category of ready-to-eat meals for infants and young children or to establish a ML of 0.02 mg/kg for ready-to-eat meals for infants and young children, excluding products containing cereals as proposed by the EWG established by CCCF15 (For comments at Step 3)

COMMENT	MEMBER/ OBSERVER
<p><u>Considérese la posibilidad de establecer un único NM de 0,03 mg/kg para toda la categoría de comidas listas para el consumo para lactantes y niños pequeños, o establecer un NM de 0,02 mg/kg para las comidas listas para el consumo para lactantes y niños pequeños, excluidos los productos que contengan cereales, como propone el GTE establecido por el CCCF, en su 15.ª reunión.</u></p> <p>Con respecto a las Comidas listas para el consumo para lactantes y niños pequeños, Argentina acuerda con fijar un límite de 0,03 mg/kg para toda la categoría, incluyendo los productos que contienen cereales.</p> <p>Estas observaciones se basan en distintos puntos:</p> <ul style="list-style-type: none"> -Dificultad de discernir categorías. -Facilita la aplicación unificar categorías con Límites Máximos similares -Los valores mencionados contemplan los principios ALARA y las tasas de rechazo del 5% que son consistentes con los distintos trabajos del Comité. <p>Por otra parte, se observa en el cuadro 13 del anexo II que se excluyeron una gran cantidad de datos (1657) por haber sido obtenidos con límites de cuantificación superiores al Límite máximo propuesto; la media y las tasas de rechazo suben notablemente cuando se incluyen los datos que fueron retirados: para un límite de 0,02; TR=13,0% y, para 0,03; TR=7,1%;</p>	Argentina
<p>All of the proposed MLs for RTE infant foods are readily achievable for products sold in Canada. However, Canada questions whether an exclusion specific to RTE infant foods containing cereals is warranted based on the information presented in the subject document. Based on the data summaries in Annex I, there do not appear to be major differences in lead concentrations reported across the different subcategories of RTE infant food being considered. As well, given that these are multi-ingredient products and that information is not available on the percentage of certain ingredients present, it would be difficult to ascertain whether the higher lead concentrations in the products exceeding an ML of 0.02 mg/kg are a result of the cereals specifically. A higher ML for RTE infant foods containing cereals would also be inconsistent with the ML of 0.02 mg/kg for cereal-based food for infants and young children adopted by CAC45, as it would be expected that cereals in RTE products would be diluted.</p> <p>Further consideration may also want to be given to some of the data (i.e. quantified results) that were excluded for RTE infant foods, as noted previously.</p> <p><u>Consider either to establish a single ML of 0.03 mg/kg for the whole category of ready-to-eat meals for infants and young children or to establish a ML of 0.02 mg/kg for ready-to-eat meals for infants and young children, excluding products containing cereals as proposed by the EWG established by CCCF15.</u></p> <p>The portion of the commodity/product to which the ML applies indicates "Whole commodity" for the RTE infant food ML option of 0.03 mg/kg but should be "Whole commodity."</p>	Canada
<p>En general, se apoyan los niveles máximos propuestos considerando que, las matrices revisadas, están dirigidos a proteger a una población sensible, como son los niños, y tomando en cuenta que no existe una ingesta diaria admisible para este contaminante, tener un nivel máximo establecido, en lugar de no regular, es el enfoque más conservador.</p>	Chile

