U.S. DRAFT POSITIONS for the

Codex Committee on Pesticide Residues (CCPR)

54th Session

Beijing, China

June 26 – 29, 2023 (Plenary Sessions)

July 1, 2023 (Report Adoption)

Prepared for U.S. Public Meeting May 24, 2023

Updated: May 25, 2023

These positions may be revised or updated prior to the Committee meeting.

Agenda Item 1 CX/PR 22/54/1 Adoption of the Agenda

Background:

• The Codex Committee on Pesticide Residues (CCPR) will review the Provisional Agenda and consider its adoption.

U.S. Position:

 The United States has reviewed the Provisional Agenda and does not have any proposed changes to recommend.

Agenda Item 2

Appointment of Rapporteurs

Background:

• The CCPR will appoint a Rapporteur(s).

U.S. Position:

• The United States supports this action.

Agenda Item 3 CX/PR 22/54/2

Matters Referred to the CCPR by the Codex Alimentarius Commission (CAC) and Other Subsidiary Bodies

Background:

Pending document.

A. MATTERS ARISING FROM THE CODEX ALIMENTARIUS COMMISSION (CAC)

B. MATTERS ARISING FROM SUBSIDIARY BODIES AS RELATED TO THE WORK OF CCPR

U.S. Position:

• The document is not currently available. The United States will develop positions if warranted.

Agenda Item 4(a)
CX/PR 22/54/3
Matters arising from FAO and WHO

- The document was only recently made available for review and provides information from the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) on the following topics of interest to CCPR:
- One Health and Pesticide Risk Reductions
 - Under this framework, FAO promotes integrated pest management (IPM), biopesticides, agroecology and other green production practices to reduce reliance on chemical pesticide use and to reduce pesticide residues and risks to human health and the environment.

- FAO continues to support Member states to strengthen sound pesticide management and risk reduction through the lifecycle management approach. In addition, FAO supports Members on capacity building of residue standards setting and monitoring, promoting food safety and facilitating international trade of produce through trainings and projects.
- FAO has launched several new tools and training resources in 2022. With respect to
 pesticides, these include new models as part of the FAO Pesticide Registration Toolkit and
 a Manual on Microbial Pesticide for FAO/WHO.

National databases on individual food consumption and dietary exposure assessment

- FAO/WHO maintains a database of chronic individual food consumption data based on 68 datasets containing at least two days of consumptions.
- The database continues to offer Members the possibility to submit monitoring data on chemicals hazards, including pesticides residues in food and help understand global occurrence and dietary exposures to residues. M

Early warning alert and response to food safety emergencies

 The Secretariat of the joint FAO/WHO International Food Safety Authorities Network (INFOSAN) continues to develop and strengthen the Network and develop capacity for preparedness and response to food safety incidents. During 2022, the INFOSAN Secretariat was involved in 195 international food safety incidents involving 156 Member States from all regions.

U.S. Position:

• The document just became available and we are currently reviewing it. The United States will develop positions if warranted.

Agenda Item 4(b) CX/PR 22/54/4

Matters of interest arising from other international organizations

Background:

- In this instance, it is related to the activities of the International Atomic Energy Agency (IAEA) and reports on the activities Joint FAO/IAEA Centre of Nuclear Techniques in Food and Agriculture (Joint FAO/IAEA Centre).
- The document was only recently made available for review and provides information on joint activities between FAO and the International Atomic Energy Agency (IAEA) relevant to CCPR work . FAO and IAEA have established the Joint FAO/IAEA Center of Nuclear Techniques in Food and Agriculture (Joint FAO/IAEA Center). This Joint Center helps build technical capacity on the use of nuclear and isotopic analytical techniques to test and monitor pesticide residues and related hazards in food.
- The document is for information only.

U.S. Position:

• The document just became available and we are currently reviewing it. The United States will develop positions if warranted.

Agenda Item 5(a)

Report on items of general consideration arising from the 2022 Joint FAO/WHO Meeting on Pesticide Residues (JMPR) Meeting

Section 2 of the 2022 JMPR Report (English only)

2022 JMPR Report (https://www.fao.org/3/cc4115en/cc4115en.pdf)

Background:

