

## RISK ANALYSIS : Dietary Risk Assessment of Pesticide Residues and Implementation for Philippine Food Safety<sup>1/</sup>

Amelia W. Tejada  
and  
Aida Ordas

<sup>1/</sup>Paper presented at APEC Seminar –Workshop on Food Safety Risk-Benefit Analysisi 22- 24 Nov 2011

## INTRODUCTION

- The use of pesticides on crops for human or animal consumption could lead to residues remaining at harvest.
- The levels of these residues are being assessed for the risk that may pose the consumers before it could be registered in the Philippines.
- The benefits of pesticides should outweigh the risk after consideration of the socio- economics, health aspect and environmental effects.

## What is CODEX?

- CODEX is a book of all standards on food safety.
- The Codex Alimentarius Commission is the international body that develops food safety standards and is being recognized by the WTO in international trade.

## Codex Alimentarius Commission (CAC)

The CAC was founded in 1963 by FAO and WHO to develop CODEX standards, guidelines and other documents (eg. 'Code of Practice') for foods.

→ >180 Member States, representing 99% of the world's population



## Codex Alimentarius Commission

- Protecting the health of consumers
- ensure fair practices in food trade

“... to guide and promote the elaboration and establishment of definitions and requirements for foods, to assist in their harmonization and, in doing so, to facilitate international trade”.



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

## CAC & the World Trade Organization (WTO)

WTO: Administers multilateral agreements on trade

- Forum for trade negotiations
- Handles trade disputes

CODEX standards were identified as key reference points in the WTO “Agreement on the Application of Sanitary and Phytosanitary Standards (SPS)”

### The SPS Agreement

recognizes, as the international reference, the standards, guidelines and recommendations established by the **Codex Alimentarius Commission**

- As long as a country employs the CODEX standards, its measures are presumed to be consistent with the provisions of the SPS Agreement

### RISK ANALYSIS

CODEX FOOD STANDARDS are established on the basis of risk analysis.



### RISK ASSESSMENT

- **Scientific evaluation** of known or potential adverse health effects from exposure to chemical / microbial **hazards**.
- It is the basis for food standards development at Codex based on scientific evaluations by FAO/WHO experts on pesticide residues (JMPR), and food additives (JECFA)

### RISK ASSESSMENT

- will aid the harmonization of regulations and control procedures and facilitate international trade .
- Needs a reliable data, both toxicology and residue data, for establishing CODEX Food Standards.

### RESIDUE DATA AND INFORMATION REQUIRED FOR JMPR EVALUATIONS For MRL Establishment

- Identity
- Metabolism and environmental fate
- Residue analysis and stability of pesticide residues in stored analytical samples
- Use pattern
- Residues resulting from supervised trials on crops
- Fate of residues in storage and processing
- Information and data from farm animal feeding and external animal treatment studies
- Residues in food in commerce and at consumption
- National maximum residue limits
- Reconsideration of previous recommendations
- Data requirements for EMRL estimation

### TOX. DATA AND INFORMATION REQUIRED FOR JECFA/JMPR EVALUATIONS (FAO) for MRL Establishment

- Biological data
  - Biochemical aspects
  - Absorption, distribution, and excretion
  - Biotransformation
  - Effects on enzymes and other biochemical parameters
- Toxicological studies
  - Acute toxicity
  - Short-term toxicity
  - Long-term toxicity/carcinogenicity
  - Genotoxicity
  - Reproductive toxicity
  - -Special studies

## RISK ASSESMENT

**Codex definition** –consists of the following steps:

- (i) hazard identification;
- (ii) hazard characterization;
- (iii) exposure assessment;
- (iv) risk characterization.”

### 1. Hazard identification

e.g.

- a. **birth defects on animals** exposed during pregnancy,
- b. **sterility** or decreased fertility in males,
- c. **acute toxic poisoning**,
- d. other potential adverse effects on health and the environment.

### 2. Hazard Characterization

- The qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical, and physical agents which may be present in food.

### 3. Exposure/Dietary Risk Assessment-

- The qualitative and/or quantitative evaluation of the degree of intake of food
- Assessments may be undertaken for acute or chronic exposures, where acute exposure covers a period of up to 24 h and long-term exposure covers average daily exposure over the entire lifetime.

### 3. Exposure/Dietary Risk Assessment cont'd

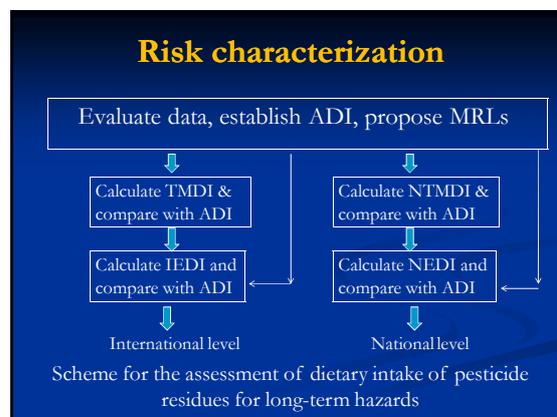
- Exposure assessment has been the central work of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in performing risk assessments.
- Codex MRLs are convenient for making a first estimate of dietary intake which is referred to as the Theoretical Maximum Daily Intake (TMDI).

