



Update on International Efforts to Harmonize MRLs

Codex Committee on Pesticide Residues (CCPR)

Asian Pacific Economic Cooperation (APEC)

“Series II: Trading Up – how crop protection influences agricultural exports (and vice versa)”

Crop Life America/RISE Annual Meeting 2018

April 26, 2018

Renaissance Hotel

Arlington, VA

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U.S. Delegate, Codex Committee on Pesticide Residue (CCPR)

Office of Pesticide Programs

US Environmental Protection Agency

Overview

- **Codex Committee on Pesticide Residues (CCPR)**
 - Overview
 - What is the Codex Alimentarius?
 - U.S. participation in CCPR
 - Highlights from CCPR-50, April 9-14, 2018
- **Asian Pacific Economic Cooperation (APEC)**
 - Expert Workshop, April 5-6, 2018
 - US EPA Import Tolerance Pilot Program
 - Successes
 - Challenges
 - Lessons Learned
 - Next Steps

Codex Committee on Pesticide Residues (CCPR)

Overview and Highlights
from CCPR-50



**Food and Agriculture
Organization of the
United Nations**



**World Health
Organization**

Codex Mandate

- **Ensure fair practices in the food trade**

Fosters harmonization of food standards worldwide

- **Protect the health of consumers**

Science-based public health and food safety standards

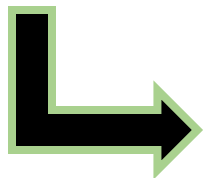
Importance of Science-Based Standards

- **WHO and FAO expert bodies and ad hoc consultations provide scientific advice in a variety of food safety areas including:**
 - Food Additives
 - Contaminants
 - Veterinary Drugs
 - Pesticide Residues

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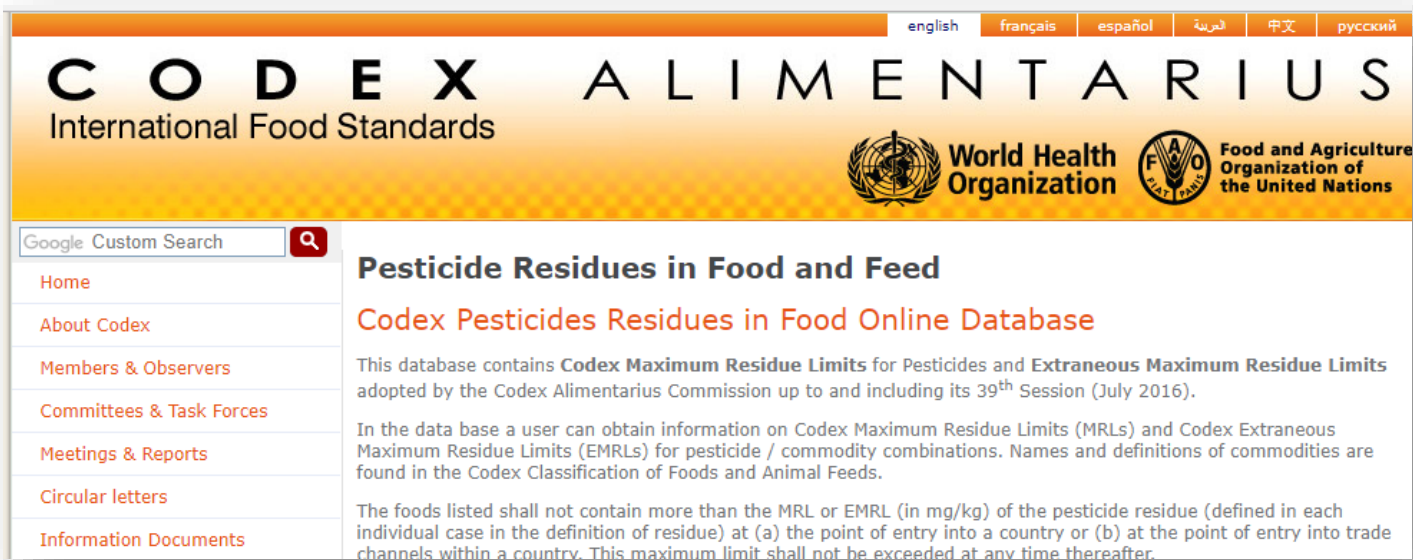
- Food Additives
- Contaminants
- Veterinary Drugs
- Pesticide Residues



