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Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 13 **CX/PR 20/52/17**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

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DISCUSSION PAPER ON THE MANAGEMENT OF UNSUPPORTED COMPOUNDS WITHOUT PUBLIC HEALTH CONCERNS SCHEDULED FOR PERIODIC REVIEW

(Prepared by the Electronic Working Group chaired by Chile and co-chaired by Australia, India and Kenya)

Background

1. At CCPR50 (2018), when considering the establishment of Codex schedules and priority lists of pesticides for evaluation by the Joint FAO/WHO Meetings on Pesticide Residues (JMPR), the Chair of the Electronic Working Groups on Priorities (Australia) reported that several unsupported compounds were listed in the Schedule for periodic review re-evaluations.

2. In the context of the CCPR prioritization process, an unsupported compound is a pesticide that is due for re-evaluation for which neither a manufacturer nor member country has committed to submit the data required for evaluation by JMPR. Unsupported compounds are identified in prioritization Tables 2A and 2B[1].

   Table 2A: Schedules and priority lists of periodic reviews (pesticides scheduled for periodic review)

   Table 2B: Periodic review list (pesticides that have been last evaluated 15 years ago or more, but not yet scheduled or listed for periodic review)

3. CCPR50 noted two key situations which arose in the periodic review:

   (i) unsupported compounds without public health concerns and

   (ii) unsupported compounds with public health concerns

4. Several members indicated the need for the preparation of a discussion paper to consider strategies for the management of unsupported compounds scheduled for periodic review by JMPR.

5. CCPR50 consequently agreed that this work would be carried within the framework of the EWG on Priorities chaired by Australia and co-chaired by Canada, Chile and Kenya, and were tasked to present a discussion paper on the management of unsupported compounds scheduled for periodic review for consideration by CCPR51.[2]

6. CCPR51 (2019) considered the discussion paper[3] which presented proposals on how to address the management of unsupported compounds (with and without public health concerns) listed in Tables 2A and 2B.

7. CCPR51 noted that the major concern was on the management of unsupported compounds without public health concerns and focused its discussions on the management options provided for these compounds. CCPR noted the preference of delegations for either option 2, in particular option 2b or option 3. An excerpt of the options presented at CCPR50 is reproduced in Appendix III for information. The full details of these options can be found in the working paper[3] presented at CCPR51.

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[1] See CX/PR 20/52/19 (Tables 2A and 2B and other tables providing a record of all periodic reviews (past, present and future) and records of chemical-commodity combinations for which specific GAP is no longer supported)

[2] REP18/PR, paras. 147-151 & 153

[3] CX/PR 19/51/17

8. CCPR51 noted that it was difficult to reach consensus on the management options in view of the complexity of the issue and agreed to assess options 2 (in particular 2b) and 3 to determine an appropriate way forward suited to those supporting either of the options.

9. CCPR51 therefore agreed to establish an EWG on unsupported compounds without public health concerns scheduled for periodic review chaired by Chile and co-chaired by Australia, India and Kenya with the following Terms of Reference (TORs):[4]

   (i) Investigate the circumstances that lead to unsupported compounds and obstacles that prevent providing support;

   (ii) Explore options for efficient data support;

   (iii) Explore the advantages and challenges that arise from the options 2b and 3 as recommended by CCPR51;

   Option 2b - *Only those CXLs for which there are registrations listed in the national registration database (NRD) will be retained*

   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*, and

   (iv) Based on the above considerations, present a proposal for consideration by CCPR52.

Proceedings of the EWG

10. The EWG prepared two drafts for comments within the EWG. The initial document was developed by Chile, Australia, India and Kenya. The list of participants is provided in Appendix IV.

First round of comments

11. In order to address TORs (i) and (ii), some questions were presented to the EWG participants. For TOR (iii), the EWG participants were requested to provide advantages and challenges from options 2b and 3.

12. Comments from Chile, Costa Rica, Germany, European Union, Uruguay, and the United States of America were received.

13. A consolidated report with replies to the first round of comments is provided in Appendix II.

Second round of comments

14. Based on the answers received in the first round of comments, summary conclusions were prepared under each TOR.

15. Additionally, EWG participants were asked to propose alternative solutions for the management of options 2b and 3.

16. For the second round, comments from Chile, Uruguay and THIE were received.

Summary and conclusions

17. Appendix I presents the conclusions on TORs (i) to (iv). Appendix II provides a summary of the comments received on first and second round of consultation within the EWG.

18. Appendix I, Section 1 presents the summary conclusions reached in respect of TORs (i) – (iii).

EWG participants were also invited to provide alternatives for the management of unsupported compounds without public health concerns scheduled for periodic review, taking into account the challenges detected for options 2b and 3. Appendix I, Section 2 presents the summary conclusions in respect of TOR (iv).