### 3. Exposure/Dietary Risk Assessment- cont'd

- Long-term dietary intakes are calculated by multiplying the residue concentrations (STMRS,STMR-Ps or MRLs) by the average daily per capita consumption estimated for each commodity on the basis of the GEMS/Food diets(cultural diets) and summing the intakes for each food.

#### 4. Risk characterization-

- Integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties.



#### JECFA /JMPR Risk Assessment Process

- JMPR evaluates supervised residue trial data resulting from pesticide use according to Good Agricultural Practices .
- JECFA evaluates residue depletion studies using radiolabelled parent compound for veterinary drugs to determine a marker residue based on Good Practices on the Use of Veterinary Dugs (CPVD)

#### JECFA / JMPR Risk Assessment Process Cont'd

- JECFA develops MRLs based on chronic intake estimates of theoretical food basket consisting of 300g muscle , 100 g liver, 50 g kidney, 50 g fat, 1500 g milk, 100g eggs, 20 g honey.
- When the estimated dietary exposure to a chemical is below the ADI, MLs in food contributing to the exposure are unlikely to have any health.
- If there is exceedance, the estimated daily intake (EDI) could be undertaken for refinement at national level.

#### Endpoints of Evaluation by JMPR

1. Acute Reference Dose (RfD)- derived from Toxicological evaluation of the NOAEL w/safety factor of 10.
2. Acceptable Daily Intake (ADI) - derived from Toxicological evaluation of NOAEL w/ safety factor of 100.
3. Maximum Residue Limit- the limit set for agricultural commodities based on Good Agricultural practices which are allowed to go in trade.

#### BENEFITS of PESTICIDES

- The most obvious benefits and easiest to calculate are economic benefits derived from the protection of commodity /crop yield and quality. Also, maintenance of aesthetic quality, and protection of human health from disease carrying organisms

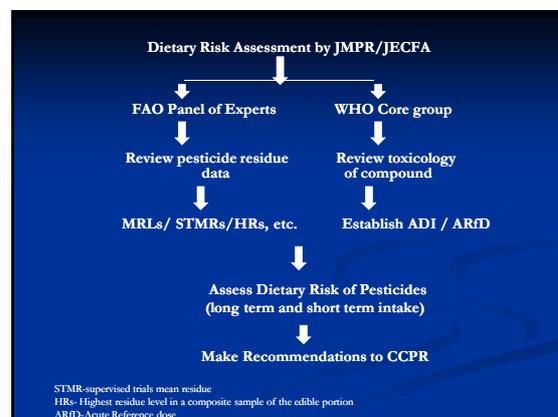
## RISK/BENEFITS

### Economics

- Available reliable loss data- monetary benefits are easy to calculate
- Non monetary data- difficult to calculate e.g. aesthetic quality

### Biology

- Effect of use of pesticides on pest reduction, yield and quality
- Alternative pest management strategies



## General Considerations in Risk Assessment

- If international dietary exposure assessments exceed a health based guidance value, then national authorities should be asked to submit their national exposure estimates through CAC or its technical committees.
- This applies to both acute and chronic intake assessments.

## General Considerations in Risk Assessment Cont'd

- when the acute RfD is exceeded, JMPR should consider alternative GAP with adequate field trials to identify the GAPs resulting in the highest residue value for which the IESTI would be below the Acute RfD

As long as the residues of a certain chemical do not exceed the ADI/acute RfD, the safety of the consumer is considered to be adequately protected

\*ADI -Acceptable Daily Intake

\*Acute RfD- acute reference dose

- CODEX states that food containing residues at the level of the adopted Codex MRLs must be safe for the consumers.
- It retains the current policy that when there is exceedance of the acute RfD, the MRLs are not advanced to higher step of the Codex Procedure.

- When applying import requirements which are stricter than CODEX standards, guidelines and recommendations, **countries ought to ensure that those measures are based on risk assessment.**

### CODEX Maximum Residue Limits (MRLs)

- JMPR evaluates supervised residue trial data resulting from pesticide use according to Good Agricultural Practices .
- JECFA evaluates residue depletion studies using radiolabelled parent compound for veterinary drugs to determine a marker residue based on Good Practices on the Use of Veterinary Dugs (CPVD)

### MRLs/ADI

- JECFA develops MRLs based on chronic intake estimates of theoretical food basket consisting of 300g muscle , 100 g liver, 50 g kidney, 50 g fat, 1500 g milk 100g eggs, 20 g honey.
- If the estimated dietary exposure exceeded the ADI on the basis of worst case calculation an estimated daily intake (EDI) could be undertaken for refinement at national level.

