

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda item 5

CX/CF 24/17/5-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

Comments at Step 3 in reply to CL 2024/2-CF

submitted by

Canada, Chile, Cuba, Egypt, Iraq, Japan, Panama, Peru, Philippines, Singapore, Türkiye, USA and IFT

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2024/2-CF¹ issued in January 2024. 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 appendix

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**

<p>Canada appreciates and thanks Brazil for all of their hard work on this agenda item over the years.</p> <p>Canada is supportive of the development of MLs for lead in spices and herbs, which is an area of importance in international food safety and trade, and agrees with establishing MLs for the broader food category, as appropriate. Further consideration may want to be given on whether specific exclusions are warranted for scenarios where a notably higher lead contamination profile is observed for a specific spice or herb within the broader category. If sufficient data are available (i.e. adequate number of samples and geographic representation), specific MLs could be considered. If there is not enough data available for ML development, a list of exclusions could be created/maintained and considered by CCCF at a future time. These instances are highlighted in our comments below.</p>	Canada
<p>Chile revisó las recomendaciones de esta carta circular y el documento CX/CF 24/17/5. Al respecto, Chile quisiera emitir los siguientes comentarios:</p> <p>- Chile apoya los niveles máximos propuestos para Plomo en especias ya que están de acuerdo con la aplicación del principio ALARA y de acuerdo con la tasa de rechazo máxima aplicada (5%) para no ser un obstáculo al comercio. Específicamente para la categoría especias, semillas secas, y considerando que la tasa de rechazo utilizada para establecer el nivel máximo propuesto de 0,8 mg/kg es prácticamente del 5%, Chile quisiera sugerir establecer un nivel máximo de 0,9 mg/kg.</p> <p>- Respecto de los niveles máximos sugeridos para hierbas culinarias, Chile aprueba ambos niveles propuestos, considerando los mismos argumentos expuestos para especias.</p>	Chile
<p>Cuba agradece la oportunidad de responder a la carta circular CL 2024/02-CF y en principio apoya los niveles máximos de plomo considerados en el documento.</p>	Cuba
<p>Egypt appreciates the work and efforts done by the EWG in drafting of this circulated document; and in this regard, Egypt adopts the following limits:</p> <ul style="list-style-type: none"> - For Spices, dried bark 2 mg/kg - For Spices, dried floral parts 1 mg/kg - For Spices, dried rhizomes, bulbs and rootse 1.5 mg/kg 	Egypt
<p>Agree</p>	Iraq
<p>Panama agrees with the document presented, and appreciates the efforts of the countries for providing relevant data to strengthen Codex regulations. We agree with the advancement of the document to the next stages.</p> <p>Panamá está de acuerdo con el documento presentado, y agradece el esfuerzo de los países por aportar datos relevante para fortalecer las normativas del Codex. Estamos de acuerdo con el avance del documento a las siguientes etapas.</p>	Panama
<p>Singapore notes that all of the MLs proposed are health-protective against levels of lead that would cause acute lead poisoning. However, we are concerned that the large number of categories proposed for dried spices, each having a different ML, could be challenging to implement for the following reasons:</p> <ul style="list-style-type: none"> • Prevalence of products consisting of a mixture of dried spices from multiple categories being traded and sold. • Difficulty distinguishing and separating spice parts especially if the spice is the ground, powder or crushed form. 	Singapore

<p>For these reasons, Singapore would like to propose for harmonised MLs for dried spices in line with the approach for dried and fresh culinary herbs i.e. to have a single category and ML for dried spices.</p> <p>Considering that lead is ubiquitous in the food supply, dried spices contribute minimally to the total dietary exposures to lead due to their relatively low consumption by weight. Hence, some flexibility on the 5% rejection rate guideline can be tolerated in lieu of a harmonised, enforceable ML for dried spices. This ensures that the ML can be implemented reasonably and remains aligned with the principle of ALARA.</p>	
<p>The IFT welcomes science-based standards for chemical contaminants in food that protect human health from dietary exposure based on sound scientific risk assessment and that are reasonably achievable globally based on occurrence data and following established and realistic best production practices.</p> <p>For lead in spices, based on the available data shared, overall we support the science basis of the proposed MLs. We also support the CCCF approach to establishing differing maximum levels based on spice type and portion of the plant, where MLs are considered to be achievable. However, IFT questions why the CCCF proposed MLs exceed the established EU MLs, which have been generally embraced by industry as reasonably achievable following the ALARA principle. Alignment of the CCCF proposals with existing EU lead MLs in spices appears reasonable and practical to apply globally. For seed spices, the proposed Codex ML is lower than the current EU ML (0.8 ppm vs 0.9 ppm), while the ML for dried flower spices and dried aril spices are lower than the EU ML of 1 ppm for bud and flower pistil spices. The EU MLs cover risk concerns and are achievable. IFT supports aligning the Codex MLs with those of the EU, to help facilitate global harmonization, trade, and simplicity in execution.</p>	<p>IFT</p>

