

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 9

CX/PR 23/54/11-Add.1

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

54th Session

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26 June - 1 July 2023

MANAGEMENT OF UNSUPPORTED COMPOUNDS

WITHOUT PUBLIC HEALTH CONCERN SCHEDULED FOR PERIODIC REVIEW

Comments in reply to CL 2023/37-PR

*Comments of Brazil, Canada, Chile, Egypt, European Union (EU), Iraq, Peru,
Uruguay, United States of America (USA)*

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2023/37-PR¹ issued in April 2023. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby annexed and are presented in tabulated format. Specific comments are divided in those related to Sections 1 and 2 of Appendix I to CX/PR 22/53/11.

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=CCPR>

GENERAL COMMENTS

COMMENT	MEMBER/OBSERVER
<p>Brazil agrees with the following recommendations:</p> <p>(i) The proposal for the management of unsupported compounds without public health concern scheduled for periodic review described as presented in Section 1 of Appendix I, and, if agreeable, to consider its adoption by CCPR54 (2023).</p> <p>(ii) The different options for data support that could be addressed by Codex, FAO/WHO, JMPR, governments, and industry to further assist countries in implementing the proposed management approach as presented in Section 2 of Appendix I, and, if necessary, provide comments to further enhance the options given in the paper or additional options as appropriate.</p> <p><u>However regarding the recommendation (i) CRITERIA FOR PERIODIC REVIEWS - CCPR should extend the period of periodic review in the Codex Procedural Manual for 25 years, especially for the non-toxic pesticides and compounds without public health concern, if the GAP remains unchanged the Codex MRLs should be retained.</u></p>	Brazil
<p>BACKGROUND</p> <p>CCPR53 agreed to re-establish an EWG on unsupported compounds without public health concern scheduled for periodic review chaired by Chile and co-chaired by Australia, India, and Kenya, working in English with the following ToRs:</p> <p>(i) To further develop and refine the management proposal for unsupported compounds without public health concerns scheduled for periodic review presented in the Section 1 of Appendix I of CRD09.</p> <p>(ii) To further develop the recommendations of Section 2 of Appendix I of CRD09, to explore further options for efficient data support that could be addressed by Codex, FAO/WHO, JMPR, governments and the industry to assist countries in the preparation of data packages required to conduct periodic reviews.</p> <p>(iii) That proposals should take into consideration the information presented in CX/PR 22/53/13, CRD09 and the written comments submitted and those received during the plenary meeting.</p> <p>(iv) Based on the above considerations, to present a management proposal for consideration and adoption by CCPR54.</p>	Canada
<p><u>Sección 1. Enfoque para la gestión de los compuestos no apoyados que no plantean preocupaciones en materia de salud pública calendarizados para la revisión periódica</u></p> <p>Chile considera que luego del intenso trabajo realizado durante 5 años, desde el 2018, para perfeccionar la propuesta de gestión, el enfoque presentado está listo para ser adoptado por el CCPR en su 54.a reunión.</p> <p><u>Sección 2. Opciones para un apoyo en materia de datos eficiente que podría ser abordado por el Codex, la FAO/OMS, la JMPR, los gobiernos y la industria para seguir asistiendo a los países en implementar el enfoque de gestión propuesto</u></p> <p>Chile considera que las distintas opciones que se proponen están completas para ser consideradas para apoyar el enfoque de gestión propuesto y junto con este, debieran ser finalizado en la 54.a reunión del CCPR.</p>	Chile
Egypt appreciates the work done in the document & agrees on it	Egypt

