



Report of the U.S. Delegate 51st Session of the Codex Committee on Pesticide Residues

*April 8-13, 2019
Macau, SAR, China*

Introduction

The 51st Session of the Codex Committee on Pesticide Residues (CCPR51) met in Macau, SAR, China from April 8-13, 2019. Professor Xiongwu Qiao, Director of the Shanxi Academy of Agricultural Sciences, served as Chair, assisted by Dr. Guibiao Ye, Director of the CCPR Secretariat, Institute for Control of Agrochemicals, Ministry of Agriculture of the People's Republic of China (ICAMA). The Session was attended by 52 Member countries, one Member organization (the European Union), and Observers from 13 international organizations. The United States was represented by U.S. Delegate Mr. David Miller of the U.S. Environmental Protection Agency (EPA), and Alternate Delegate Dr. John Johnston of the U.S. Department of Agriculture (USDA), Food Safety and Inspection Service, along with additional members of the U.S. Delegation representing the U.S. Codex Office, the U.S. Food and Drug Administration (FDA), the Foreign Agricultural Service, USDA, the Rutgers University Interregional Research Project No. 4 (IR-4), and nongovernmental advisors.

Highlights

CCPR51 concluded a productive session and advanced 326 Maximum Residue Limits (MRLs) for final adoption by the Codex Alimentarius Commission (CAC) at its next session, scheduled for July 2019. Three of the seven new compounds reviewed by the Joint Meeting on Pesticide Residues (JMPR) in 2018 were nominated by the United States.

The Committee also reached consensus on the classification work on crop groupings for: *primary feed commodities of plant origin and processed food commodities of plant origin*. Specifically, the Committee agreed with working principles for transferring commodities from Class D (Processed Feed Commodities of Plant Origin) to Class C (Feed Commodities of Plant Origin) and revisions to the table on examples of representative commodities. The United States had a leadership role as co-chair in advancing work on the classification of food and feed.

The Committee continued to discuss potential new work on the International Estimate of Short-Term Intake (IESTI) equation and an electronic Working Group (EWG) was re-established to continue its exploratory work on the advantages and challenges of the current IESTI equation once information is available on the scientific review and

benchmarking of the IESTI equation by the Food and Agriculture Organization (FAO) and World Health Organization (WHO).

CCPR51 also discussed a proposal from India that CCPR undertake new work to develop guidelines on harmonized risk management approaches for endocrine disruptors. CCPR declined to take up India's proposal, as the majority of the intervening delegations, including the United States, agreed that the work is outside the mandate of CCPR and may be more appropriate for discussion/action in other international fora.

The following report summarizes issues of interest to the United States. Complete details of CCPR51 may be found in the final meeting report which is or soon will be posted on the Codex Alimentarius website at: www.fao.org/fao-who-codexalimentarius/meetings-reports/en/.

Meeting Summary

Matters of Interest Arising from the UN Food and Agriculture Organization (FAO) and World Health Organization (WHO)

The Representatives of WHO, Dr. Soren Madsen, and FAO, Madame Yongzhen Yang, informed the Committee about activities other than the Joint FAO/WHO Meeting on Pesticide Residues (JMPPR) that are relevant to the work of CCPR, including:

- **FAO/WHO/OECD (Organization for Economic Co-operation and Development) workshop on the harmonization of residue definition:** As part of the efforts to improve the international harmonization of methods, a joint FAO/WHO/OECD workshop was held in Geneva on December 3-7, 2018. At the workshop, the experts further discussed the way forward and concluded that for the residue definition (RD) for risk assessment, a number of points remained open for discussion which would require case studies to better inform positions, including 1) selection of metabolites to include in the RD, 2) definition of toxicological burden, and 3) the need for different strategies for different organizations or due to differences in available data at the time of evaluation.
- **Acute probabilistic dietary exposure assessment for pesticide:** FAO/WHO performed a draft probabilistic assessment of acute exposure assessment using national pesticide monitoring data and individual food consumption data from Australia, Brazil, Canada, European Union, and the United States. A scientific Committee has also been established to ensure the quality and the transparency of the assessment, which will be done by an independent consultant. Results were provided to CCPR51 in a document entitled, "[Acute Probabilistic Exposure Assessment for Pesticides](#)."



