

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 13

CX/PR 21/52/17-Add.1

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ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

52nd Session

(Virtual)

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MANAGEMENT OF UNSUPPORTED COMPOUNDS

WITHOUT PUBLIC HEALTH CONCERN SCHEDULED FOR PERIODIC REVIEW

Comments of Australia, Canada, Chile, Egypt, Iran, Thailand, United States of America (USA)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/44-PR issued in May 2021. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific paragraphs.
2. The comments submitted through the OCS are, hereby attached as an Annex and are presented in table format.
3. Comments in the Annex are presented in accordance with the information presented in CX/PR 21/52/17, Appendix I as follows:
 - CXCX/PR 21/52/17, Appendix I, Section I, TOR(i): No comments requested (unnecessary)
 - CX/PR 21/52/17, Appendix I, Section I, TOR(ii): Comments requested as shown in the Annex.
 - CX/PR 21/52/17, Appendix I, Section I, TOR(iii): To support comments on Section II, TOR(iv) therefore no comments have been request on TOR(iii) as such but the information has been presented to inform comments on Section II, TOR(iv)
 - CX/PR 21/52/17, Appendix I, Section II, TOR(iv): Comments requested as shown in the Annex based on the informaton provided in Section I, TOR(iii) to improve the text in Options 2b/3 and whether the additional practices presented in support of the implementation of either options (in particular Option 3) are practical to be implemented and if so whether further improvements or additional practices could be identified.

GENERAL COMMENTS

General Comments on whether Option 2b or Option 3 would be the most appropriate option to be implemented by CCPR to address the management of unsupported compounds without public health concern scheduled for periodic review by JMPR as described in CX/PR 21/52/17, Appendix I, Section II taking into account the challenges and advantages identified for each option in CX/PR 21/52/17, Appendix I, Section I, TOR (iii) of the Terms of Reference (TOR).

COMMENT/RATIONALE	MEMBER/OBSERVER
<p>Australia prefers Option 3 because it is consistent with the Risk Analysis Principles in the Procedural Manual and minimises risk of diminishing protection of user and consumer health. Delays may occur due to limitations imposed by JMPR resources, but these delays should be minimised where possible. Australia favours consistent use of the 4 year rule where members/observers commit to providing the necessary data for evaluation within four years. Australia notes that the Procedural Manual advises that pesticides that have not been reviewed toxicologically for more than 15 years should be listed in Table 2B. Compounds can be moved from Table 2B to Table 2A on the basis of an identified public health concern or because a periodic review has not been undertaken for 25 years. If a PHC has not been formally identified, the review at 25 years ensures that the compound continues to protect consumer health.</p>	<p>Australia</p>
<p>Egypt appreciates the approach taken by the CCPR, and would like emphasize the previous comments sent before.</p>	<p>Egypt</p>
<p>Indonesia supports option 2b. "Only those CXLs for which there are registrations listed in the NRD will be retained" in Discussion Paper on the Management of Unsupported Compounds Without Public Health Concern Scheduled for Periodic Review.</p>	<p>Indonesia</p>
<p>TOR(iv) 1-whether there is room to improve the text used to describe either options in Section II, Text in section II in sufficient to describe both options 2. whether there is support for the additional measures to support implementation of either options in Section II, Establishment of a forum for information sharing would be helpful in both options 2b and 3. This forum also allows simplifying the procedure for the periodic review, reducing the workload and costs. So according to results of consensus in this forum the text can be improved. Whether Option 2b or Option 3 would be the most appropriate option to be implemented by CCPR to address the management of unsupported compounds without public health concern scheduled for periodic review by JMPR as described in CX/PR 21/52/17, Appendix I, Section II taking into account the challenges and advantages identified for each option in CX/PR 21/52/17, Appendix I, Section I, point (iii) of the Terms of Reference (TOR). Option 2b may be the most appropriate option to be implemented by CCPR to address the management of unsupported compounds without public health concern scheduled for periodic review by JMPR.</p>	<p>Iran</p>
<p>Thailand prefers the option 2B because it helps to maintain more CXLs, which helps to facilitate international trade, to reduce the existing gap between developed and developing countries, and to simplify the procedure for the periodic review. Also, we prefer JMPR to review the updated information of "GAP" and propose new recommended CXLs rather than the deletion of the CXLs of the compounds without public health concern.</p>	<p>Thailand</p>

