How a Dis-harmonized Pesticide MRL System Impacts Global Agricultural Trade

Luis Suguiyama, USEPA
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Basic Human Need: Adequate and **SAFE** Supply of Food
Global Realities

Increasing Demand For Global Food Production
### Value of Agricultural Exports

<table>
<thead>
<tr>
<th>Years</th>
<th>$ (US billion)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1979-81</td>
<td>224.1</td>
</tr>
<tr>
<td>1989-91</td>
<td>319.3</td>
</tr>
<tr>
<td>1989-2001</td>
<td>414.3</td>
</tr>
<tr>
<td>2003</td>
<td>523.9</td>
</tr>
<tr>
<td>2004</td>
<td>604.3</td>
</tr>
</tbody>
</table>

Source: FAO
Sustainable Agriculture
GAPs

Production

Field/crop selection
Crop production
Harvest
Transport
Worker hygiene/safety

Processing

Packing
Storage
Transport
Worker hygiene/safety
GAPs
Pest Control, IPM, and Pesticide Use hazards

Importance of pest control in good agricultural practices
Integrated pest management (IPM) strategies
The use of approved pesticides is one of available IPM tools
Minimize hazards posed by pesticides
Use of Pesticides

1997 global total of 5.7 billion lbs. of agricultural pesticides used (est.)

2001 global total of 5.3 billion lbs. of agricultural pesticides used (est.)
EPA - receives studies from registrant
- Routes studies for interdisciplinary reviews
- Schedules risk assessment

Human health hazard and exposure studies reviewed

Determine endpoints of concern from Toxicity studies

Determine Worker exposure

Establish RfD by applying safety factors to NOAEL

Determine Dietary exposure

Determine aggregate human exposure and consider common mechanism

Determine Residential exposure

Determine Ecological exposure

Establish endpoints from toxicity studies

Determine drinking water exposure

Characterize Human Health Risk

Characterize Ecological Risk

Characterize Human Health and Ecological Risks

Registrant responds; EPA modifies risk assessment if appropriate

EPA formulates risk mitigation and risk management decisions

MRL Decision Published

New Active Ingredient Registered
What are pesticide MRLs?
MRL - Maximum Residue Level

- Maximum amount of a pesticide that can be present on a certain crop/crop group.
- Example: U.S. MRL for Azoxystrobin

- MRL = 10 parts per million (ppm)
- MRL = 0.2 ppm
- MRL = 0.006 ppm

This pesticide has an RfD of 0.19 mg/kg/day, but different MRLs for different commodities. Why is that?
Setting MRLs:

- MRLs represent the pattern of use of a pesticide on a particular crop/crop group based on field residue studies.
- MRLs are set according to GAP and approved pesticide labels.
- MRLs apply equally to domestic and imported crops (WTO obligation).
- Often the actual pesticide residue level found on a crop is below the established MRL.
<table>
<thead>
<tr>
<th>Pesticide</th>
<th>US MRL</th>
<th>Residue detected (actual field studies under GAPs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethephon</td>
<td>2 ppm</td>
<td>0.06 - 0.84 ppm</td>
</tr>
<tr>
<td>Methomyl</td>
<td>5 ppm</td>
<td>0.07 – 0.39 ppm</td>
</tr>
</tbody>
</table>
MRLs – important facts

- Approved MRLs in a crop represent only pesticide control options
- MRLs are not necessarily measures of toxicity of a given pesticide
- Codex MRLs are not currently but should be the single global standard
- Some countries have established many more pesticide MRLs than Codex, especially for ‘reduced-risk’ pesticides and for crop groups
- This difference in the number of MRLs is more substantial for specialty crops (minor use crops)
MRLs in the real world...

- Some countries set their own MRLs, and in many cases, with different numerical values for a certain pesticide in the same crop/crop group.
- Most countries defer to Codex MRLs.
- But most countries will reject crops containing residues of pesticides that they have not explicitly approved (even if Codex MRLs have been established).
MRLs are not harmonized internationally. This creates agricultural trade irritants.

Paraquat example (values in ppm):

<table>
<thead>
<tr>
<th></th>
<th>US</th>
<th>EU</th>
<th>Japan</th>
<th>Codex</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.5</td>
<td>0.02</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td>0.01</td>
<td>-</td>
<td>0.01</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>0.05</td>
<td>0.02</td>
<td>0.1</td>
<td>0.1</td>
</tr>
</tbody>
</table>
## California – Table Grapes

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Range detected</th>
<th>US MRL</th>
<th>Codex MRL</th>
<th>Proposed EU MRL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethephon</td>
<td>0.06-0.84 ppm</td>
<td>2 ppm</td>
<td>1 ppm</td>
<td>0.05 ppm</td>
</tr>
<tr>
<td>Methomyl</td>
<td>0.07-0.39 ppm</td>
<td>5 ppm</td>
<td>5 ppm, but proposed to be lowered to 0.3 ppm</td>
<td>0.02 ppm</td>
</tr>
</tbody>
</table>
Countries routinely reject crops with pesticide residue levels higher than their national MRL values or when MRLs are absent.

US FDA – Data from 1998-2004 indicate that (imported) vegetable and vegetable products have the largest total number of food safety violations (14,463 cases, or 27%); ‘unsafe pesticide residues were the most cited reason’
Should we continue with Global Dis-harmonization of MRLs?
Preferred Approach for MRLs

- Global harmonization of MRLs
- Cooperation (joint reviews) and transparency in risk assessments and establishment of MRLs
- International data sharing and promoting regulatory efficiencies
- Codex/JMPR to set MRLs for new and ‘reduced-risk’ pesticides prior to setting national MRLs
MRL Harmonization - benefits

- Agricultural producers will use newer and ‘reduced-risk’ pesticides if trade partners have established same MRLs.
- Globally harmonized MRLs reduce and/or eliminate potential trade barriers.
- Without harmonization, even the use of “science-based methods” often results in different MRLs.
- Cooperation and transparency will increase harmonization of MRLs and facilitate trade.