Dow AgroSciences

Registrant Perspectives on MRL Strategies

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MRL= Maximum legal limit of a residue in/on food

What it is

Derived from residue studies of maximized use pattern to set upper bound for local enforcement of GAP (labeled use)

Regulatory standard which may facilitate or impede global trade of food

Set in context of an acceptable dietary risk/safety assessment

Conservative input of exposure for dietary risk/safety assessment for humans

What it is not

Final Value not set by registrants, although based on data they provide

Simple to plan globally

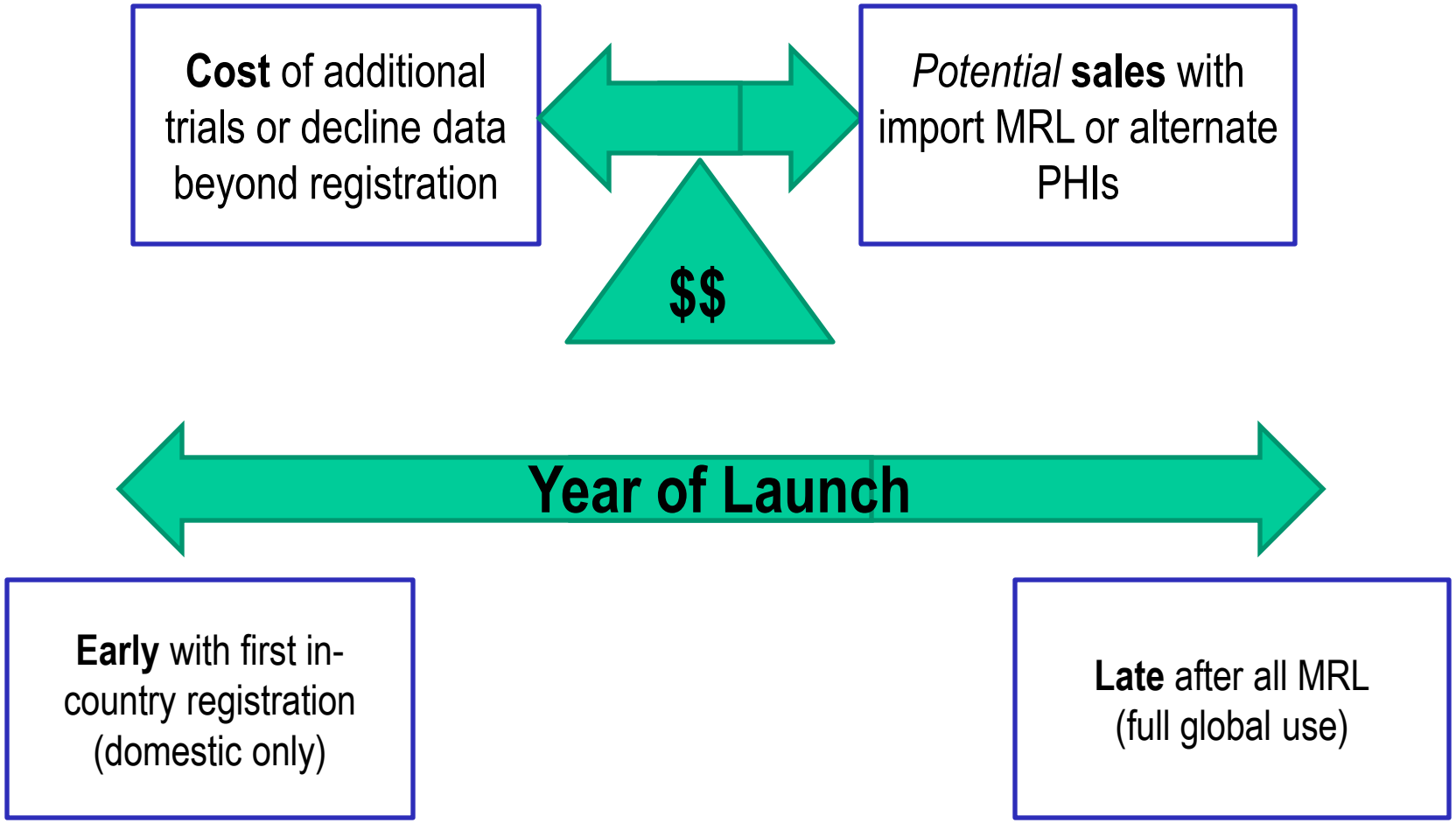
A stand-alone health standard

Realistic measure of typical exposure

Registrant R&D and Regulatory Actions

- Established in-country MRL = price of market entry with much R&D behind MRL:
  - Efficacy trials, mammalian health endpoints, plant metabolism, analytical methods and residue trials
- Import MRLs are important (up to critical), to support crop exports and trade
  - Customer/food chain expectations for comprehensive coverage increasing
  - But import country timing often trails initial registration

