# **U.S. DRAFT POSITIONS**

# for the

# Codex Committee on Pesticide Residues (CCPR)

51<sup>st</sup> Session Macao SAR, China April 8-13, 2019

## CX/PR 19/51/1

## **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 supports adoption of the Provisional Agenda as proposed.

## Agenda Item 2

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## **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 19/51/2

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

## **Background:**

• The document outlines information and actions taken by the CAC41 in 2018 with regard to the proposals forwarded by CCPR 2018. It also includes matters for action by the CCPR in 2019.

#### **U.S. Position:**

 Although this document has not yet been made available, we are aware of the actions taken by the CAC41 with regard to CCPR. The United States supports the actions taken by the CAC in adopting, revoking, and withdrawing the proposals the CCPR sent forward in 2018.

Agenda Item 4(a) CX/PR 19/51/3

Matters of interest arising from FAO and WHO

#### **Background:**

The document outlines matters of interest to CCPR related to the Food and Agriculture
Organization (FAO) and the World Health Organization (WHO), in addition to the 2018 Joint
FAO/WHO Expert Meeting on Pesticide Residues (JMPR) Activities.

 Although this document has not yet been made available, the United States is actively engaged on CCPR matters of interest that relate to FAO and WHO and will develop positions on issues if warranted.

Agenda Item 4(b)

CX/PR 19/51/4

Matters of interest arising from other international organizations

#### **Background:**

• The document outlines the actions taken by other International Organizations.

#### **U.S. Position:**

 As this document was just issued, the United States is currently reviewing it and will develop positions if warranted.

# Agenda Item 5(a)

Report on items of general consideration by the 2018 JMPR Section 2 of the 2018 JMPR Report (English only)

#### **Background:**

- The document outlines the actions taken by the 2018 JMPR on Section 2: General Considerations.
  - 2.1 Toxicological profiling of compounds and less-than-lifetime dietary exposure assessment
  - 2.2 Need for sponsors to submit all requested data
  - **2.3** Hazard characterization in the 21st century: assessing data generated using new mechanism-based approaches for JMPR evaluations
  - **2.4** Update on the revision of Principles and Methods for Risk Assessment of Chemicals in Food Environmental Health Criteria (EHC) 240
  - 2.5 Microbiological effects
  - **2.6** Transparency of JMPR procedures
  - **2.7** Review of the large portion data used for the International Estimated Short-term intake (IESTI) equation
  - 2.8 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
  - **2.9** Recommendations for (sub) group maximum residue levels for Fruiting vegetables, other than Cucurbits revisited
  - **2.10** Preliminary results for probabilistic modelling of acute dietary exposure to evaluate the IESTI equations

#### **U.S. Position:**

• As the 2018 JMPR report was just recently issued, the United States is still reviewing the 2018 JMPR Report and will develop a position if warranted.

#### Agenda Item 5(b)

Report on 2018 JMPR responses to specific concerns raised by CCPR Section 3 of the 2018 JMPR Report (English only)

#### **Background:**

- The document outlines the actions taken by 2018 JMPR on Section 3 of the 2018 JMPR Report (3. RESPONSES TO SPECIFIC ISSUES) which deals with specific issues brought up at JMPR, including any concern forms submitted during CCPR50 (2018). At that Session, the United States submitted concern forms for 2,4-D (Cotton) and Picoxystrobin (Oilseed rap, seed). Section 3 is outlined below.
  - **3.1** Benzovindiflupyr (261)
  - **3.2** Bromopropylate (070)
  - 3.3 Crop groups Reconsideration of maximum residue estimations made by the 2017 JMPR for fenpyroximate (193), fluopyram (243), oxamyl (126) and spinetoram (233)
  - 3.4 Cyprodinil (207) and Propiconazole (160) Post-harvest uses 19
  - **3.5** 2, 4-D (020)
  - **3.6** Fluopyram (243)
  - **3.7** Phosphonic acid (301) / Fosetyl-aluminium (302)
  - 3.8 Picoxystrobin (258)
  - **3.9** Quinclorac (287)
- As indicated above, the United States submitted a concern form on 2,4-D that indicated that no recommendation for an MRL for 2,4-D on cottonseed was made and no reason (such as a study deficiency) for not recommending a cottonseed MRL for 2,4-D was listed in the 2017 JMPR report. In response to this concern, JMPR noted that its 2017 determination was based on deficiencies in the supervised field trial data that were considered inadequate for estimating a maximum residue level. JMPR determined that the available supervised field trial study was inadequate because samples in the study were frozen for 84-118 days, whereas storage stability in an available cotton seed study suggests declines in stability after 30 days of frozen storage. Therefore, the 2018 JMPR confirmed its previous 2017 determination and concluded, "that due to the questionable storage stability of 2,4-D in cotton seed, the residue data were inadequate for estimating a maximum residue level".
- The United States also submitted a concern form on picoxystrobin that requested an "explanation of why the JMPR concluded that there were an inadequate number of MOR [magnitude of residue] trials available for review to recommend a maximum residue level for picoxystrobin on oilseed rape." In response, JMPR 2018 reaffirmed its previous 2017 determination and further described inadequacies in the fields residue trials that were not conducted at the Critical GAP (cGAP).

