

# Codex MRL Setting and Harmonization

Yukiko Yamada, Ph.D.

## CCPR and JMPR

- Codex Committee on Pesticide Residues (CCPR)
  - One of subsidiary bodies of the Codex Alimentarius Commission
  - Intergovernmental meeting
  - Risk manager
- Joint FAO/WHO Meeting on Pesticide Residues (JMPR)
  - **Independent** scientific advisory body
  - Meeting of individual scientists
  - Risk assessor

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Neither CCPR nor JMPR is a registration body.

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## Definition of MRL for Pesticide Residues (Codex)

- **Maximum Residue Limit** is a maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on **food** commodities and animal **feeds**.
- Based on GAP data
- Foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.

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## JMPR

- First meeting in 1963
- WHO Core Assessment Group and the FAO Panel of Experts on Pesticide Residues in Food and the Environment
- Participants must not represent their countries or organizations
- Conducts **scientific** evaluations of pesticide residues in food and feed
- Provides advice on the acceptable levels of pesticide residues in food and feed moving in international trade

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## JMPR Recommendation

- Toxicological assessment of pesticide and its residue -> **ADI, ARfD** (WHO Group)
- Review of residue data from supervised uses including those reflecting national GAP -> **maximum residue levels**, supervised trials median residue values (STMRs), highest residues (HRs) (FAO Panel)
  - Maximum residue level -> recommended as MRL
  - Data from supervised trials conducted at the **highest** national GAP are included in the review

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- In order to accommodate variations in national pest control requirements, maximum residue levels take into account the **higher levels** shown to arise in such supervised trials, which are considered to represent effective pest control practices.
- Consideration of the various **dietary residue intake estimates** and, in comparison with the ADI, determination whether foods complying with MRLs are safe for human consumption (FAO Panel)

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## Residue Evaluation

- Plant metabolism
  - Animal metabolism
  - Environmental fate
  - Analytical methods
  - Storage stability
  - GAP information
  - Supervised residue trials
  - Effect of processing
  - Animal transfer studies
- Residue Definition
- ✓ Maximum residue levels
  - ✓ STMR(P)
  - ✓ HR(P)

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## Codex Alimentarius Commission



- Founded by FAO and WHO in 1963
- To implement the Joint FAO/WHO Food Standards Programme
- Inter-governmental Body + international organizations
- *Codex Alimentarius*
  - Latin for “Food Law” or “Food Code”

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## Objectives

- Consumer protection
- Fair practices in the food trade
- Coordination of all food standards work

**Founded for international harmonization of food standards**

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## Structure of the Codex Alimentarius Commission

- Commission
- Executive Committee of the Commission
- **General Subject Committees** (10)
- Commodity Committees (11)
- *ad hoc* Intergovernmental Task Forces
- Regional Coordinating Committees (6)
- Secretariat of the Commission

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## Terms of Reference of CCPR

- Maximum limits for pesticide residues in
  - specific food items or in groups of **food**;
  - Certain animal **feedingstuffs** moving **MRLs** international trade;
- Priority lists of pesticides for evaluation by JMPR;
- **Methods of sampling and analysis** for the determination of pesticide residues in food and feed

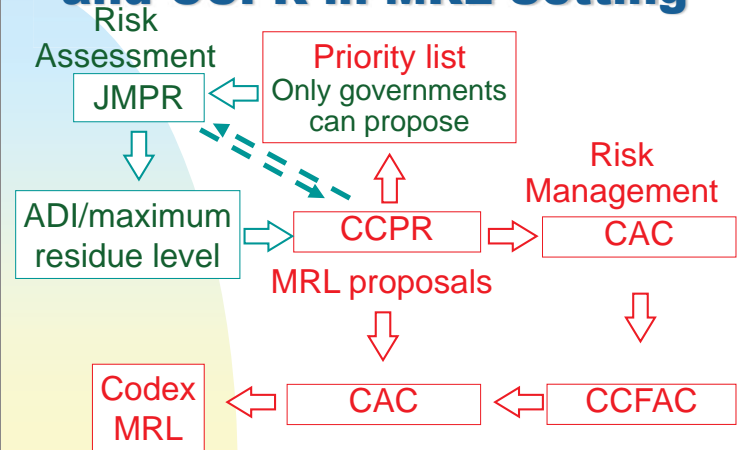
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## Terms of Reference of CCPR (2)

- Other matters in relation to the safety of food and feed containing pesticide residues; and
- Maxim limits for environmental and industrial contamination showing **EMRLs**, in specific food items or groups of food. (for compounds previously registered as pesticides but not registered any longer)

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## Relationship between JMPR and CCPR in MRL Setting



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## Article 3 Harmonization of the SPS Agreement

(modified for food safety)

- Members shall base their food safety measures on Codex standards, guidelines or recommendations, where they exist.
- Food safety measures which conform to Codex standards, guidelines or recommendations shall be deemed to be necessary to protect human life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

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- Members may introduce or maintain food safety measures which result in a higher level of protection than would be achieved by measures based on the Codex standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of protection a Member determines to be appropriate. All such measures shall not be inconsistent with any other provision of this Agreement.

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- Members shall play a full part, within the limits of their resources, in the Codex Alimentarius Commission and their subsidiary bodies to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of food safety measures.
- The SPS Committee shall develop a procedure to monitor harmonization.

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## Discussion of MRLs at CCPR

- Safety of food and feed
- Consumer implications
- Economic implications (incl. trade)
- Methodology, data and decisions regarding MRL recommendations by JMPR -> concern form to JMPR
- Methodology, data and decisions regarding ADI/ARfD by JMPR -> concern form to JMPR

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## Codex Recommendations Regarding Pesticide Residues

- MRLs
- Extraneous maximum residue limits (EMRLs)
- Sampling methods
- Analytical methods
- GLP
- Classification of food and feed

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**Thank you for your attention!**

## Additional Information

## Risk Assessment (Toxicological evaluation)

- Acute toxicity
- Short-term studies of toxicity
- Long-term studies of toxicity
- Carcinogenicity
- Genotoxicity
- Neurotoxicity
- Reproductive toxicity
  - Multi-generation studies
  - Developmental toxicity
- Endocrine activities
- Metabolism studies
- Epidemiological data

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## Estimation of ADI/PTDI

No-observed-adverse-effect level (NOAEL) or no-observed-effect level (NOEL)



Safety factor (usually 100)  
(inter-species x intra-species)

**ADI: for intentionally used products or  
PTDI/PTWI: for contaminants**

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## Estimation of ADI/PTDI

ADI: amount that can be ingested daily over lifetime without appreciable risk

PTDI: permissible human exposure

Expressed on a body weight basis

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## Dietary Exposure Assessment for Pesticide Residues

- Current Practice
  - According to the Revised *Guidelines for Predicting Dietary Intake of Pesticide Residues* (1997)
  - Use of all available relevant data
  - As realistic as possible
- Key factor in MRL setting

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## Elaboration Procedure of Codex Standards

- Normally 8 Steps
  - 2 rounds of written comments
  - 2 rounds of discussions by the Committee
  - 2 rounds of discussions by the Commission
  - Opportunity to omit Steps 6 & 7
- Can be reduced to 5 Steps

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