SPECIFIC COMMENTS

<p>SPICES - Consider the following MLs for spices</p>	
<p>While Japan agrees with the proposed draft MLs for spices, Japan can support slightly higher MLs for the following reasons:</p> <ul style="list-style-type: none"> •although the rejection rates of proposed draft MLs are consistent with a range of rejection rates less than 5% accepted by CCCF, some of them are very close to 5%. •For some individual commodities, rejection rates of the proposed MLs will exceed 5% (e.g., dried star anise, dried ginger, dried celery seeds, etc.). •Given that consumption volume of spices is small, enforcing the MLs would not contribute much to reduction of total lead exposure. Nevertheless, there are significant intake reductions even at slightly higher MLs than the proposed draft MLs. <p>Based on the data and information from Appendices II and III of CX/CF 24/17/5, the following alternative MLs are proposed.</p> <p>For spice, dried bark, CCCF may consider an ML of 3 mg/kg with 4.2% sample rejection and 25.3% intake reduction.</p> <p>For spice, dried floral parts, CCCF may consider an ML of 3 mg/kg with 2.8% sample rejection and 31.8% intake reduction.</p> <p>For spice, dried flowers, CCCF may consider an ML of 0.5 mg/kg with 1.6% sample rejection and 18.1% intake reduction.</p>	<p>Japan</p>

<p>For spice, dried fruits and berries, we propose excluding star anise, as well as Sichuan pepper, from the proposed ML of 0.6 mg/kg, since contamination patterns of lead in these two commodities are significantly different from other dried fruits and berries according to Table A in Appendix III.</p> <p>For spice, dried star anise, we propose an ML of 3 mg/kg or higher as 95th percentile value of lead concentration for this commodity is 3.23 mg/kg.</p> <p>For spice, dried rhizomes, bulbs and roots excluding galangal and garlic, we propose an ML of 2.5 mg/kg with 2.7 % sample rejection and 62.5 % intake reduction considering occurrence data of dried ginger. Enforcing an ML of 2.0 mg/kg for dried ginger would result in the sample rejection of 11.7%, which is higher than the cut-off level of 5%.</p> <p>For spices, dried seeds, CCCF may consider an ML of 1 mg/kg with 2.7 % sample rejection and 22.1 % intake reduction.</p> <p>These MLs would be protective of consumer’s health while ensuring a minimum negative impact on trade.</p>	
<p>On the proposed ML for lead in the following Spices and Culinary herbs:</p> <p>Spices: dried bark (2.5 mg/kg) dried flowers (0.4 mg/kg) dried floral parts (2.5 mg/kg) dried fruits and berries (0.6 mg/kg) sichuan pepper (3.0 mg/kg) dried rhizomes, bulbs and roots (2.0 mg/kg) dried seeds (0.8 mg/kg) dried aril (0.9 mg/kg)</p> <p>Culinary herbs: fresh (0.2 mg/kg) dried (2.5 mg/kg)</p> <p>The Philippines finds the proposed ML as acceptable in providing an appropriate level of consumer protection based on highly conservative assumptions in estimating the Margin of Exposure (MOE) of lead from spices and culinary herbs consumption in the Philippines.</p> <p>Rationale:</p> <p>Dietary exposure to lead from spices and culinary herbs consumption was assessed based on the mean body weights of the different population groups, mean “condiments & spices” consumption of 1-2 g/day, and the proposed ML. The conservative risk estimate using the MOE approach was computed to be ≥ 10 across all population groups, which is interpreted as “no appreciable risk of a clinically significant effect on Systolic Blood Pressure (SBP) and Intelligence Quotient (IQ)”.</p>	<p>Philippines</p>