#### **U.S. Position:**

• As the 2018 JMPR report was just recently issued, the United States is still reviewing the 2018 JMPR Report and will develop a position if warranted.

Agenda Item 6 CX/PR 19/51/5

Proposed maximum residue limits (MRLs) for pesticides in food and feed (at Steps 7 and 4) (English only)

CX/PR 19/51/5-Add.1

Comments at steps 6 and 3 (in reply to CL 2018/97-PR)

#### **Background:**

- The annual JMPR was held in Berlin, Germany from 18 to 27 September 2018.
- The Meeting evaluated 29 pesticides, including 8 new compounds and 3 compounds that were re-evaluated for toxicity or residues, or both, within the periodic review program.
- The Meeting established (Acceptable Daily Intakes) ADIs and Acute Reference Doses (ARfDs), estimated maximum residue levels and recommended them for use by CCPR, and estimated supervised trials median residue (STMR) and highest residue (HR) levels as a basis for estimating dietary intakes.
- The Meeting also estimated the dietary intakes (both short term and long term) of the
  pesticides reviewed and, on this basis, performed a dietary risk assessment in relation to their
  ADIs or ARfDs. Cases in which ADIs or ARfDs may be exceeded were clearly indicated in order to
  facilitate the decision-making process by CCPR.
- The Meeting considered a number of general issues addressing current procedures for the risk assessment of chemicals, the evaluation of pesticide residues and the procedures used to recommend maximum residue levels.

#### **U.S. Position:**

 At this time, the United States is reviewing recent comments received recommending submission of concern forms to CCPR51 based on the 2018 JMPR reviews.

Agenda Item 7

Revision of the Classification of Food and Feed (CXM 4/1989)

#### **Background:**

- This is part of the ongoing effort of the CCPR electronic Working Group (EWG) on the Revision of the Classification to revise all the crop groups in the Food and Animal Feeds Classification.<sup>1</sup>
- 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.

The United States has provided below the specific background information for Agenda Items 7(a) - 7(g).

Agenda Item 7(a)
CL 2019/01-PR and CX/PR 19/51/6

Class C – Primary feed commodities

<sup>&</sup>lt;sup>1</sup> Report of the 50<sup>th</sup> Session of CCPR. REP18/PR, para. 129

Type 11: Primary feed commodities of plant origin

- Group 050: Legume feed products
- Group 051: Cereal grains and grasses (including pseudocereals) feed products
- Group 052: Miscellaneous feed products

Comments at Step (CX/PR 19/51/6-Add.1)

# **Background:**

- CCPR50 (2018) agreed the EWG would (i) continue the work on the revision of Class C based on the structure<sup>2</sup> agreed by CCPR50; (ii) consider the addition of new commodities to Class C; and (iii) consider the addition of subgroups to the groups of feed that would include processed commodities in order to group all feed commodities under Class C which may involve the relocation of commodities from Class D to Class C in accordance with the Terms of Reference (TOR) i-iii given to it by CCPR50.<sup>3</sup>
- The EWG considered the following Class C, Type 11 commodity groups: *Group 50* Legume feed products; *Group 51*, Cereal grains and grasses (including pseudo-cereals) feed products; and *Group 52* Miscellaneous feed products.
- Following deliberation by the EWG, the following conclusions were made and will be discussed further at CCPR-51:
  - The revised Type 11 includes an additional subgroup for processed products (such as meal, hulls, dried pulps, molasses), and a number of additional commodities for groups 50, 51 and 52.
  - Addition of new commodities or relocation of commodities from Class D to Class C follows the approach agreed by CCPR50 on the revision of the Classification.
  - Specific discussion on the transferring of commodities from Class D to Class C are described in Agenda Item 7(c).

# **U.S. Position:**

- We agree with the conclusions of the EWG, however we await receipt of any new comments in response to the Circular Letter, in the event we need to provide further comments.
- The United States supports the position of Canada (item 9 in CX/PR 19/51/6) that separate warm season grasses and cool season grasses should be included in Group 51.