COMMENT/RATIONALE	MEMBER/OBSERVER
<p>The United States would like to provide the following comments in response to Circular Letter CL2021/44-PR (Request for comments on the management of unsupported compounds without public health concern scheduled for periodic review).</p> <p>The United States appreciates the efforts of the Electronic Working Group (EWG), chaired by Chile and co-chaired by Australia, India, and Kenya, to advance work on the management of unsupported compounds without public health concern. The discussion paper summarizes the progress of the EWG and provides a clear description of how the document was developed based on two rounds of comments and an additional request for feedback through the earlier CL 2020/40-PR (Request for comments on the management of unsupported compounds without public health concern scheduled for periodic review).</p> <p>Broadly speaking, the United States supports efforts to develop a clear process for managing unsupported compounds and determining when Codex Maximum Residue Limits (CXLs) are retained. The United States also recognizes that selecting a management option will require balancing the need for a robust listing of zCXLs that supports international trade while also ensuring that the risk assessments are not based on obsolete toxicological or Good Agricultural Practices (GAP) information. Therefore, The United States generally believes that absent other concerns, CXLs should not be revoked unless clear public health concerns have been raised and ratified by the FAO/WHO Joint Expert Meeting on Pesticide Residues (JMPR).</p> <p>With regard to the request for general comments on Option 2b (i.e., retain CXLs for which there are registrations listed in the national registration database) or Option 3 (i.e., Codex members and observers are granted 4 years to fulfil the data requirements to maintain the CXLs) for the management of unsupported compounds without public health concerns, the United States appreciates the efforts of the EWG to facilitate discussion of the advantages and challenges of both Options. The EWG discussion paper highlights that there was consensus that Option 2b helps maintain more established CXLs and facilitates international trade (CX/PR 21/52/17, Appendix I, Para. 33). The United States supports this option for unsupported compounds with no public health concern and believes this approach is consistent with previous deliberations by the Codex Alimentarius Commission (CAC, 39th Session, REP16/CAC, 173).</p> <p>The United States recognizes that some Codex Members may support Option 3. Given that this option may result in the loss of CXLs with no impact on public health, the United States believes that CCPR needs to further understand the barriers that limit support and propose solutions that may be adopted by CCPR to expand the capacity of CCPR Members and Observers to generate the data required by JMPR on unsupported compounds. The EWG discussion paper provides supporting information from Codex Members and Observers on potential barriers (CX/PR 21/52/17, Appendix I, Section 1). Importantly, the discussion paper highlights that greater 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 (CX/PR 21/52/17, Appendix I, Para. 14).” The EWG discussion paper then discusses a range of activities that Codex Members and Observers can collaborate on efficiently and develop a framework for promoting exchange of information and data on unsupported compounds (CX/PR 21/52/17, Appendix I, Para. 15-28). As such, the United States believes that further exploratory work is needed before Option 3 could be fully considered by CCPR.</p> <p>At this time, the United States does not have specific comments with regard to Section 1. TOR (ii) –“Explore options for efficient data support,” or with regard to Section 2. Conclusions for TOR (iv) – “Proposed alternatives for the management of unsupported compounds without public health concern schedule for periodic review.” However, the United States believes these considerations will be important when adopting either management option and looks forward to further discussion with Codex Members and Observers at CCPR52.</p>	<p>USA</p>

SPECIFIC COMMENTS

Following general comments on the selected option (Options 2b or 3) to provide specific comments on:

TOR(iv): Possible improvements to Options 2b and 3**including additional practices within CCPR in support of either options (in particular of Option 3)**

1. whether there is room to improve the text used to describe either options in Section II,
2. whether there is support for the additional measures to support implementation of either options in Section II, i.e. additional practices within CCPR, capacity development to strengthen capacities in Codex members, establishment of an forum for information sharing, if so, whether the text can be improved and whether there are other options that could also be implemented to support the implementation of these options.

COMMENTS/RATIONALE	MEMBER
<p>Option 3. Codex Members and observers are granted 4 years to fulfil the data requirements to maintain the CXLs. (i.e., 4-year rule). If Members or observers are unable to address the data requirements, all CXLs are to be revoked</p> <p><u>Enhanced presentation of the information on the schedules and priority lists of pesticides for evaluation by JMPR prepared by the EWG/Priorities relevant to the periodic review</u></p> <p>(46) For each compound included in the table 2A, the following should be noted:</p> <p><u>Comment:</u> Government agencies may not be able to provide their latest evaluation due to restraints associated with the release of confidential information based on domestic legislation.</p>	Australia
<p><u>To create a forum or similar platform to share information</u></p> <p>(49) To provide a forum or similar platform for allowing different Codex Members have the possibility to provide data or partial studies of compounds in order to help Members with difficulties to gather the data required.</p> <p><u>Comment:</u> The industry/sponsor that initially registered the compound may be reluctant to provide toxicological and residues background for the pesticides to be re-evaluated based on commercial reasons.</p>	Australia
<p>Option 2b. Only those CXLs for which there are registrations listed in the NRD will be retained</p> <p><u>Partial revision of the Risk Analysis Principles applied by CCPR</u></p> <p>(43) To introduce an amendment to the Risk Analysis Principles applied by CCPR under its "Periodic Review" section. Regarding to this amendment, two alternatives (i, iii) are proposed to include <u>for inclusion</u> in the letter "a." of section 5.4 Revocation of CXLS (paragraph 88), of Codex Alimentarius Commission Procedural Manual:</p>	Canada
<p>(43, ii) As a result of the periodic review procedure including CXLs of pesticides that have not been reviewed for more than 25 years and are not supported by any member/observer and there are not <u>no</u> registrations listed in the National Registration Database (NRD)</p>	Canada