- **Use of antimicrobials in plant agriculture:** A FAO/WHO Joint Expert Meeting on Microbial Risk Assessment (JEMRA) was held in collaboration with [The World Organization for Animal Health](#) (OIE) on the topic of Foodborne Antimicrobial Resistance: Role of the Environment, Crops and Biocides, Rome, Italy, June 11-15, 2018. Experts noted the potential role of the use of antimicrobials and copper in plant production in contributing to antimicrobial resistance and environmental contamination, as well as the lack of available data for risk assessment. A report was produced, and a follow-up study was launched to collect pilot data on antimicrobial use in plant agriculture in several low- and middle-income countries. Outcomes of that study are expected before the end of 2019.

Additional details on these topics can be found in CCPR51 Agenda Item 4(a) Summary Document entitled, "[Matters of Interest Arising from FAO and WHO in addition to 2018 JMPR Activities.](#)"

Report on Items of General Consideration by the 2018 JMPR

The JMPR Secretariat provided relevant information to the Committee on the 2018 JMPR Regular Meeting, regarding:

- Toxicological profiling of compounds and less-than-lifetime dietary exposure assessment
- Need for sponsors to submit all requested data
- Hazard characterization in the 21st century: Assessing data generated using new mechanism-based approaches for JMPR evaluations
- Update on the revision of principles and methods for risk assessment of chemicals in food (EHC 240)
- Microbiological effects
- Transparency of JMPR procedures
- Review of the large portion data used for the IESTI equations
- Update of the International Estimated Daily Intake (IEDI) and IESTI models used for the calculation of dietary exposure: commodity grouping according to the revised Codex classification and new large portion data
- Recommendations for sub-group maximum residue levels for fruiting vegetables, other than cucurbits revisited
- Preliminary results for probabilistic modelling of acute dietary exposure to evaluate the IESTI equations

Additional details on these topics can be found in Section 2.0 of the [2018 JMPR Evaluation Report](#).



Proposed Maximum Residue Limits (MRLs) for Pesticides in Food and Feed

The CCPR agreed to forward 326 MRLs to the Codex Alimentarius Commission (CAC) for final adoption (at Step 5/8) at its next session in July 2019. These MRLs are associated with 31 pesticides; 183 of the MRLs are for plant commodities, while 143 are for animal commodities. Three of the seven new compounds reviewed by JMPR in 2018 were nominated by the United States. Crop Group and Subgroup MRLs accounted for 43 of the 326 MRLs forwarded for adoption.

The accelerated procedure and criteria for decision-making were again used with great success at this session; all of the MRLs recommended for adoption by the CAC were advanced using the accelerated Step 5/8 procedure. The European Union (EU), Norway and Switzerland conveyed reservations on 105 of the 326 MRLs recommended by the JMPR; therefore, a large number of MRLs may not have advanced if not for the concern form procedure.

The Committee returned 11 MRLs for Bifenthrin and Metalaxyl-M to Step 7 while the JMPR awaits additional information. The Committee also recommended revocation for 150 previously adopted CXLs (Codex MRLs) associated with 22 pesticides. Of these, 92 of the MRLs proposed for revocation are for plant commodities; 58 are for animal commodities. These are typically CXLs being replaced based on review of additional data; uses no longer supported; or CXLs deemed by JMPR to have potential dietary intake concerns with no alternative good agricultural practice (GAP). Finally, 12 draft MRLs for five pesticides were withdrawn from further consideration.

The United States did not submit any concern forms to CCPR51 on the 2018 JMPR recommendations. During the plenary discussion, the United States did intervene to support advancement of MRL recommendations for imazalil on the two citrus subgroups *Lemons and Limes* and *Oranges, Sweet, Sour*. JMPR had proposed withdrawal of the existing citrus group MRL because insufficient studies were available on representative commodities for the Citrus Subgroups *Mandarin* and *Pummelos*; however, the United States successfully requested that the existing citrus group CXL be retained for mandarin and pummelos while the sponsor conducts the additional field residue trials required by JMPR.