- The document outlines the results of the JMPR on topics covered in Section 2 of its 2022 Report: General Considerations. The topics are listed below and are for information only:
 - 2.1 Requirements for data on the impact of residues on the human intestinal microbiome
 - **2.2** Non-linear kinetics (KMD)
 - 2.3 Interpretation and follow-up of positive results in *invitro* gene mutation assays
 - **2.4** A risk-based decision tree approach for the safety evaluation of residues of pesticides, veterinary drugs, food additives and contaminants
 - **2.5** Unnecessary use of *in vitro* animal studies
 - 2.6 Establishment of Maximum Residue Limits (MRL)s for pesticides for okra
 - **2.7** Blank (No Item Listed)
 - 2.8 Enhancing operational procedures of JMPR to reduce the backlog
 - **2.9** Organization for Economic Co-operation and Development (OECD) Update to the Guidance on Residue Definitions
 - 2.10 Information on residues in rotational crops following use on paddy rice
 - **2.11** Common pyrazole metabolites

U.S. Position:

• The United States has reviewed the findings in Section 2 of the 2022 JMPR Report and has the following comments:

2.6: Establishment of MRLs for pesticides for okra

- CCPR requested guidance from JMPR on the establishment of MRLs for pesticides for okra, based on the following options:
 - Option 1: Include a footnote to the current Subgroup 12B(i.e., "Pepper and pepper-like commodities, such as martynia and roselle" and indicate that data from chili pepper can be used to set a Codex MRL (CXL) for Okra; or
 - Option 2: Create a separate Subgroup 12D Okra with chili pepper as the representative commodity.
 - Option 3: Create a separate Subgroup 12D Okra (including martynia and roselle) with okra as the representative commodity.
- o JMPR2022 received monitoring data from the European Union, India and Singapore on okra in combination with data on chili pepper from Singapore. JMPR also considered data from Thailand, Australia, and Uganda and additional information in the public literature. Based on these data, JMPR concluded that Options 1 and 2 lacked robust data to support the proposed grouping/extrapolation. JMPR acknowledged that Option 3 (i.e., creating a separate subgroup for okra) would be difficult because okra is a minor crop so there is limited financial support for the required data generation.
- The United States recognizes that there are limitations in the available data on okra that must be balanced with concerns that there is insufficient financial support for the required data generation. For this reason, the United States continues to support practical efforts to include okra in an existing subgroup, such as Options 1 and 2 above (e.g., iclude okra in Subgroup 12B). In 2022, the United States supported a

similar risk management approach at CCPR53, based on monitoring data provided by Canada and India, that suggested that chili pepper (non-bell pepper) could be an appropriate representative commodity for okra. Further supporting information was summarized for CCPR53 in CX/PR 22/53/6 and suggested that the low exceedances for okra in available monitoring data and the sufficient conservatism in MRLs derived using the Organisation for Economic Co-operation and Development (OECD) MRL calculator would be protective and cover anticipated actual residues in okra.

2.8: Enhancing operational procedures of JMPR to reduce the backlog

o CCPR will have more detailed discussion on this topic under Agenda Item 13.

Agenda Item 5(b)

Report on responses to specific concerns raised by CCPR arising from the 2022 JMPR meeting Section 3 of the 2022 JMPR Report (English only)

2022 JMPR Report (https://www.fao.org/3/cb8313en/cb8313en.pdf)

Background:

 This Item is for information only. Section 3 of the 2022 JMPR Report outlines JMPR's conclusions in response to specific issues raised by CCPR, including concern forms submitted at CCPR53 (2022).

3.1 Chlorothalonil (081)(R):

- <u>Description of Concern:</u> The United Kingdom submitted a concern form at CCPR52 (2021) stating that the exposure estimated for the high temperature hydrolysis product R613636 from cranberry exceeded the threshold of toxicological concern, that the overall chronic exposure to R613636 from all commodities had not been addressed, and that the acute exposure to R613636 from cranberry had not been addressed.
- o <u>JMPR Conclusion:</u> JMPR2022 reconfirmed the conclusion that exposure to R613636 from the uses of chlorothalonil is not expected to be a safety concern.

3.2 Terbufos (167) (T):

- Description of Concern: Canada filed a concern form based on its assessment of terbufos. Both the JMPR and Canadian assessments agree on the selection of a No-Observed-Adverse-Effect Level (NOAEL) of 0.15 mg/kg body weight (bw) for the acute neurotoxicity study used in the derivation of the Acute Reference Dose (ARfD). However, a key difference between the Canadian and JMPR assessments is that the Canadian assessment applied an extra 10-fold safety factor (above the default factor of 100-fold) based on what Canada described as a steep dose response curve.
- JMPR Conclusion: JMPR2022 concluded that there is no reason to review the ARfD and ADI for terbufos ahead of its scheduled periodic review based on the available evidence.

U.S. Position:

 The United States has reviewed the findings of Section 3 of the 2022 JMPR Report and has no objections to JMPR's conclusions.

