

# Report of the U.S. Delegate, 49th Session, Codex Committee on Pesticide Residues

#### Introduction

The CCPR held its 49th Session in Beijing, China from April 24-29, 2017. 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 11 international organizations. The United States was represented by Mr. David Miller of the U.S. Environmental Protection Agency, Delegate to CCPR, and Dr. John Johnston of the U.S. Department of Agriculture, Food Safety and Inspection Service, along with three additional governmental and eight nongovernmental advisors.

#### Highlights

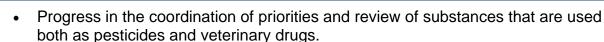
The Committee concluded a productive session, advancing a record number 488 Maximum Residue Limits (MRLs) for final adoption by the Codex Alimentarius Commission (CAC) at its next session, scheduled for July 2017. Six of the ten new compounds reviewed by Joint Meeting on Pesticide Residues (JMPR) in 2016 were nominated by the United States. The Committee also reached consensus on crop groupings for vegetable and grass commodities, and on the guidelines on performance criteria for methods of analysis used to determine pesticide residues in food and feed; the United States had a leadership role as chair or co-chair in bringing both of these projects to a successful conclusion. The Committee continued to discuss potential new work on the IESTI (International Estimate of Short Term Intake) equation, and a new electronic Working Group (eWG) was formed to continue exploratory work. Canada proposed to support an extraordinary session of JMPR to address the backlog of pesticides awaiting evaluation.

The following report summarizes issues of particular interest to the United States. Complete details of the 49th Session of the Codex Committee on Pesticide Residues (CCPR49) may be found in the final meeting report which will soon be posted on the Codex Alimentarius Web site at: <u>http://www.fao.org/fao-who-</u> <u>codexalimentarius/meetings-reports/en/</u>.

#### Meeting Summary

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

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



- A call for pesticide monitoring data through the Global Environment Monitoring System/Food Contamination Monitoring and Assessment Program (GEMS/Food) platform to serve the ongoing review of the International Estimated Short-Term Intake (IESTI) equations.
- Work on antimicrobial resistance (AMR) with a focus on antimicrobial use in horticulture, and a request for information on products used and specific use patterns for the purpose of enhancing plant health, treating or preventing plant diseases, or reducing post-harvest loss. (Additional information on this topic can be found in the CCPR document <u>CX/PR 17/49/03 Add. 1</u>, which requests information on various products that are used for bacterial and fungal infection of plants.)

Regarding the FAO/WHO GEMS call for pesticide monitoring data (http://www.who.int/foodsafety/CFD-ScientificAdvice-2017.pdf) to serve the ongoing review of the IESTI equation, the United States conveyed that USDA's Pesticide Data Program (PDP) maintains a very large, robust pesticide residue monitoring dataset, and that the data are freely available for download going back to 1994\_. The United States encouraged use of real-world data by JMPR to review and compare exposure assessment methods, and supported comments from other delegations about the need for data collection to be ongoing so that all regions can be represented. The United States also noted uncertainty regarding whether resources would be available to the United States to transfer pesticide residue monitoring data from the USDA PDP website to the WHO GEMS/Food platform as called for in the FAO/WHO GEMS announcement.

### Report on Items of General Consideration by the 2016 JMPR

The JMPR Secretariat provided relevant information to the Committee on the two JMPR sessions held in 2016--Special Meeting (May) and Regular Meeting (September), regarding:

- General considerations on the evaluation of genotoxicity studies. JMPR is not currently recommending MRLs for carcinogens with a genotoxic mode of action. A background paper will be reviewed by an expert working group prior to publication.
- Methods for the evaluation of epidemiological evidence for risk assessment. JMPR has published a report establishing criteria for making better use of epidemiological studies for the purposes of risk assessment.
- Evaluation of data for acceptable daily intake (ADI) and acute reference dose (ARfD) for humans, and the need to establish criteria for using benchmark doses.
- Guidance on the use and interpretation of statistical evaluations and historical control data.
- Use of the Organisation for Economic Co-operation and Development (OECD) livestock dietary burden table calculator. Starting in 2017, FAO will use the updated OECD spreadsheet.