The Registrant Balancing Act



Residues and MRLs at Dow AgroSciences

- Long history of residue data development
- Active with Codex MRL process for many years
- Global MRL Initiative launched during 2003
  - New global project management system
  - To provide training for new staff in residue chemistry or regulatory manager roles
  - Increasing interest in international trade, MRL harmonization
  - Global, cross-functional team formed to provide leadership and guidance across projects, functions, and regions

DAS Global MRL Initiative

- **Mission - Drive development of effective molecule, project and regional regulatory strategies related to MRLs and import residue issues**
- Areas of emphasis
  - **Awareness** and **communication** regarding residue and MRLs
  - Enhance effective planning at global and local levels with practical **tools** and **training**
  - Encourage regulatory **molecule strategies** with explicit coverage of MRL issues, including existing MRL discrepancies
  - Ensure development of **regional strategies** to address significant changes in MRL regulations
  - Cultivate **external** relationships for advancing MRL harmonization and a favorable regulatory climate

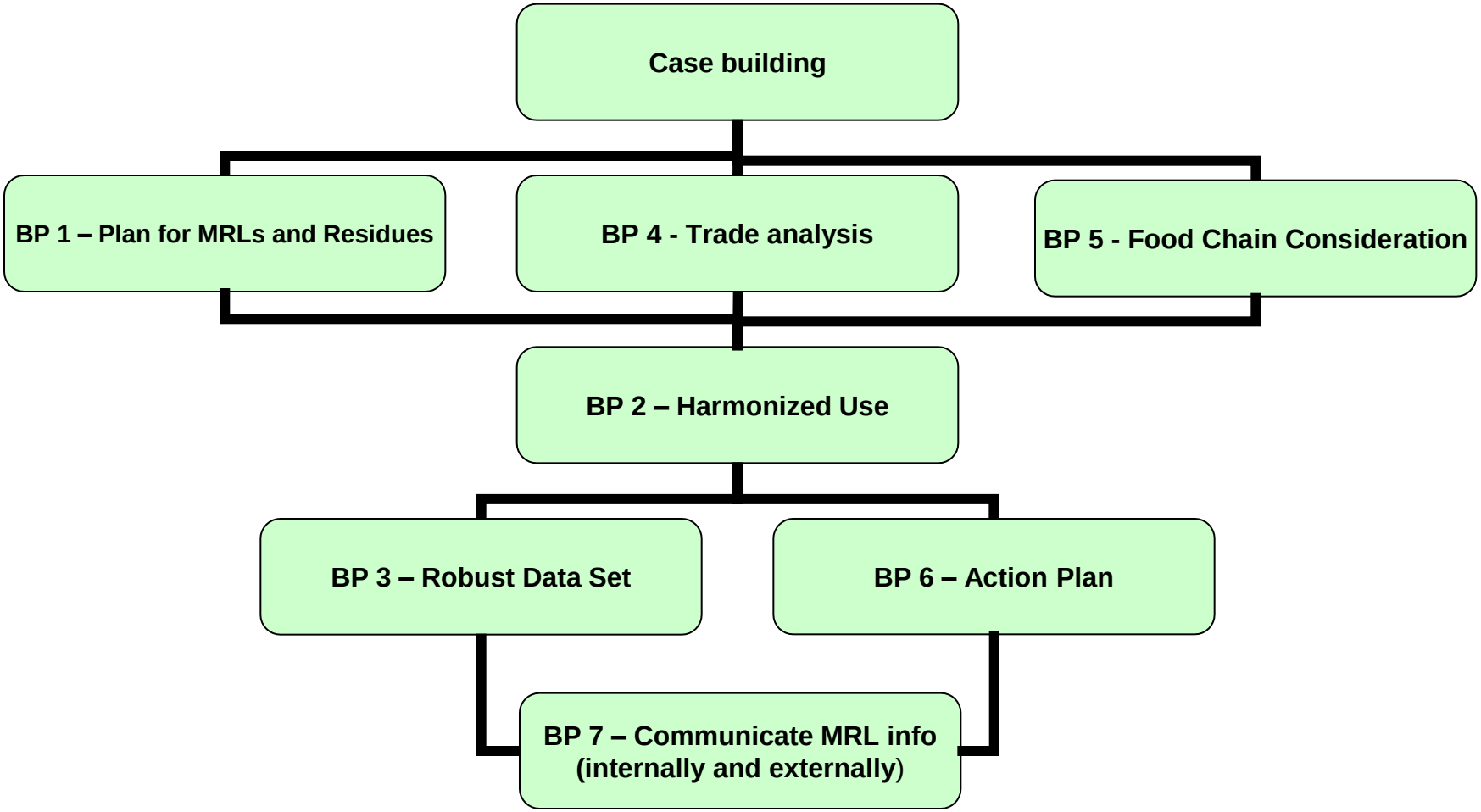
7 Best Practices for MRL/Residue Focus in New Projects

