

# 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](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

Agenda Item 11

CX/PR 22/53/13-Add.1

June 2022

ORIGINAL LANGUAGE ONLY

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON PESTICIDES

53th Session

Virtual

4-8 and 13 July 2022

### MANAGEMENT OF UNSUPPORTED COMPOUNDS WITHOUT PUBLIC HEALTH CONCERN SCHEDULED FOR PERIODIC REVIEW

#### Comments in reply to CL 2022/39-PR

*Comments of Canada, Chile, Egypt, European Union (EU), Ghana, Kenya, Philippines, United Kingdom,  
United States of America (USA) and Institute of Food Technologists (IFT)*

#### Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2022/39-PR<sup>1</sup> issued in May 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 appendix

2. The comments submitted through the OCS are hereby attached in the **Annex I** and are presented in table format.

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<sup>1</sup> Codex circular letter, including CL 2022/39-PR, 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:

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

**Annex**

<b>COMMENT</b>	<b>MEMBER / OBSERVER</b>
<ol style="list-style-type: none"> <li>1. Canada would like to acknowledge the eWG's efforts in preparing the discussion paper which explores workflow management alternatives and data support opportunities.</li> <li>2. Canada supports in principle the management proposal, including the establishment of an eWG for the Management of Unsupported compounds working in collaboration with the eWG on Priorities. However, 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 searching the chemical-specific databases for the acceptability of the available residue chemistry and toxicology data and identifying the missing studies. Considering JMPR resources are very limited at this time, adding to the workload of JMPR may prove to be challenging.</li> <li>3. One recommendation in the proposal that may address capacity building challenges is the reliance on national authorities to provide the recent (within 5 years) assessments of the unsupported compound in question. However, this may be precedent-setting and require potential modifications to the Codex risk analysis principles. Nevertheless, it warrants further discussions.</li> <li>4. For data support, Canada notes the various collaboration initiatives between government, JMPR, other international organizations and industry, all of which merit further detailed discussions.</li> </ol>	<b>Canada</b>
<p>La delegación de Chile agradece el trabajo realizado por el grupo de trabajo por medios electrónicos, y apoya la propuesta de gestión revisada para los compuestos no apoyados, presentada en la sección 1 del Apéndice del documento CX/PR 22/53/13</p> <p>Por otro lado, Chile considera que es necesario establecer un GTE para perfeccionar la propuesta de gestión y presentar una versión revisada para consideración de la CCPR54 y que permita dar solución a este asunto.</p>	<b>Chile</b>
Egypt appreciates the work done in the document and agrees on it	<b>Egypt</b>
<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 of the discussion paper on the management of unsupported compounds without public health concerns scheduled for periodic review with reference CX/PR 22/53/13.</p> <p><u>General comments:</u></p> <p>The EU notes that the title of the current document and the eWG might be misleading as it includes the term “without public health concern” that could be confused with the same term used in the context of agenda item 9. Therefore, the EU proposes to add the following explanation to the document. “In the context of this document/eWG the term “unsupported compounds without public health concern” describes compounds, for which no public health concern form has been lodged by a Member or where JMPR has not indicated any public health concern. These compounds are waiting for a periodic review after 15 years without a sponsor stating his willingness to support the compound”.</p> <p>The EU notes that the current proposal aims to find a solution for the management of unsupported compounds without public health concern scheduled for periodic review. The EU is fully supportive of this aim and of the actions proposed in the discussion paper. It also welcomes recent discussions on increasing the capacity of JMPR to ensure improvements in the medium/long term.</p>	<b>EU</b>

COMMENT	MEMBER / OBSERVER
<p>However, while the EU acknowledges that actions proposed in the discussion paper can contribute to a certain improvement of the current situation, the EU believes that the current proposal will not be sufficient to reduce the heavy and growing backlog of evaluations for substances for which the periodic review is overdue (see EU position on CX/PR 22/53/15 – agenda item 13). Concrete action is urgently needed to address this problem.</p> <p>The EU is strongly in favour of a stringent approach for deleting compounds from the system that are no longer supported by a manufacturer. Consequent withdrawal of the corresponding CXLs will contribute to reducing the number of substances for which a periodic review is overdue.</p> <p><u>Specific comments:</u></p> <p>The EU supports the collaboration activities suggested in the discussion paper for unsupported compounds.</p> <p>Additionally, as already indicated in its comments on Circular Letter CL 2021/44 PR the EU 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 this or a new working group.</p> <p>The establishment of an eWG on Management of Unsupported Compound:</p> <p>The EU supports the establishment and the management of an eWG on Management of Unsupported Compounds as proposed in the discussion paper. This eWG should work in close collaboration with the eWGs on Priorities and National Registrations of Pesticides in order to achieve the best possible outcome.</p>	
<p><u>Position:</u> Ghana commends and also supports the recommendation by the EWG for CCPR to agree with the revised proposal, to consider the establishment of a EWG to refine the work for consideration by CCPR54 (2023).</p> <p><u>Rationale:</u> There are national data base for registered pesticides, therefore we can get monitoring data of the pesticides.</p>	<b>Ghana</b>
<p><u>General Comment:</u> Kenya supports this proposal. It touches not only on collaboration, but also capacity building to strengthen the capabilities of Codex member countries. It also offers a chance of scheduled periodic re-evaluation. Member countries within this framework are able to share costs of data generation.</p>	<b>Kenya</b>
<p>The Philippines generally agrees with the overall content of the work management proposal presented in Section 1 and the options for data support presented in Section 2 and the establishment of a Working Group for the Management of Unsupported Compound as there are no additional concerns relative to this proposal that has to be addressed so far. Likewise, the country also agrees to the establishment of an EWG that will further refine this work arrangement proposal and consider different options for data support in implementing the said proposal.</p>	<b>Philippines</b>
<p>The UK would like to thank the Electronic Working Group (eWG) chaired by Chile and co-chaired by Australia, India and Kenya on the preparation of the discussion paper on the management of unsupported compounds without public health concern.</p> <p>The UK supports the proposals for the management of the unsupported compounds, without public health concerns, and supports the establishment of an eWG to refine the proposals for consideration by CCPR 54.</p> <p>In principle, the UK supports virtual workshops being organised by the JMPR/ Codex, but recognises this is highly dependent on the resources of JMPR/Codex, including the funding to undertake such activities.</p>	<b>United Kingdom</b>