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

The CCPR agreed to forward 488 MRLs (4 at Step 8; 484 at Step 5/8) to the Codex Alimentarius Commission (CAC) for final adoption at its next session. This is an unprecedented number of MRLS moving forward in one CCPR session; fewer than 400 MRLs were adopted in 2016. These MRLs are associated with 26 pesticides; 358 of the MRLs are for plant commodities, while 130 are for animal commodities. Six of the ten new compounds reviewed by JMPR in 2016 were nominated by the United States. Crop Group and Subgroup MRLs accounted for 73 of the 488 MRLs forwarded for adoption.

The accelerated procedure and criteria for decision-making were again used with great success, and most of the MRLs were advanced using the accelerated 5/8 procedure. The European Union (EU) and Norway conveyed reservations on over 300 of the 488 MRLs recommended by the JMPR; therefore, a majority of those MRLs may not have been advanced if not for the concern form procedure.

The Committee returned 16 MRLs for 4 pesticides to Step 7 while the JMPR awaits additional information. The Committee also recommended revocation for 103 previously adopted CXLs (Codex MRLs) associated with 9 pesticides. Of these, 69 of the MRLs proposed for revocation are for plant commodities; 34 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, 24 draft MRLs for 7 pesticides were withdrawn from further consideration.

Also of note, the JMPR Special Meeting (May 2016) re-evaluated all available toxicology data for diazinon, malathion, and glyphosate. JMPR concluded that each of these chemicals is unlikely to pose a carcinogenic risk to humans, and found no dietary exposure concerns. Consequently, there was no impact on existing CXLs for these three compounds.

JMPR also responded to several concern forms that were submitted by the United States for consideration by the 2016 JMPR:

- For chlorothalonil, the United States requested JMPR to reconsider the decision not to recommend an MRL for cranberries. JMPR confirmed its previous decision not to recommend a MRL, concluding that the available study was unsuitable to draw conclusions regarding the stability if the compound and its metabolite in cranberries. However, the existing cranberry MRL will be maintained and considered by the 2019 JMPR, pending submission of new storage stability data generated by the U.S. Inter-Regional Research Project Number 4 (IR-4), headquartered at Rutgers University, and expected to be made available later this year.
- For *acetochlor*, the United States requested that JMPR reconsider the decision not to recommend an MRL for soybeans. The JMPR confirmed its previous conclusion that, based on CCPR principles and guidance, the available trials did

not support the critical GAP and were not suitable for the application of the proportionality approach.

 For *flonicamid*, the United States requested that JMPR reconsider the decision not to utilize greenhouse cucumber data in its recommendation for an MRL for cucurbits. JMPR confirmed its previous conclusion that the four cucumber trials reflecting the critical United States GAP were insufficient to recommend an MRL, and also confirmed its previous MRL recommendation for fruiting vegetables, cucurbits.

### **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: vegetables; grasses of cereal grains; grasses for sugars or syrup production; and seeds for beverages and sweets, with details provided below:

# Proposed Draft Revision of the Vegetable Commodity Groups (Type 02 Vegetables)

The United States, as Chair of the eWG on the revision of the Classification, introduced the eWG's effort to compile and review all vegetable commodities to ensure consistency in the terminology and code system, as well as their locations in Table 2 (examples of representative commodities). The eWG Chair also recalled the approach agreed to by the Committee that, following the revision of the Classification, no changes would be made to existing CXLs until JMPR reconsiders them, them following the procedures in place for the establishment of Codex schedules and priority list of pesticides. The Committee agreed to forward the draft and proposed draft revised vegetable commodity groups to CAC40 for final adoption by the CAC at its July 2017 session.

### Proposed Draft Revision of the Selected Commodity Groups, 020-Grasses of Cereal Grains and 021-Grasses for Sugars or Syrup Production (Type 03 Grasses)

For Group 020 (Grasses of Cereal Grains), the eWG Chair noted that the eWG supported the inclusion of chia as a member of Group 020 (Grasses of Cereal Grains) instead of the previously proposed Group 028 (Spices). The Committee also reached a consensus on relocating canary grass from Subgroup 020D (Grain Sorghum and Millet) to Subgroup 020B (Barley), and including naked oat in Subgroup 020B (Barley). After considering a new proposal from Australia to establish a separate subgroup for maize, the Committee further agreed to create separate Subgroups 020E (Maize) and 020F (Sweet Corns), and to include grain sorghum as a representative commodity for Subgroup 020D (Grain Sorghum and Millet).