[4] REP19/PR, paras. 207-215

Recommendations

19. In view of the rescheduling of CCPR to 2021, Codex members and observers are invited to provide their views on the summary conclusions in Appendix I, in particular the proposals for alternatives to the management of unsupported compounds without public health concerns for the two options described in Section II. Comments submitted will be considered by the EWG established by CCPR51 in order to present a proposal/proposals for consideration by CCPR52 in 2021.

20. A circular letter will be issued by the Codex Secretariat to facilitate submission of comments and their analysis by the EWG.

APPENDIX I

CONCLUSIONS
(For consideration by Codex members and observers)

SECTION 1. Conclusions for the TOR (i), (ii) and (iii)

TOR (i). Investigate the circumstances that lead to unsupported compounds and obstacles that prevent providing support

Circumstances that leads to unsupported compounds

1. Many of the "old" compounds do not receive data support for periodic reviews due to technical and economic reasons. Economic reasons include (but are not limited to) the fact that "old" compounds are no longer protected by patents and can be produced by multiple generic companies, with no economic incentives for the original sponsoring companies to develop the required data to support JMPR periodic reviews. They may also be unwilling to support the generic ("old") pesticides as they have developed newer compounds that are less toxic, more effective in pest management or offer other advantages from a market perspective.

2. On the other hand, the parties that might be interested in presenting data do not always have the resources to generate all the required data.

3. Finally, some Codex member countries and observer organizations lack detailed knowledge regarding the Codex procedures for the scheduling of compounds for periodic reviews as well as the generation and submission of the required data to enable JMPR to conduct a periodic review.

Obstacles that prevent providing support to these compounds

4. Lack of technical and economic capacity of some Codex members and observers to generate and submit the data required by JMPR to conduct the periodic review.

5. The possible low demand for these compounds and market competition, where the original sponsoring companies prefer to prioritize new compounds and not support the periodic review.

Information and data that are required to support a periodic review of a pesticide and corresponding CXLs[5]

6. While there is a general understanding of the data requirements to conduct a periodic review, not all Codex members and observers participating in CCPR are sufficiently informed and trained to understand, generate and submit the required data to support a periodic review of a pesticide. The cost of generating the required data also limits the capacity of some members.

7. It is noted that those who have the best knowledge are the JMPR experts and the countries that carry out a risk assessment, so that the challenge still persists for FAO and WHO and other international organizations to strengthen and adequately support those countries with less experience.

Consequences that follow from lack of data support for certain compounds/uses

8. While there is a general understanding that the issue is important to CCPR, not all Codex members and observers participating in CCPR are sufficiently aware of the consequences of the lack of data support, which may include the revocation of existing CXLs or the complete removal of the compound from the Codex list of pesticides. This group includes members that still use or market "old" compounds for all or some of their uses.

9. Not all Codex members are clear about the costs and benefits of generating the required data, in terms of public health and trade and subsequent capacity strengthening.

TOR (ii). Explore options for efficient data support

10. It is generally agreed that it is possible that Codex members and observers participating in CCPR can collaborate efficiently with other members which currently lack the ability to independently support important uses / compounds for their production systems.

11. The existing opportunities that aim at strengthening collaboration between Codex members and observers participating in CCPR are identified in Appendix II. However, 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.

12. To carry out the above, it is key to prioritize the different cases to ensure that collaboration be carried out efficiently.

[5] CXLs (= Codex maximum residue limits for pesticides as adopted by the Codex Alimentarius Commission)

Kind of collaboration activities

13. Collaboration activities focusing on specific projects, courses and training amongst Codex members, between members and observers with the support of the JMPR Secretariat or with other international organizations such as FAO and WHO.

14. In order to carry out this collaboration, the scope of the problem with respect to unsupported compounds without public health concerns 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. Consideration could be given to reducing the data requirements for JMPR re-evaluation of such compounds.

TOR iii. Explore the advantages and challenges that arise from the options 2b and 3 as recommended by CCPR51

Option 2b. Only those CXLs for which there are registrations listed in the national registration database (NRD) will be retained

Advantages

15. There is general consensus that this option helps to maintain more CXLs, which helps to facilitate international trade, without depriving public health, since the primary toxicological assessment is still valid, and allows Codex members / observers to have access to this supporting scientific information.

16. This option also allows to simplify the procedure for the periodic review, reducing the workload and costs, mainly for JMPR but also for CCPR.

Challenges

17. The main points identified are related to the fact that some CXLs may be considered outdated in terms of the underlying risk assessment, because their GAP (= good agricultural practice) could have changed or have obsolete toxicological evaluation and, therefore, lead to possible health problems. On the other hand, it would be essential to keep the NRD up to date and improve the outreach of Codex members to send information.

18. Finally, the procedures associated with the periodic review should be adapted or modified to incorporate this option.

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

Advantages

19. With this option only CXLs that are periodically re-evaluated under the periodic review are maintained and therefore, the revised CXLs are sufficiently protective for consumers. The 4-year rule grants a sufficient period of time to address the data requirements for periodic review, not implying changes in current Risk Analysis Principles applied by CCPR.

