CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7 **CX/CF 22/15/7-Add.1**

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON CONTAMINANTS IN FOODS

15th Session
Virtual
9-13 and 24 May 2022

MAXIMUM LEVELS FOR LEAD IN CERTAIN FOOD CATEGORIES (At Step 4)

Comments in reply to CL 2022/16-CF

Comments of Canada, Chile, China, Cuba, Ecuador, Egypt, Iraq, Kenya, New Zealand, Peru, Saudi Arabia, Singapore, Syrian Arab Republic, Turkey, Uganda, United States of America (USA), FoodDrinkEurope, International Association of Consumer Food Organizations (IACFO) and International Confectionery Association (ICA)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2022/16-CF[1] issued in March 2022. 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 attached in the **Annex** and are presented in table format.

[1] Codex circular letter, including CL 2021/87-CF, are available on the Codex webpage/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/ or on the dedicated Codex webpage/CCCF/Circular Letters: http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF

Annex

GENERAL AND SPECIFIC COMMENTS

COMMENT	MEMBER/ OBSERVER
While Canada is supportive of advancing certain MLs, namely those proposed for bark and honey, in comparison the scientific logic and supporting rationale/data for the majority of the other ML proposals are unclear and/or appear inconsistent. Some of these considerations relate to (these are also discussed in more detail below for each individual proposal): • discrepancies in the reported occurrence data and the presentation of the overall data (e.g. missing occurrence data; possible errors in the various data tables; benefit of presenting additional options for ML values); • criteria/supporting rationale for certain proposals (e.g. rationale for some proposals are lacking; criteria for exclusions for some MLs are not clear and/or appear inconsistent compared to others and further discussion relating to exclusions may be needed; presenting ML options for only certain foods based on specific LOD/LOQ criteria from the Codex Alimentarius Procedural Manual without precedent or further supporting details); • criteria used to screen and select the data for ML elaboration; and • limited sample size/geographic representation for certain foods where a separate ML could be or is being proposed (in these cases, if certain proposals are revisited again the following year, the eWG on data management could be consulted). Comment by Canada on Paragraph 29 of Appendix II It is noted in para. 29 of Appendix II that due to low sample size (n=15), the aril spice category is no longer being considered for ML development. However, we note that other foods with a comparable sample size are still being considered, such as molasses (n=20). If this proposal is revisited again next year, it may benefit from further discussion and consultation with the eWG on data management, specifically as it relates minimum sample size for ML elaboration. We would also mention that Canada previously submitted data for mace spice (n=48) (which would fall under the aril spice category) that could be taken into consideration. In Appendix II, paragraph 10, second sentence, there appears to be a reference missing.	**Canada**
Item 7: Maximum levels for lead in certain food categories (at Step 4) China would like to thank Brazil for the work on MLs for lead in certain food categories, and we appreciate the opportunity to provide the following comments in respond to the circular letter CL 2022/16-CF.	**China**
En respuesta a la Carta Circular CL 2022/16-CF, Ecuador agradece al Presidente y Copresidente del Grupo de Trabajo por Medios Electrónicos - Gte por preparar y presentar el Anteproyecto de Niveles Máximos de plomo en determinadas categorías de alimentos. Tomando en cuenta el Apéndice I, Ecuador considera no fijar un nivel máximo (NM) para los huevos frescos teniendo en cuenta su escasa relevancia para el comercio internacional y los bajos niveles de presencia observados. Ecuador apoya el avance de los NM para las hierbas culinarias (frescas y secas) y las especias (secas), para azúcares, caramelos a base de azúcar, alimentos para lactantes y niños pequeños presentados en el Apéndice I.	**Ecuador**
Agree with proposal	**Iraq**

COMMENT	MEMBER/ OBSERVER
Solicitud de observaciones en el trámite 3 sobre los niveles máximos de plomo en determinadas categorías de alimentos. El Perú desea agradecer a la presidencia del GTe por todo el trabajo realizado para la determinación de niveles máximos de plomo en determinadas categorías de alimentos. En esta ocasión, el Perú apoya los niveles máximos de plomo propuestos.	**Peru**
Saudi Arabia support the Proposed Maximum Levels For Lead For Certain Food Categories	**Saudi Arabia**
Singapore supports the proposed MLs for the food categories discussed 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.	**Singapore**
We generally agree with the proposal.	**Syrian Arab Republic**
As a general comment, the Committee should consider (1) how to address ground spice mixtures and (2) clarify for spice MLs whether the MLs apply to ground spices, whole spices, or both.	**USA**
FoodDrinkEurope thanks the electronic working group (EWG) lead by Brazil, and the working group members, for the opportunity to provide comments on the document CL 2022/16-CF (March 2022). We would like to stress that while MLs should be set to serve as health-protective standards, they must also be achievable and realistic to facilitate international trade and to provide a single harmonized standard. To this regard, it should be considered that the major contributor of lead in sugar is through soil or water. Sugar is the primary ingredient in most sugar-based candies and we believe that setting and meeting sugar MLs will adequately control lead levels in finished candy products. Therefore, we believe that since MLs are currently being considered in parallel on sugar-based candies' raw ingredients that may contain lead, then there would be no reason to also set MLs (as are being proposed herein) for finished sugar-based candies themselves (hard and soft candies, gummies and jellies, candy powder). To this regard, we are able to support the proposed MLs for sugar (white and refined, brown and raw) at the 0.1 mg/kg level. We recommend not to establish MLs for finished sugar-based candies – hard candies, gummy and jellies, and soft candy - and only set MLs on raw materials. We thank the Committee for taking these points into account and look forward to further discussion at the CCCF15 session.	**FoodDrinkEurope**
IACFO has major concerns about the approach used in proposing maximum levels (MLs) for lead in food, especially those intended specifically for infants and children. The background provided for Agenda Item 7, CX/CF 22/15/7 states in paragraph 1, "Since no safe level of lead could be identified, measures should be taken to identify major contributing sources and, if appropriate, to identify methods of reducing dietary exposure that are commensurate with the level of risk reduction." This statement emphasizes the need for a targeted, health-based approach that would produce a rapid reduction in cumulative dietary lead exposures to near null levels. Instead, the approach taken is guided primarily by industry feasibility, basing MLs on an arbitrarily established maximum rejection rate of 5%, and is not appropriately grounded in taking the necessary steps to protect infants and children. There are foods for which rejection rates in excess of 5% are necessary to adequately protect public health, and conversely there are foods for which raising the rejection rate above 0% produces minimal public health benefit. MLs should be set with the intent of reducing total (i.e., cumulative) dietary lead exposure as close to zero as efficiently as possible, more aggressively targeting the foods that contribute most to total dietary lead exposures and limiting the imposition of MLs on foods that make trivial contributions to total dietary lead exposure.	**IACFO**