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For Group 021 (Grasses for Sugars or Syrup Production), the Committee agreed to maintain the group as currently established. With regard to sugars or syrups produced from tree sap, there was a consensus to create a new Group 025 (Tree Sap Producers), to be included under the renamed Type 04 Nuts, Seed and Saps. The Committee also agreed that the portion of the commodity to which the MRL applies (and which is analyzed) is the whole commodity as traded (e. g., "stalk" for sweet sorghum and "cane" for sugar cane).

The Committee agreed to forward the draft and proposed draft revised grass commodity groups—Group 020 (Grasses of Cereal Grains) and Group 021 (Grasses for Sugar or Syrup Production)—to CAC40 in July 2017 for final adoption.

# Proposed Draft Revision of the Selected Commodity Group, 024-Seeds for Beverages and Sweets

For Group 024 (Seeds for Beverages and Sweets), the Committee agreed to maintain the group as currently proposed. Further work on this Group would relate to the inclusion of additional commodities only. The Committee agreed to retain Group 024 (Seeds for Beverages and Sweets) at Step 5.

# Proposed Draft Principles and Guidelines for the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Commodity Groups (Tables 2 and 3)

The eWG Chair noted that the eWG had completed the revision of Table 2 and Table 3 on examples of representative commodities for Type 02 (Vegetables) and Type 03 (Grasses) groups and subgroups. During the course of discussion on the example representative commodities, it was emphasized that countries are free to propose to JMPR—and JMPR is free to select—representative crops for the recommendation of group MRLs on the basis of the GAP and the residue trial data available to the specific meeting. The Committee agreed to forward the proposed draft Table 2 and Table 3 to CAC40 for final adoption at Step 5/8.

Finally, the Committee agreed to re-establish the eWG, chaired by the United States and co-chaired by the Netherlands, to continue work on groups and subgroups under Type 04 (Nuts, Seeds, and Saps) and Type 05 (Herbs and Spices). The eWG was also tasked with developing a code system within the Classification for commodities not meeting the criteria for crop grouping, and with reporting back on the impact of the revised Type 03, Type 04, and Type 05 groups and subgroups on existing CXLs in the database. The eWG will also consider the revision of Class C (Primary Animal Feed Commodities) for the next session of CCPR.

### Methods of Analysis for the Determination of Pesticide Residues

Although much progress had been made on the proposed Draft Guidelines on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues in Food at recent sessions, in 2016 the Committee decided to retain the document at Step 5 to allow additional time for countries to review the guidelines with their national experts and other relevant stakeholders. During the adoption of the agenda for CCPR 49, the Committee agreed to form an in-session WG, chaired by the United States and co-chaired by China and India, to consider written comments submitted to this session and viewpoints of the participating Members and Observers in order to finalize the document. After incorporating changes to improve the clarity and consistency of the text and reaching a consensus on extending the scope of the guidelines to cover "feed" in addition to "food," the Committee agreed to forward the Draft Guidelines on Performance Criteria for Methods of Analysis for the Determination of Pesticide Residues in Food and Feed to the CAC for final adoption at Step 8.

#### **Review of the IESTI Equations**

During CCPR48 in 2016, the European Union (EU) and Australia issued a conference room document (CRD) proposing new work to explore the possible revision to the IESTI equations and the impacts thereof. The United States expressed support for a thorough evaluation of the component inputs of the IESTI equations, but also voiced concerns that the CRD was only made available a short time prior to the session and only in English. Other countries expressed similar concerns and so instead of deciding to start new work at CCPR48, the Committee agreed to establish an eWG, 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. The United States agreed with this approach and actively participated in the IESTI eWG.

During the adoption of the Agenda for the CCPR49, the Committee agreed to form an in-session WG, chaired by the Netherlands and co-chaired by Australia, to determine further steps on the possible review of the IESTI equations. During the discussions, the United States stressed that any potential revision of the IESTI equations should fully take into account the impact on trade; loss of MRLs; impact on Codex members who reference or defer to Codex MRLs; and ability to control pests if there is a loss of available pesticides with Codex MRLs. Furthermore, any changes in IESTI would need to take into account the entire IESTI equation, in a holistic manner, and not just specific parts or pieces.