Complete lists of the MRL actions recommended by CCPR51 are contained in the appendices to the official Committee report.

Revision of the Codex Classification of Foods and Animal Feeds

The revision of the *Codex Classification of Foods and Animal Feeds* is part of an ongoing effort to revise all of the crop groups. The United States has chaired/co-chaired this working group since the beginning of the effort and provided much of the



documentation for the proposed crop groups. The Committee considered proposed amendments for the following crop groups and subgroups: *Class C: Primary Feed Commodities. Type 11: Primary Feed Commodities of Plant Origin, All Groups* and *Class D: Processed Food Commodities of Plant Origin. All Types and Groups*, with details provided below.

Proposed Revision of the Classification of Food and Feed – Class C: Primary Feed Commodities. Type 11: Primary Feed Commodities of Plant Origin, All Groups

The Committee endorsed recommendations to: (i) separate grasses from Group 051 cereal grains (including pseudo-cereals) ; (ii) rename the Group of grasses to Group of grasses for feed, to avoid confusion as there is already a Group of grasses in Class A; (iii) not separate the Group of grasses into subgroups (i.e. “cool” and “warm” season grasses); (iv) move silage commodities from Subgroup 050A into Subgroup 051A; (v) agree with the revisions made to accommodate proposals for commodities under the different groups based on written comments submitted as shown in [Conference Room Document \(CRD\) 30](#) and to work further on the allocation of additional commodities in Class C; (vi) further look into the issue of “fodder” in Class C based on a paper to be prepared by Japan. The paper should be made available as soon as possible to assist the EWG and the discussion at CCPR52 (2020).

Proposed Revision of the Classification of Food and Feed – Class D: Processed Food Commodities of Plant Origin. All Types and Groups

The Committee endorsed revisions to accommodate proposals for commodities under the different groups based on written comments submitted as shown in [CRD31](#) and to work further on the allocation of additional commodities in Class D.

Proposed Revision of the Classification of Food and Feed –EWG Terms of Reference (TOR)

The Committee agreed to re-establish the EWG, chaired by the United States and co-chaired by the Netherlands, with the following terms of reference:

- (i) Continue the work on the revision of Class C, Animal feed commodities, taking into account silage, fodder, and a separate group for grasses.
- (ii) Continue the work on the revision of Class D, Processed Food commodities.
- (iii) Continue the work on transferring commodities from Class D to Class C.
- (iv) Create tables with representative crops for Class C and D.
- (v) Continue to work on edible animal tissues (including edible offal) in collaboration with the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) EWG on edible animal tissues.

Discussion Paper on the Opportunity to Revise the Guidelines on the Use of Mass Spectrometry for the Identification, Confirmation and Quantitative Determination of Pesticide Residues

Costa Rica, as co-Chair of the EWG, introduced the item on behalf of Iran (Chair of the EWG who was not able to attend CCPR51) and, based on written comments received, proposed that CCPR consider exploring the possibility to merge the *Guidelines on the Use of Mass Spectrometry for the Identification, Confirmation and Quantitative Determination of Residues* (CXG 56-2005) and *Guidelines on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues in Food and Feed* (CXG 90-2017) into one single document.

The Committee agreed to re-establish the EWG, chaired by Iran and co-chaired by Costa Rica, with the following terms of reference:

- (i) To determine if CXG 90-2017 adequately covers mass spectrometry and if so, to propose revocation of CXG 56-2005.
- (ii) If there are provisions from CXG 56-2005 that could be relevant but are not included in CXG 90-2017, to look into the feasibility to merge the two documents, and
 - if appropriate to present a proposal for new work
 - if possible to present an outline of the merged guidelines for consideration at CCPR52.

The Committee further agreed to request Argentina and India to prepare a discussion paper regarding monitoring of purity and stability of Certified Reference Materials of multi-class pesticides during prolonged storage, for consideration at the next session.