COMMENTS/RATIONALE	MEMBER
<p><u>Proper functioning of the national registration database (NRD)</u></p> <p>(44) To promote the proper functioning of the NRD, which will be presented at CCPR52 (2021) (see Agenda Item 14), CCPR will need to develop suitable mechanisms, for example, sending update reminders to nominated focal points and access from the Codex website, to ensure that the NRD is kept up-to-date.</p> <p>Canada supports option 2b, based on the identified advantages (e.g., limited resources required other than maintaining NRD), provided the NRD is appropriately updated on a consistent basis.</p>	Canada
<p>(47) <u>Additional practices within CCPR in support of Option 2(b) Option 3</u></p> <p>It is unclear if these practices pertain to both options or only one of them. They seem to be more specific to Option 3.</p>	Canada
<p><u>To create a forum or similar platform to share information</u></p> <p>(49) To provide a forum or similar platform for allowing different Codex Members <u>to</u> have the possibility to provide data or partial studies of compounds in order to help Members with difficulties to gather the data required.</p>	Canada
<p>1. Si hay margen para mejorar el texto utilizado para describir cada una de las opciones en la Sección II.</p> <p><u>Respuesta de Chile:</u></p> <ul style="list-style-type: none"> • No se considera necesario realizar modificaciones a al texto utilizado para describir las opciones. <p>2. Si existe apoyo para las medidas adicionales para apoyar la aplicación de cualquiera de las opciones en la Sección II, es decir, prácticas adicionales en el CCPR, fomento de la capacitación para fortalecer las capacidades de los miembros del Codex, establecimiento de un foro para el intercambio de información, y en caso afirmativo, si el texto puede mejorarse y si hay otras opciones que pudieran aplicarse para apoyar la aplicación de estas opciones.</p> <p><u>Respuesta de Chile:</u></p> <ul style="list-style-type: none"> • No se considera necesario realizar modificaciones a al texto utilizado para describir las opciones. • No se identifican propuestas adicionales, y se apoyan las medidas identificadas en la Sección II. 	Chile
<p><u>Prácticas adicionales en el CCPR como apoyo de la opción 2(b) y la opción 3</u></p> <p>Chile considera que la opción 3 es la más adecuada para la gestión de los compuestos no apoyados.</p> <p><u>Justificación:</u> Están opción, sumada a las propuestas de mejora de la gestión de la misma, se condice con los objetivos del Codex y con los Principios de Análisis de Riesgos del CCPR vigentes.</p> <p>En la misma línea, esta alternativa fomentaría la actualización de las prácticas agrícolas en uso, y al mismo tiempo, motivar a los países Miembros hacia la generación de datos propios que permitan apoyar aquellos CXLs críticos, en riesgo de ser revocados.</p> <p>Las alternativas de gestión y el procedimiento propuesto, apuntan a optimizar en el CPPR, la gestión de estos compuestos, lo que permitiría, basado en las reglas de los 4 años, contar con mayor posibilidad de levantar la información requerida para aquellos compuestos sobre los cuáles exista real interés en mantener sus CXLs.</p>	Chile

COMMENTS/RATIONALE	MEMBER
<p><u>Additional practices within CCPR in support of Options 2b or 3</u> Field trials (residues)</p>	Iran
Toxicological studies	Iran
Data submission within periodic review procedures	Iran
<p>Option 2b. Only those CXLs for which there are registrations listed in the NRD will be retained</p> <p>Partial revision of the Risk Analysis Principles applied by CCPR</p> <p><u>Comment:</u> We are of the opinion that both proposals of “i” and “ii” should be included in the document because the scenarios should cover substances with and without public health concern. In addition, we realize that the National Registration Database (NRD) is in the process of development and there is no clear mechanism and responsible organization. Hence, NRD, not yet officially recognized, should not be mentioned in the Procedural Manual. Therefore, we propose the amendment as follows:</p> <p>“a. As a result of the periodic review procedure including CXLs of pesticides that have not been reviewed for more than 25 years:</p> <p>i. with public health concerns, and are not supported by any member/observer;</p> <p>ii. without public health concern, are not supported by any member/observer and there is no national registration”</p>	Thailand
<p><u>(43, i) a. As a result of the periodic review procedure including CXLs of pesticides that have not been reviewed for more than 25 years, As a result of the periodic review procedure including CXLs of pesticides that have not been reviewed for more than 25 years, i. with public health concerns, and are not supported by any member/observer;</u></p> <p>The rationale as above.</p>	Thailand
<p><u>(43, ii) As a result of the periodic review procedure including CXLs of pesticides that have not been reviewed for more than 25 years and without public health concern, are not supported by any member/observer and there are not registrations listed in the National Registration Database (NRD) is no national registration;</u></p> <p>The rationale as above</p>	Thailand