- To minimize impact of potential trade issues associated with new product or use development /launch from residue issues or disharmonized MRLs globally
  - Can also be used for existing uses for unaddressed MRL gaps, at times
- Bridge intersection of commercial planning , marketing & regulatory legal requirements

7 Best Practices for MRL/Residues

1. Develop **residue and MRL assumptions** at planning stage of new actives, crop uses, and formulations.
2. For new use in multiple countries, **standardize GAP** to support harmonized MRL standards.
3. Develop **robust residue database** for regulatory, food chain and stewardship.
4. Perform **global trade analysis** of treated crops to identify and prioritize critical import/export connections.
5. Assess **food chain** needs in residue/MRL assumptions, action plans, and communication.
6. Forge **MRL action plan** to minimize residue concerns and trade irritants.
7. **Communicate MRL/residue strategy** with stakeholders as appropriate..

MRL Practice Interrelationships



Best Practice 1: Planning

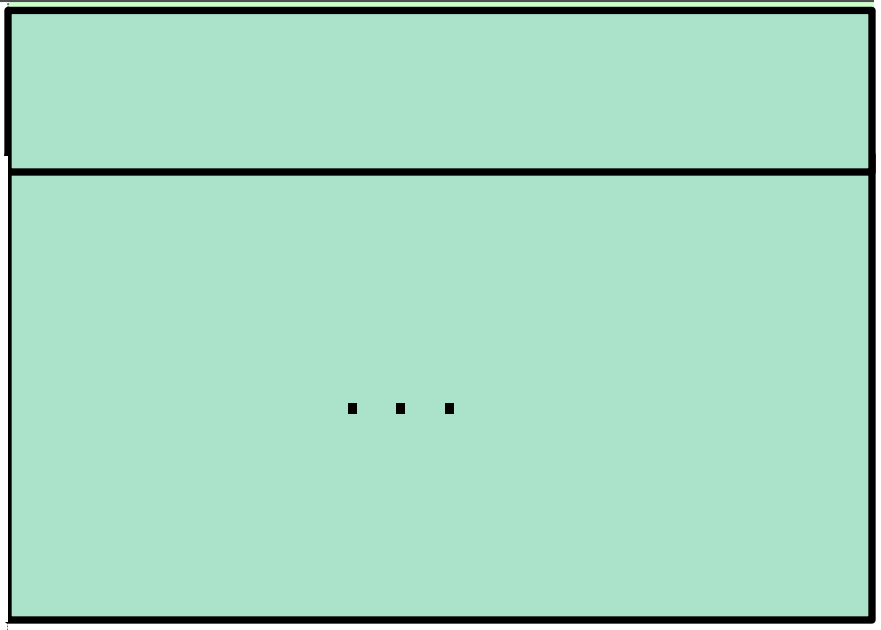
Develop residue and MRL assumptions at planning stage for all projects involving new active ingredients, new or revised crop uses, and new formulations

Planning Tools

- Residues and MRLs Checklist
  - Series of diagnostic questions to catalyze planning
    - e.g., (examples from next slide)
- Technical Assumptions and Issues document
  - Captures key residue and MRL assumptions
- USDA IR-4 Project Clearance Request (PCR) form

Example of Checklist

Residue, Food Chain, and MRL Considerations for CPS Projects

Key Question	Project-Specific Responses and Explanation
What specific crops and countries are being supported in the business case, and which local MRLs are being proposed?	

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USDA IR-4 Project Clearance Request (PCR) Form

Is this an export commodity:		**Yes** **No**
Key Export Markets:		
Are there MRLs established in key export markets?:		**Yes** **No**
	Which markets?:	

Best Practice 2: Use Harmonized

When pursuing a new crop use in multiple countries, develop harmonized critical GAP (i.e., label use directions) for establishment of harmonized MRL

- Critical GAP = way product used from a maximum residues perspective
  - eg: max use rate, growth stage, No. applications, shortest PHI
- Benefits of Harmonized Use
  - share residue data between countries with fewer trials in each country
- Potential to have same MRLs in each country
  - GAP determines MRL; methods to set are not consistent around world (yet) - Closer with OECD MRL calculator

Difficulties Harmonizing GAPs

- Global Variation in Product Expectations
- Different agronomic practices and business cases
- Sometimes acceptable GAP is the result of avoiding environmental risks e.g. EU groundwater levels.
- Local use patterns can if necessary, beneath global harmonized GAP.
- Not all countries use the same crop grouping; choosing crops for residue analysis can be difficult.