CX/PR 22/54/5 and Add.1

Proposed maximum residue limits (MRLs) for pesticides in food and feed (at Steps 7 and 4) Comments in reply to CL 2023/22 PR Due May 25, 2023

2022 JMPR Report (https://www.fao.org/3/cb8313en/cb8313en.pdf)

Background:

- JMPR 2022 met in Rome, Italy from September 13-22, 2022. At this meeting, JMPR evaluated 34 pesticides, including seven new compounds and four compounds that were re-evaluated as prescribed by CCPR's the periodic review program, for toxicity or residues, or both.
- The Meeting established Acceptable Daily Intakes (ADIs) and ARfDs, estimated supervised trials median residue (STMR) and highest residue (HR) levels as a basis for estimating dietary exposures, and recommended maximum residue limits (MRLs) for consideration by CCPR and subsequent adoption by CAC.
- It also estimated the dietary exposures (both acute and long-term) to the pesticides reviewed and, on this basis, performed a dietary risk assessment in relation to the relevant ADI and where necessary the ARfD. Cases in which ADIs or ARfDs may be exceeded, if they occur, are clearly indicated in order to facilitate decision-making by CCPR.

U.S. Position:

- The United States generally supports the MRL recommendations from JMPR 2022.
- The United States may submit a concern form for head lettuce and mefentrifluconazole.

Agenda Item 7

Revision of the Classification of Foods and Animal Feeds (CXA 4 1989)

- Agenda Items 7(a-d) reflect the ongoing work of the CCPR Electronic Working Group (EWG) on the Revision of the Classification of Foods and Animal Feeds (CXA 4-1989) to revise all the crop groups in the Classification. Revisions are advanced to the CAC for adoption once CCPR has completed work on a final compilation of related groups and tables for CXA 4-1989 and updated the Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups (CXG 84-2012) as appropriate. Existing CXLs remain unchanged until JMPR reviews are completed.
- The United States has co-chaired or chaired the EWG from the start of this effort, has provided much
 of the documentation for the proposed crop groups, and strongly supports this project.
- At CCPR53 (2022), the EWG was re-established, co-chaired by the United States and the Netherlands. Its terms of reference were to:
 - Continue working on Class B Primary food commodities of animal origin and Class E Processed food of animal origin (CX/PR 23/54/6) and prepare tables with examples of representative commodities for both classes (CX/PR 23/54/7);
 - (ii) Consider the proposals on the portion of the commodity to which maximum residue limits apply, and which is analyzed for Group 006 Assorted tropical and sub-tropical fruits inedible peel and Group 023 Oilseeds (CX/PR 23/54/8); and
 - (iii) Review the Guidelines on portion of commodities to which MRLs apply and which is analyzed (CXG 41- 1993) with a comparison to the Classification of Food and Feed (CXA 4- 1989) (CX/PR 23/54/9).

Agenda Item 7(a)

CX/PR 23/54/6

Revision of the Classification of Foods and Animal Feeds (CXA 4 1989)

- Class B Primary Food Commodities of Animal Origin and
- Class E Processed Foods of Animal Origin (All Types) (at Step 4)

Comments at Step 3 in Response to CL2023/34 PR Due May 31, 2023

Background:

- The EWG asked Members and Observers to submit comments on the proposed revised Classes B and E of the Classification of Foods and Animal Feeds (CXA 4-1989), as contained in Appendices I and II of CX/PR 23/54/6, and the respective tables (9 and 10) of examples of selection of representative commodities contained in Appendices I and II to CX/PR 23/54/7.
- According to the working document for this agenda item (CX/PR 23/54/6), the EWG recommends that this item be considered in conjunction with CX/PR 23/54/7 (Agenda Item 7b).
- EWG Recommendations on Class B Primary Food Commodities of Animal Origin
 - o Current Class B includes 5 types, 16 groups, 2 reserved groups and no subgroups.
 - Based on discussions and comments from the EWG, the proposed revised Class B includes 6 types, 18 groups, no reserved groups and 65 subgroups.
 - The additional groups include groups for Amphibians and Reptiles (replaces reserved Group 046) and the Invertebrate Animals group (replaces reserved Group 047).
 Numerous commodities have also been added to the respective groups/subgroups.
- EWG Recommendations on Class E Processed Foods of Animal Origin (All Types) (at Step 4)
 - Current Class E includes 4 Types, 8 groups (and 1 reserved groups) and no subgroups.
 - Based on discussions and comments from the EWG, the proposed revised Class E includes 10 groups with Group 081 Dried muscle and other avian products replacing Reserved Group 081.
 - Group 083 Secondary invertebrate food commodities of animal origin has also been added. Additional subgroups (13) have been added along with numerous commodities.