Comments in response to Circular Letter (CL) <u>CL 2019/01-PR</u> are due to the U.S. Delegation as soon as possible, but no later than **March 13, 2019.** The U.S. delegation will consider any comments received in preparing our responses to the Circular Letters due to the CCPR and Codex Secretariats by March 20, 2019. Note that there are several related Circular Letters on classification of food and feed, so there should be close synchronization between comments submitted in reply to <u>CL 2019/01-PR</u>, <u>CL 2019/02-PR</u>, <u>CL 2019/03-PR</u> and <u>CL 2019/19-PR</u>.

Agenda Item 7(b)
CL 2019/02-PR and CX/PR 19/51/7
Class D – Processed foods of plant origin
All types in Class D

<sup>&</sup>lt;sup>2</sup> Report of the 50<sup>th</sup> Session of CCPR. REP18/PR, Appendix X.

<sup>&</sup>lt;sup>3</sup> Report of the 50<sup>th</sup> Session of CCPR. REP18/PR, para. 129 (points i-iii)

#### **Proposed groups in different types**

#### Comments at Step 3 (CX/PR 19/51/7-Add.1)

# **Background:**

- The EWG on the Revision of the Classification initiated work on Type 12 –Secondary Food Commodities of Plant Origin in Class D Processed Foods of Plant Origin in accordance with (i) the TOR given by CCPR50<sup>4</sup> and (ii) in line with the decision taken by CCPR50 on the approach to the revision of the Classification to include a commodity only in one group or subgroup to avoid confusion of having two different CXLs for the same commodity.
- Class D contains four types (each type consists of several groups):
  - Type 12 Secondary Food Commodities of Plant Origin;
  - Type 13 Derived Products of Plant Origin;
  - Type 14 Derived Products of Plant Origin; and
  - o Type 15 Manufactured Foods (Multi-ingredient) of Plant Origin.
- Type 12 and Type 13 are strongly related, in both groups commodities originating from the same raw agricultural commodities are included, e.g. cereals and fruits. Only a limited number of commodities are included in Type 15 and no commodities in Type 14. Therefore, the EWG initiated work on the whole Class D.
- Following deliberation by the EWG, a number of changes and conclusions were made and may be found in CX/PR 19/51/7, including:
  - Changes in the introduction text of types
  - New commodities
  - Codes for synonyms are replaced by a reference
  - Subgroups with a code are proposed, formed in the same way as in Class A
- Comments in relation to proposals for the transfer of processed commodities from Class D –
  Processed Food Commodities of Plant Origin to Class C should be submitted in reply to CL
  2019/19-PR.

#### **U.S. Position:**

 We agree with the conclusions of the EWG found in CX/PR 19/51/7, however we await receipt of any new comments in response to the Circular Letter, in the event we need to provide further comments.

Comments in response to <u>CL 2019/02-PR</u> are due to the U.S. Delegation as soon as possible, but no later than **March 13, 2019.** The U.S. delegation will consider any comments received in preparing our responses to the Circular Letters due to the CCPR and Codex Secretariats by March 20, 2019. Note that there are several related Circular Letters on classification of food and feed, so there should be close synchronization between comments submitted in reply to <u>CL 2019/01-PR</u>, <u>CL 2019/02-PR</u>, <u>CL 2019/03-PR</u> and <u>CL 2019/19-PR</u>.

<sup>&</sup>lt;sup>4</sup> Report of the 50<sup>th</sup> Session of CCPR. REP18/PR, para. 129 (points ii & iv)

Agenda Item 7(c)
CL 2019/19-PR & CX/PR 19/51/8
Transfer of commodities from Class D to Class C

**Comments (CX/PR 19/51/8-Add.1)** 

## **Background:**

- The EWG on the Revision of the Classification on the transfer of commodities from Class C and Class D had a discussion on processed commodities under Class D that could either be consumed as feed and/or food, and could therefore be transferred to Class C, or be retained in Class D.
- CCPR50 decided to group all feed commodities under the agreed new structure for Class C / Type 11, and consequently, processed commodities identified as feed under Class D should be transferred to Class C.
- The EWG recommends the transfer of processed commodities to the group of animal feed. This
  recommendation is based on deliberation of the EWG and the classification described in the
  Organization for Economic Cooperation and Development (OECD) Guidance Document on
  Residues in Livestock.
- In the case of a dual purpose of a commodity (food and feed), it should be decided whether the product should be classified in Class C or Class D.
- CCPR50 agreed that a commodity can have only one place in the Classification. The EWG
  therefore agreed with the premise that a commodity that is used as food, cannot be included in
  the group of feed. Also, when only a small part of the total quantity of a product is used as food,
  and most of it is intended as animal feed, then the commodity will be included in processed
  food commodities and not classified as a feed commodity.