Challenges

20. The main points identified are that, with this option, the loss of CXLs would occur if the necessary data is not generated, reducing the options of pesticides for agriculture and trade. Under this option, CXLs for unsupported compounds would be revoked by the Codex Alimentarius Commission without identified public health problems.

21. The foremost challenge is to create capacity and collaborative work among Codex members and observers, so as to generate the data required by JMPR within 4 years, and not lose CXLs of unsupported compounds for which no public health concerns have been raised.

SECTION 2. Conclusions for TOR (iv) - Proposed alternatives for the management of unsupported compounds without public health concerns scheduled for periodic review

Option 2b. *Only those CXLs for which there are registrations listed in the NRD will be retained*

22. To introduce an amendment to the Risk Analysis Principles applied by CCPR under its "Periodic Review" section to incorporate this variant. The EWG could prepare a proposal for amendment of the relevant section of the Risk Analysis Principles applied by CCPR, based on proposals submitted by Codex members and observers, for consideration by CCPR52 (2021).

23. 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, to ensure that the NRD is kept up-to-date.

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*

24. Option 3 is adequately covered by the Risk Analysis Principles applied by CCPR under the section on periodic review. However, there may be room to improve Codex members compliance with this option by considering additional practices within the EWG on Priorities as indicated in paragraph 25. This is in addition to all the practices already established within the EWG to draw the attention of Codex members and observers on compounds scheduled for periodic review listed in Tables 2A and 2B. The following alternatives could be considered:

25. To establish *practices* within the EWG on Priorities, whereby the countries which do not have the capacities to provide the data required to take forward the periodic review, identify the CXLs listed in Tables 2A and 2B of interest to them. These practices should stipulate a limited period of time to request comments from Codex members and the deadline for their submission, in order to present a summary of the answers at the next CCPR meeting with a view to promoting collaboration across members and observers for the generation and submission of data.

26. 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. Ideally, these activities could be directed towards different actors whether within the government, as well as private actors, research institutes or other partner bodies/institutions.

27. To create a forum or similar platform for allowing different Codex members to provide data or partial studies of compounds in order to help members with difficulties to gather the data required.

APPENDIX II
(ORIGINAL LANGUAGE)

Consolidated report for replies to first round of comments
Comments received from Chile, Costa Rica, Germany, European Union, Uruguay and the United States of America
(For information)

TOR/Question	Commenter	Comment
TOR 1/Question 1 **Which are the circumstances that leads to unsupported compounds?**	Chile	• Desconocimiento de los Miembros en relación a los procedimientos para aportar información sobre los análisis de riesgos necesaria para apoyar compuestos, a pesar de la existencia de los manuales de procedimientos adoptados por el Codex Alimentarius, los cuales se señalan a continuación: a) Principios de aplicación práctica para el análisis de riesgos aplicables en el marco del Codex Alimentarius. (Adoptados en 2003) b) Principios para el análisis de riesgos aplicados por el Comité del Codex sobre residuos de plaguicidas. (Adoptados en 2007. Revisado en 2014, 2015) c) Bajo interés de las empresas patrocinadoras en aportar datos para la reevaluación
	Costa Rica	Compuestos que son antiguos que en algunos casos podrían tener problemas de generación de resistencia de las plagas y enfermedades o que el retorno económico es bajo y estas pueden ser menores que generar los datos adecuados para la evaluación de la JMPR, por lo que llegan a ser de desinterés para los registrantes. En nuestras zonas tropicales se tiene, una gran variedad de cultivos que se consumen y son parte de nuestra cultura, es tanta la variedad que se dificulta la generación de datos para todos ellos para cada plaguicida, tanto por razones de retorno económico, de capacidad estructural para poder dar atención a la generación de datos para todos esos usos menores.
	European Union	Currently, there is a lack of consequences when a compound is no longer supported, as the CXLs stay in place and revocation of CXLs has been limited to few exceptions (e.g. azinphos-methyl and phosalone in 2019). There is at present no clear incentive for interested parties to invest in compiling a dossier, or even generation of new data. However, even if revocation of CXLs was agreed for additional substances, there are structural issues that complicate matters: the cost for dossier compilation and/or data generation must be borne by one or several interested party(ies), whereas the benefits of a CXL, once set resp. confirmed, are accessible to all (i.e. all manufacturers of pertinent plant protection products, all farmers that could potentially use such PPP on their crops, all food business operators downstream of production), without them contributing to recovery of the costs.
	Germany	It is most likely economic reasons not to support an active substance any longer. After 15+ years there is no longer any protection on the studies provided for the active substance and the plant protection products in many countries. Market access will play a major role. For many markets the turn-over will not justify the development of new studies.

