

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 19

CX/CF 22/15/18

April 2022

ORIGINAL LANGUAGE ONLY

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

**15<sup>th</sup> Session**

**Virtual**

**9-13 and 24 May 2022**

**FOLLOW-UP WORK TO THE OUTCOMES OF JECFA EVALUATIONS  
AND**

**FAO/WHO EXPERT CONSULTATIONS**

**Comments in reply to CL 2021/89-CF**

*Comments of Canada, Chile, Cuba, Egypt, Kenya, Peru, Uganda, United States of America (USA)*

**Background**

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/89-CF<sup>1</sup> issued in December 2021. 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 attached in the **Annex** and are presented in table format.

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<sup>1</sup> Codex circular letter, including CL 2021/89-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>

## GENERAL COMMENTS

COMMENT	MEMBER / OBSERVER
<ul style="list-style-type: none"> <li>• <b>Ciguatera toxins</b>  <u>Substantive</u>: Ciguatera poisonings in Canada are limited to date. However, Canada recognizes the potential for ciguatera toxin prevalence to expand north due to global warming. Canadian researchers have been working with international colleagues to accurately analyze ciguateras in suspect algae and fish samples. As research both in Canada and internationally is expected to be on-going and is challenged by a lack of analytical standards, reference material and internationally validated methods, Canada supports ongoing risk management that uses, and builds on, that which is already established (e.g. IAEA and IOC-Unesco e learning course on monitoring and preventing ciguatera poisoning) and the establishment clear protocols that minimize the risk of consuming potentially impacted seafoods.</li> <li>• <b>Tropane alkaloids ((-) scopolamine and (±) hyoscyamine)</b>  <u>Substantive</u>: Additional follow-up actions relating to the tropane alkaloids (-) scopolamine and (±) hyoscyamine may not be required as practical guidance has been developed and made publically available in order to protect cereals and grains destined for human consumption.</li> <li>• <b>Pyrrrolizidine alkaloids</b>  <u>Technical</u>: CCCF14 (2021) agreed to establish an EWG chaired by European Union to prepare a discussion paper on pyrrolizidine alkaloids to look into the feasibility of possible follow-up actions for consideration by CCCF15 (REP 21/CF, para. 235). Canada is awaiting this discussion paper, which has not been shared with the EWG as of mid-March, 2022. Once reviewing this discussion paper, Canada will provide comments on possible follow-up actions to the outcomes of the JECFA evaluation on pyrrolizidine alkaloids.</li> <li>• <b>Ergot alkaloids &amp; trichothecenes</b>  <u>Technical</u>: CL 2021/89-CF requests comments on possible follow-up actions to the outcomes of the JECFA evaluations and FAO/WHO expert consultations in particular those for which the full report is already available. As the full JECFA 90 (2020) report is not yet available, which includes JECFA's latest assessments of ergot alkaloids or the trichothecenes T-2 and HT-2, Canada will provide comments once the full JECFA 90 report is available.</li> </ul>	Canada
<p>Al respecto de presentar observaciones sobre posibles medidas de seguimiento respecto a los resultados de las evaluaciones del JECFA y las consultas de expertos FAO/OMS, y establecer un orden de prioridad de los trabajos sobre estos temas, y tomando en cuenta los Criterios para el establecimiento de prioridades en los trabajos, así como las secciones pertinentes de los Principios del análisis de riesgos aplicados por el CCCF que figuran en el Manual de procedimiento, las secciones pertinentes del Preámbulo de la Norma general para los contaminantes en alimentos y piensos (CXS 193-1995) y el Plan estratégico del Codex para 2020-2025, para proponer un orden de prioridad, Chile quisiera comentar lo siguiente:</p> <p><b>Alcaloides tropánicos</b></p> <p>Tomando en cuenta que, el reporte de la reunión de expertos FAO/OMS sobre alcaloides tropánicos, de abril del 2020, indica que está disponible un método analítico validado que utiliza cromatografía líquida acoplada a espectrometría de masas en tándem (LC-MS/MS) para la determinación de la suma de (-)-hiosciamina y (+)-hiosciamina, y escopolamina en alimentos a base de cereales; y a la vez propone límites operacionales para los alimentos entregados por el programa mundial de alimentos (WFP) basándose en la ingesta recomendada de estos productos por el programa, y relevando la importancia de estos alimentos para resguardar la seguridad alimentaria en varios países del mundo, es que Chile considera que, se le debería dar prioridad a este trabajo en primer lugar.</p>	Chile