#### **U.S. Position:**

• We agree with the conclusions of the EWG, however we await receipt of any new comments in response to the Circular Letter, in the event we need to provide further comments.

Comments in response to <u>CL 2019/19-PR</u> are due to the U.S. Delegation as soon as possible, but no later than **March 13, 2019.** The U.S. delegation will consider any comments received in preparing our responses to the Circular Letters due to the CCPR and Codex Secretariats by March 20, 2019. Note that there are several related Circular Letters on classification of food and feed, so there should be close synchronization between comments submitted in reply to <u>CL 2019/01-PR</u>, <u>CL 2019/02-PR</u>, <u>CL 2019/03-PR</u> and <u>CL 2019/19-PR</u>.

Agenda Item 7(d)

CL 2019/03-PR & CX/PR 19/51/9

Proposed table on examples of representative commodities for commodity groups in different types under Class C and Class D (for inclusion in the Principles and Guidance for the Selection of Representative Commodities for the Extrapolation of MRLs for Pesticides to Commodity Group (CXG 84-2012))

Comments at Step 3 (CX/PR 19/51/9-Add.1)

#### **Background:**

- The EWG on the Revision of the Classification proposed the following examples for the selection of representative commodities for Class C Primary Animal Feed Commodities and Class D Processed Food Commodities of Plant Origin based on: (i) the TOR agreed upon by CCPR50 for the revision of both classes; and (ii) the discussion, conclusions and recommendations provided under the CCPR51 Agenda Items 7(a-c).
- The EWG has proposed examples of representative commodities for the revised Class C and Class D commodities (Appendix I and Appendix II of CX/PR 19/51/9, respectively).
- Appendix I includes proposed examples for the selection of representative commodities for groups and subgroups for Class C, Type 11. Appendix II includes proposed examples for the selection of representative commodities for Class D.
- It was not possible to establish representative commodities for all groups/subgroups under the different types because of the diversity of commodities in various groups/subgroups.

## **U.S. Position:**

- We agree with the conclusions of the EWG found in CX/PR 19/51/9, however we await receipt of any new comments in response to the Circular Letter, in the event we need to provide further comments.
- The United States supports inclusion of separate warm season and cool season grasses as proposed in Table 7 (Group 051).

Comments in response to <u>CL 2019/03-PR</u> are due to the U.S. Delegation as soon as possible, but no later than **March 13, 2019.** The U.S. delegation will consider any comments received in preparing our responses to the Circular Letters due to the CCPR and Codex Secretariats by March 20, 2019. Note that there are several related Circular Letters on classification of food and feed, so there should be close synchronization between comments submitted in reply to <u>CL 2019/01-PR, CL 2019/02-PR, CL 2019/03-PR</u> and <u>CL 2019/19-PR</u>.

Impact of the revised types in Class C and Class D on Codex MRLS (CXLs)

#### **Background:**

- CCPR has previously agreed that no changes would be made to existing Codex MRLs (CXLs) until such time as the JMPR reviews were completed, as per current procedures for the establishment of Codex schedules and priority list of pesticides.
- The Committee agreed that the same approach would be taken when reviewing other commodity groups in the database following the adoption of revised commodity groups in the Classification.
- The EWG on the Revision of the Classification proposed revisions to Class C (Primary Animal Feed Commodities) and Class D (Processed Food Commodities of Plant Origin). These revisions are described in Appendix I and II of CX/PR 19/51/10, respectively, and include recommendations on new commodity codes, new subgroup codes, and commodities transferred to another group.

#### U.S. Position:

• We agree with the conclusions of the EWG.

Agenda Item 7(f)

CL 2019/04-PR & CX/PR 19/51/11

**Any Class** 

Type on miscellaneous commodities not meeting the criteria for crop grouping Proposed groups (including any possible impact of the new types on CXLs)

Comments at Step 3 (CX/PR 19/51/11-Add.1)