TOR/Question	Commenter	Comment
	United States	There may be several contributing factors that relate to the fact that unsupported compounds are no longer protected by patents and may be produced by multiple generic manufacturers. These generic manufacturers may not have ownership rights of existing data and may lack the financial resources and technical capacity to generate additional data to support JMPR reviews. The manufacturers may also lack awareness of CCPR/JMPR policies and procedures and understanding of the potential implications of CCPR/JMPR designating compounds as unsupported. Finally, some manufacturers may not wish to support older, generic pesticides if they have developed newer products that are less toxic, more effective at management of pests, or offer other advantages from a market perspective.
TOR1/Question 2 **Which are the obstacles that prevent providing support to these compounds?**	Chile	Falta de recursos económicos, equipos de trabajo y tiempo, tanto para los patrocinadores originales y por parte de los Miembros que podrían estar interesados en apoyar total o parcialmente los CXL de un determinado plaguicida.
	Costa Rica	• Altos costos la generación de datos adecuados para la evaluación de la JMPR • Baja demanda • Muchos competidores en el mercado • Falta de capacidades para la generación de datos
	European Union	See response to question 1.
	Germany	To earn money with a plant protection product mean to have a dossier according to the current scientific and technical knowledge at hand. The original sponsor knows best how much he has to investigate to have such a dossier in hand. Third party companies did not normally know this and may refrain from becoming a sponsor.
	United States	As described in the response to TOR 1 - Question 1, the following obstacles may prevent support of these compounds: • Unsupported compounds may be produced and marketed by multiple, independent manufacturers who do not have commercial ownership of original data used to support registration at the national-level and review by JMPR (i.e., toxicology studies and field residue trials). This data may be proprietary and require manufacturers of unsupported compounds to purchase data from the original sponsor. As a result, providing support for compounds may require multiple companies to form a partnership and then negotiate with companies that own proprietary data. • Manufacturers of unsupported compounds may lack experience with Codex and be unaware of the ramifications of not supporting the JMPR periodic review process. These companies may be unaware of the periodic review process, data requirements, and timelines for providing information to CCPR/JMPR. • Some companies may develop newer compounds that are in the same market as existing, unsupported compounds (e.g., target pest/crop combinations). They may wish to market these newer compounds and not support the period review process for older compounds.

TOR/Question	Commenter	Comment
TOR1/Question 3 **Do you believe that all Codex members and observers participating in CCPR are sufficiently aware of what information and data are required to support a periodic review of a pesticide and existing CXLs?**	Chile	Se considera que probablemente no todos los Miembros están adecuadamente informados respecto a la información requerida para apoyar una evaluación periódica. También se podría mencionar, que persiste el desafío en la actual institucionalidad Codex y de otros organismos internacionales de apoyar adecuadamente a los países, en particular a los no desarrollados, en que se informen, comprendan e implementar los procedimientos existentes.
	Costa Rica	No, solo los miembros que han generado la información y datos que se requieren pueden tener una conciencia real de las necesidades, países en desarrollo que no generan los datos y realizan adopción de LMR es poco probable por la falta de experiencia. Es necesario fortalecer las capacidades.
	European Union	The necessary information are applicable to all substances. They are provided in the JMPR Call for Data, the Environmental Health Criteria (EHC) 240 Principles and methods for the risk assessment of chemicals in food (2009) (http://www.inchem.org/documents/ehc/ehc/ehc240_index.htm), and in the FAO Manual (Plant Production and Protection Paper 225).
	Germany	We believe the best knowledge is with the JMPR experts and those countries recently do a risk assessment.
	United States	We believe members and observers have a general understanding of the information and data requirements for periodic review – specifically that organizations (e.g., manufacturers, trade groups, etc) must affirm that they will support a compound and submit a data package and dossier to JMPR. While there is a general understanding of the information/data requirements, we do not believe that all members and observers are sufficiently aware of what information and data that are required to support a periodic review of a pesticide and existing CXLs. Therefore, it may be helpful to characterize why existing assessments may be insufficient and what additional supporting information and data is required to support periodic review. For example, it may not be clear if organizations are required to submit a complete data package that includes all available information and data or is it sufficient to submit a more targeted submission that is focused on deficiencies. It is also unclear when these deficiencies are identified and by whom.
TOR1/Question 4 **Do you believe that all Codex members and observers participating in CCPR are sufficiently aware of the consequences that follow from lack of data support for certain compounds/uses?**	Chile	Muchos países, posiblemente la mayoría de los miembros que participan en el CCPR, no están conscientes de las consecuencias, dado que no están informados. Por otra parte, no existe un documento que describa la importancia de contar con CXL y que pasa cuando un CXL se suprime, contemplando ejemplos claros para los diferentes escenarios (se suprimen todos los CXL, se suprimen algunos, se mantiene solo los individuales, etc.).
	Costa Rica	La mayoría de los miembros y observadores conocen las consecuencias que trae la falta de apoyo de datos para ciertos compuestos/usos, sin embargo, algunos de ellos no son los suficientemente conscientes de las consecuencias que puede traer en diferentes países, por ejemplo, los países subdesarrollados. No hay claridad en algunos miembros sobre beneficio a nivel de salud y económico que obtiene el miembro al generar los datos requeridos, falta abordar el costo/beneficio de la generación de datos

