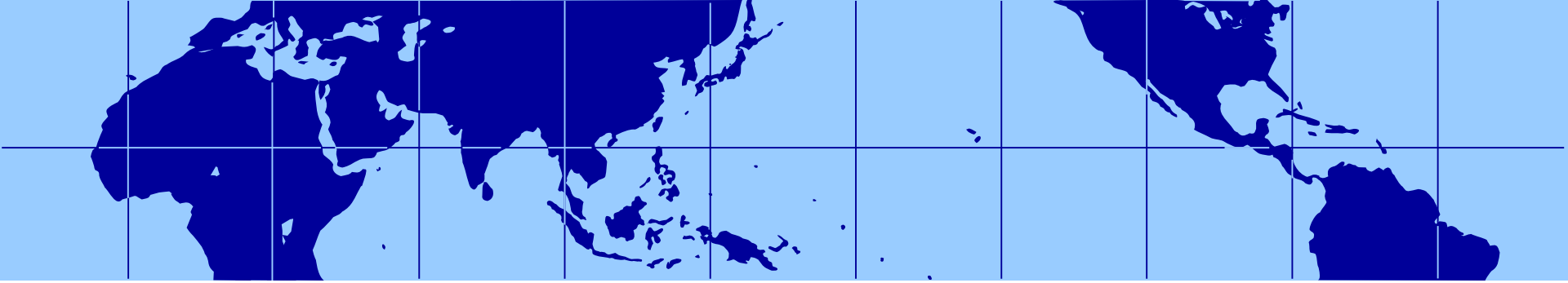

International Initiatives

Lois Rossi
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Pesticide Program Dialogue Committee
June 5-6, 2014

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EPA's Office of Pesticide Programs

- Principal Business
  - Based on high quality scientific evaluations and open transparent processes:
    - Protect human health and the environment.
    - Ensure access to safe and effective pesticides and pest management technologies.
- International efforts linked to meeting these goals.

OPP: Role in Engaging in International Registration Activities

- Leadership
  - Promote joint registration reviews and harmonization efforts internally and externally
- Advocacy/Championship
  - Identify opportunities for collaboration and cooperation
- Foster Communication
  - Promote dialogue between regulatory authorities
  - Promote dialogue with and among all stakeholders

Opportunities

- **North America**: NAFTA and Regulatory Cooperation Council (RCC)
- **OECD**: Working Group on Pesticides and Registration Steering Group and Expert Groups; Test Guideline Program: Task Force on Biocides
- **Codex Alimentarius**: Joint Meeting on Pesticide Residues (JMPR) and Codex Committee on Pesticide Residues (CCPR)
- **Other Opportunities:**
  - Bilateral partnerships
  - Commodity /chemical specific issues
  - Participation in international summits and follow-up work

North American Initiatives

- Progress towards a North American workplan.
- IR-4 (US) and PMC (Canada) partnerships.
- Work sharing and joint reviews of new active ingredients, use expansions and minor uses routine business; Increased participation of Mexico.
- Resolving trade irritants/technology gap retrospectively and consideration prospectively; Grower Priority Data Base.

Regulatory Cooperation Council (RCC)

- An initial 29 item RCC Action Plan was announced in December 2011.
- Regulatory Cooperation Council – initiative to identify mechanisms to encourage registrants to submit applications for joint review to Canada and the US that include increased numbers of minor uses. Will help facilitate equal access to products and uses in both countries as well as align maximum residue limits where possible (http://www.trade.gov/RCC/documents/Crop-Protection-Products.pdf).

Regulatory Cooperation Council (RCC)

- **Action Item 1: Encourage Joint Submission of Use Expansions and Fully Aligned Labels**
- Successfully completed a pilot project to register additional minor uses and establish MRLs/tolerances within the submission.
  - Resulted in harmonized Maximum Residue Levels (MRLs), eliminating potential trade barriers;
  - Resulted is shorter review time for import MRL review;
  - PMRA and EPA agreed to use same principles in ongoing joint review projects; and
  - The approach is being applied, as appropriate under the minor use joint review programs in EPA/PMRA.

Regulatory Cooperation Council (RCC)

- **Action Item 2: Develop Joint Guidelines for Residue Field Trials**
  - Developing joint principles for a field trial guideline;
  - Agreed on the use of the proportionality concept under certain conditions as proposed at the 45th CCPR meeting of 2013; and
  - Continue to develop harmonized crop groupings, resulting in the need for less residue data to support a greater number of crops.