SPECIFIC COMMENTS

Establish an ML of 0.25 mg/kg for fresh eggs (chicken and ducks) considering the performance criteria of Codex Alimentarius Procedural Manual[1] and the fact that the methods used to analyse 95% of the egg samples had a Limit of Quantification (LOQ) of 0.05 mg/kg or to not establish a maximum level (ML) for fresh eggs, considering their low relevance for international trade and the low occurrence levels observed

COMMENT		MEMBER/ OBSERVER
Canada supports the option to refrain from establishing an ML for fresh eggs (chicken and/or duck). Our understanding is that previous information provided on international trade volume only included "processed eggs", not fresh; additional context regarding the trade of fresh chicken and duck eggs was also not provided. Considering the apparent low relevance to international trade and the overall low levels of lead observed in fresh eggs, an ML for this food category is likely not needed. With respect to the ML option based on specific LOD/LOQ criteria from the Codex Alimentarius Procedural Manual, this appears to be the first time Canada has seen this approach employed in the development of a new ML and if this proposal is revisited again next year, this approach may benefit from further discussion and consultation with the eWG on data management. If there is precedent for using this approach, it would also be useful to reference it in the discussion paper. We note that an ML value of 0.25 mg/kg is well above what is achievable for fresh eggs and that there appears be differences in lead concentrations in chicken vs duck eggs thus suggesting a single ML for both may not be appropriate.		**Canada**
MLs for Lead in eggs: China supports the ML of 0.25mg/kg lead in fresh eggs.		**China**
Chile está de acuerdo con no establecer un nivel máximo para los huevos frescos, teniendo en cuenta su escasa relevancia para el comercio internacional y los bajos niveles de presencia observados.		**Chile**
Comment: Interchange the wordings Justification: Editorial for more clarity.	Comment: Kenya proposes not setting of MLs. Rationale: The parameter has low relevance in international trade and occurrence observed so far is very low to justify setting a limit in eggs. Therefore, Kenya requests for monitoring data to be submitted to JECFA for evaluation.	**Kenya**
If there is a risk in eggs, which is one of the main components of human diet, it needs to be consider to determine the maximum limit (ML). However, we think that the data used for the evaluation of the proposed MLs are insufficient and doesn't reflect the regional situation. Moreover, it is not clear which approach is used to determine the ML. Although 5% rejection rate approach was adopted in the draft document of EWG, it seems that this approach was not taken into account. As we have stated in tour comments that we submitted to EWG, Türkiye is an important exporter of eggs. In addition to the data provided from the GEMS database, Türkiye propose the implementation of a 3-year monitoring programme with countries that are willing to take part in, by considering the regional representation of data. Until this study is completed, Türkiye propose to set a more tolerant ML temporarily and to amend this ML at the end of the study.		**Turkey**
Uganda appreciates the efforts of the EWG on setting the proposed maximum limits for lead in eggs, culinary herbs and spices. Uganda supports the proposed MLs for lead in all the identified food categories.		**Uganda**
The United States does not support adoption of the proposed ML of 0.25 mg/kg for fresh eggs (chicken and ducks). • There are only a small number of samples with detectable lead levels. For chicken eggs, which are the majority of the dataset, less than 1% of 1694 samples are above the limit of detection. • An ML of 0.25 mg/kg would result in a rejection rate of 0.1% and would have negligible public health impact in reducing dietary lead exposures. • Lower lead levels than 0.25 mg/kg are routinely seen in eggs; the ML proposal is driven by Codex analytical requirements. • Data on duck eggs are only from one country, which is not geographically representative, and does not provide evidence that duck eggs are significant for international trade.		**USA**

COMMENT	MEMBER/ OBSERVER
IACFO opposes this ML because, based on typical consumption of eggs, an ML of 0.25 mg/kg is not sufficiently protective of infant and child health. The United States Food and Drug Administration (FDA) has established interim reference levels, or IRLs, for lead, which are the "calculated amount of dietary lead intake that would be required to reach the [US Centers for Disease Control and Prevention (CDC)] blood reference level, including a 10x safety factor." For children, the IRL is 3 micrograms of lead per day, based on a 2012 CDC blood lead reference value (BLRV) of 5 micrograms per deciliter (ug/dl; https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods). The BLRV is established at the 97.5th percentile of blood lead values among U.S. children ages 1-5 years (notably, in 2021 CDC lowered the BLRV to 3.5 ug/dl; https://www.cdc.gov/nceh/lead/prevention/blood-lead-levels.htm). While the US FDA IRL is not a safe exposure level, because there is no safe level of lead exposure, it provides a public health-based metric we can use to assess the efficacy of the proposed MLs in protecting infants and children. According to reference consumption data used by the US FDA (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=101.12), young children in the US typically consume 55 grams of egg per eating occasion. At the proposed ML of 0.25 mg/kg, a child consuming a single 55 g serving of egg would be exposed to 13.75 micrograms of lead, 4.6 times higher than the US FDA IRL. Thus, children can exceed the US FDA IRL by consuming a single serving of eggs at this ML. Children who consume eggs more frequently (e.g., multiple times per day) or at larger quantities or who are consuming other foods contaminated with lead would face even greater exposures and be at even higher risk for adverse effects from lead. This ML is associated with only a 0.1% rejection rate, leaving plenty of room to increase the ML to approach the 5% rejection rate deemed acceptable. An ML for chicken eggs between 0.05 mg/kg and 0.02 mg/kg would achieve a 5% rejection rate, and an ML for duck eggs of 0.12 mg/kg would achieve a 5% rejection rate. Exceeding a 5% rejection rate may be warranted for eggs, considering the ease with which children can exceed the US FDA IRLs at the proposed MLs. It would be preferable if CCCF set MLs that use the protection of children's health as the driving factor, not the associated rejection rate. Efforts should be made to improve the methods used to measure lead in eggs to achieve lower limits of quantification and facilitate imposition of lower MLs.	**IACFO**