**Codex Committee on Pesticide Residues
(CCPR)**

CCPR | Importance to US National Interest

- Codex has established more than 3,500 Pesticide Residue MRLs covering over 200 pesticides



The screenshot shows the Codex Alimentarius website interface. At the top, there is a navigation bar with language options: english, français, español, العربية, 中文, and русский. Below this is the main header with the text "C O D E X A L I M E N T A R I U S International Food Standards" and logos for the World Health Organization and the Food and Agriculture Organization of the United Nations. A search bar labeled "Google Custom Search" is visible. The main content area is titled "Pesticide Residues in Food and Feed" and "Codex Pesticides Residues in Food Online Database". It contains a paragraph stating: "This database contains Codex Maximum Residue Limits for Pesticides and Extraneous Maximum Residue Limits adopted by the Codex Alimentarius Commission up to and including its 39th Session (July 2016). In the data base a user can obtain information on Codex Maximum Residue Limits (MRLs) and Codex Extraneous Maximum Residue Limits (EMRLs) for pesticide / commodity combinations. Names and definitions of commodities are found in the Codex Classification of Foods and Animal Feeds. The foods listed shall not contain more than the MRL or EMRL (in mg/kg) of the pesticide residue (defined in each individual case in the definition of residue) at (a) the point of entry into a country or (b) at the point of entry into trade channels within a country. This maximum limit shall not be exceeded at any time thereafter."

<http://www.fao.org/fao-who-codexalimentarius/standards/pestres/en/>

Codex Committee on Pesticide Residues (CCPR)

- **US is represented by a US delegate from US EPA and an alternate US delegate from USDA**
 - David Miller, USEPA/OPP [*delegate*]
 - John Johnson, USDA/FSIS [*alternate delegate*]
- **Meetings held each spring in China to consider the MRLs recommended by the JMPR (Joint Meeting on Pesticide Residues)**
 - CCPR will determine if the MRL can be advanced to next step in the process for final approval by CAC (Codex Alimentarius Commission)

Codex Committee on Pesticide Residues (CCPR)

- **US has played an active role in setting the priorities and focus of the CCPR sessions.**
 - Maintains close contact with U.S. stakeholders throughout the year
 - offer realistic viewpoints and best practices on the setting of MRLs
 - advise the delegation on the benefits and shortcomings of the draft Codex Standards.
 - Reach-out to other interested parties
 - frequent U.S. delegation meetings throughout the year
 - International outreach symposia/workshops
 - Public meetings held prior to CCPR meetings to communicate draft U.S. positions and solicit additional input.

CCPR | Update on 50th Session of CCPR

- **Most recent CCPR was held in Haikou China 9-14 April, 2018 (CCPR 50).**
 - 52 member countries
 - One member organization (the European Union)
 - Observers from 11 international organizations
- **The Committee reached consensus on a number of crop groups and advanced 386 MRLs for final adoption by the CAC.**
 - These MRLs are associated with 39 pesticides;
 - 248 and 138 MRLs forwarded for adoption are for plant and animal commodities, respectively
 - Five of the nine new compounds reviewed by JMPR in 2017 were nominated by the United States.

CCPR | Update on 50th Session of CCPR

• Highlights of Other Discussion Topics

▪ **Matters of Interest from FAO/WHO**

- FAO/WHO Benchmarking of acute dietary exposure methods (IESTI)

▪ **2017 JMPR Evaluation**

- New field use pattern residue comparison model

▪ **Revision of the Codex Classification of Foods and Animal Feeds**

- Type 04 Nuts, seeds and saps
- Type 05 Herbs and Spices
- Type 11 Primary feed commodities of plant origin

▪ **Discussion Paper on the Possible Revision of the IESTI Equations**

- Ongoing work on advantages and challenges that might arise from the possible revision of the current IESTI equations
- Work is closely reviewed by U.S. EPA and U.S. stakeholders
- Discussion paper not yet complete and will be informed by FAO/WHO (probabilistic) benchmarking
- New terms of reference give greater focus to information related to bulking and blending practices and their impact on residue concentrations in bulked/blended commodities (e.g., orange juice, wheat flour).