U.S. Position:

The United States supports the proposed revisions to Classes B and E.

Agenda Item 7(b)

CX/PR 23/54/7

Tables of examples of representative commodities for commodity groups in different types under Class B and Class E (at Step 4) (for inclusion in the *Principles and Guidance for the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups* (CXG 84 2012)

Comments at Step 3 in Response to CL2023/PR 34 Due May 31, 2023

- According to the working document for this agenda item (CX/PR 23/54/7), the EWG recommends
 that this document should be read in conjunction with the revised provisions for Class B and Class
 E as provided in CX/PR 23/54/6 (Agenda Item 7(a).
- The EWG continued work on examples of representative commodities for:

- Class B Primary Food Commodities of Animal Origin and
- Class E Processed Foods of Animal Origin.
- Table 9 of Appendix I in CX/PR 23/54/7 includes proposed examples for the selection of representative commodities for groups and subgroups for Class B, Types 6-10a:
 - Type 6 Mammalian products
 - Type 7 Avian products
 - Type 8 Aquatic animal products
 - Type 9 Amphibians and reptiles
 - Type 10 Invertebrate animals
 - Type 10a Miscellaneous primary food commodities of animal origin
- Table 10 of Appendix II in CX/PR 23/54/7 includes proposed examples for the selection of representative commodities for Class E, Types 16-19:
 - o Type 16 Secondary food commodities of animal origin
 - Type 17 Derived edible products of animal origin
 - o Type 18 Manufactured Food (single ingredient) of animal origin
 - Type 19 Manufactured food (multi-ingredient of animal origin)
- In making its recommendations, the EWG also noted that is not possible to establish representative commodities for all groups / subgroups, because of the diversity of commodities in some of the groups/subgroups.

• The United States supports the proposed examples of representative commodities for Class B and Class E and Tables 9 and 10.

Agenda Item 7(c) CX/PR 23/54/8

Portion of the commodity to which the MRLs apply, and which is analyzed for Group 006 Assorted Tropical and Sub tropical fruits Inedible Peel and Group 023 Oilseeds Comments at Step 3 in Response to CL2023/PR 35 Due June 5, 2023

- According to the working document for this agenda item (CX/PR 23/54/8), the EWG recommends that this document should be read in conjunction with CX/PR 23/54/9 (Agenda Item 7d).
- As part of its terms of reference, the EWG was requested to make recommendations on proposals on the portion of the commodity to which MRLs apply and is analyzed for:
 - o Group 006 Assorted tropical and sub-tropical fruits inedible peel
 - Ecuador proposed in a working document submitted to CCPR53 (CX 22/53/19) that the portion of commodities to which CXL apply and is analyzed should be the whole product without the peel for Group 006 Assorted Tropical and Sub-tropical fruits inedible peel (avocado, passion fruit, banana, pineapple, kiwi, mango, papaya).

- Group 023 Oilseeds (CX/PR 23/54/8)
 - Australia proposed in the Conference Room Document (CRD) submitted to CCPR53 (CRD11) that the EWG reconsider the portion of the commodity to which the MRL applies as there appears to be no record of discussion or agreement at CCPR to justify the change from "after removal of shell or husk" to "with shell or husk".
- The EWG reached consensus on the following proposed changes:
 - o For <u>Group 006</u>, the EWG recommended that the portion of the commodity to which the MRL applies is the whole fruit unless qualified. Examples of exceptions include:
 - Banana after removal of crown tissue and stalks.
 - Pineapple after removal of crown.
 - Avocado, mangos, and similar fruit with hard seeds: Whole commodity after removal of stone (residue calculated and expressed on whole fruit).
 - For Group 023, the EWG recommended that the portion of the commodity to which the MRL applies is as follows:
 - Oilseeds: Unless otherwise specified, seed or kernels, with shell or husk. –
 - Peanuts: Kernels
 - Castor beans: Whole product after removal of capsules
 - Cotton seeds: Undelinted
 - Oilfruits: Whole commodity

The United States notes that the change proposed by Ecuador at CCPR53 (2019) for Group 006, to
"whole product without the peel," does not reflect the commodities in trade and could
necessitate reconsideration of current CXLs. The United States supports the recommendations of
the EWG for Group 006 Assorted tropical and sub-tropical fruits – inedible peel and Group 023
Oilseeds and oilfruits.