Establish the following MLs for culinary herbs (fresh and dried) and spices (dried)

COMMENT	MEMBER/ OBSERVER
Culinary herbs: Culinary herbs (fresh) (except Rosemary) Canada notes the following considerations related to the supporting rationale/data for the proposed ML of 0.25 mg/kg for fresh culinary herbs with an exclusion for rosemary. • Supporting data for rosemary are not provided in Table B1 of Annex I and therefore we cannot comment on whether a separate ML would be warranted. • The criteria/rationale for exclusions from the fresh culinary herb category are not clear. It appears that rosemary may contain somewhat similar lead concentrations relative to other fresh herb subcategories (based on the hypothetical MLs presented) but is excluded whereas mint and fennel (fennel also contains a lower sample size (n=26) and is lacking in geographic representation) contain lower lead concentrations relative to other herbs within this category but both are included in the proposed ML for the general category of culinary herbs (fresh) (except rosemary) of 0.25 mg/kg. Culinary herbs: Rosemary (fresh) Canada notes the following considerations related to the supporting rationale/data for the proposed separate ML of 0.5 mg/kg for fresh rosemary. • Supporting data for rosemary are not provided in Table B1 of Annex I and therefore we cannot comment on whether a separate ML would be warranted. • Based on the hypothetical MLs presented in Table 5 of Appendix II for rosemary, it would appear that lower MLs, more consistent with an ALARA approach, are possible and it is unclear why a higher value of 0.5 mg/kg was selected as a rationale was not provided. • While hypothetical MLs of 0.2 and 0.3 mg/kg are presented fresh rosemary, 0.25 mg/kg is not and it may beneficial for this ML option to also be presented in Table 5 for consideration, as it is the proposed ML for culinary fresh herbs. Culinary herbs: Culinary herbs (dried) Canada notes the following considerations related to the supporting rationale/data for the proposed ML of 2.0 mg/kg for dried culinary herbs. • It appears that there may be errors in the data presentation for this food category. For example, for basil and thyme, the sample rejection rates for various hypothetical MLs presented in Table 5 of Appendix II are identical (e.g. MLs for basil of 2.5, 2 and 0.6 mg/kg each correspond to the same sample rejection rate of 3.84%). • The supporting occurrence data in Table B1 of Annex I does not always follow the hypothetical MLs in Table 5 of Appendix II (e.g. an ML for basil of 0.6 mg/kg would correspond to a rejection rate of 3.84%, however, the p95 concentration is reported to be 0.57 mg/kg and would presumably result in a 5% rejection rate). • Based on the data summary presented in Table B1, it appears that basil contains lower lead concentrations relative to other dried culinary herbs and could potentially be considered for exclusion and a possible separate ML could be proposed. However, data that are available for basil (n=26) are limited and lacking in geographic representation. It is unclear why this subcategory was not considered for exclusion when this was similarly done for other subcategories (e.g., carom, dill, mahlab, etc.) where only limited data were available. If this proposal is revisited again the following year, this could be further discussed with the eWG on data management. Dried spices: Floral parts (cloves, excluding saffron) Canada agrees that differences in lead concentrations between saffron and cloves may warrant an exclusion but would mention following considerations related to the supporting rationale/data for the proposed ML of 2.5 mg/kg for floral parts (cloves, excluding saffron).	**Canada**

COMMENT	MEMBER/ OBSERVER
• The supporting occurrence data in Table B1 of Annex I does not always reflect the hypothetical MLs presented in Table 7 of Appendix II. For example, a hypothetical ML for cloves of 2.0 mg/kg would correspond to a rejection rate of 7.5%, however, the p95 concentration is reported to be 2.14 mg/kg and would presumably result in a 5% rejection rate. • The sample rejection rates for some of the hypothetical MLs presented in Table 7 are identical (e.g. MLs for cloves of 2.0, 1.5 and 1.0 mg/kg each correspond to the same sample rejection rate of 7.5%). • Canada questions whether a separate, lower ML should be considered for saffron but recognize the limited data that are available (n=19). If this proposal is revisited again the following year, the eWG on data management could be consulted on potential minimum sample size requirements. Dried spices: Fruits and berries spices (excluding star anise and sumac) Canada notes the following considerations related to the supporting rationale/data for the proposed ML of 0.8 mg/kg for fruit and berry spices (excluding star anise and sumac). • The criteria/rationale for exclusions from the fruit and berry spice category is not clear/consistent. It is noted in para. 32 of Appendix II that star anise and sumac may contain higher levels of lead but that there are limited samples (n <20) available and thus were excluded. While it is noted from Table 8 of Appendix II and Table B1 of Annex I, that there were less than 20 (n=12) of sumac, it also indicates that there are n=83 samples of star anise whereas godji berry, which was not excluded from the proposed ML, only has n=15 samples available. • The supporting occurrence data in Table B1 does not always follow the hypothetical MLs presented in Table 8. For example, a hypothetical ML for pepper of 0.8 mg/kg would correspond to a rejection rate of 2.2%, however, the p95 concentration is reported to be 0.79 mg/kg and would presumably result in a 5% rejection rate. • Another ML option of 0.9 mg/kg be presented for consideration. Based on information provided in Table B1, it appears that all of the fruit and berry spices could potentially meet a hypothetical ML of 0.9 mg/kg and the target rejection rate of up to 5% (the rejection rate for star anise may slightly exceed this value). • Data for godji berry, star anise and sumac appear to be lacking in geographic representation. • If this proposal is revisited again the following year, the eWG on data management could be consulted on whether fruit and berry spice subcategories that have comparable lead concentrations but smaller sample sizes and/or limited geographic representation, could be rolled into the general ML for fruit and berry spices. Dried spices: Rhizomes, bulbs and roots spice (excluding garlic) Canada agrees with excluding garlic from the proposed ML for rhizomes, bulbs and root spices but notes the following considerations related to the supporting rationale/data for the proposed ML of 3.5 mg/kg. • It is unclear why an ML of 3.5 mg/kg was selected when it appears that lower MLs (e.g. ML of 3 m/kg, rejection rate of approximately 5% or less for all subcategories based on supporting data reported in Table B1 of Annex I), more consistent with an ALARA approach, would be possible as no rationale was provided. • It appears that there may be errors in the data presentation for this food category. For example, for turmeric and ginger, the sample rejection rates for some of the hypothetical MLs presented in Table 9 of Appendix II are identical (e.g. MLs for turmeric of 3.0 and 3.5 mg/kg each correspond to a sample rejection rate of 4.9%). Dried spices: Garlic Canada agrees with a separate, lower ML for dried garlic but notes the following considerations related to the supporting rationale/data for the proposed ML of 0.4 mg/kg.	