<p>As a general comment, the Committee should consider how to address ground spice mixtures.</p> <p>Dried spices:</p> <p>Spices, dried bark, 2.5 mg/kg. The United States does not support the proposed ML of 2.5 mg/kg for “spices, dried bark.” Cinnamon is used heavily in children’s foods, so a lower ML would be appropriate.</p> <p>Spices, dried flowers (chamomile), 0.4 mg/kg. The United States does not support establishing an ML for chamomile flowers as “spice, dried flowers,” given its primary use in preparing herbal tea (infusions). In 2021, CCCF14 agreed not to set MLs for herbal teas specific for infants and young children. It is also not clear if “spices, dried flowers” is distinct from “spices, dried floral parts” per the Codex Committee on Spices and Culinary Herbs (CCSCH).</p> <p>Spices, dried floral parts, 2.5 mg/kg. The United States can support an ML of 2.0-2.5 mg/kg for “spices, floral parts.”</p> <p>Spices, dried fruits and berries, 0.6 mg/kg. The United States can support an ML of 0.6 mg/kg for “spices, dried fruits and berries.”</p> <p>Sichuan pepper, 3.0 mg/kg. The United States does not support establishing an ML for “Sichuan pepper” as the data are only from one country.</p> <p>Spices, dried rhizomes, bulbs, and roots, 2.0 mg/kg. The United States can support an ML of 1.5-2.0 mg/kg for “spices, dried rhizomes, bulbs, and roots.”</p> <p>Spices, dried seeds, 0.8 mg/kg. The United States can support an ML of 0.8-0.9 mg/kg for “spices, dried seeds.”</p> <p>Spices, dried aril, 0.9 mg/kg. The United States can support an ML of 0.9 mg/kg for “spices, dried aril.”</p> <p>Culinary herbs:</p> <p>Fresh culinary herbs, 0.2 mg/kg. The United States does not support adoption of the proposed ML for fresh culinary herbs, which appears to be above the 97.5th percentile (0.15 mg/kg) and based on data on fresh herbs from a limited number of countries. Based on the range of lead levels reported in Table B (Appendix III of CX/CF 24/17/5), further review of this category may be needed to determine if a lower ML or several different MLs would be appropriate.</p> <p>Dried culinary herbs, 2.5 mg/kg. The United States can support an ML of 2.0-2.5 mg/kg for dried culinary herbs.</p>	<p>USA</p>
<p>Spices, dried bark Canada supports an ML of 2.5 mg/kg lead in bark spice, which would reflect a sample rejection rate of 4.2% and a reduction of lead exposure. The ML would also be readily achievable for product sold in Canada.</p> <p>Spices, dried floral parts An ML of 2.5 mg/kg in floral parts is readily achievable for product sold in Canada. However, there is a notable difference in the lead profile of cloves relative to the other types of spice in the dried floral parts general category based on data presented in Table A of Appendix III. The working group may want to consider whether an exclusion and ML specific to cloves should be established. It is noted that there appears to be limited available samples for other types of spice in this general</p>	<p>Canada</p>

category, i.e. saffron (n=15) and capers (n=3). Therefore, there may not be a sufficient number of samples remaining in the dried floral parts category if an exclusion/ML specific to cloves is made.

Spices, dried rhizomes, bulbs and roots

Canada agrees with the exclusions noted for galangal and garlic. Canada would have no objections to the proposed ML of 2.0 mg/kg lead in dried rhizomes, bulbs and roots (excluding galangal and garlic) as it is readily achievable for product sold in Canada and would result in a reduction of lead exposure. However, there appear to be two different datasets being considered for the ML proposed for this general category and an ML of 2.0 mg/kg may not be feasible for ginger using the dataset based on only “dried” samples (rejection rate of 11.7%).

Spices, dried seeds

An ML of 0.8 mg/kg in seed spice is readily achievable for product sold in Canada. However, Canada questions whether an exclusion should be considered for celery seed. Table A in Appendix III reports a p95 concentration of 1.47 mg/kg lead, which is well above the proposed ML of 0.8 mg/kg. Based on the international dataset, there appears to be sufficient data to develop a separate ML for celery seed (n=60), although geographic representation of this data is not known and could be clarified by the working group.

