Registrants Role in Trade; Ensuring Export Market Maximum Residue Levels

Heidi Irrig, M.S,
March 5, 2017
Overview

I. Developing a Pesticide Product

II. What are the Industry Trade Goals?

III. Global Food Standards and Trade
   - Global Trade Challenges
   - Global MRL Issues
   - International Efforts to Harmonize MRLs/ITs

IV. Trade Examples

I. Questions
Developing a Pesticide Product

The “Perfect” Product

- Biologically Efficient
- Environmentally Sound
- User Friendly
- Economically Viable

Ability to register in key countries

Source – Crop Life International
<table>
<thead>
<tr>
<th>Year</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9/10</th>
<th>Costs in US$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chemistry</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>~67 Million</td>
</tr>
<tr>
<td>Active ingredient</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formulation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Synthesis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Production</td>
</tr>
<tr>
<td>Synthesis optimization</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot plant production</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formulation / packaging</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Biology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>~80 Million</td>
</tr>
<tr>
<td>Research Development</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory / greenhouse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Optimization of application</td>
</tr>
<tr>
<td>Pilot trials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Field trials for development and registration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>~53 Million</td>
</tr>
<tr>
<td>Mammals Environment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute, sub-chronic, chronic toxicity / mutagenicity carcinogenicity / teratogenicity / reproduction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Algae / Daphnia / fish / birds / micro-organisms / bees / non-target organisms</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Official evaluation of registration documents / registration / first sales</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Environment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>~250 Million</td>
</tr>
<tr>
<td>Metabolism Residues</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plants / animals / soil / water and air</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plants / animals / soil / water and air</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Substances</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15k</td>
<td>500</td>
<td>10</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>~250 Million</td>
</tr>
</tbody>
</table>

Source – Crop Life International
What are the Pesticide Industry Trade Goals?
Industry Trade Goals
What are Maximum Residue Limits (MRLs)?

*Simple Concept, Complex Factors*

- a legal trading limit
- Maximum concentration of pesticide residue in or on food commodities
- established by national and international (Codex) regulatory authorities after the assessment of residues field trial data and dietary intake assessments

*MRLs reflect the use patterns/pest pressures in the growing region.*
Industry Trade Goals
How are MRLs Established?

Residue Definition

Residue field trials conducted at label rate established for different pest pressures and conditions

MRL established

OK Not OK

Dietary intake assessment

Method of calculation
- range of data
- statistical analysis
- expert judgment
Industry Trade Goals
Managing Risk Assessments
Around the World

Bottom-line: MRLs are granted after the impact of residues have been evaluated from the standpoint of the consumer relative to dietary exposure.

Source: Purdue Pesticide Programs
Industry Trade Goals
Goal and Requirements for Achieving Trade Goals

- Requirements to facilitate trade without residue barriers; harmonized MRLs/ITs
  - Understand Trade
  - Coordinated MRL strategy
  - Data requirements

Simultaneous registrations in domestic and export markets
Global Food Standards and Trade
Global Trade Challenges

- Dynamic
- Predictability
- Barriers to trade
- Moving goalposts
- Complexity
- Harmonization
- Risk benefit analysis
- Impact evaluation
- Public perception of safety
- Cut offs of science
Global Trade Challenges
US MRLs versus Foreign Market MRLs

Foreign MRLs differ from US MRLs – Why?

a) Misconception regarding the purpose of MRLs
b) Different grower needs around the world; registered use patterns
c) Regulatory criteria based on national policies and legal standards
d) Representative Crop/Crop groupings
e) Definition of Residue
Global MRL Issues
Registrant Objectives

Registrants strive to be aware of the changing registration process and data requirements where crops are traded.

Unique markets:

- China
- Japan
- Taiwan
- Korea
- Hong Kong
Global MRL Issues

Common situations

- Different pests, pest pressures & applications
- Crop groupings
- Definition of residues vary (parent, metabolites)
- Data point selection in MRL calculation

For these reasons and others, the same pesticide residue data can lead to different MRLs being established and creating barriers to trade.
Global Trade Issues
International Efforts to Harmonize MRLs/ITs

Registrants, regulators and international organizations are working together to establish consistency in a number of regulatory data requirement areas.

- OECD MRL Calculator
- OECD Field Residue Guideline 509 & Guidance Document
- Global Zoning
- Proportionality
- Global/NAFTA Joint Reviews
- US Grower Priority Database
- Harmonized Crop Groupings & Representative Crops
- Bilateral government efforts
- UN Codex Alimentarius Commission – multilateral international organization
Registrant MRL Examples
Apples & Raspberries
Where are Apples Grown?

Production (FAOSTAT) Dataset: Production quantities of Apples by country Average 1994 - 2016
Top Apple Producing Countries in the World

Production of Apples: top 10 producers
Average 1994 - 2016

Source: FAOSTAT (Mar 03, 2018)

Production (FAOSTAT) Dataset: Production quantities of Apples by country Average 1994 - 2016
China Top Fresh Apple Export Markets

- **Thailand**: 13.3%
- **Philippines**: 10.8%
- **Indonesia**: 7.0%
- **Korea North**: 5.5%
- **Vietnam**: 9.5%
- **Bangladesh**: 8.5%
- **India**: 10.1%
- **Myanmar**: 6.3%
- **Russia**: 7.7%
- **Hong Kong**: 3.6%
- **Korea North**: 5.5%

Source: Global Trade Atlas
USA Top Fresh Apple Export Markets (US $K)

- Mexico: 25%
- Codex Countries: 32%
- Canada: 17%
- India: 11%
- Taiwan: 7.8%
- China: 2%
- EU countries: 0.44%
- Japan: 0.16%
- Iceland: 0.06%
- Korea, South: 0.06%
- Hong Kong: 4.2%

Source: USDA FAS GATS Data: U.S. Census Bureau Trade Data
Where are Raspberries Grown?

Production (FAOSTAT) Dataset: Production quantities of Raspberries by country Average 1994 - 2016
Top Raspberry Producing Countries in the World

Production of Raspberries: top 10 producers
Average 1994 - 2016

Production (FAOSTAT) Dataset:

Source: FAOSTAT (Mar 03, 2018)
USA Top Fresh Berries Export Markets
(after Canada 82%)

Source: USDA FAS GATS Data: U.S. Census Bureau Trade Data
THANK YOU
Questions?