### Sources of data

Pesticide residues	Proposed MRLs	Monitoring and surveillance data TDS GEMS/Food database on chemical concentrations Scientific literature
	HR STMR	
Veterinary drug residues	Residue depletion studies	Monitoring and surveillance data TDS Scientific literature
Nutrients	Proposed MLs for fortification	Monitoring and surveillance data TDS Scientific literature
	Food composition data	

e.g TOXICOLOGICAL ENDPOINTS

	Value (mg/kg bw)	Study	Safety factor
ADI	0-0.01	Rat, 2 yrs, dietary	100
		Rat , reproductive tox	
		Rat, developmental tox	
		Dog, 2yrs	
ARfD	0.1mg/kg bw	Single-dose study in human volunteers	10

#### National Theoretical Maximum Daily Intake (NTMDI)

Pesticide Code - 196  
Name - Tebufenozide  
ADI = 0.02 mg/kg bodyweight or 1.1 mg/person (55 kg)

		National			
Commodity Code	Name	MRL mg/kg	Note	Diet g/day	NTMDI mg/day
FB 269	Grapes	0.5		18.00	0.0090
CM 649	Rice, Husked	0.1		12.00	0.0012
FP 9	Pome fruits	1		45.00	0.0450
VR 589	Potato	0.5	1/	240.00	0.1200
TN 678	Walnuts	0.05		1.00	0.0001

TOTAL = 0.18  
% ADI = 16%

1/ National maximum limit

(Rounded) % ADI = 20%

- In the case of pesticide residues and food, the determining criterion is that dietary exposure estimates should be below the acceptable daily intake (ADI).
- If the NTMDI had exceeded the ADI, however, a further refinement of the dietary intake must be conducted including the determination of STMR levels and other factors to improve the estimate of residues in food as consumed.

### The Fertilizer and Pesticide Authority (FPA)

#### Risk Assessment at National Level

- The FPA under PD 1144, is mandated to protect the health of the public and eliminate environmental risk from the use of pesticides
- It has the authority in approving the registration of pesticides and regulating their use after the evaluation of all the data requirements.

### FPA Risk Assessment of Pesticides

- For food safety, FPA is mandated to establish Maximum Residue Limits (MRLs) based on good agricultural practices (GAP) for use of pesticides in raw agricultural practices.
- It prevents the importation of agricultural commodities containing pesticide residues above the accepted tolerance levels

### FPA Risk Assessment

- Before a pesticide is registered, data on use pattern, toxicology, residues, fate and effects in the environment should be complied in accordance to the required FPA protocol to ensure that the chemical will not leave residues that may pose hazards to the consumers.

### FPA Risk Assessment for Food Safety

- MRL Establishment  
Pesticide registration on food crops will not be allowed without a proposed MRL based on Supervised trials conducted in accordance to Good Agricultural Practice (GAP).  
  
These are evaluated and validated by a pool of experts in accordance to FPA-approved guidelines.

### FPA Risk Assessment

- FPA has established pool of expert scientists, medical doctors and technical consultants. I has reactivated the Phil. Pesticide Advisory Committee (PPTAC) who can be assigned to evaluate and study data submission related to pesticide regulation, residue monitoring including risk assessment among others.

### Post Registration

- Monitoring activities to ensure enforcement – data generated in monitoring food and environmental and environmental contamination shall be reported to FPA by the National Pesticide Laboratory.
- Such residue data shall be the basis for modifying use patterns and taking regulatory action on particular pesticide

### Post Registration

- Monitoring is required of the registrant on pesticide movement in the farms and the potential pollution and contamination of the fish and other non target animals, and also contamination to subsequent crops or cross contamination to neighboring crops.

### Risk Assessment

- Example chlorpyrifos in mangoes
  - MRL of chlorpyrifos on mangoes-0.05 mg/kg
  - Given: ADI set by WHO for chlorpyrifos =0.001 mg/kg bw
  - Assume per capita consumption of mango =0.25kg/55 kg b.w
- TMDI=0.05 mg/kg x 0.25/55 = 0.25mg/55 kg bw  
=0.0011
- Compare with ADI = 0.0011/0.001 x 100% = 1.1%

### FPA

- Also adopt CODEX MRLs for those pesticide/commodity that has no national MRLs.
- Shall not allow registration of pesticide without proposed MRLs to cover residues of pesticides for each commodity.
- MRLs are based on Supervised Trials following Good Agricultural Practices (GAPs).