COMMENT	MEMBER/OBSERVER
<p>The European Union (EU) would like to thank the Electronic Working Group (eWG) on management of unsupported compounds without public health concerns scheduled for periodic review by JMPR chaired by Chile and co-chaired by Australia, India and Kenya for the preparation on the recommendations for the management of unsupported compounds without public health concern scheduled for periodic review.</p> <p><u>General comments on the readiness of the approach to be adopted by CCPR54 and specific comments on possible improvements to the existing provisions or additional provisions, as necessary, for completeness, in order to finalize the approach at CCPR54</u></p> <p>The EU in general supports the approach proposed in this section.</p> <p><u>General comments on the various options available to the different stakeholders to implement the approach and specific comments on existing or possible additional provisions as necessary, for completeness, in order to finalize the options at CCPR54</u></p> <p>The EU supports the collaboration activities suggested.</p>	EU
<p>Agree with regards.</p>	Iraq
<p>Solicitud de observaciones sobre las recomendaciones para la gestión de los compuestos no apoyados que no plantean preocupaciones en materia de salud pública calendarizados para la revisión periódica.</p> <p>Considerando que los miembros del Codex y observadores que participan en el CCPR pueden colaborar eficientemente con otros miembros que en la actualidad carecen de la capacidad para apoyar independientemente usos/compuestos importantes para sus sistemas de producción.</p> <p>Sin embargo, necesitamos grandes esfuerzos para tener las condiciones de generar los datos, a saber: definir el alcance del problema con respecto al número de LMR, identificar a los miembros y observadores que les interesan compuestos específicos, y describir los datos que se requieren para que la JMPR lleve a cabo la revisión periódica.</p> <p>Para llevar a cabo lo anterior, es esencial dar prioridad a los distintos casos con el fin de asegurar que la colaboración se lleva a cabo eficientemente. La información sobre el sistema del Codex y el proceso de revisión periódica de la JMPR, la generación del conjunto de datos y el expediente deben transferirse a los fabricantes genéricos y a los miembros y observadores que tienen productos no apoyados. Esta debía ser una de las funciones del GTE sobre compuestos no apoyados.</p> <p>En este sentido el comité nacional considera que la mejor opción es que las diferentes opciones de apoyo en materia de datos que podrían ser abordadas por el Codex, la FAO/OMS, la JMPR, los gobiernos y la industria para ayudar más a los países a implementar el enfoque de gestión propuesto que se presenta en la Sección 2 del Apéndice I.</p>	Peru
<p>Agradecemos la oportunidad de enviar nuestros comentarios.</p>	Uruguay
<p><u>General comments on the readiness of the approach to be adopted by CCPR54 and specific comments on possible improvements to the existing provisions or additional provisions, as necessary, for completeness, in order to finalize the approach at CCPR54</u></p> <p>The United States would like to highlight the importance of developing a flexible management approach and makes note of previous discussions at the Codex Committee on Pesticide Residues (CCPR) “to develop a clear process for managing unsupported compounds and determining when Codex Maximum Residue Limits (CXLs) are retained, and that selecting a management option would require balancing the need for a robust listing of CXLs that supported international trade while ensuring that the risk assessments are not based on obsolete chemistry, toxicology or Good Agricultural Practices (GAP) information. (REP21/PR, PARA 232).”</p>	USA

COMMENT	MEMBER/OBSERVER
<p>Section 1 of the discussion paper (CX/PR 23/54/11) describes a proposed process that can be used to identify CXLs for compounds with no public health concerns that are unsupported but important to Codex's mission to protect consumer health while supporting fair trade practices. The discussion paper also recommends the establishment of an EWG that will be responsible for managing unsupported compounds. As described in the discussion paper, this EWG will be responsible for: (i) maintenance of a list of compounds for which Member countries have expressed concern about possible revocation of CXLs; (ii) engagement with the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) on data requirements for periodic review; and (iii) convening discussions with stakeholder groups to obtain support based on whether there is national registration support by Codex Members/Observers.</p> <p>The United States generally supports the approach outlined in Section 1 of the discussion paper and endorses the establishment of an EWG to manage the process and maintain a list of compounds that Member countries wish to support. We believe the proposed approach provides flexibility in the management of unsupported compounds without public health concerns. While the United States generally supports the approach, we also note that additional clarity is needed on how to engage JMPR on data requirements. There may be challenges related to data ownership and development of supporting scientific dossiers that require further consideration and make it difficult to determine the timeline for provision of data submission to JMPR. As such, it may be helpful for CCPR and the EWG to build experience with some specific compounds of interest and then re-examine the proposed process to make future improvements.</p>	
<p><u>General comments on the various options available to the different stakeholders to implement the approach and specific comments on existing or possible additional provisions as necessary, for completeness, in order to finalize the options at CCPR54</u></p> <p>The United States generally supports the range of collaboration activities outlined in Section 2 of the EWG discussion paper (CX/PR 23/54/11). Paragraph 14 recognizes that the management approach may be challenging to implement and highlights that further effort is needed to "define the scope of the problem with respect to the number of MRLs, identify members and observers who are interested in specific compounds, and describe the data required for JMPR to conduct the periodic review." As such, an important starting point for building collaboration will be to define the scope of the work and determine initial priorities for collaboration.</p> <p>Section 2 also proposes a range of activities related to capacity building, technical training, and development of data packages. While these activities could help gain support for compounds that are currently unsupported, further discussion is likely needed on what type of projects should be a priority. There is also no established financial support mechanism for the proposed activities, so it remains unclear how they would be managed and/or supported by Codex, relevant national authorities, international organizations, and external parties, such as trading associations and agricultural organizations.</p>	

