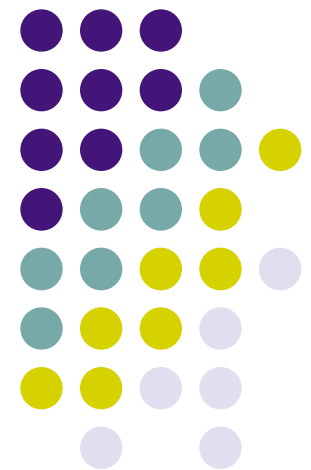


Codex Regulations

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2015 MRL Harmonization Workshop
San Francisco, California
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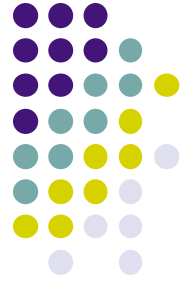


Codex Committee on Pesticide Residues (CCPR)



- Once there is a US registration for a specific chemical/commodity growers often find there is a need to also have maximum residue limits (MRLs) established in other countries to allow for exportation of the commodity.
- Outside of the OECD countries, many national authorities rely on Codex MRLs instead of creating their own regulatory scheme.
- Before a Codex MRL can be established a chemical/commodity must first be nominated by a Member Country to the CCPR Electronic Working Group on Priorities.

Codex



- In preparation for the CCPR meeting there will be several meetings held by the US Delegation prior to the CCPR to prepare.
- Typically the Delegate's meetings held in the Fall Winter prior to the Spring CCPR mainly address the need for Codex MRLs and if there are any nominations to be made.
- Once the US Delegation is informed there is a need for a specific Codex MRL, the delegation will work with registrants and IR-4 to determine if there are data available to submit to the JMPR for review.

Codex



- If data are available, the US Delegation will then nominate a chemical/ commodity to the Electronic Working Group on Priorities so that chemical can be scheduled for review by the JMPR.
- Nominations are due in November prior to the CCPR Meeting.
- At the CCPR meeting the nominations will be scheduled and the schedule finalized for the next year.

Joint Meeting on Pesticide Residues (JMPR)

- Once a chemical is scheduled for review, the registrant and/or IR-4 will submit the appropriate data to the Secretariats of the Joint Meeting on Pesticide Residues (JMPR) in December the year prior to the September JMPR.
- JMPR meets once a year in September for three weeks.
- Before a Codex MRL can be established, human health risk assessments must be conducted to ensure the food supply is safe.

Risk Assessment Process

- It is the responsibility of the JMPR to review the appropriate toxicology (WHO) and residue field trial data (FAO), conduct dietary risk assessments and to recommend specific MRLs to the CCPR.
- Once JMPR has conducted its review, provided there are no issues or concerns, the CCPR will consider the establishment of the MRL the following Spring after the September JMPR meeting.

Risk Management Process

- The CCPR meets once a year in the Spring in April or May.
- The CCPR will consider the MRLs recommended by JMPR. These MRLs come to the meeting at step 4.
- CCPR will determine if the MRLs can be advanced to step 8 or 5/8 or if they should remain at a different step pending further consideration by JMPR.
- Those advanced to step 8 or 5/8 will be sent to the CAC for adoption at the next meeting.

Codex Alimentarius Commission (CAC)



- The Codex Alimentarius Commission, established by FAO and WHO in 1963 develops harmonized international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair practices in the food trade.
- The Commission also promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations.
- The CAC meets once a year in July to consider the work of all of the Codex Committees.



Codex MRLs

- If the CAC agrees with the CCPR recommendations the Codex MRLs will be adopted.
- Due to the “Concern Form” process of the CCPR the Codex MRLs typically are not blocked at the CAC meeting.
- This is not always the case for the other Committees.

Codex Process



Grower or Company Identifies need for Codex MRL

U.S. Delegation works with registrants and IR-4 to determine if there are data available to support a nomination to Codex.

U.S. Delegation Submits Nomination

In order for a chemical/commodity to be considered for review by the JMPR it must first be nominated by a Member Country to the CCPR Electronic Working Group on Priorities.

Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

JMPR reviews the appropriate toxicology and residue field trial data, conducts dietary risk assessments and to recommend specific MRLs to the CCPR – meets in September

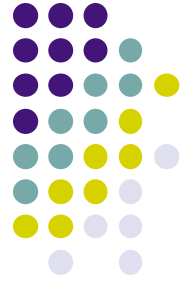
The Codex Committee on Pesticide Residues (CCPR)

CCPR is responsible for establishing MRLs for pesticide residues in specific food items or in groups of food; establishing maximum limits for pesticide residues in certain animal feeding stuffs moving in international trade where this is justified for reasons of protection of human health – meets in April/May

Codex Alimentarius Commission (CAC)

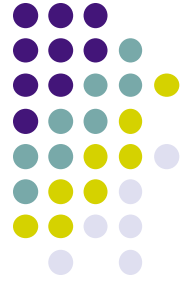
CAC was created by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme – meets in July.

2015 CCPR



- 348 MRLs for 32 pesticides were advanced to Step 8 for adoption by the CAC (all 348 were advanced using the accelerated 5/8 procedure).
- 48 of the 348 MRLs were for crop groups or subgroups.
- Nine new compound evaluations, 16 new use and other evaluations, and five existing compound re-evaluations are scheduled for review by JMPR in 2016. Two new compounds (pinoxaden and cyclaniliprole) and two re-evaluation compounds (chlormequat and fenpropimorph) were given reserve status.
- In 2016 the ratio of new and old compound evaluations will be reviewed with a possible stronger focus on periodic reviews. This review will occur prior to the next session of CCPR in the EWG.

CCPR Initiatives



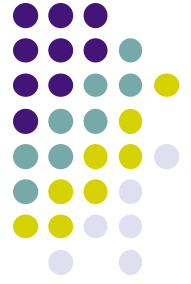
- The CCPR agreed to forward the Guidance to Facilitate the Establishment of MRLs for Pesticides for Minor Crops together with the Appendix on Methodology to assign Crops into Consumption Categories to CAC for adoption and inclusion as an Annex to the *Risk Analysis Principles Applied by CCPR*.
- Work on the ***Methods of Analysis for the Determination Pesticide Residues*** will continue and it is anticipated to be completed in 2016.
- Work on the Revision of Codex Classification of Animal Food and Feeds (aka Crop Grouping) will continue and it is anticipated to be completed in 2016.

Crop Groups



- Draft Principles and Guidelines including Table 1 on fruit commodities were adopted by the CAC in 2013.
- Work on all other crop groups is expected to be completed during the 2016 CCPR meeting and all groups sent forward for adoption once work on cereal grains, cucurbits, grasses and seeds of beverages and sweets is complete.
- No agreement was reached regarding proposed cucurbit and cereal grains crop groups in 2015. Member countries will be asked to provide a rationale on how their option meets the criteria for crop grouping.
 - Other than Canada, there was little support for the US position regarding cucurbits. Most countries want winter squash represented by melon or in a separate subgroup.
 - There was also no agreement regarding the small grains subgroup. EU proposes a separate subgroups for barley, wheat and pseudocereals grains and the US does not agree.

Calculating Crop Group MRLs



- Despite the use of OECD calculation procedures, this difference in comparison of the median versus the maximum value has resulted in differences of crop group MRLs between Codex and the United States based on the submission of data and GAP submitted by the United States.
- The United States will present a paper to the OECD RCEG (Residue Chemistry Expert Group) this July proposing that national authorities revisit the use of the 5X range whether it be the median or the maximum value and determine if agreement can be reached on the use of a statistical approach to determine when it is appropriate to establish crop group MRLs.
- At the recent CCPR meeting the United States proposed that JMPR participate in this activity and provide their input into the development of an aligned method for the establishment of group MRLs.

Useful Websites

Codex website

<http://www.codexalimentarius.org/>

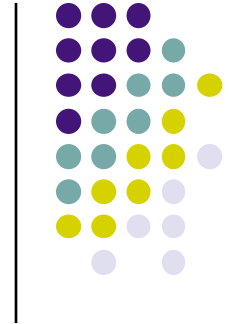
Codex MRLs for a given chemical

<http://www.codexalimentarius.net/pestres/data/pesticides/index.html?lang=en>

U.S. Codex

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius>

Questions?



Thank you.