Not all MRL disconnections are equal

- Case 1 – **Different Use Pattern**
  - observable residue differences are real

US	Codex	EU
2.5	2.0	0.05

- Case 2 – Same Data, but **Different Interpretation**
  - of lower limit by authorities, residue profile is the same

US	Codex	EU
0.04	0.01	0.02

Best Practice 3: Robust Database

Develop a robust residue database for regulatory, food chain, and stewardship purposes

A Robust database of residue-related information supports:

1. **Basic Regulatory activity** –registration approval (new products, new uses, re-registration, etc.), obtaining import MRLs, supporting minor uses activity.
2. **Food chain activity** –guidance to stakeholders seeking advice of the fate and behaviour of residues.
3. **Product stewardship activity** - post-registration queries and product stewardship issues

Best Practice 4: Trade Analysis

Complete a global trade analysis of treated crops to identify and prioritize critical import/export connections supporting MRL and/or food chain action plans.

BP 4: Trade Analysis

- Identification of **country/crop** (food or feed) combinations (e.g. cherries from US)
- Target **export/import trade relations** of interest (e.g. Canada and Japan are largest US cherry importers; also trade with EU, Korea, Taiwan)
- Consider **total size of market** as well as domestic vs export market (e.g. US exports ~14% of production)
- Determine existing or projected **MRL value** in country of production for a given active ingredient (US tolerance 0.2 ppm)
- Consider national **policies, defaults** and extent of residue **monitoring** program and MRL enforcement in key importing countries (e.g. Japan sets own MRL has very strict program)
- Are there **MRLs** in importing countries that **facilitate trade**? (If none or lower MRL value in importing country compared to exporting country**, then is trade irritant**)
- Consider actions as to establish new import MRL, revise GAPs, conduct residue decline trials, or communicate residue and/or MRL information to growers. (e.g. Japan MRL proposed for further action)

UN comtrade

United Nations Commodity Trade Statistics Database | Statistics Division

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Home

Shortcut Query

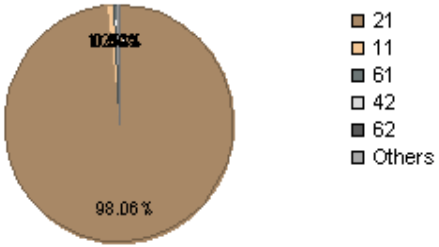
Show Export of Corn in the year recent years

from USA to World

in any classification. Search

Trade in Graph

Other Asia, nes in 2009 :
Top 5 imported commodities (2 digit code BEC)
from Togo



1. **Industrial supplies nes, primary** (98.06%)
2. **Food and beverages, primary** (1.25%)
3. **Consumption goods nes, durable** (0.54%)
4. **Parts and accessories of capital goods (except transport equipment)** (0.12%)
5. **Consumption goods nes, semi-durable** (0.03%)
6. **Others** (0.00%)

(details). graph more...

Data Availability

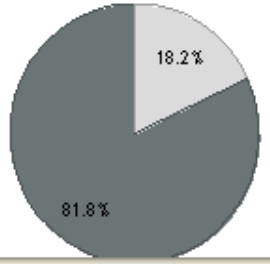
Welcome to UN Comtrade!
You are identified as Comtrade Guest.

What's New on Comtrade RSS

[2010.07.28]Monthly Bulletin of Statistics tables updated more...

What's inside

Available Trade in UN Comtrade
as share of World Trade for 2009
(world trade 2009 is estimated
at 24.9 trillion US dollars)



Work on IMTS

- Methodology IMTS
- Analytical Tables*
- Int.Coop. & Workshops
- Newsletter*

* regularly updated

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UNdata A world of information