- CCPR50 endorsed the approach to create a separate Type within each Class of the Classification
  to provide a list of commodities and codes that do not meet the criteria for inclusion in a crop
  group as a system within the Classification to provide codes for commodities that do not meet
  the criteria for grouping.
- The EWG on the Revision of the Classification considered the development of a system within
  the Classification to provide codes for commodities that do not meet the criteria for crop
  grouping. These additional commodities are not expected to have an impact on any CXLs since
  these are added commodities and these types will not have representative commodities. This
  includes the recommendation to establish a system for miscellaneous commodities.
- Miscellaneous commodities are those commodities which do not meet the criteria for crop
  grouping. These criteria include (1) commodity's similar potential for pesticide residues, (2)
  similar morphology, (3) similar production practices, growth habits, etc., (4) edible portion, (5)
  similar GAP for pesticides uses, (6) similar residue behavior, and (7) to provide flexibility for
  setting subgroup tolerances. Due to the heterogeneous nature of miscellaneous commodities,
  no representative commodity will be established for miscellaneous groups.
- The system for miscellaneous commodities was supported by the EWG and further information may be found in CX/PR 19/51/11. Miscellaneous commodities that have been proposed for Class A are shown in Appendix I of CX/PR 19/51/11 along with appropriate codes. The Type is

described as "TYPE MISCELLANEOUS" since types are already sequentially numbered from 1 to 20. The format for miscellaneous commodities for other Classes, as needed, are shown in Appendix II of CX/PR 19/51/11.

#### **U.S. Position:**

• We agree with the conclusions of the EWG, however we await receipt of any new comments in response to the Circular Letter, in the event we need to provide further comments.

Comments in response to <u>CL 2019/04-PR</u> are due to the U.S. Delegation as soon as possible, but no later than **March 13, 2019.** The U.S. delegation will consider any comments received in preparing our responses to the Circular Letters due to the CCPR and Codex Secretariats by March 20, 2019.

Agenda Item 7(g)

CL 2019/05-PR & CX/PR 19/51/12

Class B – Primary food commodities of animal origin

Common definition of edible animal tissues for the establishment of MRLs of pesticides and veterinary drugs for compounds with dual uses as pesticides and veterinary drugs for use by CCPR and the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)

Comments at Step 3 (CX/PR 19/51/12-Add.1)

- At the 24th session of the Codex Committee on Residues of Veterinary Drugs (CCRVDF24) in Chicago, Illinois, USA (23-27 April 2018), the Committee agreed to establish an EWG that will coordinate with the CCPR EWG on the Classification of Food and Feed on the definition for edible offal and for any other animal tissues of relevance.
- Based on coordination between the CCRVDF and CCPR EWGs, a discussion paper was prepared that identified opportunities to harmonize definitions and classification structures that pertain to edible offal. These opportunities include:
  - A consolidated edible offal definition for both CCPR and CCRVDF.
  - A consolidated edible offal hierarchical classification for both CCPR and CCRVDF.
  - Consideration of animal extrapolation rules using representative animal edible offal tissues
  - Consideration of target edible offal tissue for risk assessment.
- CCPR is invited to consider the following questions based on the considerations provided in the
  working document and comments submitted in reply to CL 2019/05-PR in order to provide
  guidance to further progress work on a common definition for edible animal tissues (including
  edible offal tissues):
  - 1. CCRVDF uses the term muscle, while CCPR uses meat. Can these terms be consolidated? If so, what is the appropriate term to use?
  - 2. Is the proposed consolidated edible offal definition acceptable: "Those parts of an animal, apart from meat from the carcass, that are considered fit for human consumption".
  - 3. Should a consolidated edible offal hierarchical classification be used for CCPR and CCRVDF and how can this be accomplished?
  - 4. Can animal extrapolation rules be developed for both CCPR and CCRVDF using representative animal edible offal tissues.

- 5. What is the best procedure to establish harmonized descriptors? Examples include different descriptors such as "fat", "fat with skin", "fat/skin" and "skin".
- 6. Should honey be included in the Classification system as a miscellaneous commodity? If so, should honey be included in Class B (primary food commodities of animal origin) or Class E (processed food of animal origin?

- The United States supports continued cooperation between CCRVDF and CCPR to harmonize the definition of edible offal and to consider other cooperative issues.
- The US Delegations to the CCRVDF and CCPR will work together to develop answers to the questions above in response to CL 2019/05-PR for the upcoming CCPR51.

Comments in response to <u>CL 2019/05-PR</u> are due to the U.S. Delegation as soon as possible, but no later than **March 13, 2019.** The U.S. delegation will consider any comments received in preparing our responses to the Circular Letters due to the CCPR and Codex Secretariats by March 20, 2019.