Discussion Paper on the Possible Revision of the IESTI Equations

The Committee first established an EWG on IESTI during CCPR48 (2016), chaired by the Netherlands and co-chaired by Australia, to identify advantages and challenges that might arise from the possible revision of the current IESTI equations, and the impact on risk management, risk communication, consumer protection goals, and trade. Four sessions of CCPR have considered the issue, as summarized below:

- CCPR49 (2017), following further discussion about the possible review of the IESTI equations, agreed to re-establish the EWG to perform further exploratory work and requested FAO/WHO to review the parameters of IESTI and benchmark the current IESTI approach using probabilistic exposure assessment methods that incorporate data from Member countries on food consumption and pesticide residue monitoring.

- CCPR50 (2018) completed a review of the history, background and use of the IESTI equation, but was unable to complete discussion on the advantages and challenges of the current IESTI equation. The EWG was re-established to further review on this topic and provide information on bulking and blending as outlined in Table 3 of Appendix 2 of CX/PR 17/49/12.

At CCPR51 (2019), the EWG reported that it was unable to complete its review of the advantages and challenges of the current IESTI equation, pending results from the ongoing FAO/WHO probabilistic benchmarking assessment of the IESTI equations using real-world national residue monitoring and food consumption data. Preliminary work on FAO/WHO's exposure assessment was disseminated to CCPR51 ([CCPR Document Link](#)), but the benchmarking assessment has not been performed and the results have not been submitted to JMPR for scientific deliberation. The preliminary report concludes that, "The results of the probabilistic assessment do confirm the conservativeness of the [current IESTI] model when compared with national assessments based on accurate data and the absence of appreciable risk for the population."

Given that FAO/WHO's assessment is needed to understand the advantages and challenges of the current IESTI equation, the Committee agreed to renew the EWG to continue work after FAO/WHO's benchmarking assessment is complete. The Committee also endorsed the EWG recommendation to issue a Circular Letter to collect information on bulking and blending practices.

The Committee agreed to re-establish the EWG, chaired by European Union and co-chaired by Brazil and Uganda, with the following terms of reference (TOR):

- (i) Build on discussion of the benefits and challenges identified in the discussion paper submitted to CCPR51 (CX/PR 19/51/14 Appendix I "Advantages and challenges that arise from the current IESTI equations") to reflect the findings of the FAO/WHO review of the basis and the parameters of the IESTI equations and benchmark of the outcomes of the IESTI equations to a probabilistic distribution of actual exposures. In addition to information provided by FAO/WHO, the EWG should consider recent publications on acute dietary exposure assessment in the peer-reviewed literature.
- (ii) Gather bulking and blending information and prepare an overview that will be discussed at CCPR52 and distributed to JMPR 2020 after completion. The Codex Secretariat will issue a Circular Letter that will request information on bulking and blending.
- (iii) Prepare a discussion paper and recommendations for deliberation at CCPR52 that take into account TOR i-ii.

While the United States did not object to the re-establishment of the EWG, the United States did raise concerns that the exploratory activities of the EWG have been ongoing since CCPR48, but the EWG has not completed its primary terms of reference with respect to the advantages and challenges of the IESTI equation. This concern was also highlighted as an issue by the JMPR Secretariat during the plenary, who advised the EWG to outline clear timelines so that CCPR and JMPR resources are used efficiently.

Discussion Paper on Opportunities and Challenges for JMPR Participation in International Review of a New Compound

Canada, as Chair of the EWG, provided a summary of the EWG's work and highlighted key findings related to the benefits and challenges that needed to be addressed through the recommendations made by the EWG. The Committee endorsed the recommendations and agreed to re-establish the EWG, chaired by Canada and co-chaired by Costa Rica and Kenya, with the following terms of reference:

- (i) Develop draft principles and procedures to facilitate the participation of the JMPR in parallel reviews of a new compound. These draft principles and procedures will address the benefits, challenges, and recommendations proposed in the discussion paper submitted to CCPR51 (CX/PR/19/51/15).
- (ii) Such draft principles and procedures will include, but will not be limited to, considerations related to current CCPR and JMPR working principles such as the nomination and scheduling process and requirements, review timelines, evaluation methodology, and roles and responsibilities of JMPR and participating government reviewers.
- (iii) The EWG will develop the draft principles and procedures in consultation with the FAO/WHO JMPR Secretariats, and will submit them to CCPR52 for comments and consideration.

