

# **Same Data, Different Outcome?**

**A comparison of pesticide residue evaluations by EPA and JMPR**

**Michael Doherty, Ph.D.**

**US EPA Office of Pesticide Programs  
Health Effects Division**



## Introduction

Within a given jurisdiction, Maximum Residue Levels (MRL) serve to

- Promote proper use of pesticide products,
- Allow foods with residues to be in commerce

Across jurisdictions, MRLs become more of a tool for trade than for compliance.

## Introduction

Disharmonized MRLs can disrupt trade and result in wasted food and lost profits





## Introduction

Two groups that determine MRL values are



US EPA



FAO-WHO

Joint Meeting on Pesticide Residues



## Topics



What are...

Evaluation commonalities?

Root causes for differences?

Ways to improve harmonization?

## Commonalities



Data

Metabolism Studies

Residue Studies

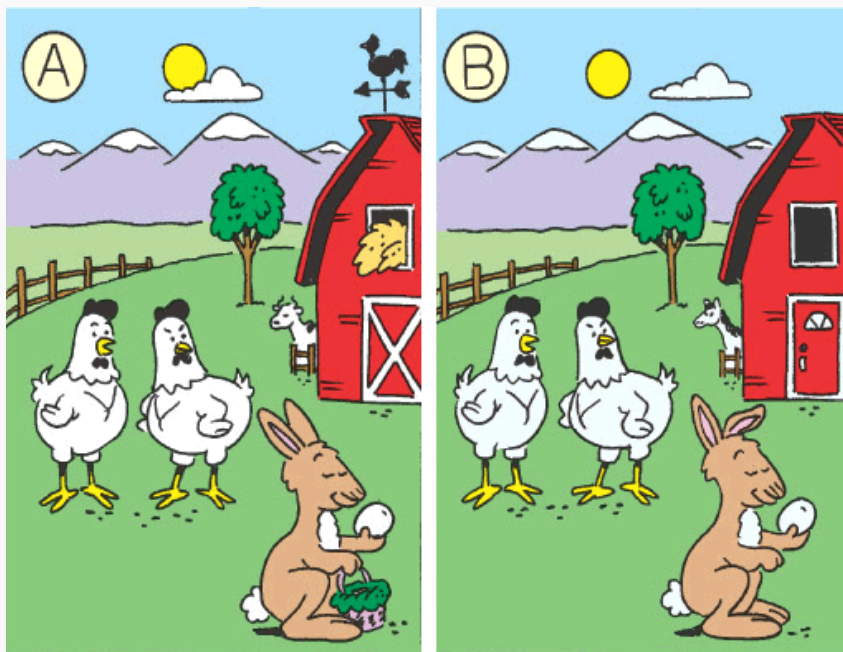
Supporting Studies

Review Policies

Tools

OECD Calculator

## Differences



Review Policies

Tools

Dietary Burden Calc.

Dietary Exposure Model



## Policies

Policy	US EPA	JMPR
Residue Definition	Now - Simplest possible Then – Toxic residue E-fate given low consideration	Simplest possible  E-fate included in evaluation
Analytical Method	70-120% recovery; 20% RSD Multi-residue Method preferred	Sliding scale recovery and RSD Multi-residue Method preferred
Storage Stability	Correct for procedural recovery	Do <b>not</b> correct for procedural recovery





## Policies

Policy	US EPA	JMPR
Field Trials/ OECD Calc.	Defined representative commodities Count based on US production Low concern field cutting Field trial independence Include statistical outliers Then – US-only data Now – Consider global data	Crop translations Count based on global production High concern field cutting Field trial independence Include statistical outliers Use global data but stop when you have enough  Step-down process if critical use pattern not supported by trials



# Policies

<b>Policy</b>	<b>US EPA</b>	<b>JMPR</b>
Processing Factor	Default for some commodities	Default for dried peppers