Enter search terms Go

Help / Guideline / FAQ

- What is UN Comtrade?
- Subscribe to UN Comtrade
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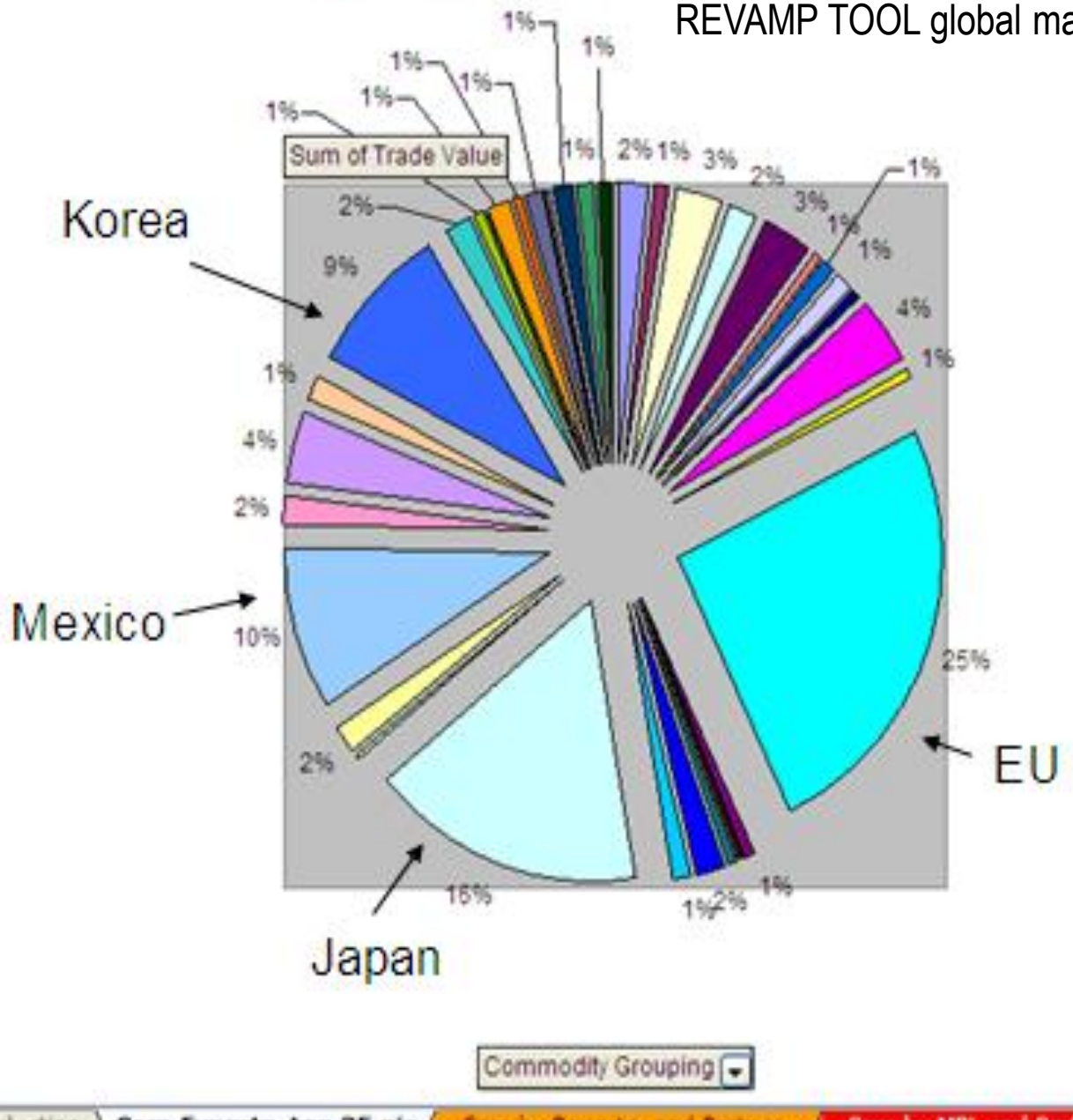
- Quick search knowledgebase

Released data

	# of country periods
today (2010.08.04)	0
in a week	8
in a month	37
year-to-date	238
in a year	392
all data	6084

Period (All) Trade Flow (All) Reporter (All)