### NATIONAL CODEX ORGANIZATION (NCO)

- The establishment of the NCO was a call from CODEX c for **full participation of each member country to contribute to the work of the Codex Alimentarius Commission.**
- This was organized under Joint Administrative Order signed by the Secretaries of the DOH and the DA in November 25, 2005 which was amended on October 22, 2008 to improve its operations.

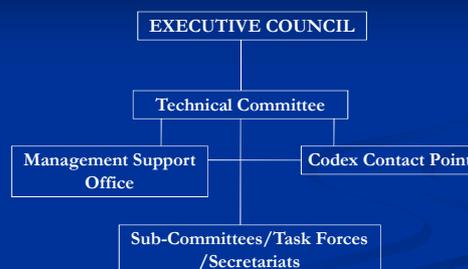
### NATIONAL CODEX COMMITTEE

- NCO is an advisory body chaired by the Sec. of Agriculture and co-chaired by the Sec. of Health on **the implication of various food standards** and food control issues arising from CODEX to protect the health of the consumers and ensure fair trade practices.

### National Codex Organization

NCO has participation of various government and private industries which serve as a focal point for information exchange and the development of a national Codex policy. In addition to sending delegations to Codex meetings, countries can provide written comments in reply to Codex Circular Letters, which is a cost-effective means of participating in the work of Codex.

**Fig 1. Organizational Structure of the National Codex Organization**



### EXECUTIVE COUNCIL

- Department of Agriculture (DA)
- Department of Health (DOH)
- Department of Trade and Industry (DTI)
- Department of Foreign Affairs (DFA)
- Department of Science and Technology (DOST)
- A processed food industry association
- A consumer organization
- The Chairperson of the NCO Technical Committee
- Rep. from National Sectoral Committees (NSCs) of the National Agricultural and Fishery Council (NAFC) elected among the Sectoral Chairs

### Technical Committee

- Composed of the Chairs of various sub-Committees from regulatory authorities
- Other agencies may chair a Sub-Committee or when regulatory agencies cannot perform the task, provided such agency has the necessary technical capability for the task, as determined by the Technical Committee.
- Identify cross-cutting issues, evaluate its implications to national policies before endorsement of country positions

### Technical Committee cont'd

- Provide overall technical support and administrative guidance to the Sub-Committees and Task Forces for effective country participation in the work of Codex
- Evaluate country positions and the list of delegates to Codex meetings from the Sub-Committees and Task Forces and endorse these to the Codex Contact Point for transmittal to the Codex Secretariat.

### SUB-COMMITTEES

- Carry out research and data gathering when necessary, in the preparation of country positions.
- Support the information needs for the participation of the NCO in other regional and international Codex
- Strive for the participation of national experts and relevant stakeholders from the government and private sector in the work of the Sub-Committees and Task Forces.

### Risk Assessment Policy in JECFA and JMPR

- JECFA and JMPR utilise certain significant risk assessment policies at specific decision points in their work. Such risk assessment policies are properly the responsibility of CCFAC, CCRVDF, CCPR and CAC. They are, however, used by JECFA and JMPR and are described in detail in relevant WHO Environmental Health Criteria documents.

- CCRVDF may determine that an MRL should not be adopted because adequate methods of analysis are not available for detecting the residues in specific animal-derived foods, or because pertinent new information has been generated which was not available to JECFA when it undertook its evaluation. CCRVDF may request that JECFA reassess the recommendation for an MRL based on concerns raised by CCRVDF. On occasion CCRVDF has elected not to accept the recommendations of

- In principle, CCRVDF considers socio-economic and political issues as does CCFAC. Health-based end-points which are not related to toxicity, such as allergenic potential, pharmacological effects and antimicrobial effects of particular residues, are complex issues which often are addressed on a case-by-case basis.

### CONCLUSION

- Assessment of dietary exposure are used for deciding on the acceptability of proposed draft Codex MRLs. If the ADI is exceeded by the estimate of exposure after all relevant factors are applied, dietary exposure concerns become a risk management issue.
- Because of different approaches in dietary exposure estimates, Members of CCPR may arrive at different conclusions about the acceptability of certain MRLs

#### Websites

[http://www.codexalimentarius.net/web/index\\_en.jsp](http://www.codexalimentarius.net/web/index_en.jsp)  
[http://www.codexalimentarius.net/web/standard\\_list.jsp](http://www.codexalimentarius.net/web/standard_list.jsp)

#### WHO JMPR:

<http://www.who.int/ipcs/food/impr/en/>  
<http://www.inchem.org/pages/impr.html>

#### FAO/WHO JMPR:

<http://www.fao.org/ag/agp/agpp/Pesticid/Default.htm>

### References

- Guidelines on the Prediction of Dietary Intake of Pesticide Residue. 1989 .
- Fertilizer and Pesticide Authority Manual.