Asian Pacific Economic Cooperation (APEC)

Status Update on the EPA's
Pilot Import Tolerance
Process



Asia-Pacific Economic Cooperation

APEC Expert Workshop, April 5-6, 2018

- APEC Food Safety Cooperation Forum convened expert workshop on harmonization of import MRLs
- **Key Objective:** Brain storming and consensus-building on key information on APEC economies processes and contact points for establishing regulatory import MRLs
- Included discussion of U.S. EPA's Import Tolerance Pilot Program

Background on US EPA Tolerances

- EPA is responsible for regulating the amount of pesticide residues that can remain in or on food or feed commodities as the result of a pesticide application.
- This is done through an EPA “tolerance”. A tolerance is the maximum residue level of a pesticide that legally can be present in food or feed.
 - If residues of a pesticide exceed the established tolerance, or no tolerance has been established, the crop is considered adulterated and may be seized
- The requirement for a tolerance applies equally to domestically produced and imported food and feed found to contain pesticide residues.
 - Even though the use of a pesticide in a foreign country is not subject to EPA registration requirements, a pesticide residue in imported food or feed must conform with a tolerance or tolerance exemption established by EPA.

Background on US EPA Tolerances (cont'd)

- **Residues of a pesticide not registered for use in the United States may be present in raw agricultural commodities (RACs) and processed foods produced abroad and imported into this country if EPA has established an “import tolerance” for a pesticide residue and the residues are within the tolerance**
 - “import tolerance” = a tolerance that exists in the United States for which there is no accompanying U.S. registration
 - Term of convenience | no specific (legal) designation
- **When a U.S. registration does not exist:**
 - an import tolerance (or tolerance exemption) for a pesticide residue on a food or feed commodity can be established which will allow the food or feed treated with the pesticide in foreign countries to be lawfully imported into the United States.
- **When a U.S. registration does exist, but is insufficient to cover foreign-produced foods:**
 - a petition needs to be submitted in order to increase the tolerance to a level adequate to cover the imported food.

Background on US EPA Tolerances (cont'd)

Two Important Points:

1. Import Tolerances Are Based on the Same Safety Standards As “Regular” U.S. Tolerances

There is no statutory or regulatory distinction between an import tolerance and any other tolerance established by EPA. Both must meet all current statutory requirements, including the safety standard (“reasonable certainty of no harm”) for pesticide residues in food.

2. Import tolerances generally require the same types of data as are needed to establish tolerances associated with U.S. registrations

This includes: product chemistry, residue chemistry, and toxicology data, as well as data representative of actual growing conditions. EPA needs these data to assess the potential dietary risk and make the required safety finding.

APEC Import MRL Guideline for Pesticides



- Developed from a series of 2015 APEC workshops on Harmonization of Pesticide Maximum Residue Limits
- Held to assist in minimizing discrepancies in MRLs and facilitate trade while continuing to protect human health
- Guidance document (2016) developed on approaches to achieve alignment of MRLs for pesticides within APEC
- Seeks to provide a framework within which science-based standards can be developed and applied uniformly and transparently across APEC economies