REVAMP TOOL global market



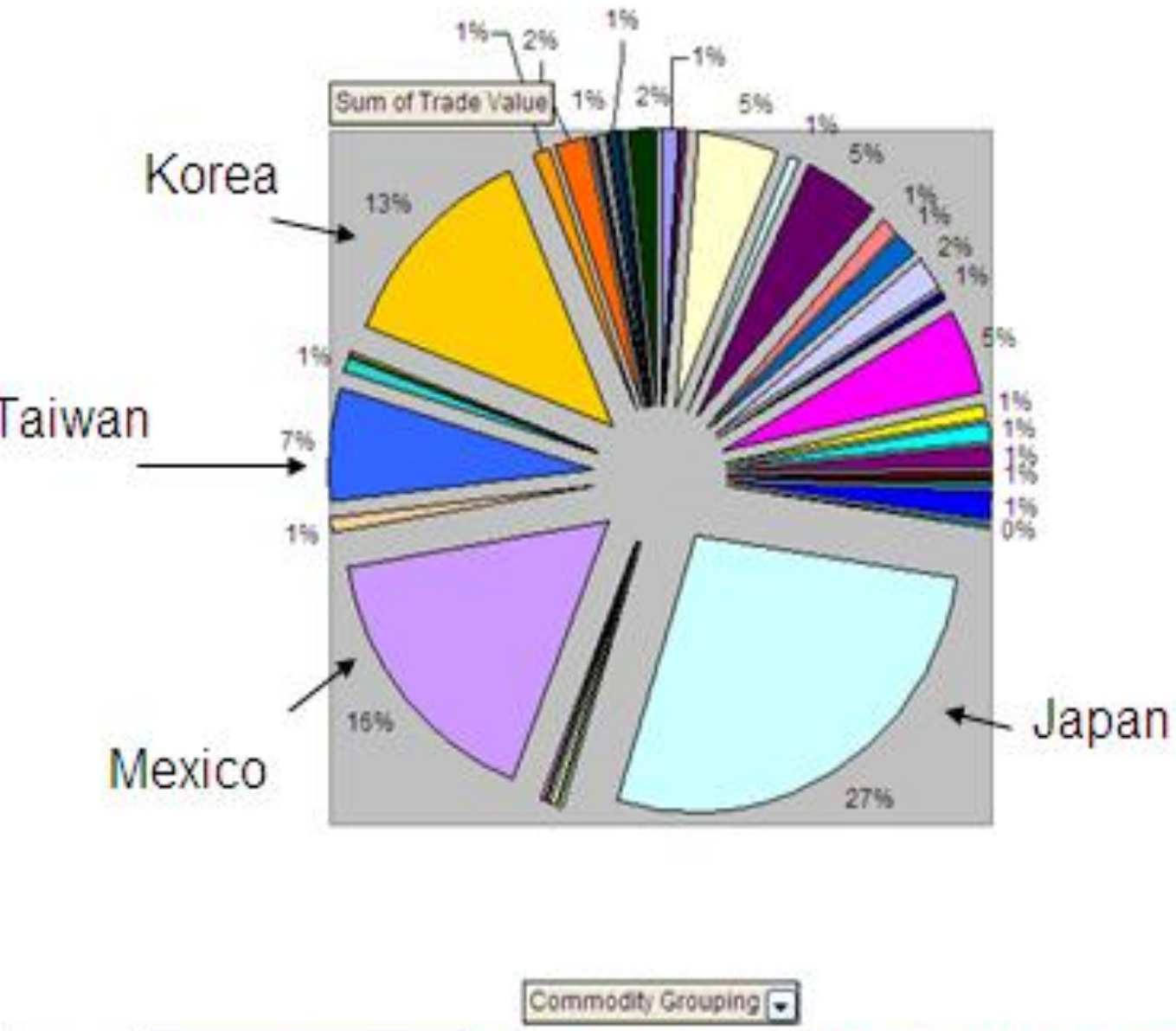
Partner with EU Grouping

- Algeria
- Brazil
- Canada
- Chile
- Colombia
- Costa Rica
- Cuba
- Dominican Rep.
- Ecuador
- Egypt
- El Salvador
- EU
- Guatemala
- Honduras
- Indonesia
- Iran
- Israel
- Japan
- Libya
- Malaysia
- Mexico
- Morocco
- Other Asia, nes
- Peru
- Rep. of Korea
- Saudi Arabia

Commodity Grouping

Introduction | Corn Exports, top 35 pie | Corn by Reporter and Partner | Corn by MRL and Partner | Corn by Groups