COMMENT	MEMBER/ OBSERVER
• It is unclear why an ML of 0.4 mg/kg has been proposed when there are lower values that would meet the target rejection rate (i.e. up to 5%) and are more consistent with an ALARA approach. Additional ML options between 0.3 and 0.4 mg/kg (e.g. 0.35 mg/kg) could be presented and rationale provided for a specific proposed ML value for this subcategory. • The supporting occurrence data in Table B1 of Annex I does not always reflect the hypothetical MLs presented in Table 9 of Appendix II. For example, the hypothetical ML for garlic of 0.3 mg/kg would correspond to a rejection rate of 7.1%, however, the p95 concentration is reported to be 0.31 mg/kg and would presumably result in a 5% rejection rate. • Occurrence data for dried garlic also appear to be lacking in geographic representation (i.e. only US, Singapore and Brazil data are available). Dried spices: Bark Canada supports an ML of 2.5 mg/kg lead in bark (rejection rate of 4.7%) and would have no concerns if this ML was moved forward for consideration by the Codex Alimentarius Commission. Dried spices: Seeds spices (excluding, carom, celery, dill, mahlab, mustard and poppy) Canada agrees that differences in lead concentrations between celery seeds and other subcategories within the general category for seed spices may warrant separate MLs. However, we note the following considerations related to the supporting rationale/data for the proposed ML of 0.8 mg/kg for seed spices herbs (excluding carom, celery, dill, mahlab, mustart and poppy). • The criteria/rationale for exclusions for other seed spices is not clear/consistent. It is noted in para. 40 of Appendix II that carom, dill, mahlab, mustard and poppy are excluded due to limited samples (n <20) available. However, limited samples are also only available for fenugreek and anise (approximately 20 samples) but these were not excluded from the proposed ML. • It may beneficial to present another ML option of 0.7 mg/kg for consideration. Based on information provided in Table B1 of Annex I, it appears that all of the seed spices, excluding celery seed, could meet a hypothetical ML of 0.7 mg/kg and the target rejection rate of up to 5%, which would be more consistent with an ALARA approach. • The supporting occurrence data in Table B1 does not always reflect the hypothetical MLs presented in Table 11 of Appendix II. For example, the hypothetical ML for fennel of 0.6 mg/kg would correspond to a rejection rate of 4.3%, however, the p95 concentration is reported to be 0.22 mg/kg and would presumably result in a 5% rejection rate. • While we recognize there is a limited sample size for fenugreek, we would mention that the P95 and P97.5 concentrations differ greatly (approximately 9-fold difference) and question whether these values are accurate. • If this proposal is revisited again the following year, the eWG on data management could be consulted on whether seed spice subcategories that have comparable lead concentrations but smaller sample sizes and/or limited geographic representation, could be rolled into the general ML for seed spices. Dried spices: Celery seeds Canada agrees that differences in lead concentrations between celery seeds and other subcategories within the general category for seed spices may warrant separate MLs and that the data in Table B1 of Annex I supports a higher ML of 1.5 mg/kg for celery seeds. However, the supporting data for celery seeds are lacking in geographic representation. If this proposal is revisited again the following year, the eWG on data management could be consulted. Based on the data in Table B1, it also appears that a lower ML of 1.4 mg/kg for celery seeds would be achievable and is more consistent with an ALARA approach.	