Agenda Item 7(d) CX/PR 22/54/9

Review the *Guidelines on Portion of Commodities to which MRLs apply and which is analyzed* (CXG 41 1993) with a comparison to the *Classification of Food and Feed* (CXA 4 1989)

Comments at Step 3 in Response to CL2023/PR 35 Due June 5, 2023

- According to the working document for this agenda item, the EWG recommends that this
 document should be read in conjunction with CX/PR 23/54/8 (Agenda Item 7c) regarding the
 following EWG recommendations:
 - For Group 006, the EWG recommended that the portion of the commodity to which the MRL applies is the whole fruit unless qualified. Examples of exceptions include:
 - Banana after removal of crown tissue and stalks.
 - Pineapple after removal of crown.
 - Avocado, mangos, and similar fruit with hard seeds: Whole commodity after removal of stone (residue calculated and expressed on whole fruit).
 - For <u>Group 023</u>, the EWG recommended that the portion of the commodity to which the MRL applies is as follows:

- Oilseeds: Unless otherwise specified, seed or kernels, with shell or husk. –
- Peanuts: Kernels
- Castor beans: Whole product after removal of capsules
- Cotton seeds: Undelinted
- The EWG reached consensus that the Classification of Food and Animal Feed (CXA 4-1989) should take precedence over the Guidelines on portion of commodities to which MRLs apply and which is analyzed (CXG 41-1993) and that the changes to the Classification concerning Group 006 Assorted tropical and sub-tropical fruits (inedible peel) and Group 023 Oilseeds and oilfruits should be implemented.

• The United States supports the recommendations of the EWG.

Agenda Item 8
CX/PR 23/54/10
Coordination of Work Between CCPR and CCRVDF
Joint CCPR/CCRVDF Working Group on Compounds for Dual Use Status of work
Due June 5, 2023

- The 25th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF25, 2021) sought advice from the Executive Committee (CCEXEC) on a mechanism for cooperation between CCPR and CCRVDF on the establishment of harmonized MRLs for compounds with dual use (use both as a pesticide and as a veterinary drug).
- CCPR52 (2021) also encouraged efforts to promote cooperation between CCRVDF and CCPR on cross-cutting issues. The 81st Session of CCEXEC (CCEXEC81, 2021) recommended the use of a joint EWG to advance work on cross-cutting issues and facilitate the establishment of single/harmonized MRLs for edible animal tissues for compounds with dual use.
- Following the recommendation of CCEXEC81, the EWG was established by CAC44 (2021) with the following Terms of Reference:
 - (i) to review work already done cooperatively between CCRVDF and CCPR and to identify, and if possible, prioritize areas of possible further collaboration between CCRVDF and CCPR and how this could be carried out (e.g., jointly, in parallel, etc.) to facilitate the consideration of compounds with dual uses by both committees and the possible harmonization of MRLs.
 - (ii) this may include reflections on improved synchronization of work between CCPR and CCRVDF as well as collaboration between CCPR/CCRVDF and JMPR/JECFA.
- Based on this proposed work, the Joint EWG collected information from Codex Members and Observers on the following questions:
 - O What work has been done cooperatively between CCRVDF and CCPR?
 - What are areas where CCRVDF and CCPR could collaborate in the future?
 - O What mechanisms could be used to collaborate between CCRVDF and CCPR?
 - What mechanisms could be recommended to JMPR and JECFA to facilitate data sharing between the two risk assessments groups?

- What are ways in which a new Joint EWG could identify and recommend adoption of single, harmonized MRLs for dual-use compounds that have different MRLs for the same edible commodity of animal origin?
- Are there any additional topics affecting both CCPR and CCRVDF that have not been considered by either the draft discussion paper or questions?
- Based on the EWG feedback received to the above questions, the EWG made the following recommendations to CCPR and CCRVDF. These recommendations were discussed at the 26th Session of CCRVDF (2023), which endorsed the first three recommendations and modified Recommendations 4 and 5 as additional Terms of Reference for a re-established joint EWG.
 - The EWG recommends that CCPR and CCRVDF ask JECFA and JMPR to continue working towards harmonizing their risk assessment methodologies, including ways to establish single, harmonized acceptable daily intake values and MRLs for dual-use compounds. This might include exploring the feasibility of a joint evaluation of dual-use compounds and the formation of Joint JMPR/JECFA EWG.
 - The EWG recommends that CCPR and CCRVDF ask JECFA and JMPR to consider ways in which data can be shared between the two expert committees. This might include JECFA/JMPR asking sponsors to consent to data sharing upon submission of the data packages.
 - 3. The EWG recommends that CCPR and CCRVDF continue to support the current joint EWG to identify and prioritize issues affecting both committees.