# Agenda Item 8 CX/PR 19/51/13

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* (CXG 56-2005)

#### **Background:**

- The purpose of the EWG was to develop a proposal for CCPR51 on new work to revise the
  "Guidelines on the Use of Mass Spectrometry (MS) for Identification, Confirmation and
  Quantitative Determination of Residues" (CAC/GL 56-2005) in order to improve and clarify the
  content. The revised guideline CAC/GL 56-2005 covers general aspects on analyzing pesticide
  residue by MS, with recommendations on identification, confirmation and quantitative
  determination.
- Based on deliberation by Codex members and observers, the EWG will propose new work that cover the following aspects of CAC/GL 56-2005:
  - General principles of confirmatory tests in determination of pesticide residues especially in multiresidue methods and demonstrating advances of MS technique for Gas Chromatography (GC) and High-Performance Liquid Chromatography (HPLC) to applicable pesticides.
  - 2. Criteria for selection of precursor and product ions for identification, confirmation, and quantitative detection.
  - 3. Criteria for confirmation of residue identities.
  - 4. Quality control criteria of quantification of identified residues.

#### **U.S. Position:**

 At this time, the United States is still reviewing these materials and will develop a position in the coming weeks.

- At the CCPR48 (2016), the European Union (EU) and Australia developed a conference room document (CRD03) proposing new work to explore possible revision to the IESTI equations and the impacts thereof.
- At the CCPR49 (2017), the Committee agreed to establish an EWG, chaired by the Netherlands and co-chaired by Australia and Uganda, in order 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 EWG formed after CCPR49 did not complete its terms of reference, so a new EWG was
  established at CCPR50 (2018) that focused on advantages and challenges of the current IESTI
  equation. The TOR of this EWG were:
  - 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.
  - ii. To gather relevant information on bulking and blending, in order to feed into the risk assessors' work through the JMPR Secretariat.
  - iii. Based on the above considerations develop a discussion paper providing recommendations for consideration at CCPR 51.
  - iv. To append the information on the history, background and use of the IESTI equations as part of the CCPR report.
  - v. To append the table on technical / risk assessment challenges that either arise from the possible revision of the current IESTI equations or are current challenges as well as part of the CCPR.
- The United States actively participated in the IESTI EWG and provided comments on TOR i, ii, and iii in December 2018 and participated in subsequent web conferences on December 11, 2018 and January 22, 2019.
- The conclusions and recommendations of the EWG are summarized below:
  - The EWG prepared an updated discussion paper on the advantages and challenges of the current IESTI equation on risk management, risk communication, consumer protection goals and trade.
  - The EWG has not yet received scientific guidance from FAO/WHO on the parameters of the IESTI equations or benchmark of the outcomes of IESTI equations relative to a probabilistic assessment of actual exposures. Therefore, the EWG recommends that the discussion paper on advantages and challenges of the current IESTI equation be further developed once FAO/WHO's scientific guidance and benchmarking assessment is made available.
  - The EWG prepared a draft CL to gather information on bulking and blending practices for commodities that are intended for intended for international trade. The EWG recommends distributing the CL to Codex members and observers so that the information gathered can be further discussed at CCPR52 (2020) and provided to the 2020 JMPR.
  - In order to continue work on the recommendations above, the EWG proposes to re-establish the EWG during CCPR51 to continue work and interact with the JMPR Secretariat.

- At this time, the United States is still reviewing these materials and will develop its position in the coming weeks.
- The United States notes, however, that FAO/WHO has not yet provided CCPR: (i) scientific
  guidance on the parameters of the IESTI equations; and (ii) a probabilistic benchmarking
  assessment the of IESTI equations national residue monitoring and food consumption data. The
  JMPR 2018 report indicates that a final report on the benchmarking assessment should be
  discussed at JMPR's 2019 regular meeting.
- With respect to another element in the current EWG TOR, the United States will also support
  efforts to gather information on commodities that are in international trade and routinely bulked
  and blended. This [may be the focus of a future CL that will solicit comments and be further
  discussed at CCPR52 (2020).

Agenda Item 10 CX/PR 19/51/15

Discussion paper on opportunities and challenges for the JMPR participation in an international review of a new compound