TOR(ii): Additional practices in support of either options that could be recommended for action by CCPR, FAO, WHO, etc.

1. To consider the different options for data support that may assist in the implementation of either options that could be recommended for action by CCPR, FAO, WHO, etc. as described in CX/PR 21/52/17, Appendix I, Section I, TOR (ii). Please indicate if there is support for some or all of these activities, considering feasibility, effectiveness, etc. and whether other activities could be proposed in addition to those described under TOR (ii).

COMMENTS/RATIONALE	MEMBER
<p>TOR (ii). Explore options for efficient data support (15) To carry out the above, it is key to prioritize the different cases to ensure that collaboration <u>can</u> be carried out efficiently.</p>	Canada
<p>TOR (ii). Explore options for efficient data support (16) Information on the CODEX system and the JMPR periodic review process, <u>generation of the required</u> data package and <u>accompanying</u> dossier, should be <u>transferred to shared with</u> the generic manufacturers as well as to members and observers having unsupported products. This would be the role of Codex and International Organizations involved.</p>	Canada
<p>TOR (ii). Explore options for efficient data support <u>Kind of collaboration activities</u> (18) In order to carry out this collaboration, the scope of the problem with respect to unsupported compounds without public health concern scheduled for periodic review and the number of CXLs in question must be clearly defined. It is necessary to identify if there is a common interest in specific compounds, what are the existing and missing data, and how the collection of such data would be carried out. <u>Comment:</u> Canada agrees that this scoping exercise is critical in initiating the process and meeting the requirements of TOR (ii), identifying options for data support.</p>	Canada
<p>TOR (ii). Explore options for efficient data support <u>Following collaborative activities can efficiently be developed within the framework of Codex, FAO, WHO, others international organizations, government agencies, industry, etc.:</u> (a) <u>Codex</u> (19) Codex or Codex/FAO can <u>provide develop</u> a collaboration portal/platform/forum for the exchange of views, information and data between all interested parties, <u>which</u> would be helpful <u>to bring in bringing relevant</u> parties together. Within CODEX, linkage between the National Registration Database and Tables 2A and 2B of Priorities is key for identifying which compounds should be the focus of activity.</p>	Canada
<p>TOR (ii). Explore options for efficient data support <u>Following collaborative activities can efficiently be developed within the framework of Codex, FAO, WHO, others international organizations, government agencies, industry, etc.:</u> (a) <u>Codex</u> (20) Through the JMPR and the Codex Secretariat, coordinate and carry out workshops on periodic re-evaluations, including <u>in detail providing details of</u> each stage of the procedure, <u>requirements</u>, and data to be submitted by the industry or country interested in supporting the re-evaluation, and they could be virtual to facilitate participation and reduce costs. <u>Comment:</u> Suggest including further clarification on which requirements are referred to here ; data, format, etc.</p>	Canada

COMMENTS/RATIONALE	MEMBER
<p>TOR (ii). Explore options for efficient data support</p> <p><u>Following collaborative activities can efficiently be developed within the framework of Codex, FAO, WHO, others international organizations, government agencies, industry, etc.:</u></p> <p><i>(c) Relevant government agencies (i.e. twinning activities between Codex members)</i></p> <p>(25) Interested countries could finance translation into native languages, in order to carry out the trainings proposed in letter a)</p> <p><u>Comment:</u> Canada acknowledges the benefits of government agencies providing their most recent evaluations, however, this may present many difficulties for JMPR (influence the independent decision-making process, different evaluation frameworks, etc).</p>	Canada
<p>Chile apoya las actividades propuestas bajo la Sección I, TDR (ii). No se identifican actividades adicionales.</p> <p><u>Justificación:</u> Para hacer una adecuada gestión de los compuestos no apoyados en el CPPR, es esencial poder desarrollar acciones que mejoren de manera efectiva el procedimiento actual del CCPR, y para esto, se requiere que aparte del trabajo que puedan hacer los Miembros y observadores, exista un apoyo de la FAO, OMS y en términos amplios del sistema Codex.</p>	Chile
<p>TOR (ii). Explore options for efficient data support</p> <p>Proposed activities are sufficient.</p>	Iran