TOR/Question	Commenter	Comment
	European Union	The consequences are clear from the Risk Analysis Principles that are part of the Codex Alimentarius Procedural Manual. The ongoing discussion at CCPR level and in this electronic Working Group serves to further increase awareness of the already existing framework.
	Germany	We believe that we have some deficiencies concerning the consequences with some members. It seems that they do not believe that CCPR will strictly apply the Risk analysis principles. The original sponsors are aware of the consequences but as stated above are not normally interested. Other observers more like behave like some members.
	United States	CCPR is still developing its procedures for managing unsupported compounds. Therefore, while there is a general understanding that the issue is of importance to CCPR, we do not believe that all CCPR members and observers are sufficiently aware of the potential consequences of lack of data support, which may include revocation of existing CXLs. Therefore, it may be helpful for the EWG to more fully quantify the number of unsupported compounds and the MRLs that could potentially be impacted if supporting organizations are not identified.
	Uruguay	1. La causa principal desde nuestro punto de vista es que las empresas patrocinadoras no tienen interés en continuar sosteniendo compuestos antiguos ya que actualmente están abocadas en la generación de datos sobre nuevas moléculas. Los costos económicos para realizar los estudios necesarios para mantener vigentes estos compuestos desalientan a las empresas debido a que los nuevos plaguicidas producen mayores beneficios ya sea económicos como de eficiencia en su uso u otras ventajas. 2. Existen dificultades en proporcionar la información necesaria para que la JMPR realice la reevaluación periódica de los plaguicidas no apoyados. Muchas veces hay desconocimiento de cuál es la información que se debe proporcionar y de qué forma debe canalizarse. Como consecuencia de que las empresas no están dispuestas a invertir en este tema serían los gobiernos que deberían hacerlo, allí es donde surgen obstáculos económicos, de infraestructura y recursos humanos para poder realizarlos. 3. Desde nuestro punto de vista, muchos de los miembros no conocen en profundidad qué información y datos se requieren para apoyar una evaluación periódica de un plaguicida y sus CXL existentes. 4. Los países miembros que dependen de determinados compuestos no apoyados por los fabricantes son conscientes de que la eliminación de los CXL en el Codex traerá graves repercusiones en el comercio de sus productos. Por este motivo muchos países adhieren su preocupación por el tema y creen que se deben proponer alternativas para la gestión de los compuestos sin apoyo.

TOR/Question	Commenter	Comment
TOR2/Question 1 **Do you believe it is possible that Codex members and observers participating in CCPR could efficiently collaborate to assist other Member states, currently lacking the capacity to independently support pesticides/uses important to their production systems, to develop data packages adequate for JMPR evaluation?**	Chile	Sería posible, siempre y cuando exista un procedimiento o guía para hacerlo, elaborada por el CCPR, junto con tener la capacidad de participar o postular con proyectos que apunten a este objetivo, para lo cual se requiere buscar financiamiento. Se debiera analizar los actuales "Principios para el análisis de riesgos aplicados por el Comité del Codex sobre residuos de plaguicidas", para identificar si es posible esta cooperación de manera explícita y clara. Además los países miembros que no cuentan con las organizaciones capaces de apoyar plaguicidas, deberían indicar cuáles son sus obstáculos, de tal forma que se les otorgue el sustento necesario para abordar dichas situaciones y puedan aportar futuramente en la emisión de datos.
	Costa Rica	Sí es posible que los miembros y observadores que hayan generado información importante sobre los compuestos sin apoyo puedan colaborar a otros estados Miembros que carecen de la capacidad de apoyar de forma independiente usos/plaguicidas importantes para sus sistemas de producción para desarrollar paquetes de datos adecuados para la evaluación de la JMPR. Sim embargó es un gran desafío, en especial porque para soportar los datos entre los miembros para un estudio, se requiere que las BPA utilizadas en los ensayos hayan sido iguales o muy similares y en los países con climas tropicales donde los productos están sujetos a altos niveles de presión de plagas y enfermedades es difícil tener BPA armonizadas con otras zonas climáticas. Lo que genera que el miembro deba de realizar la totalidad de los ensayos (un nuevo estudio) que se requieren para realizar la evaluación.
	European Union	The European Union supports several programmes of relevance in this regard, of which the following two are worth mentioning: • The "Fit for market" programme, implemented by COLEACP: its objective is to allow smallholder farmers, producer groups, farmer organisations, and small and medium enterprises, to access international and domestic fruit and vegetable markets by complying with the SPS standards and market requirements, in a sustainable framework. • The "Plantwise+" programme, to be implemented by CABI, following the past "Plantwise" project: its objective is to increase food security and improve rural livelihoods by reducing crop losses and addressing issues regarding safe use of pesticides. While the data generation and dossier compilation with a view to requesting import tolerances have been supported by "Fit for market" in the past, this was limited to residue trials. Whether the costs for toxicity studies could also be covered under this programme would have to be established. Besides the development of data packages, the EU's "Better Training for Safer Food" (BTSF) training initiative covers food and feed law, animal health and welfare and plant health rules. Courses are delivered in EU and non-EU countries, targeting the staff of competent authorities from EU and selected non-EU countries dealing with official controls. The initiative follows the "train the trainers" principle and participants should disseminate the knowledge acquired from the training amongst their colleagues in their home countries. Specific training courses relate to plant health, integrated pest management and food safety, in relation to residues of PPP.