- At the 2018 CCPR, the Committee agreed to establish an EWG to assess the opportunities and
  potential challenges that may be associated with the participation of the JMPR in an international
  joint review of a new compound.
- The terms of reference of the EWG were to:
  - To identify and assess the benefits, challenges and proposed solutions of the participation of JMPR in an international joint review of a new compound, using previous national and international experience to inform the assessment, such as the sulfoxaflor pilot project;
  - ii. This assessment of benefits, challenges and proposed solutions will include but will not be limited to considerations such as resource efficiencies, timelines, enhanced communication and cooperation between competent authorities and the JMPR Secretariat, and science policy issues; and,
  - iii. Based on the above considerations, to develop a discussion paper for discussion at CCPR51.
- The EWG initiated work in early September 2018 and engaged with Codex members and observers
  during two rounds of discussion. The discussion paper incorporated feedback from Codex
  members and observers and identified benefits and challenges of JMPR participation in
  international review. The benefits and challenges are summarized below:
  - Key benefits include earlier global access to newer and safer pesticides, facilitation of international trade, improved management of JMPR resources, and improved harmonization of data packages.
  - Key challenges include evaluation of new pesticides without national registration, differences in registration timelines and data requirements between JMPR and national regulatory authorities and maintaining independence of JMPR and managing its resources efficiently.
- Based on consideration of the benefits and challenges identified in the EWG discussion paper, the EWG recommends new work to develop draft terms of reference and procedures, in consultation with the JMPR Secretariat, that will facilitate the participation of JMPR in parallel international reviews.

 The United States supports the recommendations of the EWG and proposal to develop terms of reference and procedures to facilitate the engagement of JMPR in parallel international reviews.

Agenda Item 11 CX/PR 19/51/16

Discussion paper on the development of guidance for compounds of low public health concerns that could be exempted from the establishment of CXLs

- At the CCPR50, the Committee agreed to establish an EWG to develop international guidelines
  that establish harmonized concepts and criteria that can be used to identify pesticides that are of
  low public health concern and can be considered exempt from the establishment of CXLs.
- The terms of reference of the EWG were to:
  - i. Provide background (such as trade problems and possible risk to human health) for justifying new work under the mandate of CCPR.
  - ii. To develop a proposal for guidelines to harmonize concepts to recognize biological and mineral substances used as pesticides of low public health concern which are or should be exempted of CXLs and/or that do not produce residues.
  - iii. Provide classification of such substances and possible lists or criteria, etc.
  - iv. Provide a revised project document with the work's scope.
- The EWG engaged with Codex members and observers during two rounds of comments. The discussion paper first identifies general considerations, including the relevance of the guidelines to the strategic objectives of Codex, relevance of national legislation on pesticides of low public health concern, and feasibility of establishing standards at the level of Codex.
- The EWG's discussion paper defines different criteria that can be used to identified pesticides of low risk or low public health concern and proposes that these criteria may be used to identify substances considered exempt from the establishment of a MRL. These criteria are summarized below:
  - Active substances without hazardous properties identified (very low or no toxicological concern). This includes: (i) substances for which it is not necessary to establish Reference Values based on their low-risk human health profile and (ii) substances and relevant metabolites that do not bioaccumulate or have the capacity to cause neurotoxic, immunotoxin, carcinogenic, mutagenic, reproductive, developmental or endocrine disrupting effects.
  - 2. Substances for which it is not possible to differentiate between the exposure associated with its use as pesticide from its other uses in the food chain. For example, natural exposure associated with the food substance cannot be differentiated from the one linked to the use as pesticide.
  - 3. Substances for which no consumer exposure linked to the mode of application is foreseen. For example, natural substances such as pheromones and semiochemicals dispersed through dispensers for sexual confusion purposes.
  - 4. Other criteria
    - **4(a)** Substances for which there is a long history of equivalent level of exposure (similar to the level of exposure that would be incurred by the proposed use of the pesticide) to humans, e.g., 50 years or longer. This approach could include natural substances used in consumer products such as natural health products, cosmetics and other extractable

- commodity chemicals that have a range of non-pesticidal uses (e.g., garlic oil). It could also include semiochemicals where applications to food crops are not expected to result in residue levels that exceed natural background levels during outbreaks of the pest and that any residues present are not expected to be toxic.
- **4(b)** Microorganisms which are not acutely toxic and do not produce mammalian toxins or other potentially toxic secondary metabolites of human health concern.
- Based on the results of the EWG, the EWG recommends to:
  - o Approve the new work outlined in the EWG's discussion paper and submit to the CAC; and
  - Re-establish the EWG to prepare guidelines for compounds of low public health concerns that could be exempted from the establishment of CXLs.

• The United States, which is serving as co-chair on the discussion paper, supports this work since products of low public health concern, such as biopesticides, continue to play a more important role in plant protection. There is a concern that if they are not being viewed as "safe" or included as part of the Codex standards, then growers will be reluctant to incorporate these important tools in to their farming practices.