Regulatory Cooperation Council (RCC)

- **Action Item 3: Address Obstacles to Joint Registration**
- Completed analysis of regulatory timelines for pesticide actions:
  - Identified many areas of existing timeline harmonization;
  - PMRA and EPA are working to manage differences in timelines with the joint review projects;
  - Alignment between US-EPA and PMRA one-year storage stability study data requirements; and
  - Leveraging of second entry joint review approach has alleviated impact of registration process differences, and to a degree, timeline differences between PMRA and EPA.

Regulatory Cooperation Council (RCC)

- **Action Item 3 (continued): Address Obstacles to Joint Registration**
- Agreed to the content of the joint draft Confidential Statement of Product Specifications (CSPS) form:
  - Completed a pilot to populate the new form using existing data; and
  - The development of a wizard tool to support the CSPS has been initiated between EPA and PMRA.
- Currently mapping registration processes to further harmonize approaches and timelines:
  - Anticipate harmonizing business rules that are required for a joint IT strategy; and
  - Efforts towards the alignment of IT Tools (such as a shared electronic submission gateway and a common e-CSPS wizard tool) have been initiated.

Regulatory Cooperation Council (RCC)

- **Action Item 4: Align Data Collection Processes and Procedures for Residue Trials (IR-4, PMC)**
- Documentation for data collection and reporting has been aligned to the extent possible.
- Final Reports aligned in OECD format pilot project and submitted to PMRA/EPA with registrant new active ingredient joint review.
- Aligned research protocols and raw data field notebooks to be implemented for the 2014 field trial season.
- PMC's new analytical laboratory completing their first final analytical report, based on IR-4 template.

Regulatory Cooperation Council (RCC)

- **Action Item 4 (continued): Align Data Collection Processes and Procedures for Residue Trials**
- PMC and IR-4 continue to undertake minor use joint projects for joint regulatory review by PMRA/EPA.
- 15 new joint projects undertaken for 2014.
- PMRA/EPA work plan for 2014 joint regulatory reviews established.
- Continuing stakeholder engagement to encourage joint projects

Regulatory Cooperation Council (RCC)

- ***Crop protection products: Moving Forward***
- Enhancing the existing bilateral system of joint product reviews, including use expansion submissions, and move towards the establishment of a single application for crop protection products that will be accepted in both countries.
- Including coordinated work planning; data sharing; aligning approaches to risk assessment; coordination of submissions; and the alignment of submission requirements.
- Developing information technology solutions for applicants to facilitate the joint review and processing of pest control product applications submitted to both countries.

Global Initiatives through OECD

- Global joint review process for review of new active ingredients and use expansions.
  - Goal – align regulatory endpoints, MRLs and decisions to extent possible.
  - Countries involved continues to increase (Australia, Brazil, Canada, China, EU member states, Japan, Korea, Mexico).
  - Expansion of companies involved.

Global Initiatives through OECD

- Tool development – OECD calculator ; residue chemistry expert working group (harmonization of residue chemistry guidelines), developed policy for use of proportionality.

- Coordination of issues – pollinator protection and persistent chemicals.

- Minor Use Initiatives
  - Expert Group on Minor Uses (EGMU) - projects aimed at increasing number of products registered for minor uses.

Status of Global Joint Reviews: 2007-2014

- Twenty one Joint Reviews for new active ingredients completed since 2007.
  - **Ametoctradin – fungicide (AU, CA, US) - 2012**
  - **Chlorantraniliprole – insecticide (reduced risk) (AU, CA, EU (IR, UK), NZ, US - 2008**
  - **Cyantraniliprole – insecticide (reduced risk) (AU, CA, EU (FR, UK), US) – 2013**
  - **Cyflumetofen – 2014 (CA, MX, US)**
  - **Ethaboxam – 2013 (CA, US)***
  - **Ethiprole – insecticide (CA, US)**
  - **Fluopyram – fungicide (CA, EU (DE), US) - 2012**
  - **Fluxapyroxad – fungicide (AU, CA, US) – 2012**
  - **Kasugamycin – fungicide (CA, US) - 2013**
  - **Penflufen – fungicide (AU, CA, US) - 2012**
  - **Penthiopyrad – fungicide (AU, CA, EU (UK), US) - 2012**

Status of Global Joint Reviews: 2007-2014

- Picoxystrobin – fungicide (CA, US) - 2012
- Pyroxasulfone – herbicide (AU, CA, US) - 2012
- Pyrasulfotole – herbicide (AU, CA, US) - 2007
- Pyroxsulam – herbicide (AU, CA, US) - 2008
- Saflufenacil – herbicide (AU, CA, US) - 2009
- Sedaxane – fungicide (AU, CA, US) – 2012
- Spinetoram – insecticide (reduced risk) (CA, US) - 2007
- Spirotetramat – insecticide (reduced risk) (CA, EU (AT), US) - 2008
- Sulfoxaflor – insecticide (AU, CA, US) – 2012
- Thiencarbazone – herbicide completed in (CAS, EU (UK), US) - 2008