COMMENT	MEMBER/ OBSERVER
<p><u>Consider to establish a single ML of 0.02 mg/kg for the whole category of ready-to-eat meals for infants and young children as proposed by CCCF15 and adopted at Step 5 by CAC44 in 2022</u></p> <p>Egypt agrees on the proposed limit (0.02)</p> <p><u>Consider either to establish a single ML of 0.03 mg/kg for the whole category of ready-to-eat meals for infants and young children or to establish a ML of 0.02 mg/kg for ready-to-eat meals for infants and young children, excluding products containing cereals as proposed by the EWG established by CCCF15.</u></p> <p>Egypt suggests to establish a single ML of 0.02 mg/kg for the whole category of ready-to-eat meals for infants and young children</p>	Egypt
<p>Indonesia considers the need for higher level ML for ready-to-eat meals for infants and young children. Indonesia proposes ML of 0.05 mg/kg for all ready-to-eat meals for infants and young children.</p>	Indonesia
<p>Japan supports to advance the ML to cover the whole category of ready-to-eat meals for infants and young children to Step 8 for adoption by CAC 2023 for the following reasons:</p> <ul style="list-style-type: none"> the rejection rate of 5.3% (for the dataset excluding those data from analytical methods with high LOQs) is, although slightly higher than 5% (see the comment for (i)), regarded as consistent with the agreed range of rejection rates; and is acceptable for providing a high level of health protection for infants and young children; excluding products containing cereals from the category of products covered by the ML is neither practicable or appropriate since many RTE meals for infants and young children contain cereal ingredients; and as the RTE meals for infants and young children are mostly in wet form, an ML for these products should be set at or lower than 0.02 mg/kg, which was the same level as the ML adopted by the CAC-42 for cereal-based foods for infants and young children including dry form products. <p>Japan prefers to establish a single ML at 0.02 mg/kg for the whole category of RTE meals for infants and young children as shown in our comment (ii) above, taking into consideration the ML of 0.02 mg/kg for RTE meals for infants and young children including dry form products already adopted by the CAC-42.</p>	Japan
<p><u>Consider to establish a single ML of 0.02 mg/kg for the whole category of ready-to-eat meals for infants and young children as proposed by CCCF15 and adopted at Step 5 by CAC44 in 2022</u></p> <p>Kenya supports the establishment of a single ML of 0.02 mg/kg for the whole category of ready-to-eat meals for infants and young children as proposed by CCCF15 and adopted at Step 5 by CAC44 in 2022.</p> <p><u>Consider either to establish a single ML of 0.03 mg/kg for the whole category of ready-to-eat meals for infants and young children or to establish a ML of 0.02 mg/kg for ready-to-eat meals for infants and young children, excluding products containing cereals as proposed by the EWG established by CCCF15.</u></p> <p>Kenya supports the proposal of 0.02mg/kg as opposed to 0.03mg/kg</p> <p><u>Justification:</u> This exempts ready to eat meals containing cereals whose MLs can be set separately. CAC 45 also adopted the MLs at step 5.</p>	Kenya
<p>New Zealand acknowledge the difficulty of two separate MLs for ready-to-eat meals for infants and young children, however does support establishing MLs for both products. New Zealand does support the proposed ML of 0.3 mg/kg for the whole category of ready-to-eat meals for infants.</p>	New Zealand
<p><u>Consideramos Nivel Máximo mg/ kg 0.02</u></p>	Peru

COMMENT	MEMBER/ OBSERVER
<p><u>Consider to establish a single ML of 0.02 mg/kg for the whole category of ready-to-eat meals for infants and young children as proposed by CCCF15 and adopted at Step 5 by CAC44 in 2022</u></p> <p>We would like to support the criteria(0.02 mg/kg) for RTE meal for infants and young children.</p> <p><u>Consider either to establish a single ML of 0.03 mg/kg for the whole category of ready-to-eat meals for infants and young children or to establish a ML of 0.02 mg/kg for ready-to-eat meals for infants and young children, excluding products containing cereals as proposed by the EWG established by CCCF15.</u></p> <p>We would like to support to establish a ML of 0.02 mg/kg for the whole category of RTE meal for infants and young children.</p>	<p>Republic of Korea</p>
<p>Singapore supports the establishment of a single ML of 0.02 mg/kg for the whole category of RTE meals for infants and young children and the advancement of the ML to step 8.</p> <p>JECFA has established that there is no safe level of lead, and that infants and young children are more sensitive to the effects of lead due to neurodevelopmental effects. Therefore, it is imperative to prioritise protecting children from the effects of lead.</p> <p>Singapore does not support the option of excluding products containing cereals for the following reasons:</p> <ol style="list-style-type: none"> i. The ML of 0.02 mg/kg for cereal-based products for infants and young children has been adopted at CAC45, hence, having a ML of 0.02 mg/kg for RTE meals, including products containing cereals, is reasonable and consistent with the ML for cereal-based products. ii. The exclusion of foods from the scope of the ML is equivalent to having no MLs and is not a health protective outcome particularly for infants and young children. iii. Ingredients for foods for infants and young children can be sourced in a way to achieve the ML of 0.02 mg/kg. 	<p>Singapore</p>
<ul style="list-style-type: none"> • The United States thanks Brazil for their work on this agenda item. • The United States can support an ML of 0.02 mg/kg for ready-to-eat (RTE) meals for infants and young children given the significance of lead exposures in infants and young children. An ML of 0.02 mg/kg corresponds to a sample rejection rate of 5.3%. • The United States does not support excluding products containing cereals from the proposed ML of 0.02 mg/kg for RTE meals for infants and young children, given that Codex established an ML of 0.02 mg/kg for cereal-based foods for infants and young children in 2022. • The EWG should clarify in the plenary whether the ML for ready-to-eat meals applies to single-ingredient foods (e.g., carrots or apples) in addition to multi-ingredient foods. 	<p>USA</p>
<p><u>Consider either to establish a single ML of 0.03 mg/kg for the whole category of ready-to-eat meals for infants and young children or to establish a ML of 0.02 mg/kg for ready-to-eat meals for infants and young children, excluding products containing cereals as proposed by the EWG established by CCCF15.</u></p> <p>Typographical error at "WholSe commodity"</p>	<p>AHPA</p>