US EPA's (APEC-inspired) Import Tolerance Pilot

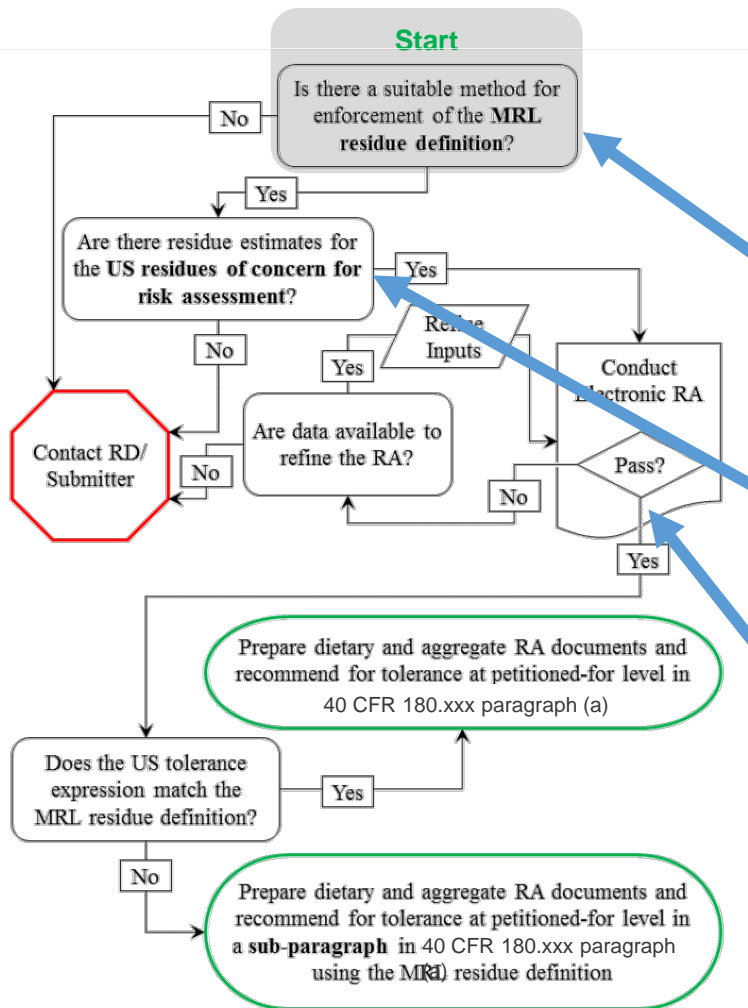
- **Test a streamlined data review strategy for establishing MRLs on imported commodities, APEC- and non-APEC**
- **Pilot to determine the feasibility of acceptance of other National Authority/JMPR reviews of residue chemistry data to support establishment of import tolerances**
 - Rely on data reviews from JMPR or other National- or Supranational- authorities rather than a *de novo* U.S. review
 - Compound generally must have food-use registration in the U.S.
 - In-depth review of competent authority's data evaluation report
 - No OECD MRL Calculator
 - Tolerance = MRL from Codex, EU, or exporting country
 - if national/supranational authority reviews contain sufficient information, there may be significant resource savings to EPA and potentially reduced timelines to establish import tolerances.
- **Will (still) require US EPA human health risk assessment/safety finding**

US EPA Import Tolerance Pilot Strategy requires:

(i) suitable enforcement method for MRL residue definition

(ii) residue estimates for US residues of concern for Human Health Risk Assessment (HHRA)

(iii) EPA to conduct HHRA



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(iii) EPA to conduct HHRA

US EPA Import Tolerance Pilot Program

- **Evaluations from Brazil, EFSA, Japan, JMPR**
- **10 chemical/crop combinations submitted since the inception of the pilot**
 - Represents 7 chemicals x 10 uses (banana, barley, coffee, ginseng, hops, legumes, olive, oats, tea, and wheat)
- **3 additional chemical/crop combinations were self-identified by the Agency**
 - 1 chemical x 3 uses
 - Foreign field trials only
- **Participation by major agrochemical companies**

Status:

- **Two completed: [Boscalid on the \(edible podded\) legume subgroup 6A and Ametoctradin on hops](#)**
 - Boscalid: <https://www.gpo.gov/fdsys/pkg/FR-2017-11-30/pdf/2017-25832.pdf>
 - Ametoctradin: <https://www.gpo.gov/fdsys/pkg/FR-2017-07-27/pdf/2017-15762.pdf>
- **One chemical should publish shortly (three additional uses)**

US EPA Import Tolerance Pilot Successes

- **All submissions to-date have been successfully reviewed**
- **All reviewers reported a positive experience**
- **Significant savings over “traditional” reviews**
 - ~ 50 hours shorter science review time
- **Faster decisions**
 - Tolerances for boscalid and ametoctradin were published six weeks before the PRIA due date

US EPA Import Tolerance Pilot Successes (cont'd)

- **EFSA and JMPR Reviews**

- High quality
- Easy to verify scientific integrity
- Solid support for proposed tolerance levels

- **Individual Country Reviews**

- Suitable quality
- Sufficient demonstration of scientific integrity and support for tolerance levels

US EPA Import Tolerance Pilot Challenges

- **Initial reluctance**
 - amongst registrants to submit pilot candidates
 - amongst science reviewers to accept reviews from other regulatory authorities
- **Importance of enforcement methodology as part of submission**
- **Differing tolerance definitions**