COMMENT	MEMBER/ OBSERVER
MLs for Floral parts spices (Cloves, excluding saffron) China questions whether the data is sufficient to provide the necessary basis to set a global standard for floral parts spices as only 40 samples of one specific spice were provided and rejection rate at 2.5 mg/kg is 5% (see Table 7 of CX/CF 22/15/7). And China would like to limit the ML only to reported floral and wait for more data collection. MLs for fruits and berries spices（excluding star anise and sumac） There are only 7 types of spices data (cardamom, chilli, godji, paprika, pepper, sumac and star anise), more than 80% data is for chilli and peper, without data for Sichuan Peper (Zanthoxylum bungeanum Maxim.). The analysis results are not suitable for Sichuan Peper. According to the Sichuan Peper data from China national food contamination monitoring programme, large amounts of Sichuan Peper (36.61%) exceed the recommended MLs of 0.8mg/kg. China suggests excluding Sichuan Peper from the MLs for fruits and berries spices as star anise and sumac. MLs for Bark For the ML for lead in Bark, the rejection rate of 2.5 mg/kg (4.7%) is very close to the cut-off of 5%. Considering its low consumption and only 448 data, 3.0 mg/kg (3.6%) would be more suitable for Bark. Besides, China collected 235 data for lead in Bark, which indicate the proposed ML of 2.5mg/kg would provide the rejection rate of 19.57%. Therefore, China proposes the ML of 3.0 mg/kg lead in Bark. MLs for seeds spices (excluding carom, celery, dill, mahlab, mustard and poppy) EWG exclude carom, celery, dill, mahlab, mustard and poppy for the ML for seeds spices because of few data. We only have 7 types of seeds spices (anise, celery, coriander, cumin, fennel, fenugreek and nutmeg) stand for all the seeds spices, and 72% data is for coriander and cumin. Celery seeds From the data of lead in celery seed, we could know the level of lead between different spices maybe obviously different. Since the data is limit, China suggests only setting the MLs for lead in coriander and cumin, not for seeds spices.	**China**
Chile apoya los niveles máximos propuestos por el GTE para hierbas culinarias y especias secas.	**Chile**
Egypt recommends the following ML Food — Maximum Level (ML) (mg/kg) Dried spices - Fruits and berries spices (excluding star anise and sumac) — 0.6 Dried spices- Root and Rhizome spices — 1.5 Dried spices- Bark spices — 2 Dried spices -Seed spices — 0.9	**Egypt**
We Agree with all MLs for spices except Fruits and seed spices we prefer ML 0.9 (mg/kg)	**Syrian Arab Republic**
We think that the submitted data is not enough to determine ML in spices, especially floral parts and garlic, and does not provide regional representation. In addition to the data provided from the GEMS database, Türkiye propose the implementation of a 3-year monitoring programme with countries that are willing to take part in, by considering the regional representation of data. Until this study is completed, Türkiye propose to set a more tolerant ML temporarily and to amend this ML at the end of the study.	**Turkey**

COMMENT	MEMBER/ OBSERVER
Fresh and dried culinary herbs and subcategories: • *Fresh culinary herbs (except rosemary), 0.25 mg/kg, and fresh rosemary, 0.5 mg/kg* The United States would prefer more data collection before setting MLs for this category, including more information on the breakdown by geographic origin of samples in this category. Basil and parsley have rejection rates similar to rosemary, and no data are included for cilantro, a widely used fresh herb. • *Dried culinary herbs, 2.0 mg/kg* The United States can support an ML of 2.0-2.5 mg/kg for dried culinary herbs. • *Floral parts (cloves), 2.5 mg/kg* The United States does not support setting an ML of 2.5 mg/kg for floral parts (cloves) based on the current dataset. This ML appears too high. o *Saffron* The United States agrees with the exclusion of saffron with only 19 samples. • *Spices of fruit and berries (excluding star anise and sumac), 0.8 mg/kg* The United States can support an ML of 0.8-0.9 mg/kg for spices of fruit and berries (excluding star anise and sumac). • *Rhizomes, bulbs and roots, excluding garlic (3.5 mg/kg)* The United States does not support the proposed ML of 3.5 mg/kg for rhizomes, bulbs and roots (excluding garlic), corresponding to a rejection rate of 4.0%. The previous proposed ML, 2 mg/kg, corresponds to a rejection rate of 4.9%. o A lower ML could be set for the whole category if turmeric were excluded. For example, an ML of 3.5 mg/kg with turmeric corresponds to a rejection rate of 4%, while the identical ML with no turmeric has a rejection rate of 1.4%. • *Garlic, 0.4 mg/kg* The United States does not object to an ML in the range of 0.4 – 0.5 mg/kg, but also would not object to further review of this category. The level of 0.4 mg/kg appears achievable based on the dataset in the current analysis, but over 200 dried powdered garlic samples from the U.S. were not included, which would align with a higher ML than 0.4 mg/kg. • *Spices from bark, 2.5 mg/kg* The United States does not support the proposed ML of 2.5 mg/kg. Cinnamon is used heavily in children's foods, so a lower ML would be appropriate. • *Seeds spices, 0.8 mg/kg; celery seed, 1.5 mg/kg* The United States can support an ML of 0.8-0.9 mg/kg for spices, dried seeds.	**USA**

Establish the following MLs for sugars:

COMMENT	MEMBER/ OBSERVER
Sugar, white and refined: Canada notes the following considerations related to the supporting rationale/data for the proposed ML of 0.1 mg/kg for white and refined sugar. • Supporting occurrence data in Table C1 does not always follow the hypothetical MLs presented in Table 12 of Appendix II. For example, the proposed ML for white sugar of 0.1 mg/kg would correspond to a rejection rate of 0.78%, however, the p95 concentration is reported to be 0.1 mg/kg and would presumably result in a 5% rejection rate. • In Table 12 of Appendix 11, the hypothetical ML for refined sugar 0.09 mg/kg would result in a rejection rate of 30% but the proposed ML of 0.1 mg/kg, which is only slightly higher, would correspond to a 0% rejection rate; the p95 and p97.5 concentrations reported in Table C1 are also both 0.1 mg/kg. • If this proposal is revisited again the following year, the eWG on data management could be consulted on whether a single ML for sugars, including other types of sugar that that have comparable lead concentrations but smaller sample sizes and limited geographic representation, could be considered. Sugar, brown and raw: Canada notes the following considerations related to the supporting rationale/data for the proposed ML of 0.1 mg/kg for white and refined sugar. • Supporting occurrence data in Table C1 does not always follow the hypothetical MLs presented in Table 12 of Appendix II. For example, the proposed ML for white sugar of 0.1 mg/kg would correspond to a rejection rate of 0.78%, however, the p95 concentration is reported to be 0.1 mg/kg and would presumably result in a 5% rejection rate. • In Table 12 of Appendix 11, the hypothetical ML for refined sugar 0.09 mg/kg would result in a rejection rate of 30% but the proposed ML of 0.1 mg/kg, which is only slightly higher, would correspond to a 0% rejection rate; the p95 and p97.5 concentrations reported in Table C1 are also both 0.1 mg/kg. • If this proposal is revisited again the following year, the eWG on data management could be consulted on whether a single ML for sugars, including other types of sugar that that have comparable lead concentrations but smaller sample sizes and limited geographic representation, could be considered. Honey: Canada supports an ML of 0.06 mg/kg lead in honey (rejection rate of 4.4%) and would have no concerns if this ML was moved forward for consideration by the Codex Alimentarius Commission. Corn and maple syrups: Canada notes the following considerations related to the supporting rationale/data for the proposed ML of 0.1 mg/kg for corn and maple syrups. • The proposed ML appears to be notably higher than the P95 concentrations reported for most syrups (excluding beet syrup) in Table C1 of Annex I (approximately 5-fold higher for corn syrup and 1.7-fold higher for maple syrup) and it is unclear why a value 0.1 mg/kg was selected when lower MLs more consistent with an ALARA approach would be possible. It may be beneficial to provide additional ML options in Table 13 of Appendix II (e.g. corn syrup: 0.02, 0.03, 0.04, 0.06; maple syrup: 0.06, 0.07, 0.08, 0.09). • If this proposal is revisited again the following year, the eWG on data management could be consulted on whether a single ML for syrups, including other types of syrups that have comparable lead concentrations but smaller sample sizes and limited geographic representation, could be considered. Molasses: Canada agrees that the supporting data appear to demonstrate that an ML of 0.3 mg/kg for molasses would be reasonable (rejection rate of 5%) but would mention the following considerations related to the supporting rationale/data for the proposed ML.	**Canada**

COMMENT	MEMBER/ OBSERVER
• Molasses has a limited sample size (n=20) but is still being considered for ML development whereas other foods with a similarly low sample size, e.g. aril spices (n=15), are not being considered. If this proposal is revisited again next year, it may benefit from further discussion and consultation with the eWG on data management. • There appears to be an error in Table 13 of Appendix II. For example, the MLs for molasses of 0.4 and 0.3 mg/kg each correspond to a sample rejection rate of 5%.	
Chile apoya los niveles máximos propuestos por el GTE para azúcares, y alimentos a base de azúcar. Además, Chile apoya los niveles máximos propuestos para productos a base de cereales y comidas preparadas para lactantes y niños pequeños, expresados como "tal cual".	**Chile**
Egypt recommends the following MLs: Food Maximum Level (ML) (mg/kg) Honey 0.1	**Egypt**
New Zealand thanks you for the opportunity to comment on the requested proposals as stated in Appendix I of CX/CF 22/15/7. • <u>Establish the following MLs for sugars</u> NZ position Previous feedback from New Zealand noted concerns with work process followed in that the role of outliers and consistency in the rejection rates applied do not appear well addressed. Outliers in the sugar group, that are indicative of adulteration or major contamination should have been removed. Further work is necessary to standardize the assessment.	**New Zealand**
We Agree with all MLs for Sugars except Honey we prefer 0.1	**Syrian Arab Republic**
Türkiye's proposal: Sugar, white and refined 0.2 Sugar, brown and raw 0.2 Blossom Honey or Nectar Honey 0.15 Honeydew Honey 0.1 1. <u>Sugars Justification</u>: We support the consideration of the lead exposure from sugar, which is an important food in daily consumption, in the evaluation of the total lead exposure and taking precautions accordingly. However, in the draft document, it would be appropriate not to ignore the regional representation and the current situation. It will be realistic to reduce the maximum limits with the measures to be taken during the process. For this purpose, a risk assessment has been made for maximum limits of 0.1-0.2 and 0.3 mg/kg in white sugar, based on Türkiye and World consumption data. We would like to share the evaluation findings: International and European health-based guidance values for Pb exposure are updated as new information becomes available. In 2010, the EFSA Contaminants Panel noted that there was no evidence of a threshold for a number of critical endpoints, including developmental neurotoxicity and adult nephrotoxicity. It therefore concluded that the Provisional Tolerable Weekly Intake (PTWI) of 25 µg/kg body weight, set by JECFA in 1986 and approved by the European Commission's Scientific Committee on Food (SCF) in 1990, is no longer appropriate. While this decision was confirmed by JECFA in 2010, a concern was also expressed about the potential to affect neurodevelopment in infants, children and fetus at current exposure levels (EFSA, 2012a).	**Turkey**

