Perspectives on the Future of Pesticide Regulation and Use

- CPDA Annual Meeting, July 2011-

Global Pesticide Markets

Established Markets:

- U.S.A.
- Canada
- Western Europe
- Japan
- (Australia)

Low growth expected due to market maturity and heavy regulation.

Growth Regions:

- China
- India
- South America, esp. Brazil
- Central America
- (Mexico)
- Thailand
- Indonesia
- Africa
- Middle East

Key U.S. Agricultural Export Markets

1. Canada
2. China
3. Mexico
4. Japan
5. Western Europe
6. Middle East
7. Africa
8. South Korea
9. South America
10. Caribbean
11. Taiwan
12. Central America
13. Indonesia
14. Russia

Global Harmonization of Pesticide Regulation - Benefits

- Harmonized trade standards (tolerances/MRLs) facilitate market access for food commodities. Can have a direct impact on pesticide product sales.

- Efficient Use of industry and government resources:
  - ✓*Uniform guidelines for required studies*
  - ✓*Mutual recognition of study reviews*

- Increased trust in regulatory decisions when they don't significantly differ between countries (e.g., NGOs, food retail outlets, restaurant chains, media).

Barriers to Harmonization

- Economic/Political: Domestic lobbying to enact trade barriers related to competition from imports.

- Differing societal philosophies regarding what level of "precaution" is appropriate in authorizing pesticide (and other chemical) sale and use.

Precaution
and the "Precautionary Principle"

- Precaution – A measure taken beforehand to prevent harm or secure good.

- Precautionary Principle – (1) The precept that an action should not be taken if the consequences are uncertain or potentially dangerous; (2) The theory that if the effects of a product or action are unknown, then the product should not be used or the action should not be taken.

Precaution, Risk, and Risk Assessment

- Precaution – A measure taken beforehand to prevent harm or secure good.
- Risk – Probability of injury, disease, or death from exposure to a chemical agent.
- Risk Assessment – The assessment of potential adverse effects from exposure to chemicals.

Risk Assessment Components

- Hazard Identification = toxicity/potential to cause harm, by duration (e.g., acute, sub-chronic, chronic) and route of exposure (e.g., oral, dermal, inhalation).

- Dose Response Assessment = Relationship between exposure level and toxicity (followed by selection of a Point of Departure [e.g., NOAEL] + application of Uncertainty Factors).

- Exposure Assessment = prediction of exposure via various routes, with consideration of temporal and spatial aspects.

- Risk Characterization = Integration of Hazard, Dose-Response and Exposure Data/Information.

Hazard-Based Regulation

- No consideration of dose-response or exposure information (e.g., how much? how often? by what route? where?)

- May be used to severely restrict or ban chemicals considered to be: acutely toxic, carcinogenic, mutagenic, reproductive or developmental toxins, or endocrine disrupters.

- Existed in the U.S. until 1996 for pesticide "carcinogens" that concentrated in processed foods (Delaney Clause). Dropped upon enactment of FQPA.

Hazard-Based Regulation

- Assumes society is not capable of achieving compliance with controls on use to avoid adverse outcomes and/or assumes risk assessment may be unable to predict adverse outcomes.

- Reduces pest management options; potential impacts on IPM, resistance management, input costs.

- Creates trade barriers.

- *May create food security issues?*

Risk Assessment-Based Regulation

- Assumes society can achieve compliance with registered use, through product labeling, training, applicator licensing, inspection and enforcement.

- Assumes risk assessment is, in fact, "precautionary" and can predict the likelihood of adverse outcomes, even for carcinogens, reproductive or developmental toxins, and "endocrine disrupters."

- Provides greater options and flexibility in pest management, thus facilitating IPM, resistance management and input cost controls.

Some Observations Related to Hazard vs. Risk Assessment-Based Regulation

- EU
- Serbia
- Guatemala
- Dominican Republic
- Colombia
- Brazil
- China
- NGOs
- Codex

European Union – Hazard-Based Cutoff Criteria -

- 1A and 1B Carcinogens
- 1A and 1B Mutagens
- 1A and 1B Reproductive Toxins
- "Endocrine Disrupters" (not yet defined)
- PBT
- POP

Exceptions: "negligible exposure" or to control "a serious danger to plant health."

Expected Losses:

- **Bifenthrin**
- **Esfenvalerate**
- **Bitertanol**
- **Carbendazim**
- **Flusilazole**
- **Quinoxyfen**
- **Cyproconazole**
- **Epoxiconazole**
- **Fenbuconazole**
- **Mancozeb**
- **Maneb**
- **Metconazole**
- **Tebuconazole**
- **Flumioxazine**
- **Glufosinate ammonium**
- **Linuron**
- **Pendimethalin**
- **Amitrole**
- **Ioxynil**

Serbia
- Compliance with EU Standards -

- Serbia's goal is to achieve EU accession by 2014.
- Recently adopted EU MRLs and working on compliance issues. Labels need to be changed.
- Agriculture is one of the most important industries in the Serbian economy.
- Challenges: many small farmers; average farm size is 1 acre; understaffed/underfunded regulatory infrastructure; compliance with EU regulations will be difficult (training/certification/record-keeping/obsolete products and labels); illegal import of pesticide products.