Agenda Item 12 CX/PR 19/51/17

Discussion paper on the management of unsupported compounds

- Following discussion at CCPR50, an EWG was formed that prepared of a discussion paper on the
  management of unsupported compounds for deliberation at CCPR 51. In the context of the CCPR
  prioritization process, an unsupported compound is a pesticide that is due for re-evaluation (i.e.,
  periodic review) for which neither a Codex Member Country/Observer or a manufacturer has
  committed to submit the data required for evaluation by the JMPR.
- The EWG discussion paper proposes a general process for the management of (i) unsupported compounds <u>with</u> public health concerns and (ii) unsupported compounds <u>without</u> public health concerns.
  - o For unsupported compounds with public health concerns the discussion paper proposes:
    - If adequate data is submitted by a manufacturer or Codex Member Country/Observer in time for the scheduled JMPR evaluation, the normal re-evaluation process will take place and CCPR will consider the JMPR recommendations for new MRLs or MRLs for withdrawal according to normal practice.
    - If the pesticide remains unsupported, or adequate data is not submitted for the scheduled re-evaluation, the CCPR will consider removal of the pesticide from the Codex List and revocation of all CXLs at its next Session following the scheduled reevaluation.
  - For unsupported compounds <u>without</u> <u>public health concerns</u> the discussion paper proposes a process to issue a request to Codex Member Countries/Observers to submit toxicology, residue and other relevant data to support the re-evaluation of pesticides. For compounds that remain unsupported after this request, the discussion paper proposes several options, based on the evidence of national registration, to determine if CXLs will be retained. These options will be further discussed at CCPR51.

• The United States supports efforts to develop a clear process for managing unsupported compounds and determining when CXLs are retained.

# Agenda Item 13

CX/PR 19/51/18

Information on national registrations of pesticides (Based on information submitted in reply to CL 2018/50)

#### Note from the Codex Secretariat

The Committee will consider document CX/PR 19/51/18 prepared by Australia and Germany in reply to CL 2018/50 following information submitted by Codex members on their registration of pesticides. This document should be read in conjunction Agenda Item 14 to aid discussion on the establishment of Codex priority lists of pesticides.

#### **Background:**

- Following CCPR48 (2016), a CL was issued requesting information from Member Countries regarding national registrations for all compounds on the CCPR Pesticide List. CL 2018/17-PR was then issued following CCPR49 to obtain information on national registrations using a new data submission template. The CL also requested feedback on the submission process and the format of the complete database of national registration information for Member countries.
- Collection of data on national registrations was further discussed at CCPR50and an EWG was formed to obtain input on the data submission process (e.g., number and frequency of submissions and updates) and data format.

# **U.S. Position:**

- The United States supports efforts to improve access to information on national registrations of pesticides. Development of this information will require close coordination by Member countries and consideration of how to structure data collection to standardize submission.
- The United States supports further discussion at CCPR51 on how to efficiently collect and report standardized information on national registrations of pesticides.

# Agenda Item 14 CX/PR 19/51/19

Establishment of Codex Schedules and Priority Lists of Pesticides (Based on comments submitted in reply to CL 2019/06-PR)<sup>5</sup>

#### Note from the Codex Secretariat

The elaboration of the Priority List corresponds to Step 1 of the Codex MRLs Elaboration Procedure. The Committee will consider a document prepared by the Chair of the Working Group on Priorities (presented as a conference room document) based on CX/PR 19/51/19, which contains collated proposals for priority lists of pesticides based on comments submitted in reply to CL 2019/06-PR.

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<sup>&</sup>lt;sup>5</sup> CL 2019/06-PR

#### **Background:**

- At CCPR50, it was agreed that an EWG would be reconvened to obtain nominations for the Codex schedule and priority list of pesticides for JMPR for the years 2020 2021 and beyond.
- The United States coordinated the nomination process with U.S. stakeholders and submitted nominations in November 2018.
- After receiving nominations from the United States and other member countries, the EWG issued CL 2019/06-PR requesting feedback on the updated Codex schedules and priority lists of pesticides.

#### **U.S. Position:**

- The United States has reviewed the Codex schedules and priority lists of pesticides provided in <u>CL</u> <u>2019/06-PR</u>. The schedules and priority lists are consistent with United States' nominations that were submitted to the EWG in November 2018.
- As such, the United States did not submit formal comments in response to the Circular Letter and has verified that the Codex Schedules and Priority Lists reflect nominations submitted by the United States in 2018.

Agenda Item 15
Other Business and Future Work

# **U.S. Position:**

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

Agenda Item 16
Date and Place of the Next Session

#### **U.S. Position:**

No U.S. position needed in advance.

Agenda Item 17
Adoption of the Report

#### **U.S. Position:**

• No U.S. position needed in advance.