Spices, dried aril

Canada supports an ML of 0.9 mg/kg in aril spice, which would reflect a sample rejection rate of 3.1% and a reduction of lead exposure. The ML would also be readily achievable for product sold in Canada.

Spices, Sichuan pepper

Canada agrees that an exclusion for Sichuan pepper may be appropriate given the higher lead concentrations observed for this specific spice (p95 concentration of 2.80 mg/kg) relative to most other spices in the broader fruit and berry spice category. Based on the international dataset, there is a sufficient number of samples to develop a separate ML for Sichuan pepper (n=825) and a ML of 3.0 mg/kg appears to be achievable. However, para. 26 of CX/CF 24/17/5 notes that these data are from a single country and Canada agrees that further discussion is needed on whether setting an ML would be appropriate in this instance. Canada further asks that it be clarified by the working group whether these data are from a main producing country. If it is decided to exclude Sichuan pepper but not develop an ML, this specific spice could be added to a list of exclusions where data are lacking and could be considered by CCCF at a future time.

Spices, Sichuan pepper

If an ML is agreed upon for Sichuan pepper, suggest consistency across the commodity/product name for spices and “Sichuan pepper” be renamed to “Spices, dried Sichuan pepper.”

Spices, dried fruits and berries

An ML of 0.6 mg/kg lead in fruit and berry spices is readily achievable for similar products sold in Canada. However, while Canada agrees that an exclusion for Sichuan pepper may be appropriate given the higher lead concentrations observed for this specific spice (p95 concentration of 2.80 mg/kg), this also appears to be the case for star anise (p95 concentration of 3.23 mg/kg). As well, the proposed ML of 0.6 mg/kg may not be achievable for paprika (p95 concentration of 0.73 mg/kg for “dried” results only) and sumac (p95 concentration of 0.80 mg/kg) based on their slightly higher reported p95 concentrations. Consideration could be given to establishing a slightly higher ML of 0.8 mg/kg for fruit and berry spices, which may address potential achievability concerns for paprika and sumac, and listing exclusions for star anise in addition to Sichuan pepper. Based on the international dataset, there appears to be sufficient data to develop a separate ML for star anise (n=68), although geographic representation of this data is not known and could be clarified by the working group.

<p>Spices, dried flowers</p> <p>It is noted that all supporting data for the dried flower spice category are specific to chamomile. Canada questions whether the data submitted to the GEMS/Food Database for chamomile under the “herbs, spices and condiment” food code were appropriately categorized and are instead considered herbal infusions/tea. We suggest verifying this with the member countries that submitted the samples (n=126).</p> <p>In Canada, we are only aware of the use of chamomile as a herbal infusion/tea. We ask if the working group can clarify whether they are aware of potential uses of chamomile as a spice. Please note that CCCF13 agreed to focus new lead MLs on specific foods, including spices and herbs, and that herbal infusions/teas were scoped out of this work (para. 92 of REP19/CF).</p>	
<p>Espicias, corteza seca^a</p> <p>Considerar sólo las especias especifica: Canela, casia.º</p> <p>Espicias, partes florales secas^c</p> <p>Considerar sólo las especias especifica: Flor de manzanilla.</p> <p>Espicias, partes florales secas^c</p> <p>La norma del Codex para productos pertinente es la CXS 344-2021.</p> <p>Considerar sólo las especias especifica: Azafrán, clavos de olor, alcaparras.</p> <p>Espicias, frutas y bayas secas^d</p> <p>El NM no se aplica a la pimienta de Sichuan.</p> <p>Considerar sólo las especias especifica: Anís estrellado, cardamomo, cayena, pimienta negra, pimienta verde, pimienta blanca, pimienta rosa, pimienta roja, pimentón dulce, chile, pimienta de Jamaica, tamarindo, zumaque, vainilla.</p> <p>Espicias, rizomas, bulbos y raíces secos^e</p> <p>La norma del Codex para productos pertinente es la CXS 343-2021.</p> <p>Considerar sólo las especias especifica: Jengibre, cúrcuma.</p> <p>Espicias, semillas secas^f</p> <p>Las normas del Codex para productos pertinentes son la CXS 327-2017 y la CXS 352-2022.</p> <p>Considerar sólo las especias especifica: Semillas de Anís, semillas de Coriandro, semillas de Comino, semillas de Eneldo, semillas de Fenogreco, semillas de Hinojo, mostaza, nuez moscada.</p> <p>Espicias, arilo seco^g</p> <p>Considerar sólo las especias especifica: Macis.</p>	Peru