TOR/Question	Commenter	Comment
	Germany	In the beginning it needs a lot of efforts to convince different members and observers to work together to find out whether or not it make sense to support an active substance and which additional data might be necessary. Some kind of collaboration platforms are needed to bring partners together. An example might be the EU's "Better Training for Safer Food" (BTSF) training initiative covers food and feed law, animal health and welfare and plant health rules.
	United States	There are opportunities to foster general collaboration between CCPR members and observers. This collaboration could focus on (i) defining the scope of the issue with respect to unsupported compounds and number of MRLs, (ii) identifying CCPR members and observers that have an interest in specific compounds that are unsupported, and (iii) outlining the data package requirements for JMPR evaluation. More targeted collaboration on development of data packages may require more intensive use of CCPR member/observer resources to assemble and prepare data package submissions. As such, it will be important to prioritize specific pesticides uses, outline data requirements, and identify key stakeholders to ensure collaboration is done efficiently.
TOR2/Question 2 **What kind of collaborations activities you believe can be developed?**	Chile	Cursos y Capacitaciones específicas. Desarrollo de guías claras en el marco del CCPR para realizar la presentación de datos, una propuesta concreta fue la realizada en el documento CX/PR 19/51/17, en la cual se planteó la siguiente alternativa para facilitar la entrega de datos: • *La Secretaría del Codex emitirá una carta circular a principios de septiembre de cada año a todos los miembros/observadores, solicitando la presentación de datos sobre toxicología, residuos y de otro tipo pertinentes para respaldar la reevaluación de los plaguicidas enumerados en el Cuadro 2A y los remitirán al Presidente del GTe sobre prioridades y a las secretarías de la FAO/OMS y la JMPR.* • *La carta circular deberá ser preparada por la JMPR en coordinación con el Presidente del GTe sobre prioridades.*
	Costa Rica	Foros de discusión donde participen los Miembros y Observadores que han generado datos y poseen información de los compuestos sin apoyo. Realizar estudios en conjunto, desarrollo de capacidades; para países en desarrollo, es necesario agrupar por zonas climáticas y desarrollar los estudios en conjunto, de modo que el LMR establecido, contemple los usos que realmente están autorizados en nuestros países. • Crear políticas, de generación de datos, incentivos de registro, de extrapolación, entre otros, de modo que los esfuerzos que sean generados, sirvan de sustento para abarcar varias autorizaciones de uso.
	European Union	Development of data packages through indirect support of some Codex members to other Codex members may help punctually, i.e. on few selected substances. A more general solution would require collaboration with industry. As described under the response to TOR1-Q1, the current system does not provide suitable incentives for industry to invest in data generation for substances that do not enjoy sufficient protection of intellectual property.

TOR/Question	Commenter	Comment
	Germany	Support of the substance • Why is an active substance not in use in certain areas of the world? (members, observers) Existing and missing data • Which data are available? (JMPR) • Which existing data are no longer valid? (JMPR) • Which additional data are needed to support the active substance? (GAP of interested members) Data collection • Who is willing to conduct the necessary studies? (interested parties) Therefore, different player will be needed and they may change depending on the substance in question.
	United States	As described above, collaboration could focus on (i) defining the scope of the issue with respect to unsupported compounds and number of MRLs, (ii) identifying CCPR members and observers that have an interest in specific compounds that are unsupported, and (iii) outlining the data package requirements for JMPR evaluation and organizations that may be able to provide the supporting information/data.
TOR2/Question 3 **Do you consider that there is any possibility to reduce the minimum data requirements for a JMPR re-evaluation of a pesticide without a registered public health concern? If so, what are the minimum data requirements you consider appropriate?**	Chile	Se considera que los requisitos mínimos deberían ser los establecidos, teniendo la precaución de tomar en cuenta aquello que ya existe y que no ha variado. Esto para ser consecuentes y consistentes con los principios que establece el Manual de Procedimientos, en especial el rol e importancia de la ciencia.
	European Union	As the name suggests, the minimum data requirements for a JMPR re-evaluation should not be further reduced, as that may compromise JMPR's ability to assess the safety of a substance.
	Germany	A reduction will be hard to realize, especially in the area of toxicology. An important question concerning residues to be answered, are there changes in GAP in the meantime? Use of existing evaluations not older than 2 - 5 years might be a possibility to be explored by JMPR.
	United States	It may be helpful for JMPR to provide clarity on the minimum data requirements for periodic review of a compound with no public health concerns. For example, are there components of the existing JMPR data package that warrant re-evaluation or require development of new data? This would help CCPR members and observers better understand the resources required to support periodic review and deliberate on the potential minimum data requirements.
	Uruguay	1. Desde nuestro punto de vista es posible que los Miembros y Observadores del CCPR colaboren en la generación de paquetes de datos, principalmente los miembros con experiencia en presentación de información adecuada para la evaluación de la JMPR. 2. Actividades de capacitación entre países integrantes del Codex, coordinación en la realización de ensayos entre diferentes países considerando el mismo plaguicida/uso (dividir los ensayos entre los países interesados a fin de alcanzar el número de ensayos necesarios), obtención de financiamiento para la realización de los ensayos.