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<p><b>Ciguatera</b></p> <p>Respecto al Reporte de la reunión de expertos sobre intoxicación por ciguatera, de noviembre del 2018, este indica que, debido a las brechas de datos existentes, no fue posible realizar una evaluación de riesgos completa; y que, además, en cuanto a la determinación analítica de CTX, la Reunión de Expertos identificó los siguientes limitaciones principales: (i) no existe un estándar CTX certificado; (ii) no hay material de referencia; (iii) no existe un protocolo químico de referencia para la extracción de CTX en una matriz biológica validada internacionalmente; y (iv) no existe validación de ningún tipo para los métodos de ensayo, ya sea LC-MS/MS, screening o bioensayos; sumado a lo anterior, el reporte indica que, hay pruebas de que la extracción de las vísceras, el hígado y la cabeza del pescado antes del consumo reduce el riesgo de intoxicación por ciguatera, por lo que Chile considera que lo más adecuado sería para este caso, trabajar en la elaboración de una posible guía que incluya evitar órganos viscerales, huevas (huevas de pescado) y canales (por ejemplo, cabezas de pescado, ojos y huesos), ya que estos tejidos pueden contener altos niveles de CTX y otros compuestos bioactivos, puesto que no es posible establecer niveles máximos por el problema analítico que para estas toxinas se da actualmente, y por lo tanto, este tema debería ser abordado posterior a los alcaloides tropánicos.</p> <p><b>Alcaloides del cornezuelo</b></p> <p>Respecto de los alcaloides del cornezuelo, el reporte de la 91 reunión del JECFA indica en su anexo 2, que se deben reunir datos adicionales para poder continuar con la evaluación de riesgo, por lo que Chile considera que, este tema debería ser abordado posterior al término del trabajo de los expertos.</p>	
<p>Cuba apoya las propuestas que se establezcan con respecto a las prioridades de contaminantes de la lista de Evaluaciones del JECFA y reuniones de expertos de la FAO/OMS según se presenta en el documento de anexo de la carta circular.</p>	<b>Cuba</b>
<p>Prioritize the items:</p> <p>1- Ergot alkaloids (JECFA91, 2021) Recommendations: <u>Rational:</u></p> <ul style="list-style-type: none"> <li>- There is a huge difference when we are talking about therapeutic dose for any substance with high potency and the same item with a maximum limit as a contaminant in food .</li> <li>- Additional data on the occurrence of EAs in wheat and wheat-based products and in rye and rye products from WHO regions and clusters.</li> </ul> <p>2- Pyrrolizidine alkaloids 3- Marine biotoxins – Ciguatoxins 4- Tropane alkaloids</p> <p><u>Tropane Alkaloids (Atropine)</u></p> <p>Atropine is one of the substances belonging to the group of Tropane Alkaloids, which are naturally occurring substances in some plant families such as the seeds of the Datura Stramonium plant, which can be present as impurities in many seeds and grains, which are difficult to remove and purify contaminated grains and seeds.</p> <p>Due to that Egypt is one of the largest importers of wheat, corn and soybeans, and due to the increase in consumption rates of these crops, there is a possibility of food contamination due to the risks of these contaminants in the absence of limits to these components.</p>	<b>Egypt</b>