COMMENT	MEMBER / OBSERVER
<p>It is stated that the FAO and WHO can provide information on what data is available and what data is missing. It is not clear to the UK on what basis/ at what stage this information would be provided i.e. is this based on the data and assessments previously conducted by the JMPR, does it take into account data/ assessments by national authorities, is it based on the data made available from industry? It would appear that this step in the process, would require a 'completeness check' of the active substance dossier. The UK understands that such a step is not currently undertaken by the JMPR and would therefore require clear criteria and available resources to undertake this activity. In addition, the advice given by the FAO/WHO would need to be accompanied by appropriate caveats that it does not guarantee that CXLs will end up being retained.</p>	
<p>The United States appreciates the efforts of the Electronic Working Group (EWG) in advancing further CCPR deliberation on the management of unsupported compounds without public health concerns. The U.S. responses to items (a)-(c) of CL 2022/39-PR are provided below.</p> <p>a. <u>General comments</u> on the overall content of the work management proposal presented in Section 1 and the options for data support presented in Section 2:</p> <p>The United States would like to highlight the importance of developing a flexible management approach and makes note of previous discussion at CCPR52 "to develop a clear process for managing unsupported compounds and determining when CXLs are retained, and that selecting a management option would require balancing the need for a robust listing of Codex Maximum Residue Limits (CXLs) that supported international trade while ensuring that the risk assessments are not based on obsolete chemistry, toxicology or Good Agricultural Practice (GAP) information. (REP21/PR, PARA 232)." The draft discussion paper helps outline 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 promoting international trade.</p> <p>The United States notes that further discussion during the CCPR53 plenary is needed to further deliberate on the proposed process and potential ways that CCPR can build the capacity of Codex Members to support Joint Expert Meeting on Pesticide Residues (JMPR) evaluation and promote collaboration across Codex stakeholders, including Codex Members and Observers, the Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO), and external partners. The proposal outlines a number of collaboration activities. Some promising activities that may warrant further discussion include:</p> <ul style="list-style-type: none"> <li>• "Provide capacity building activities to promote the improvement of human resources for those Codex members with difficulties in carrying out the necessary technical studies. These would include technical support to meet the requirements of studies and to meet formal procedures for the data submission"</li> <li>• "greater efforts are needed to clarify the work namely: 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."</li> <li>• "FAO and WHO can provide information on what data is available and more important on what data is missing. This is necessary to define the workload for those who will provide the missing data."</li> </ul> <p>The United States would also like to highlight the recommendation to have national authorities provide "their latest evaluation as far as available and where the assessment was performed not longer than 5 years ago." For this recommendation, it would be helpful to explore if there are opportunities to leverage these national assessment and fulfill any important data gaps identified by FAO/WHO.</p>	<p><b>USA</b></p>

COMMENT	MEMBER / OBSERVER
<p>b. <u>Specific comments</u> on provisions that may require further development or additional provisions that could be included to further enhance the management proposal in Section 1 or the options presented in Section 2</p> <p>The United States does not have specific comments on provisions that may require further development, but welcomes further deliberation by CCPR to enhanced the management of unsupported compounds with no public health concerns.</p> <p>c. The establishment of an WG of Management of Unsupported Compound should the management proposal described in Section 1 is acceptable</p> <p>The United States generally supports the establishment of a working group on the management of unsupported compounds. The United States notes, however, that further discussion is needed on the specific roles and responsibilities of the EWG and its chair to ensure that they are (i) well defined and (ii) within the scope of CCPR. As an example, Paragraph 8 of CX/PR 22/53/13 states:</p> <p>The Chair of the EWG on Unsupported Compounds should seek the availability of relevant toxicology and/or residue data generated after the last evaluation of the Joint FAO/WHO Meetings on Pesticide Residues (JMPR). If necessary, the Chair must engage the JMPR in this process, through the JMPR Joint Secretaries. The engagement of JMPR at this early stage of the procedure is essential, both to avoid that the dossier to be prepared will be found incomplete, and to avoid unnecessary repetition of studies.</p> <p>It is not clear how the EWG chair will seek out this relevant data and engage with JMPR. This may require technical evaluation that goes beyond CCPR's primary role in risk management.</p>	
<p>IFT supports what has been referred to in CX/PR 22/53/13 paragraph 9 (iii) as option 2b. Specifically, in the absence of risk assessment data supporting withdrawal of unsupported compounds without public health concern, IFT believes they should not be withdrawn nor scheduled for periodic review. At a time of global food shortages, we believe it is important to maintain a continuous food supply. Further, we recommend that a compound be revisited only when there is new, sufficient data and a scientific assessment presented to Codex of a human health/food safety risk including links to cancer or other evidence of human harm to warrant further action by CCPR. While well intentioned, we believe a requirement to generate new data on compounds that no longer have registrants to generate those data for whatever reasons is unwise and may have unforeseen effects. IFT recognizes that proceeding with a standard to require periodic review of unsupported compounds may further impact an already challenged food supply chain and expose the most vulnerable of our global community to potential food shortages or contaminated products from pests.</p>	IFT