Additional Terms of Reference for the Joint EWG:

- 4. Develop a list of compounds with dual use as a pesticide and veterinary drug for which no or only one Codex MRL has been established. Member countries will provide the information to populate this list.
- 5. Identify dual-use compounds that have different Codex MRLs for a similar edible commodity of animal origin and recommend, on a case-by-case basis, single, harmonized MRL(s) for the compound(s) and affected commodity(ies). The EWG might recommend that CCRVDF/CCPR consider selecting the higher MRL value.

U.S. Position:

• The United States supports the recommendations of the EWG and modifications proposed by CCRVDF26 to re-establish the EWG to address recommendations 4 and 5 above.

Agenda Item 9 CX/PR 22/54/11

Management of Unsupported Compounds without Public Health Concern Scheduled for Periodic Review Comments in Reply to CL 2023/37 PR Due May 31, 2023

- In the CCPR prioritization process, an unsupported compound is a pesticide that is due for reevaluation (i.e., periodic review) for which neither a Codex Member Country/Observer nor a manufacturer has committed to submit the data required for evaluation by the JMPR.
- CCPR50 (2018) established an EWG that prepared a discussion paper on the management of unsupported compounds for deliberation at CCPR51 (2019). The EWG discussion paper presented at

- CCPR51 proposed a general process for the management of (i) unsupported compounds with public health concerns and (ii) unsupported compounds without public health concerns.
- CCPR51 (2019) was unable to reach consensus on the management options and re-established the EWG. CCPR51 noted that there were divergent viewpoints on the management of unsupported compounds <u>without</u> public health concerns.
- Between 2020-2021 when the Committee did not meet due to the global CCOVID19 pandemic, the EWG further developed the discussion paper with general feedback on circumstances that lead to unsupported compounds and technical/economic barriers as well as the strengths and challenges of each management option. It also provided two proposed options for the management of unsupported compounds:
 - 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) with or without public health concerns. If members or observers are unable to address the data requirements, all CXLs are to be revoked.
- CCPR52 (2021) considered the two options (Option 2b and Option 3) but was unable to reach consensus on an approach. There were also some views expressed that would affect either option chosen, including:
 - Capacity building and collaboration between national authorities and the industry to generate relevant data were of upmost importance to implement either option to enable countries, in particular developing countries, to support the evaluation of compounds for periodic reviews.
 - It was important to have precise information on the studies that are necessary in order to support a compound for review by JMPR especially for crops of interest for developing countries or a given region.
- CCPR52 agreed to re-establish the EWG, chaired by Chile, and co-chaired by Australia, India and Kenya, working in English and Spanish, to further explore options 2b and 3 in the management of unsupported compounds without public health concerns. The EWG prepared a discussion paper and held a virtual working group meeting prior to CCPR53, which provided revised recommendations in a conference room document (CRD09). The proposal was accompanied by options for data support that could be addressed by Codex, FAO/WHO, JMPR, governments and the private sector to further assist countries in implementing the proposed management approach.
- CCPR53 agreed to re-establish the EWG to further develop and refine the management proposal for
 unsupported compounds without public health concerns for consideration s by CCPR54. The EWG
 prepared a revised proposal (CX/PR 23/54/11), based on the exchange of opinions held prior to and
 during the CCPR plenary as well as two rounds of comments from EWG members. CCPR is invited to
 consider the management proposal described in Section 1 of the working document prepared by the
 EWG and provide comments to further enhance the options given in the paper or additional options
 as appropriate.
- The management proposal includes the following:
 - Creation of a standing EWG for Unsupported Compounds
 - Concerned Members will communicate with the EWG chair on unsupported compounds of interest; EWG chair will communicate with JMPR regarding the required data
 - EWG chair will present the list of unsupported compounds of interest to Members to CCPR and request support from Members; it may include some or all of the current CXLs for these compounds
 - Compounds with support will be evaluated after the data are received
 - If no support is given, the withdrawal of CXLs should be endorsed at the following CCPR meeting.

- In Section 2 of the working document, the EWG notes that collaboration and prioritization are key.
 One of the roles of the EWG on Unsupported Compounds would be to coordinate the sharing of
 information on the Codex system, the JMPR periodic review process, and generation of the required
 data package and accompanying dossier with interested generic manufacturers, Members, and
 Observers. This would include sharing of any national assessment information.
 - Suggestions were presented for Codex, FAO/WHO, government authorities, industry, and other relevant parties. Options include holding workshops for re-evaluations, trainings, financial support, commitments from Members and ingredient manufacturers/sponsors to provide information or technical support, encouraging participation from research institutes and trade associations, and cooperation between parties to conduct field trials.