The Committee agreed to establish a new eWG, chaired by the Netherlands and cochaired by Australia and Uganda, with the following Terms of Reference:

- To provide information on the history, background and use of the IESTI equations;
- To review and provide illustrative comments on advantages and challenges that arise from the current IESTI equations and their impact on risk management, risk communication, consumer protection goals and trade;
- To gather relevant information on bulking and blending, as well as other information or data as outlined in Table 3 Appendix 2 of CX/PR 17/49/12 in order

to feed into the risk assessors' work (see next paragraph) through the JMPR Secretariat; and

• On the basis of the above considerations, to develop a discussion paper providing recommendations for consideration at CCPR 50.

The Committee also agreed to request FAO/WHO:

- To review the basis and the parameters of the IESTI equations;
- To benchmark the outcomes of IESTI equations to a probabilistic distribution of actual exposures; and
- To present the outcome to CCPR.

The Committee noted that interaction between risk managers (CCPR) and risk assessors (FAO/WHO, JMPR) would be done through the JMPR Secretariat. The Committee called upon the active participation of the JMPR Secretariat in the eWG to ensure proper focus and a liaison between risk managers and risk assessors.

#### Establishment of Codex Schedules and Priority Lists of Pesticides

For the upcoming 2018 JMPR evaluation, the Chair of the eWG on Priorities (Australia) noted that eight compounds (plus two reserve compounds) are scheduled for new compound evaluation; six compounds are scheduled for periodic reevaluation. JMPR acknowledged that with eight new and six old compounds, the workload may exceed available resources. Nevertheless, the JMPR will include all 16 compounds in the "data call-in," which includes reserve compounds. Reserve compounds may replace compounds on the priority list that are withdrawn or postponed until a later date. There are 20 new use and other evaluations listed in the proposed 2018 schedule.

Canada also introduced a proposal (CRD 3)\_to fund an extraordinary session of the JMPR in May 2019 that will draw on the nominations listed in the 2019 Priority List on new use and other evaluations. The Committee expressed general support for the proposal that will help eliminate some of the backlog on the Priority Lists.

The Committee also reaffirmed the decision taken at the CCPR 48 (2016) to utilize a "date-stamp" to signify when all scheduling criteria specified in the Risk Analysis Principles applying to CCPR in the Codex *Procedural Manual* are met. Accordingly, nominations are now placed on the Priority Lists in order of receipt, by a Member, of all relevant data including product labels and evidence national registrations.

The Committee agreed to re-establish the eWG on Priorities, chaired by Australia and co-chaired by Germany.

#### Information on National Registrations of Pesticides

Following the last session of CCPR, a Circular Letter (CL 2017/18-PR, <u>Request for</u> information on national registration of pesticide compounds) seeking documented



evidence of national registrations for all compounds on the CCPR pesticide list was distributed. The CL also asked Members and Observers to list commodities for which a registered use was in place. The primary objective of this database is to provide Codex Members and Observers with a source of information indicating whether or not a national registration and current product label exist for a chemical-commodity combination.

The United States responded to the request by completing the spreadsheet accompanying the CL to provide information for pesticide tolerances listed in the Tables 2A and 2B of the CCPR Schedules and Priority Lists of Pesticides. The U.S. response included information on current tolerances available in the U.S. *Code of Federal Regulations*, derived from <u>GlobalMRL.com</u>, which may have a corresponding active national registration.

As mentioned earlier, the Committee agreed to re-establish the eWG on Priorities, chaired by Australia and co-chaired by Germany. They are also tasked with coordinating further work to develop the national registration database for consideration at the next CCPR. The Codex Secretariat will issue a new CL seeking further input on the database, ideas on the management of the database, and consideration of whether or not to broaden the scope of the database to include all compounds listed on the proposed CCPR Pesticide List.

# Other Highlights Relevant to the United States

Other highlights of the 49th Session of the CCPR included three well-attended side events on new pesticide management regulations in China [links to <u>details</u>; <u>presentation</u>]; initiatives to increase the capacity of JMPR [links to <u>details</u>; <u>presentation</u>]; and MetaPath, an international database on pesticide metabolism [links <u>details</u>].

#### Next Session

The 50th session is scheduled for May 2018 in China. Additional details and final arrangements were not provided.