TOR/Question	Commenter	Comment
		3. Asociada a la respuesta del TDR 1. Pregunta 3, muchas veces no se conoce en profundidad la magnitud de información a presentar por lo que esta respuesta debería ser dada posteriormente a profundizar en los datos que deben presentarse para apoyar la evaluación periódica de un compuesto.
TOR3/Option 2b Advantages	Chile	1. Da la posibilidad a los Miembros, de seguir contando con CXLs recomendados por el Codex Alimentarius, y todas las ventajas que esto implica, tanto desde el punto de vista de inocuidad como comercial. 2. Sólo implicaría una modificación menor en los "Principios para el análisis de riesgos aplicados por el Comité del Codex sobre residuos de plaguicidas". 3. Simplifica el procedimiento de Revisión Periódica. 4. Reduce el trabajo y costos de la JMPR y CCPR.
	Costa Rica	Las exportaciones agrícolas de los miembros que actualmente utilizan estos compuestos no se afectarán.
	European Union	Maintenance of more CXLs, leading to larger choice of PPPs for producers. Note however that exporting markets may take steps and thus be less aligned to CXLs if some of them are considered out of date
	Germany	Important uses for certain countries are still covered by a CXL
	United States	1. This option helps facilitate international trade and protect public health by maintaining existing CXLs with no public health concerns. In other words, there may be no disadvantage to maintaining CXLs if JMPR's existing review is adequate. 2. The focus on compounds that are registered at the national level helps limit the scope of acceptable compounds to only those that have been reviewed and approved by national authorities. 3. Members/observers should have access to the supporting scientific information on national reviews used to justify registration by their respective authorities.
	Uruguay	1. Mantener el CXLs solo para los usos registrados en los países limita la necesidad de generar información para la evaluación de la JMPR, ya que solo deberá generarse información para los cultivos específicos registrados por los países miembros del Codex. Se reducirían las combinaciones plaguicidas/usos para los cuales se debe presentar información. 2. Aumentar la participación en el Codex, ya que sería de interés por parte de los países que los usos específicos registrados estuvieran actualizados en la NRD. 3. Mantener los CXLs de plaguicidas con usos registrados facilitará el comercio lo cual es un mandato del Codex.
TOR3/Option 2b Challenges	Chile	1. Reunir y tener actualizada la información relativa a los registros nacionales. 2. Aprobar en el CAC modificación menor de los "Principios para el análisis de riesgos aplicados por el Comité del Codex sobre residuos de plaguicidas" en lo que dice relación a la Revisión Periódica.
	European Union	Some CXLs may be considered out of date in terms of the underlying risk assessment.

TOR/Question	Commenter	Comment
	Germany	1. outdated toxicology and therefore possible health concerns 2. GAP may have changed, CXL might be too high or too low 3. possibly high input of resources for few uses
	United States	1. Different national authorities may have different registration requirements. As a result, CCPR members may be hesitant to retain a CXL based on registration by a different national authority. 2. National registration may be subject to change so there may be some uncertainty in using it as the basis for CXL retention/revocation.
	Uruguay	1. Resulta un desafío tanto para los países como para el Codex mantener actualizada la Base de datos de Registros Nacionales. 2. Para poder aplicar la opción 2b. todos los países integrantes del Codex deben enviar la información para la construcción de la Base de Datos de Registros Nacionales.
TOR3/Option 3 **Advantages**	Chile	No requiere modificaciones de los "Principios para el análisis de riesgos aplicados por el Comité del Codex sobre residuos de plaguicidas"
	Costa Rica	1. Evitar afectación a la comercialización agrícola. 2. Tiempo prudencial para generar datos.
	European Union	Only CXLs are maintained that are periodically re-evaluated and therefore sufficiently protective for consumers based on recent regulatory science, with positive effects on consumer protection but also trust in Codex standards.
	Germany	1. Toxicology will be reviewed 2. GAPs and CXL will be updated 3. Sufficient time to update the dossier
	United States	1. This option will help ensure that all periodic reviews are based on the same information requirements. 2. The 4-year rule gives CCPR members and observes a predictable time period for addressing the data requirements for periodic review.
	Uruguay	1. Permite en un plazo prudente presentar la información necesaria para sostener un CXL y durante ese plazo mantener el CXL. 2. A medida de que los países generen las capacidades para presentar la información necesaria para la evaluación de la JMPR, se podrían mantener los CXL´s de plaguicidas vitales para la producción de sus cultivos.