Period (All) Trade Flow (All) Reporter USA



Partner with EU Grouping

- Algeria
- Areas, nes
- Canada
- Chile
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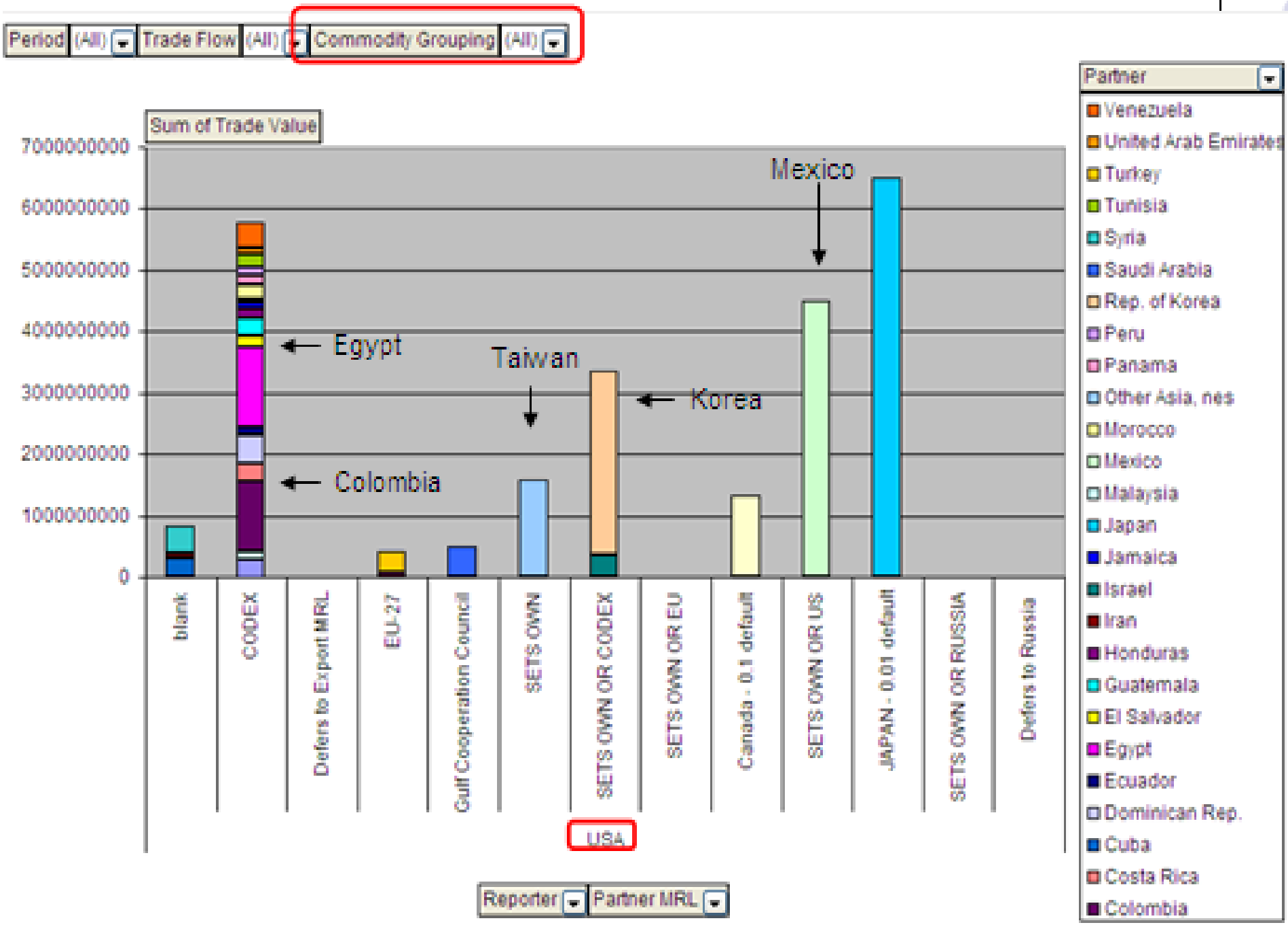
- Costa Rica
- Cuba
- Dominican Rep.
- Ecuador
- Egypt
- El Salvador
- EU
- Guatemala
- Honduras
- Iran
- Israel
- Jamaica
- Japan
- Jordan
- Lebanon
- Libya
- Malaysia
- Mexico
- Morocco
- Other Asia, nes
- Panama