- The United States appreciates the EWG's efforts in advancing further deliberations on the management of unsupported compounds without public health concerns.
- The United States would like to highlight the importance of developing a flexible management approach and makes note of previous discussions 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 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)." 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 supporting fair trade practices.
- The working document also provides more detail on the proposed collaboration activities suggested last year. The United States supports those including:
 - Providing capacity building activities to promote carrying out the necessary technical studies.
 These would include technical support to meet JMPR requirements for studies and formal procedures for data submission;
 - Greater efforts to clarify the work, namely: defining the scope of the problem with respect to the number of MRLs, identifying Members and Observers who are interested in specific compounds, and describing the data required for JMPR to conduct the periodic review; and
 - FAO and WHO providing information on what data are available and, more importantly, on what data are missing. This is necessary to define the workload for those who will provide the missing data.
 - Leveraging of national assessments to bridge any important data gaps identified by FAO/WHO.

Agenda Item 10
CX/PR 22/54/12
National Registration of Pesticides
Comments in response to CL 2023/25(Rev) PR Due August 31, 2023

Background:

There has been ongoing discussion since CCPR48 (2016) on the development of a registration
database that can be used by Members to determine the global registration status of unsupported
compounds. Since that session of CCPR, Germany has chaired an EWG that has developed an initial
approach to collect structured information from CCPR members and further refined its approach
based on feedback from EWG participants and CCPR.

- The most recent request for national registration information focuses on 31 compounds and can be found in <u>CL 2023/25-PR(Rev)</u>. The list of compounds included in this request was based on the following three subgroups of compounds that qualify for periodic review:
 - Group 1 contains pesticides that had a full toxicological evaluation (skipping only Acute Reference Dose (ARfD) setting) before 2000. These compounds have reached the 25 years mentioned in the Codex *Procedural Manual* in 2023 or will do so in 2024. This group contains 14 compounds.
 - Group 2 contains compounds with a full toxicological evaluation (skipping only ARfD setting) before 2004. All these compounds have a full toxicological evaluation from 20 23 years ago. This group contains 17 compounds.
 - Group 3 consists of compounds with a full toxicological evaluation (skipping only ARfD setting)
 from 15 and 19 years ago. This group contains 38 compounds.

The United States plans to provide national registration information on the 31 compounds that are listed in CL 2023/25-PR(Rev). The submission will be based on summary information available through www.GlobalMRL.com to align U.S. commodities and commodity groups with Codex-defined groups. This approach has limitations and is not a direct list of U.S. registrations, but is being used to minimize the amount of time/resource intensive manual data search and entry activities that would otherwise be required to generate the requested information.

Agenda Item 11 CX/23/54/13

Establishment of Codex Schedules and Priority Lists of Pesticides for Evaluation / Re Evaluation by JMPR Comments in response to CL 2023/26 PR

- At CCPR53 (2022), an EWG, chaired by Australia, was re-established to manage nominations for the Codex schedule and priority list of pesticides for JMPR for the years 2024 2025 and beyond.
- After receiving nominations from the United States and other member countries, the EWG issued CL 2023/26-PR requesting feedback on the updated proposed Codex schedules and priority lists of pesticides.
- Summary information on the proposed schedule for 2024 is summarized below:
 - New Compounds: There are seven new compound evaluations scheduled. Evidence of national registration has been provided for all compounds.
 - New Uses: There are 17 new use evaluations. Evidence of national registration has been provided for all compounds.
 - Periodic Reviews: There are five compounds scheduled for periodic review and three compounds with reserve status.
 - A 4-year rule extension has been requested by the manufacturer for ethoxyquin.
 (The sponsor has committed to providing the data package for evaluation by JMPR in 2024.)
 - The sponsor of folpet has requested that periodic evaluation of this compound be brought forward to be combined with a new-use evaluation.
 - Further advice from sponsors and JMPR is required to clarify the status of periodic review of aldicarb, dithiocarbamates, iprodione and carbendazim.
- CL 2023/26-PR also called attention to several compounds that qualify for periodic review but are designated as unsupported.

- o Amitraz PHC (122)
- o Bitertanol (144)
- o Carbaryl (8)
- o Dinocap (087)
- o Fenbutatin oxide (109)
- o Fenthion (39)
- Methamidophos (100)
- Terbufos (167)

The United States has reviewed and supports the proposed schedules and priority lists of
pesticides provided in CL 2023/26-PR. The schedules and priority lists are consistent with United
States' nominations that were submitted to the EWG.