<p>a: Cinnamon, canella, cassia.</p> <p>1- Dried Fruits and Berries For Sichuan peper, a different maximum limit is determined from the dried fruit and berries category, taking into account P95 (Appendix III, Table A). P95 levels for star anise, sumac and paprika (dried) in this category are 3.23, 0.80 and 0.73, respectively. Recommends: Maximum level is 3.0 for sichuan peper and star anise Maximum Level is 0.8 for sumac and paprika (dried)</p> <p>2- Dried seeds The P95 level (Appendix III, Table A) for Celery seeds is 1.47. Recommends: Maximum level is 0.9 for dried seeds</p>	Türkiye
<p>g: Mace.</p> <p>Comments specific to document CX/CF 24/17/5, Appendix I, para 1.1 (page 5) Singapore would also like to suggest clarification that the spices listed in the footnotes are examples of dried spices and the ML applies to the entire category dried spices.</p>	Singapore
<p>Evaluate if the MLs should consider the whole category or only the specific spices for which there are data available on GEMS/Food database be considered.</p> <p>2.1 Consider the following MLs for culinary herbs</p>	
<p>Canada supports establishing MLs for the broader food category and listing specific exclusions where warranted, e.g. a notably higher lead contamination profile is observed for a specific spice or herb within the broader category.</p> <p>For the exclusions, if there is sufficient supporting data available (i.e. adequate number of samples and geographic representation), consideration could be given to establishing specific MLs for these instances. If there is not enough data available for ML development, a list of exclusions could be created/maintained and considered by CCCF at a future time.</p> <p>Fresh culinary herbs Canada agrees with grouping culinary herbs under a single ML and supports an ML of 0.2 mg/kg in fresh culinary herbs, which would reflect a sample rejection rate of 2.2% and a reduction of lead exposure. The ML would also be readily achievable for similar products sold in Canada.</p> <p>Dried culinary herbs Canada agrees it would be simpler to group culinary herbs under a single ML and notes that a ML of 2.5 mg/kg in dried culinary herbs is readily achievable for similar products sold in Canada. However, Canada questions whether an exclusion should be considered for dried bay leaf. Table A in Appendix III reports a p95 concentration of 7.01 mg/kg lead, which is well above the proposed ML of 2.5 mg/kg. Based on the international dataset, there does not appear to be sufficient data to develop a separate ML specific to dried bay leaf (n=8) and this herb could be added to a possible list of exclusions for future consideration by CCCF.</p>	Canada
<p>Japan supports the proposed draft ML for culinary herbs in dried form for the following reasons:</p> <ul style="list-style-type: none"> the rejection rates of proposed MLs are consistent with a range of rejection rates of less than 5% (generally 2-3%) accepted by CCCF. enforcing these MLs would give significant intake reduction. 	Japan

<p>Japan supports the establishment of a separate ML for culinary herbs for fresh form different from leafy vegetables, if they are traded internationally.</p> <p>Japan prefers to establish MLs for the whole category for the following reasons:</p> <ul style="list-style-type: none"> • Contamination pattern of lead in plant generally varies depending on their part and shape. GSCTFF stipulates that “MLs may be set for product groups when sufficient information is available about the contamination pattern for the whole group, or when there are other arguments that extrapolation is appropriate.” • If a specific commodity shows different distribution pattern from other individual commodities in the group, the commodity can be excluded from the group ML. • In light of the availability of occurrence data, establishing MLs for each of minor spices are not cost-effective. <p>For better understanding and clarity of what commodities are included in each category, Japan supports listing spice names (in the bullet a – g) as examples in the Notes/Remarks of corresponding subcategory. Relevant Codex commodity standards also should be kept in Notes/Remarks.</p>	
<p>Hierbas culinarias frescas</p> <p>Ninguno</p> <p>Hierbas culinarias secas</p> <p>Las normas del Codex para productos pertinentes son la CXS 328-2017, la CXS 342-2021 y la CXS 345-2021.</p> <p>Ninguno</p>	Peru
<p>We recommend that the maximum level be determined in dry matter and that the maximum limit be set as 2.5 mg/kg in a single line for fresh and dried culinary herbs.</p>	Türkiye