TOR/Question	Commenter	Comment
TOR3/Option 3 **Challenges**	Chile	1. Mantiene la situación sin resolver, existiendo la posibilidad que se mantenga esta polémica por mucho tiempo, teniendo presente que hay otras urgencias y prioridades. 2. Intentar trabajo colaborativo entre países. 3. Se requiere sortear todos los problemas asociados a la baja capacidad de los países no desarrollados a reunir y generar información para el análisis de riesgos. 4. Incentivar a instituciones públicas y privadas para que produzcan y emitan información pertinente para el análisis de riesgos en un corto plazo.
	Costa Rica	1. Poder generar la información necesaria para cumplir con los requerimientos de datos para mantener los CXLs 2. Para los miembros que utilizan estos compuestos en estos cuatro años deben tener compuestos que los sustituyan y que sean menos tóxicos, menos ecotóxicos y más eficaces en cuanto al uso que estaba destinado los compuestos sin apoyo. 3. Aun así el costo de los datos es excesivo para poder regenerar los estudios ya hechos para una gran variedad de cultivos de las regiones tropicales, de igual manera se podría generar únicamente para los de importancia comercial pero no para aquellos que son de importancia cultural y de consumo de nuestros países, que a la vista de un registrante es un cultivo menor, del cual no tendrá retorno económico
	Germany	1. Overall 30 years without an update of toxicology and residue behavior (double the time originally foreseen) 2. Loss of CXLs due to missing support
	United States	1. This option may result in loss of CXLs even though no public health concerns were identified. 2. The minimum data requirements have not been fully described, so it is unclear if a 4-year time period for addressing data requirements is reasonable.
	European Union	1. Loss of CXLs, leading to reduced choice of PPPs for producers.
	Uruguay	Es un desafío desarrollar las capacidades en los países para generar la información necesaria para la evaluación de la JMPR en el plazo de 4 años. Es decir, poder cumplir con la regla de los 4 años.

APPENDIX III

EXCERPT OF CX/PR 19/51/17 ON MANAGEMENT OPTIONS FOR UNSUPPORTED COMPOUNDS SCHEDULED FOR PERIODIC REVIEW WITHOUT PUBLIC HEALTH CONCERNS
(For information)

III.2 Unsupported compounds without public health concerns

12. The following options are presented for managing unsupported compounds listed in Tables 2A and 2B **without public health concerns**

13. The Codex Secretariat shall issue a circular letter (CL) in early September each year to all Members/observers requesting the submission of toxicology, residue and other relevant data to support the re-evaluation of pesticides listed in Table 2A and submit the same to the Chair of the EWG on Priorities and to the FAO/WHO JMPR Secretariats.

14. The CL should be prepared by JMPR in coordination with the Chair of the EWG on Priorities.

15. If the information requested as above on the listed pesticides is not provided, the following procedure will be adopted:

16. Option 1. Maintain status quo; the pesticide is maintained in Table 2A and all CXLs for the pesticide are retained.

17. Option 2. Options 2a and 2b may be considered for compounds that have one or more registrations as per the "National Registration Database (NRD)" managed by EWG chaired by Germany and co-chaired by Australia (see Agenda Item 13).

    Option 2a. All CXLs will be retained if there is a single registered use listed in the NRD; or

    Option 2b. Only those CXLs for which there are registrations listed in the NRD will be retained.

18. Under either Option 2a or 2b, CCPR may recommend that Members do not grant new registrations for these compounds. Relevant CXLs will be withdrawn if valid national registration no longer exists.

19. Option 3. Members are granted 4 years to fulfill the data requirements to maintain the CXLs. (i.e., 4-year rule). If Members are unable to address the data requirements, all CXLs are to be withdrawn.

20. After 25 years the toxicological evaluation may be outdated and no longer reliable. Health concerns cannot be excluded in this case. Independent of the options above a re-evaluation of toxicology should take place. Otherwise all CXLs should be revoked. The health concerns should be reported to the CCPR to indicate a need for re-evaluation.

21. If at any stage a member submits a public health concern, supported by the JMPR, for a pesticide being managed under any of the above options, the provisions described under **III.1 Unsupported compounds with public health concerns** would apply. Clear guidance should be developed by the JMPR as to when a public health concern would result in Case III.I being applied.

APPENDIX IV

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