COMMENT	MEMBER / OBSERVER
<p>A Joint FAO/WHO Expert Meeting was convened virtually on 30 March–3 April 2020 to provide risk assessments for tropane alkaloids, hyoscyamine and scopolamine. These occur in several plants that can contaminate staples like cereals and grains through the presence of toxic <i>Datura stramonium</i> seeds. Food aid contaminated with tropane alkaloids was determined to be the cause of food poisoning outbreaks in the Republic of Uganda and the Republic of South Sudan in 2019. These events affected more than 300 people and even resulted in deaths (<a href="https://www.fao.org/3/cb1857en/CB1857EN.pdf">https://www.fao.org/3/cb1857en/CB1857EN.pdf</a>).</p> <p>There are currently no international regulations in place for tropane alkaloids. With global distribution of food aid increasing over the years, the issue of tropane alkaloids is of significant concern to the United Nations World Food Programme (WFP).</p> <p>The publication, Joint FAO/WHO Expert Meeting on Tropane Alkaloids, captures the discussions of the Joint FAO/WHO Expert Meeting. It lays out the risk assessments for the tropane alkaloids as well as provides guidance for the development of operational limits of the combined sum of hyoscyamine and scopolamine in products distributed by WFP.</p> <p>In order to develop appropriate risk management measures in the WFP supply chains, it was recognized that limits expressed as physical toxic <i>D. stramonium</i> seed contamination of cereals and grains will be beneficial for screening purposes at the field level.</p> <p>To address this, an FAO/WHO guidance document on physical <i>Datura stramonium</i> seed contamination was developed and published. See below link: Guidance document on physical <i>Datura stramonium</i> seed contamination (<a href="https://www.fao.org/publications/card/en/c/CB2105EN/">https://www.fao.org/publications/card/en/c/CB2105EN/</a>).</p> <p>Moreover; by reviewing previous notifications on the EU-RASFF Portal, it was found that there are a number of notification and rejection cases of food shipments as a result of contamination with atropine and scopolamine, including shipments of food and spices originating from several European countries, namely Slovenia - Czech Republic - Hungary - Slovakia - Austria - Germany - Spain - France - Britain - Bulgaria - Poland - Croatia - Albania.</p> <p>Food items that have been proven to be contaminated with this substance are “flour - corn - pastries - corn flour - popcorn - sorghum Millet - honey poppies - baby food - cumin seeds - dried herbs - herbal tea”.</p> <p>The European Commission has issued Recommendation No. 976/2015 regarding the control of Tropane Alkaloids in foods, including Atropine &amp; Scopolamine. It was based on the study carried out by the European Food Safety Authority EFSA, which determined the appropriate methods of analysis for these substances and the limits of their laboratory estimation, which range from 2 - 10 µg/kg, with the recommendation to reduce the limits of assessment for some items used in baby food to 1 µg/kg, in addition to an ARfD of 0.016 µg/kg body weight.</p> <p>See below link: <a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5160">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5160</a></p> <p>The European Commission has issued maximum limits for atropine and scopolamine pursuant to Commission Regulation 2016/239.</p> <p>A study was also conducted by the German Institute for the Study of Risks BfR, which included the risks of eating food contaminated with atropine, as study have proven that these substances have a severe toxic effect in addition to their effects on heart patients.</p>	
<p><u>General comment</u></p> <p>Kenya has no data implicating the occurrence and magnitude of marine bio toxins- ciguatoxin, tropane alkaloids, ergot alkaloids and pyrrolizidine alkaloids.</p>	Kenya
<p>De acuerdo al anexo de la CL, el Perú se acoge a la orden de prioridad propuesta por la Secretaría.</p>	Peru

COMMENT	MEMBER / OBSERVER
<p>Uganda proposes to prioritize the items as below, this is mainly based on criteria for the Establishment of Work Priorities as well as the relevant sections of the Risk Analysis Principles applied by CCCF.</p> <p>1.2 Tropane alkaloids  2.2 Pyrrolizidine alkaloids  2.1 Ergot alkaloids  1.1 Marine biotoxins – Ciguatoxins</p> <p><u>Justification:</u></p> <p>Uganda considers reports on early exposure of its people in Karamajo to the toxicological effects due to consuming super cereals contaminated with Tropane alkaloids, thus this should be first priority for country.</p> <p>Uganda proposes pyrrolizidine alkaloids as second priority because of its availability in many plant species in Uganda for example tea.</p>	<p><b>Uganda</b></p>
<p>The United States suggests the following prioritization ranking of the items referenced in CL 2021/89-CF.</p> <ul style="list-style-type: none"> <li>• Progress on or completion of current agenda items, including possible new work on pyrrolizidine alkaloids (as referenced in CL 2021/89-CF).</li> <li>• As resources permit and depending on interest, a ciguatoxins Code of Practice</li> <li>• Tropane alkaloids and ergot alkaloids</li> </ul>	<p><b>USA</b></p>