## Tools

Output	US EPA	JMPR
MRL	<p>Best judgement then NAFTA Calculator then OECD Calculator</p> <p>Crop group Group if ratio &lt;5X max; Group MRL based on rep. commodity giving maximum result.</p>	<p>Best judgement, then OECD Calculator</p> <p>Crop group Group if ratio &lt;5x median Group MRL based on combined data if similar by Kruskal-Wallis; otherwise based on commodity giving max MRL. <i>NB: Recent tendency toward subgroup MRLs</i></p>



## Tools

Output	US EPA	JMPR
Dietary Burden	Then – Maximize burden, no consideration of diet Now – Maximize burden, balance feed classes	Representation across feed classes



## Tools

Output	US EPA	JMPR
Dietary exposure/ risk	Acute Diet based, probabilistic  Chronic Diet based, average consumption, tiered residues	Acute Commodity based, deterministic  Chronic Diet based, average consumption, median residues



# Examples

## Triflumizole

### Storage Stability

US: Stable during storage based on corrected results

JMPR: Not stable in leafy veg. and tomato

### MRL Basis

US: Best judgement

JMPR: OECD Calc.

<u>Crop</u>	<u>US Tol</u>	<u>Codex MRL</u>
Leafy Veg.	35 ppm	-- ppm
Tomato	1.5	--
Cucurbit Veg.	0.5	0.5
Cherries	1.5	4
Edible Offal	0.2	0.1



# Examples

## Thiamethoxam

### Residue Definition

US: Thiamethoxam + CGA322704, combined

JMPR: Thiamethoxam

### MRL Basis

US: Mixed (Best judgement,  
NAFTA Calc., OECD Calc.)

JMPR: OECD Calc.

Crop	US Tol	Codex MRL
Legume Veg.	0.02 ppm	0.01 ppm
Oilseeds	0.02	0.01
Grains	0.02	0.05
Fruiting Veg.	0.25	0.7
Tea	20	20



## Examples

### Bifenthrin

#### Residue Definition

US: Bifenthrin

JMPR: Bifenthrin

#### MRL Basis

US: NAFTA Calc

JMPR: OECD Calc.

Crop	US Tol	Codex MRL
Bushberry	1.8 ppm	-- ppm
Blueberry	see Bushberry	3 ppm

JMPR noted a risk exceedance for currants and could not extrapolate the blueberry MRL to the bushberry group.





# Examples

## Saflufenacil

### Residue Definition

US: Saflufenacil + M800H11 + M800H35

JMPR: Saflufenacil

### MRL Basis

US: OECD Calc

JMPR: OECD Calc.

Crop	US Tol	Codex MRL
Olives	0.03 ppm	-- ppm

JMPR did not make an MRL recommendation for olive due to

- 4 trials (major crop in global production; therefore, needs 6 trials)
- Hand harvesting vs. mechanical harvesting and pickup from ground (application = ground-directed spray with 0-day PHI)



## Ways to Improve Harmonization





# Ways to Improve Harmonization

## Review Agency Responsibilities

Harmonize policies to the extent possible

EPA efforts:

- OECD Calculator Inputs (EPA and PMRA)
- NAFTA Field Trial Requirements
- Exchangeability of Data (suitability of global data sets)
- Import tolerance pilot project



# Ways to Improve Harmonization

## Review Agency Responsibilities

Make harmonization part of the evaluation process



# Ways to Improve Harmonization

## Industry Responsibilities

- Understand the evaluation policies and practices of review authorities, and
- Ensure studies and data meet the most stringent requirements



# Ways to Improve Harmonization

## Everyone's Responsibility

- ❑ Make harmonization an explicit priority for all:
  - Risk assessors
  - Risk managers
  - Industry
  - Growers
- ❑ **Understand residue data and what makes for a significant difference**



## Conclusion

1. Having harmonized MRLs is important for smoothly running global trade of agricultural products.
2. Some impediments to MRL harmonization are easy to remove while others are more recalcitrant.
3. Working towards harmonized MRLs is the responsibility of all parties, not just data evaluators.



**Thank You!**