US EPA Import Tolerance Pilot Lessons Learned

- **Pre-submission meetings**

- Confirm an appropriate analytical method
- Review risk picture for existing uses
- Confirm quality of data review

APEC Import Tolerance Pilot Next Steps

- ❑ **The Agency plans to continue to encourage submissions under this pilot to gain experience with additional national authorities**
- ❑ **At the completion of the currently submitted actions, the Agency should be positioned to understand if this can be transitioned to a standard business practice and better informed on the boundaries for a revised import tolerance policy.**

Summary and Conclusions

- **MRL harmonization efforts are important to the U.S.**
- **Alignment of Import Tolerances can be important activities associated with harmonization efforts**
 - CCPR plays a continuing role in this
 - APEC activities in 2015 regarding import tolerances were important in moving these efforts forward in the U.S.
 - Has been a generally successful and learning experience
 - EPA will determine if this can be transitioned to a standard operating practice in the future.

Thank You!

For additional questions:

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Supplemental Materials

CCPR | Importance to US National Interest

- **As major agricultural exporter:**

- maintain and expand market access for U. S. exports

Once there is a US registration for a specific chemical/commodity, US growers often find that there is a need to have MRLs established in other countries to allow exportation of the commodity.

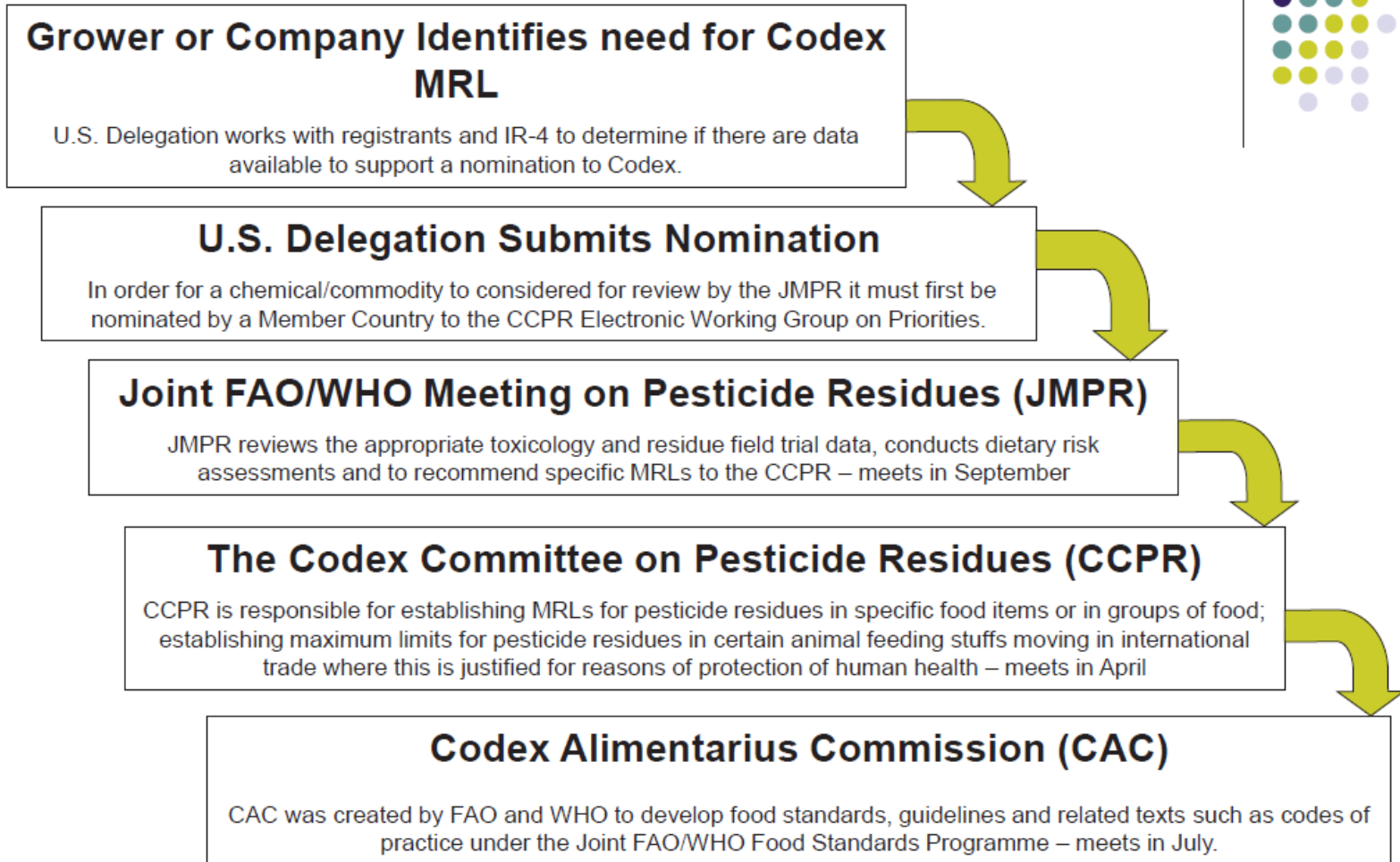
- **As major agricultural importer:**

- enhance food safety and consumer protection

CCPR | General Goals of US Involvement

- 1. Promote U.S. public health and trade goals by increasing the number and timeliness of new MRLs**
- 2. Increase the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) capacity—**
 - resources and efficiencies
- 3. Clarify the JMPR/CCPR relationship and interactions**
- 4. Strengthen Secretariat role in ensuring policies and procedures are followed**

Codex Process



CCPR | Terms of Reference

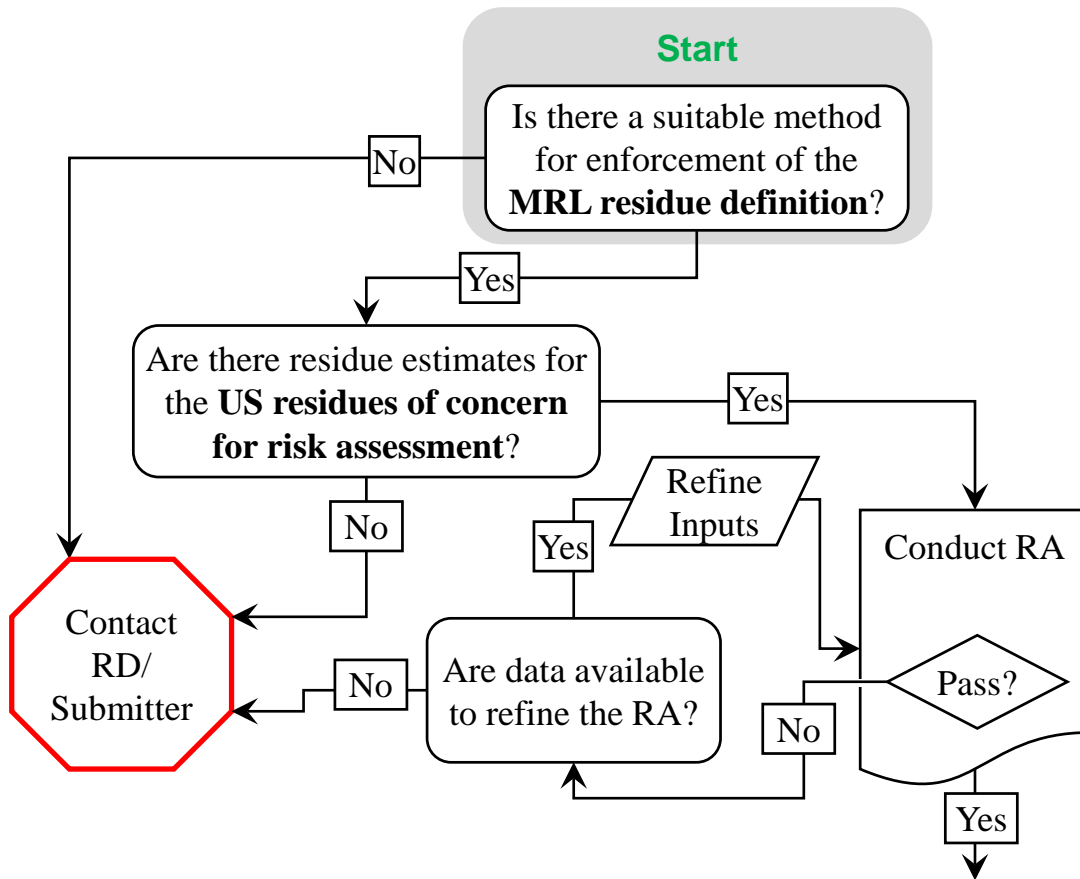
1. Establish maximum limits (CXLs) for pesticide residues in specific food items or in groups of food;
2. Establish maximum limits for pesticide residues in certain animal feeding stuffs moving in international trade where this is justified for reasons of protection of human health;
3. Prepare priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR);
4. Consider methods of sampling and analysis for the determination of pesticide residues in food and feed;
5. Establish maximum limits for environmental and industrial contaminants showing chemical or other similarity to pesticides, in specific food items or groups of food.
6. Consider other matters in relation to the safety of food and feed containing pesticide residues;