The United States supports the initiative to facilitate participation of JMPR in parallel review of new compounds and broader efforts to increase JMPR capacity and enhance the delivery of scientific advice to CCPR.

Discussion Paper on the Development of Guidance for Compounds of Low Public Health Concerns that could be Exempted from the Establishment of CXLs

Chile, as Chair of the EWG with Co-Chairs from the United States and India, provided a summary of the EWG's work on the development of guidance for compounds of low public health concerns that could be exempted from the establishment of CXLs.

CCPR51 agreed to recommend new work and to submit a project document to CAC42 (2019) for approval. CCPR51 also agreed to re-establish the EWG, chaired by Chile and co-chaired by United States and India, with the following terms of reference:



- (i) To develop common criteria for the identification of compounds of low public health concern that may be exempted of CXLs and/or that do not give rise to residues.
- (ii) Provide harmonized Codex definitions as appropriate.
- (iii) Provide examples of compounds that meet the criteria to facilitate the development of the guidelines. Such examples will not necessarily remain in the final document.
- (iv) Based on the above considerations, present a proposed draft Guidelines for consideration at CCPR52.

Discussion Paper on the Management of Unsupported Compounds

Chile, as co-Chair of the EWG on the management of unsupported compounds, provided background on the EWG and outlined proposals on how to manage unsupported compounds listed in Tables 2A (schedule and priority lists of periodic review) and 2B (periodic review list concerning pesticides that have been evaluated 15 years ago or more, but not yet scheduled or listed) of the *Codex Schedules and Priority List of Pesticides*. This includes management of unsupported compounds with public health concerns and unsupported compounds without identified public health concerns.

CCPR51 highlighted the importance of this issue but could not reach consensus on the management options. The Committee agreed to re-establish the EWG on unsupported compounds scheduled for periodic review, chaired by Chile and co-chaired by Australia, India, and Kenya, with the following terms of reference:

- (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 Options 2b and 3¹ as recommended by CCPR51.
- (iv) Based on the above considerations, present a proposal for consideration by CCPR52.

National Registration Database of Pesticides

Germany, as Chair of the EWG, provided background on the development of the national registration database over the last three years and confirmed the key objective of the registration database is to provide members with a data source to facilitate

¹ Option 2b: Only those CXLs for which there are registrations listed in the National Registration Database (NRD) will be retained; and

Option 3: Members are granted four 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.

support of commodities during periodic re-evaluation and to determine the global registration status of unsupported compounds.

CCPR51 supported maintenance of the national registration database for three years and agreed to re-establish the EWG, chaired by Germany and co-chaired by Australia, with the following terms of reference:

- (i) Provide an improved National Registration Database with about 20 compounds every year from Tables 2A and 2B for which data are requested.
- (ii) Compile the data from all respondents.
- (iii) Analyze the compiled data in view of the needs for the establishment of the Codex schedules and priority lists of pesticides for evaluation by JMPR.
- (iv) Report back on the findings to CCPR52.

Establishment of Codex Schedules and Priority Lists of Pesticides

Australia, as Chair of the EWG on Priorities, provided an update on the Codex schedules and priorities and the revised *Schedules and Priority Lists of Pesticides*. Key information is summarized below and includes: *Confirmation of the 2020 Schedule for JMPR Evaluations* and *Unsupported Compounds Designated for Deletion from the CCPR Pesticide List*.

Codex Schedules and Priority Lists of Pesticides – 2020 Schedule for JMPR Evaluations

- ***New Compounds:*** Six new compounds were confirmed on the proposed schedule, along with five reserve compounds.
- ***New Uses and Other Evaluations:*** Twenty nominations listed for new use and other evaluations, along with ten reserve compounds.
- ***Periodic Review²s:*** Six compounds listed, along with two reserve compounds.