SPECIFIC COMMENTS**SECTION 1. MANAGEMENT OF UNSUPPORTED COMPOUNDS WITHOUT PUBLIC HEALTH[1] CONCERN SCHEDULED FOR PERIODIC REVIEW**

COMMENT	MEMBER/OBSERVER
<p>Section 1 – Appendix I</p> <ol style="list-style-type: none"> 1. Canada would like to acknowledge the eWG’s efforts in preparing the discussion paper which explores workflow management alternatives and data support opportunities. 2. Canada supports in principle the proposal for the management of unsupported compounds without public health concern scheduled for periodic review, as described and presented in Section 1 of Appendix I of CX/PR 23/54/11. <ol style="list-style-type: none"> a. Canada notes that several of the steps in the approach may require significant capacity building, not only on behalf of the Member state seeking to maintain CXLs for an unsupported compound, but also on the part of JMPR in screening the chemical-specific databases for the acceptability of the available residue chemistry and toxicology data and identifying any data gaps. Considering JMPR resources are very limited at this time, adding to the workload of JMPR may prove to be challenging. b. Canada questions the need for CCPR to confirm support, or lack thereof, at two consecutive meetings, and whether there is opportunity to expedite the process by withdrawing the CXLs once lack of support is noted following one CCPR Meeting (example, no support expressed at CCPR54, therefore, withdraw CXLs at CCPR55). 	Canada
<p>Se considera que ayudaría en la comprensión del tratamiento de los compuestos sin apoyo de los fabricantes la inclusión de un diagrama de flujo con los pasos propuestos.</p>	Uruguay
<p>Para 1. Unsupported compounds without public health concerns (PHCs) due for periodic review will be managed according to the periodic review procedures described in the Codex Procedures- Procedural Manual, according to Section IV: Risk Analysis, Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues, especially Chapter 5“Risk management, Role of CCPR”, paragraphs 208 – 224².</p> <p>The EU notes that the new edition of the CAC Procedural Manual (FAO and WHO. 2023. Codex Alimentarius Commission Procedural Manual. Twenty-eighth edition. Rome. https://doi.org/10.4060/cc5042en) was recently published with some changes in the structure of the text, therefore the text of paragraph 1 be changed accordingly.</p> <p>The EU noted that footnote 2 refers to the old, twenty-seventh edition of the CAC Procedural Manual and in addition, to the latest version, which is a contradiction. As a concrete text is cited, it might be useful to cite the newest version from 2023</p>	EU
<p>Footnote 2. FAO and WHO. 2023. Codex Alimentarius Commission-Commission Procedural Manual in its latest version Manual. World Health Organization- Food and Agricultural Organization of the United Nations, Twenty-eighth edition. Rome, 2019. https://doi.org/10.4060/cc5042en.</p> <p>The EU noted that footnote 2 refers to the old, twenty-seventh edition of the CAC Procedural Manual and in addition, to the latest version, which is a contradiction. As a concrete text is cited, it might be useful to cite the newest version from 2023</p>	
<p>Paragraph 6 In said communication, the member state must provide detailed information about which CXLs it is interested in supporting, as well as information on national register status, the surface (ha) of the crop treated with the pesticide, international trade data or others (<u>e.g., availability of the alternatives etc.</u>) that justify the efforts to generate data³.</p> <p>The EU, as previously indicated in its comments on Circular Letter CL 2022/39-PR and CL 2021/44 PR would also welcome further discussions/reflections on how to support Codex Members, in particular developing countries, in moving gradually towards the use of lower risk substances. These discussions/reflections could take place within a future mandate of working group on Unsupported Compounds.</p>	