CCPR | How Countries Use Codex Standards

- **Some Codex members use standards as their domestic standards and/or apply them to imported foods**
 - U.S. regulatory agencies must base their decisions on procedures and standards established in U.S. law
 - USA does not automatically accept CXLs
- **May also be used in private commercial transactions**

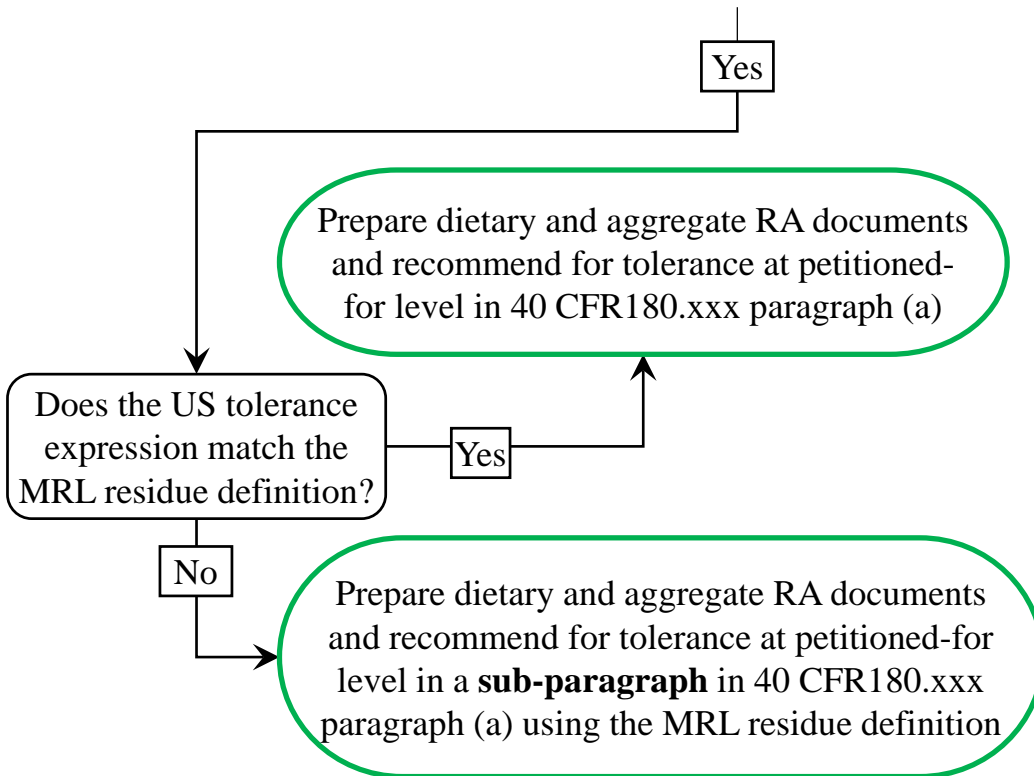
CCPR | How Countries Use Codex Standards

- **Provide basis for countries to develop their own residue standards with the knowledge and confidence that the standards are scientifically based and will protect public health**
- **For importing countries, knowing that an exporting country is using the Codex MRL provides assurance that the products they are receiving are safe for their consumers.**
- **The lack of an MRL can unnecessarily stop trade in food products that are safe or it can fail to stop food products that are not safe and, as a result, leave a lot of consumers unprotected.**
- **Adoption of MRLs that are recommended by the expert bodies maintains the science basis of Codex**



US EPA Import Tolerance Pilot Strategy (1 of 2)

Review Process



US EPA Import Tolerance Pilot Strategy (2 of 2)

Review Process