COMMENT	MEMBER/ OBSERVER
Therefore, in risk assessment recommended by EFSA; the following BMDL values were used for developmental neurotoxicity in young children as BMDL01 0.50 µg/kg bw/day and for cardiovascular effects and nephrotoxicity in adults as BMDL01 1.50 µg/kg bw/day and BMDL10 0.63 µg/kg bw/day respectively. Exposure has been calculated separately for young children (2-5 years), children (6-8, 9-11 and 12-14 years), adolescents (15-18 years), adults (19-64 years), and the elderly (65-74 years) calculated separately. Calculations were performed using minimum and maximum consumption data (Türkiye and the world), including average consumption data, for each age group. While minimum 0.0097 kg/day and maximum 0.09 kg/day values are used for Türkiye, the world average consumption data of 0.04 kg/day and maximum 0.11 kg/day (ISMA, 2022) are used. Türkiye's results indicated that there is a low health concern for each of three maximum limits (0.1-0.2-0.3 mg/kg). For example, the exposure to Pb through per capita consumption of white sugar is between 0.0636 µg/kg bw/day and 0.1909 µg/kg bw/day for young children (2-5 years). In the calculations performed for young children (2-5 years old) using world data (ISMA data), it has been determined that there are health concerns for three different ML values, except for the Asian continent. In the same calculations, all MLs evaluated in adults over the age of 18 showed low health concern. Pb exposure through consumption of white sugar for 0.1-0.2 and 0.3 mg/kg MLs in this group was calculated between the range of 0.0631-0.1822, 0.1263-0.3644 and 0.1894-0.5466 µg/kg bw/day, respectively. In line with our evaluations above and our position in world production, we expect our suggestions to be taken into account. 2. <u>Honey Justification</u>: Türkiye doesn't support proposal of EWG for honey. The proposed limit for honey, 0.06 mg/kg has not been offered or discussed during EWG study. We believed that the proposed ML (0,06 mg/kg) doesn't reflect the exist state and unrealistic standards contribute to food fraud. For this reason, it would be appropriate to take into account the views of the producer/exporter countries in the setting maximum limits for honey. Within the framework of good manafacturing practices, we would like to emphasize again that according to the getting data, the data frequency is about 0.1 mg/kg in Honeydew Honeys, while this distribution is slightly higher in Blossom Honey or Nectar Honeys. In addition, we submit the results of the risk assessment that we have performed by using the consumption data of Türkiye and the world. The same approach used for white sugar was adopted in risk assessment study of honey. For honey, a risk assessment was performed for 0.06-0.1-0.15-0.20 mg/kg MLs. Including the average consumption data, minimum 0.0091 kg/day and maximum 0.0153 kg/day values were used as consumption data for Türkiye, while the highest consumption data for the world was 0.01 kg/day (Uruguay). In all calculations performed by using data from Türkiye and the world, four different ML values were evaluated for honey and also showed low health concerns. According to the results of Türkiye, it was determined that the exposure levels determined for all age groups between the range of 0.0114 µg/kg bw/day and 0.1230 µg/kg bw/day. According to the world consumption data, all exposure levels determined for all age groups between the range of 0.0075 µg/kg b.a./day and 0.1302 µg/kg b.a./day. As an important producer/exporter country in the world, Türkiye demands that the above assessments be taken into account.	
<u>Sugars</u> • *Sugar, white and refined; sugar, brown and raw, 0.1 mg/kg* The United States does not object to an ML of 0.1 mg/kg for all sugars. • *Honey, 0.06 mg/kg* An ML of 0.1 mg/kg also seems appropriate for honey. At 0.1 mg/kg, the rejection rate for honey (1.8%) is higher than that for white sugar (0.78%). o For 0.06 mg/kg, the EWG should address methodological concerns as for other foods with proposed MLs below 0.1 mg/kg. • *Corn and maple syrups, 0.1 mg/kg* The United States does not object to the proposed ML of 0.1 mg/kg. • *Molasses, 0.3 mg/kg* The United States does not support this ML given the small sample size (n= 20) and the large variability in the dataset. More data collection is appropriate.	**USA**

COMMENT	MEMBER/ OBSERVER
ICA is able to support the proposed MLs for sugar (white and refined, brown and raw) at the 0.1 mg/kg level. The International Confectionery Association (ICA) would like to stress that while MLs should be set to serve as health-protective standards, 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. To this regard, it should be considered that the major contributor of lead in sugar is through soil or water. In fact, sugar is the primary ingredient in most sugar-based candies and we believe that setting and meeting sugar MLs will adequately control lead levels in finished candy products. Therefore, we believe that since MLs are currently being considered in parallel on sugar-based candies' raw ingredients that may contain lead (sugar, honey, syrups, molasses, spices), then there would be no reason to also set MLs (as are being proposed herein) for finished sugar-based candies themselves (hard and soft candies, gummies and jellies, candy powder).	**ICA**

Establish the following MLs for sugar-based candies

COMMENT	MEMBER/ OBSERVER
Candy powder: Canada agrees with the proposal that there be a separate ML for candy powder, which may be further dried and its lead content therefore concentrated. While the proposed ML of 0.2 mg/kg (rejection rate of 4.6%) appears to be reasonable, we note that the data for candy powder are lacking in geographic representation (all data were submitted from the U.S. as per Table C1, Annex I) and were only included in the most recent Call for Data. If this proposal is revisited again next year, it may benefit from further discussion and consultation with the eWG on data management. Hard candies, Gummy and jellies: Canada notes the following considerations related to the supporting rationale/data for the proposed MLs of 0.05 and 0.07 mg/kg for hard candies/gummies/jellies and soft candies, respectively. • Canada questions whether the differences in lead concentrations between these types of candies is significant enough to warrant separate MLs and whether a single ML for all candies, with an exclusion for candy powder, should be considered. • The supporting occurrence data in Table C1 of Annex I does not always reflect the hypothetical MLs presented in Table 14 of Appendix II. For example, the hypothetical ML for soft candy of 0.07 mg/kg would correspond to a rejection rate of 2.0%, however, the p95 concentration is reported to be 0.07 mg/kg and would presumably result in a 5% rejection rate. Soft candies: Canada notes the following considerations related to the supporting rationale/data for the proposed MLs of 0.05 and 0.07 mg/kg for hard candies/gummies/jellies and soft candies, respectively. • Canada questions whether the differences in lead concentrations between these types of candies is significant enough to warrant separate MLs and whether a single ML for all candies, with an exclusion for candy powder, should be considered. • The supporting occurrence data in Table C1 of Annex I does not always reflect the hypothetical MLs presented in Table 14 of Appendix II. For example, the hypothetical ML for soft candy of 0.07 mg/kg would correspond to a rejection rate of 2.0%, however, the p95 concentration is reported to be 0.07 mg/kg and would presumably result in a 5% rejection rate.	**Canada**
• Establish the following MLs for sugar-based candies NZ position New Zealand previously noted that the candy powder had limited results (65 observations), and requested for more data, and geographical representation. New Zealand also note that the exposure is based on mean consumption data rather than worst case scenario as for the other food categories. New Zealand does not support the proposed MLs for sugar-based candies	**New Zealand**
Confectionery • *Candy, 0.1 mg/kg; powder candy, 0.2 mg/kg* The United States can support a harmonized ML of 0.1 mg/kg for candy. o The United States does not support a separate ML of 0.2 mg/kg for powder candies. The data in this category were only submitted by the United States.	**USA**