Agenda Item 12 CX/PR/22/54/14

Monitoring the purity and stability of certified reference material of multi class pesticides during prolonged storage

Comments in reply to CL 2023/38 PR Due June 5, 2023

Background:

- At CCPR52 (2021) Argentina and India presented a discussion paper on monitoring the purity and stability of certified reference materials (CRMs) of multi-class pesticides during prolonged storage. Given that participants had little time to review the document, the Committee agreed to establish an EWG chaired by India, and co-chaired by Argentina and Iran, with the following TORs:
 - (i) To further develop the discussion paper to consider the need, feasibility and relevance:
 - (ii) To develop a proposal for harmonized guidelines/an analytical protocol on the monitoring of purity and stability of CRMs and stock solutions of multi-class pesticides during prolonged storage, including intermediate and working standards.
 - (iii) To develop harmonized criteria for the use of CRMs and stock solutions beyond the expiry date as per certified analysis.
- The EWG had two round of comments and the chairs presented an updated discussion paper and proposal for new work at CCPR53 (2022). At the CCPR53 meeting the plenary considered the proposal and several questions and concerns were raised. The committee agreed to re-establish the EWG and chairs (replacing India with Iran) to refine the discussion paper and proposal for new work, to explain the rationale more clearly.
- The EWG revised the draft of the discussion paper and circulated it for two rounds of comments ahead of CCPR54 (2023). The United States provided comments to the forum for both rounds.
- The chairs have prepared a discussion paper that provides background information on the monitoring the purity and stability of CRM and proposes an outline of new work on the development of guidelines for consideration by CCPR at this year's meeting.

U.S. Position:

• The United States supports the purpose of the discussion paper and generally agrees that CRMs can continue to be used past their date of expiry as long as they meet quality criteria. The EWG has made good progress in summarizing and organizing their ideas and the United States supports forwarding the proposal for new work on this topic to CAC46 for approval.

• The United States has reviewed the three appendices included in the working document prepared for CCPR54 and provided comments. The proposed guidance requires more work will be needed by the EWG in the upcoming year, subject to CAC approval of the work.

Agenda Item 13
CX/PR/23/54/15
Enhancement of the operational procedures of CCPR and JMPR
Comments in reply to CL 2023/39 PR Due June 5, 2023

- At CCPR53 (2022), CropLife International introduced a discussion paper (<u>CX/PR 22/53/20</u>) raising concerns about the JMPR backlog of evaluations caused by the COVID19 pandemic and cancellation of the JMPR Regular Meeting in 2020. The paper raised further concerns that the current system is unable to keep up with the demand for JMPR evaluations and made recommendations to CCPR53.
- Based on deliberations at CCPR53, an EWG was established, chaired by the United States and cochaired by Costa Rica, France, Germany, and Uganda, to collect information on the need to enhance the operational procedures of CCPR. The EWG's terms of reference were to:
 - i. Prepare a circular letter (CL) to request information from members and observers on the need to enhance CCPR/JMPR and the associated opportunities and challenges. In addition, the CL may invite members and observers to consider a second or possibly subsequent workshops that would expand on and further develop some of the themes addressed in the virtual workshop sponsored by CropLife International on March 31, 2022, as described in CX/PR 22/53/20.
 - ii. On the basis of the responses to the CL, prepare a summary of the submitted information and a discussion paper that summarizes findings for consideration at CCPR54 and later transmission to JMPR.
 - iii. Coordinate work with related EWGs such as the EWGs on priority lists, national registration database, and unsupported compounds.
- Based on these terms of reference, the EWG drafted CL 2022/75-PR and received input from
 fifteen Member Countries and three Observer Organizations. This feedback is summarized in
 discussion paper CX/PR 23/54/15 and highlights areas of consensus and divergent opinions on
 enhancements to the operational procedures of CCPR/JMPR.
- The EWG concluded its work and proposed a two-step approach for consideration by CCPR54:
 - Step 1: Submit the EWG discussion paper to JMPR for their consideration to identify initial priorities for enhancing its operational procedures and to report back on its findings to the following session of CCPR.
 - Step 2: CCPR will consider the reply from JMPR and based on consultation with the CCPR, Codex, and JMPR Secretariats, as well as FAO/WHO. CCPR and JMPR should develop an appropriate approach to identify potential priorities for enhancement and major structural reforms and develop a roadmap for implementation. U.S. Position:
- The United States served as chair of the EWG and appreciated the support of its co-chairs and feedback from a wide range of EWG participants. The United States believe the proposed path forward will enable CCPR to consider feedback from JMPR and then develop a longer-term approach for identifying priorities and an implementation roadmap.

• No documents have been provided under this agenda item, so there is nothing to comment on under this agenda item at this time.