The EWG Chair confirmed that reserve compounds in the “New Compounds” and “New Uses and Other Evaluations” schedules will be prioritized as reserves based on the earliest provision of evidence of national registration/product labels. Reserve compounds, for which use does not give rise to residues, will be prioritized lower than reserve compounds with evidence of national registrations/product labels.

² The six compounds include: Aldicarb, Metalaxyl-M (212) and Metalaxyl (138), Diazinon (22), Fipronil (202), Prochloraz (142), Methidathion (51). The EU has raised public health concerns on Diazinon, Prochloraz and Methidathion, but these public health concerns have not been reviewed by JMPR.



Codex Schedules and Priority Lists of Pesticides – Unsupported Compounds Designated for Deletion from the CCPR Pesticide List

CCPR51 (2019) identified six compounds for removal from the CCPR Pesticide List at CCPR50 (2018) based on public health concerns and/or lack of support. These include: Amitraz (122), Bromopropylate (70), Phosalone (60), Fenarimol (192), Dicloran (83) and Azinphos-methyl (02).

The EWG Chair proposed, noting the discussion on unsupported compounds at CCPR51, that several of these compounds should be retained because JMPR still needs to review the submitted public health concern forms submitted to CCPR and determine if the concerns are warranted. Accordingly, the EWG Chair proposed that Azinphos-methyl and Phosalone be removed from the CCPR Pesticide List while the other four compounds be retained awaiting further consideration at CCPR52 (2020). The Committee supported this proposal, with the United States and other Delegations reaching consensus.

CCPR also noted that both Azinphos-methyl and Phosalone have spice Codex MRLs that will be retained while all other Codex MRLs will be revoked. The retention of spice Codex MRLs is consistent with previous agreement by the Committee that MRLs for spices can be established and retained using monitoring data on pesticide residue levels.

Codex Schedules and Priority Lists of Pesticides – Conclusion and Re-establishment of the EWG

The Committee agreed to forward the proposed *Schedule and Priority List of Pesticides* for evaluation by the 2020 JMPR to CAC for approval (Appendix X) and to re-convene the EWG on Priorities, chaired by Australia. The EWG will report on proposed the schedules and priority lists for consideration at CCPR52.

Other Highlights Relevant to the United States

- ***Side Event on Global Experiences of Import MRL Regulation Using the Asia-Pacific Economic Cooperation (APEC) Import MRL Guidelines for Pesticides:*** A side event was organized by Australia that provided an update on APEC import tolerance/MRL guidelines and global efforts to facilitate establishment of import MRLs. (Import MRLs, also known as import tolerances under U.S. law, are MRLs that countries establish for pesticides that are not registered for use within their borders, to cover residues in imported foods.) The presentations included perspectives from Australia, the United States, the Republic of Korea, and Chile. Industry perspectives on import tolerances were provided by CropLife International and the Almond Board of California. U.S.



CCPR Delegate David Miller described the experience of the U.S. EPA and its import MRL pilot program. Presentation materials are available on the CCPR51 event page: [Side Event Presentations](#).

- ***U.S. Commitment to Provide Financial Resources to Support the JMPR:***
The United States submitted a [Conference Room Document](#) (CRD 27) advising CCPR51 that it has made a voluntary commitment to provide additional financial resources to support the work of JMPR. The United States welcomed input from interested parties on how these additional resources might be best utilized to increase JMPR capacity and enhance the delivery of scientific advice to CCPR. One possibility would be to convene a second extraordinary meeting of JMPR, with a focus on new uses and other evaluations to increase the number of evaluations and recommended MRLs for consideration by CCPR. This idea will be further explored in accordance with the outcomes and feedback from the first extraordinary meeting, which is scheduled to take place in May 2019. The United States will develop and submit a detailed proposal for discussion next year at CCPR52. It is anticipated that endorsed activities will be carried out in the year 2021.

Next Session

The 52nd session of CCPR will be hosted by China and is anticipated to be held in April/May 2020.