COMMENT	MEMBER/ OBSERVER
ICA recommends that the Committee not establish MLs for finished sugar-based candies – hard candies, gummy and jellies, soft candy, and candy powder. Sugar is the primary ingredient in sugar-based candies. Therefore, with these very high and unacceptable rejection rates at hypothetical lead MLs between 0.05 to 0.09 mg/kg for the sugars going into candies, ICA cannot support the current proposal to set an ML of 0.05 mg/kg for finished-product hard candies, gummies and jellies or an ML of 0.07 mg/kg for soft candies.	**ICA**

Establish the following MLs for food for infants and young children

COMMENT	MEMBER/ OBSERVER
Cereal-based products for infants and young children, expressed "as is": Canada agrees with establishing an ML for cereal-based infant foods on an "as is" basis. However, we would mention the following considerations related to the supporting rationale/data for the proposed ML of 0.05 mg/kg. • There appears to be errors in some of the data that are presented. For example, the sample rejection rates for various hypothetical ML presented in Table 15 are identical (e.g. MLs for cereal-based infant foods containing wheat of 0.1 and 0.05 mg/kg each correspond to sample rejection rate of 1.1%). As well, the supporting occurrence data in Table D1 of Annex I does not always reflect the hypothetical MLs presented in Table 15. For example, the proposed ML for cereal-based infant foods of 0.05 mg/kg (includes all types of infant foods) would correspond to a rejection rate of 1.3%, however, the p95 concentration is reported to be 0.05 mg/kg (same value as proposed ML) and would presumably result in a 5% rejection rate. • This appears to be the first time Canada has seen an approach for establishing a new ML based on specific LOD/LOQ criteria from the Codex Alimentarius Procedural Manual. If there is precedent for using this approach, it would be useful to reference it in the discussion paper. If this proposal is revisited again next year, this approach may benefit from further discussion and consultation with the eWG on data management. Ready-to-eat meals for infants and young children Canada notes the following considerations related to the supporting rationale/data for the proposed ML of 0.05 mg/kg for ready-to-eat infant foods. • This appears to be the first time Canada has seen an approach for establishing a new ML based on specific LOD/LOQ criteria from the Codex Alimentarius Procedural Manual. If there is precedent for using this approach, it would be useful to reference it in the discussion paper. If this proposal is revisited again next year, this approach may benefit from further discussion and consultation with the eWG on data management. • Based on supporting data in Table D1 of Annex I, lower ML values (e.g. 0.03 mg/kg) appear to be achievable, which would be more consistent with an ALARA approach, and may be more appropriate, especially considering that infants and young children are a more sensitive subpopulation. • The supporting occurrence data in Table D1 does not always follow the hypothetical MLs presented in Table 16 of Appendix II. For example, the hypothetical ML for all types of RTE infant foods of 0.03 mg/kg would correspond to a rejection rate of 2.9%, however, the p95 concentration is reported to be 0.03 mg/kg and would presumably result in a 5% rejection rate.	**Canada**
Egypt recommends the following MLs : Food: Cereal-based products for infants and young children, expressed "as is"; Maximum Level (ML) (mg/kg): 0.02	**Egypt**
Food for infants and young children • The United States cannot support the proposed MLs of 0.05 mg/kg lead for cereal-based products and ready-to-eat meals for infants and young children given the significance of lead exposure for infants and young children. • The data for the proposed MLs are from 2008-2019 and do not necessarily reflect current analytical methods that would be used to support the MLs. The EWG may want to consider whether current analytical methods can meet the criteria in the Procedural Manual. • The EWG should clarify the types of foods included in this category: o Does the cereal-based food dataset include both dry cereal and jarred cereal? If so, can these be analyzed separately? o Are ready-to-eat meals limited to jarred foods and purees or do they include a variety of multi-ingredient meals? If so, can they be analyzed separately? This may allow development of lower MLs.	**USA**

COMMENT	MEMBER/ OBSERVER
IACFO opposes the proposed MLs because, based on typical consumption of these products, an ML of 0.05 mg/kg for cereal-based products and ready-to-eat meals for infants and young children is not sufficiently protective of infant and child health. According to reference consumption data used by the US FDA (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=101.12), young children in the US typically consume 110 grams of prepared, ready-to-serve cereals per eating occasion. At the proposed ML of 0.05 mg/kg, a child consuming a single 110 g serving of prepared, ready-to-serve cereals would be exposed to 5.5 micrograms of lead, over 1.8 times higher than the US FDA IRL for children (see prior comment for further details on the US FDA IRLs). Young children in the US typically consume 170 grams of some ready-to-eat food products (i.e., “Dinners, stews or soups for young children, ready-to-serve”) per eating occasion. At the proposed ML of 0.05 mg/kg, a child consuming a single 170 gram serving of these ready-to-eat meals would be exposed to 8.5 micrograms of lead, 2.8 times the US FDA IRL for lead. Thus, children can exceed the US FDA IRL for lead from a single serving of one of these foods at these MLs. Children who consume these foods more frequently (e.g., multiple times per day) or at larger quantities or who are consuming other foods contaminated with lead would face even greater exposures and be at even higher risk for adverse effects from lead. An ML of 0.05 mg/kg is associated with only a 1.3% rejection rate for cereal-based products and only a 1% rejection rate for ready-to-eat meals, leaving plenty of room to increase the ML to approach the 5% rejection rate deemed acceptable. For cereal-based products, an ML between 0.05 mg/kg and 0.04 mg/kg would achieve a 5% rejection rate. For ready-to-eat meals, an ML between 0.03 mg/kg and 0.02 mg/kg would achieve a 5% rejection rate. Exceeding a 5% rejection rate may be warranted for these products, considering the ease with which children can exceed the US FDA IRLs at the proposed MLs. It would be preferable if CCCF set MLs that use the protection of children’s health as the driving factor, not the associated rejection rate.	**IACFO**