COMMENT	MEMBER/OBSERVER
In the light of this, the EU proposes to add justifications by the member state(s) for the reasons to keep the CXL(s) as this would further clarify the need to maintain the CXLs and would already give the input for the possible future discussion on the use of lower risk substances.	
Para 8. Se considera que se debe aclarar sobre la “valoración de si hay o no una justificación razonable para avanzar en la búsqueda de posibles apoyos” se realizará en base a criterios pre-establecidos por el Grupo de Trabajo Electrónico de compuestos no apoyados (aunque los criterios no se establezcan en este documento).	Uruguay
Paragraph 9 Si hay un registro nacional que respalde el CXL actual, debe considerarse”. No queda claro el alcance de la frase tal como está redactada, es decir debería aclararse cómo se considerará. Se entiende que esto debería formar parte de los criterios pre-establecidos y tal vez no incluirse en el párrafo 9.	
<p>Paragraph 10 For those compounds for which support is obtained, the member (s) should inform both the Chair of the EWG on Priorities and the Chair of the EWG on Unsupported Compounds whether all or some of the CXLs will be supported and should specify each supported and unsupported CXL and the timeframe for provision of relevant data to JMPR. <u>The timeframe proposed for generating and providing data, should not exceed four-years (four-year rule as specified in the Codex Procedures Manual).</u></p> <p>The EU notes that overall process for generating data for the unsupported compound can be lengthy therefore, in order to treat those compounds similarly to others, the EU proposes to clarify that the timeframe has limitations i.e., the four-year rule applies.</p>	European Union
Paragraph 10 En este párrafo se hace mención a que “el miembro(s) deberá informar al GTe sobre prioridades como al Presidente del GTe sobre compuestos no apoyados si todos o algunos de los CXL recibirán apoyo, y deberá especificar cada CXL con apoyo y sin apoyo, y el plazo para el suministro de datos relevantes para la JMPR”. Se considera que deberían incluirse también a los observadores en esta fase, ya que ellos también podrían ofrecer brindar apoyo.	Uruguay
<p>Paragraph 12 For compounds and their CXLs for which there is no support obtained according to points 5–9<u>paragraphs 6 to 10</u>, CCPR in its next session should once again ask for support. If-no support is given, the withdrawal of CXLs should be endorsed in the following CCPR meeting.</p> <p>The EU notes that the new paragraph 1 has been added to the text therefore, the numbering has shifted compared to the former version. Consequently, the corresponding references in paragraphs 12 and 14 should be changed as follows.</p>	European Union
Paragraph 12 En este párrafo cuando se habla de plazo, surge la duda si no se considera la regla de los 4 años para presentar la información.	Uruguay

SECTION 2. OPTIONS FOR EFFICIENT DATA SUPPORT THAT COULD BE ADDRESSED BY CODEX, FAO/WHO, JMPR, GOVERNMENTS AND INDUSTRY TO FURTHER ASSIST COUNTRIES IN IMPLEMENTING THE PROPOSED MANAGEMENT APPROACH

COMMENT	MEMBER/OBSERVER
<p>Section 2 – Appendix I</p> <p>Canada supports the opportunities for collaboration listed in this section to implement the management of unsupported compounds, provided there is agreement among all parties to follow through on their responsibilities/commitments to ensure the success of this initiative.</p>	Canada
<p>Paragraph 14 However, greater efforts are needed to clarify the work as described in paragraphs 5-6 to 9-10 namely: define the scope of the problem with respect to the number of maximum residue limits (MRLs), identify members and observers who are interested in specific compounds, and describe the data required for JMPR to conduct the periodic review.</p>	EU
<p>Paragraph 16 Se entiende que la versión en español difiere ligeramente de la versión en inglés. Se subrayan los verbos que pueden dar un énfasis diferente al párrafo en los dos documentos: “...deben transferirse a los fabricantes genéricos y a los miembros y observadores que tienen productos no apoyados. Esta debía ser una de las funciones del GTE sobre compuestos no apoyados.” “...should be shared with the generic manufacturers as well as to members and observers having unsupported compounds. This would be the one of the roles of EWG on Unsupported Compounds.” Por otro lado Se sugiere eliminar “the” en la última frase.</p>	Uruguay
<p>Paragraph 18 Se destaca la importancia de la realización de talleres virtuales para facilitar la mayor participación y reducir los costos.</p>	
<p>Paragraph 53 bullet iii. Data submission within periodic review procedures iv. Methods of analysis where necessary</p> <p>The EU proposes to consider adding methods of analysis to the list for which the capacity building could be carried out.</p>	EU