Dominican Republic
-Need to Secure and Maintain Export Markets-

- Compliance problem with U.S. and E.U. trade standards (tolerances/MRLs) for export crops, particularly in oriental vegetable production. AID intervention as part of its poverty reduction plan.

- Only country in "country-wide" detention with FDA. Country-wide detention is for snow peas, long beans, eggplant, fuzzy squash and peppers, for various OPs.

- DR regulatory authority may ban these chemicals, period, to resolve the problem. Also considering a ban of all chemicals not approved in the EU, to facilitate market access in Europe.

Guatemala
-Need to Secure and Maintain Export Markets -

- Previously had problems as severe as those of Dominican Republic. Recently achieved removal from FDA country-wide detention for snow peas. How? Removed methamidophos, entirely, from the market.

- Continuing challenges for non-traditional export crops, with U.S. and European markets.

- Some packing houses/exporters only allow use of products approved in E.U. More widespread bans on the horizon?

Colombia

-Need to Secure and Maintain Export Markets -

- Insufficient registrations and MRLs exist for minor crops, which are currently treated Illegally with active ingredients registered on other crops.

- In 2007, MRLs established, based on 2006 Codex MRLs, but insufficient Codex MRLs exist for the minor crops grown in Colombia.

- Issue: When a Codex MRL, EU MRL, and/or U.S. tolerance exist but differ, what criteria should be used to determine which is appropriate for Colombia?

Brazil
Moving to hazard-based regulation?

February 2011: ANVISA's Public Consultation

- No teratogens, mutagens, endocrine disrupters, reproductive toxicants, carcinogens.
- No registration if Class I Acute Toxicity, by any route of exposure.
- No backpack application for skin sensitizers

Brazil

Moving to "precautionary principle?"

- Article 91 – *"In all stages, the principle of precaution will be applicable, whenever there is any scientific uncertainty regarding the risks to human health relative to the active ingredients of pesticides and the like."*

- There will always be scientific uncertainty, but risk assessments can take such uncertainty into account in predicting the potential for adverse outcomes. ILSI conference held in June 2011.

China

Banned as of 11/2013:

- Ethoprophos
- Fonofos
- Phosfolan-methyl
- Calcium phosphide
- Magnesium phosphide
- Zinc phosphide
- Cadufafos
- Coumaphos
- Sulfotep
- Terbufos

Restricted/No new uses:

- Methidathion
- Fenamiphos
- Phorate
- Isofenphos-methyl
- Carbofuran
- Methomyl
- Aldicarb
- Omethoate
- Isocarbophos
- Endosulfan
- Methyl bromide
- Aluminum phosphide

China

"High Risk" Pesticides Identified for Re-Evaluation

- 2,4-D
- Butylate
- Acephate
- Atrazine
- Bensulfuron methyl
- Buprofezin
- Carbendazim
- Carbosulfan
- Chlorothalonil
- Chlorpyrifos
- Permethrin
- Dicofol
- Glyphosate
- Hexaflumuron
- Imazethapyr
- Imidacloprid
- Paraquat
- Procymidone
- Pyridaben
- Triazophos
- Tribenuron methyl
- Validamycin A

EWG's "Dirty Dozen"

- Apples
- Celery
- Strawberries
- Peaches
- Spinach
- Imported nectarines
- Imported grapes
- Bell peppers
- Potatoes
- Blueberries
- Kale
- Collards

- Based on frequency of detections by USDA's PDP, not on assessment of risk.
- Major media attention.
- Even worse than hazard-based; i.e., the assumption is that any level of any pesticide is a health risk.

Will risk-based regulation prevail?

U.S. government and
allies, e.g., Canada, Australia, etc., need to have more of a presence globally, especially in key export markets in the developing world.

- USDA's Foreign Agricultural Service
- U.S. AID
- Office of the U.S. Trade Representative
- U.S. EPA

- Capacity Building/Relationship Building = TRUST

Capacity Building, Relationship Building and Trust

Best achieved through real-world projects and hands-on trainings that involve direct contact and meaningful outcomes.

- Global Reviews and Work Shares
- Capacity Building - workshops/staff exchanges.
- FAS Project: Generation of Residue Data for establishment of Codex MRLs for minor crops in SE Asia, Latin America and Africa.

FAS Global Residue Project for Minor Crops (IR-4 model)

- Funding will be sought from AID and the WTO's Standard and Trade Development Facility

- Pilot: Tropical Fruits (representative commodities for proposed Codex crop groups) and very low-risk chemicals (sure winners in seeking Codex MRLs). Establishment of Codex MRLs is still a risk-based process.

- Partnerships:
  government, industry, growers, exporters, regional leadership (African Union, ASEAN, IICA)

Summary

- The future of pesticide markets is dependent upon many factors, including the regulatory paradigm in use (hazard vs. risk-based).
- Global food trade triggers the need for harmonization of pesticide trade standards.
- The U.S. risk-based approach to pesticide regulation may be at risk, unless the U.S. perspective is heard, understood and trusted in regions with developing regulatory systems.