Commodity Grouping

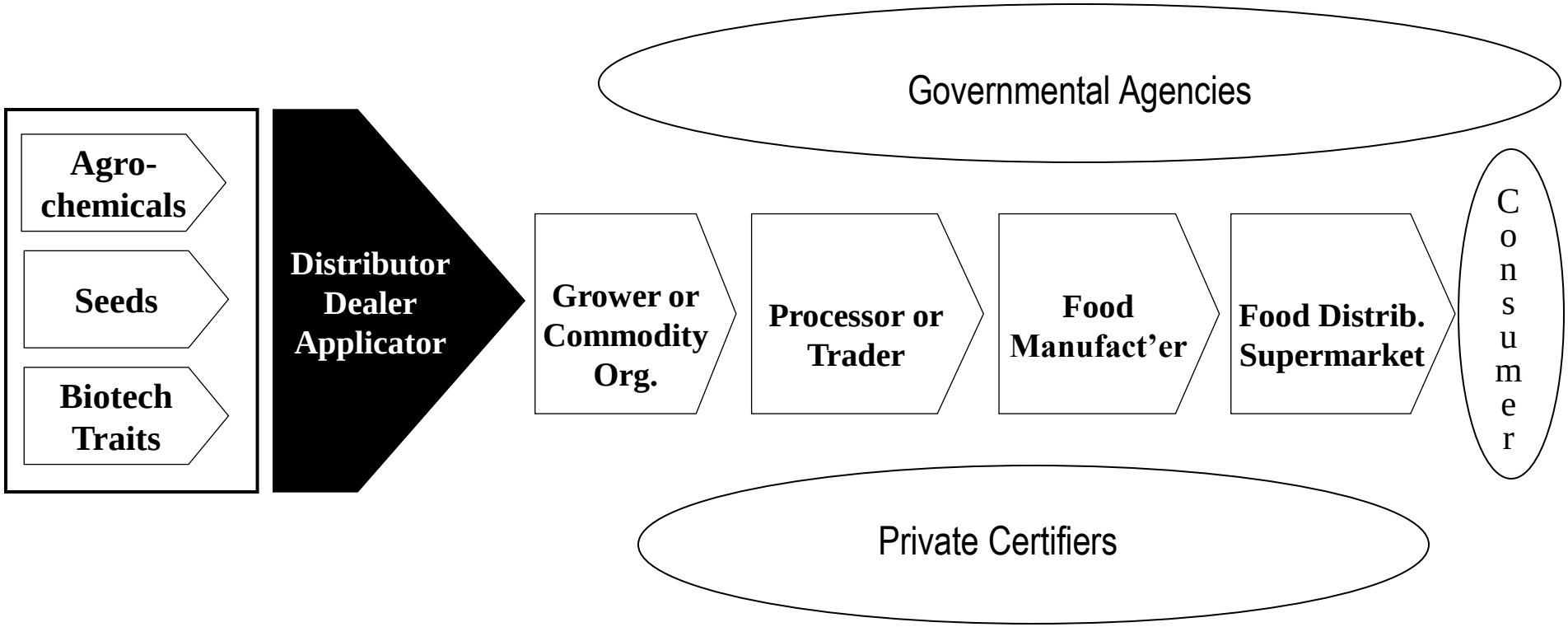

Period (All)
Trade Flow (All)
Commodity Grouping (All)
Sum of Trade Value
70000000000
60000000000
50000000000
40000000000
30000000000
20000000000
10000000000
0
Mexico
Egypt
Taiwan
Korea
Colombia
blank
CODEX
Defers to Export MRL
EU-27
Gulf Cooperation Council
SETS OWN
SETS OWN OR CODEX
SETS OWN OR EU
Canada - 0.1 default
SETS OWN OR US
JAPAN - 0.01 default
SETS OWN OR RUSSIA
Defers to Russia
USA
Reporter
Partner MRL
Partner
Venezuela
United Arab Emirates
Turkey
Tunisia
Syria
Saudi Arabia
Rep. of Korea
Peru
Panama
Other Asia, nes
Morocco
Mexico
Malaysia
Japan
Jamaica
Israel
Iran
Honduras
Guatemala
El Salvador
Egypt
Ecuador
Dominican Rep.
Cuba
Costa Rica
Colombia

Best Practice 5: Food Chain

Evaluate food chain needs and integrate appropriate food chain considerations into residue and MRL assumptions, action plans, and communication

- May establish private standards, policies, or preferences related to pesticide residues
  - Grower cooperative only use pesticides approved as "sustainable" by a private certifying body (e.g., GlobalGAP)
  - Food distributors develop lists of preferred (green), acceptable (yellow), and prohibited (red) pesticides for foods they handle
  - Supermarkets only purchase food containing non-detectable residues or residues at one-half the legal MRL
- Although not legally binding, private standards developed for products may be just as influential for use of products

BP 5: Food Chain Considerations



Best Practice 6: Action Plan

Develop and implement an MRL action plan to minimize potential residue concerns and trade irritants which may be associated with international trade of treated food crops

- Pursue **data package** and registration pathway to maximize opportunities for global harmonization
- Establish **Codex MRLs**
- Establish **import MRLs** in key export destinations
- Obtain **registration approval** and MRLs in key export destinations
- Develop residue **decline data** to support export withholding recommendations and/or communications
- *Based on limited trade or small market size, no further action*

Best Practice 7: Communicate

Develop communication strategy for effective information flow about Residue and MRLs for internal/external stakeholders

- **Stakeholders want residue/MRL information** for pesticides which they use or that may be present on foods they handle
- Communications may also include **explanations of default MRLs, LOQ MRLs or residue decline data by PHI** to support food chain needs
- Develop **standardized summaries, letter or position paper** regarding progress of global MRL action plans to share with external stakeholders.

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Dow AgroSciences **News Release**

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FOR IMMEDIATE RELEASE

Japanese Officials Approve Maximum Residue Levels for Radiant® SC and Delegate® WG Insecticides from Dow AgroSciences

INDIANAPOLIS — April 5, 2011 — Dow AgroSciences announced today that Japan has established Maximum Residue Levels (MRLs) for spinetoram, the active ingredient in Delegate® WG and Radiant® SC insecticides. The new MRLs open up a new export market for U.S grown fruits, vegetables and citrus.

Dow AgroSciences Team Experiences Implementing Best Practices

- Strong support, easiest to implement for new Active ingredients or large new use projects
- Efforts enhanced by trend in joint/global reviews
- Cultivating “residue/MRL mindset” in regulatory and R&D staff
  - Continuing to work with commercial staff and development project leaders

Acknowledgements

Dow AgroSciences Global MRL Team

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- Amalia Ponzio, Regulatory Latin America
- Colin Sharpe, Regulatory Affairs Pacific
- Sheridawn Schoeman, EU Minor Crop Specialist