Joint Reviews In Progress

- Currently there are twelve global joint reviews ongoing
  - Bicyclopyrone – herbicide (AU, CA, US)
  - Cyclaniliprole (IKI-3106) – (AT, AU, BR, CA, US)
  - Fluensulfone – nematicide (CA, US)
  - Flupyradifurone – insecticide (AU, CA, US)
  - Isofetamid – fungicide (CA, US)
  - Mandestrobin – fungicide (CA, US)
  - Oxathiopiprolin – fungicide (AU, CA, CN, JP, KR, MX, PH, US)
  - Proquinazid – fungicide (CA, US)
  - Pyriofenone – fungicide (CA, US)
  - S-1563 – insecticide (CA, US)
  - Solatenol – fungicide (CA, MX, US)
  - XDE-729 – herbicide (AU, CA, US)

Joint Reviews In Progress

- Eleven second entry global joint reviews are ongoing
  - Clodinafop-propargyl – new source of technical (CA, US)
  - Dicamba – herbicide – new use (CA, JP, US)
  - Fludioxonil, Difenoconazole – new end use product (CA, US)
  - Fosetyl-Al – fungicide – import tolerance (CA, US)
  - Glyphosate – herbicide – new source of technical (CA, US)
  - Glyphosate acid - herbicide – new source of technical (CA, US)
  - Lambda-cyhalothrin – new source of technical (CA, US)
  - Mesotrione – herbicide – new use (CA, US)
  - Picoxystrobin – new uses (CA, US)
  - S-metolachlor – herbicide – new source of technical (CA, US)
  - USF 0728 325 SC – fungicide – new use (CA, US)

Projected Global Joint Reviews

- Eleven new active ingredient global joint reviews are scheduled for submission in the remainder of 2014 - 2017.

MRL Harmonization Analysis: Active Ingredients Jointly Reviewed

- The Global Joint Review (GJR) process strives to achieve harmonized MRLs, reducing potential trade barriers.
- MRL analysis considered MRLs for active ingredients that were the subject of joint reviews completed since 2007.
- Completed on original crops reviewed as part of GJR
- Utilized the MRL database (http://mrldatabase.com) and country-specific MRL information
- Representative crop commodities were utilized
- For US registrations, used initial US MRL in analysis

MRL Harmonization Analysis: Active Ingredients Jointly Reviewed

- In September 2011, evaluated 97 MRLs
  - Harmonized on ~57%
  - MRLs close (within 0.5 ppm) for ~32%
  - ~11% of analyzed MRLs were not harmonized
- In November 2012, evaluated 173 MRLs
  - Harmonized on ~80%
  - MRLs close (within 0.5 ppm) for ~9%
  - ~10% of analyzed MRLs were not harmonized
- In October 2013, evaluated 75 MRLs
  - Harmonized on ~67%
  - MRLs close (within 0.5 ppm) for ~21%
  - ~12% of analyzed MRLs were not harmonized
- In March 2014, evaluated 278 MRLs
  - Harmonized on ~82%
  - MRLs close (within 0.5 ppm) for ~18%
  - ~0% of analyzed MRLs were not harmonized

MRL Harmonization Analysis: Active Ingredients Jointly Reviewed

- Total of all MRLs evaluated since 2007
  - Harmonized on ~76 %
  - MRLs close (within 0.5 ppm) for ~18 %
  - ~6 % of analyzed MRLs were not harmonized

- It should be noted that only one joint review project was analyzed in the 2013 – 2014 evaluation, resulting in a smaller sample size.

Conclusion

- Strong science review among national regulatory authorities; benefit of wide range of expertise.
- Agreement on endpoints, residue definition, MRLs
- The Global Joint Review (GJR) process has resulted in harmonized MRLs for most crops.
- Global Joint Reviews aid in reducing agricultural trade barriers.
- Continue analysis to articulate differences in MRLs among GJR partners as well as with Codex and MRLs set by countries beyond GJR.

OECD: Residue Chemistry Expert Group

- **History: 2004-2010**
- **Guideline**: plant, livestock, rotational crop, processing *metabolism*; field trial, processing, rotational crop *magnitude of residue;* storage stability; livestock *feeding*.
- **Guidance**: overview; analytical methods; processing; definition of residue; crop field trials; livestock feeding.
- **Statistical spreadsheet for MRL Calculator**

OECD: Residue Chemistry Expert Group

- Current Work:
- Update of Crop Field Trial Guidance
  - Two circulations/commenting periods completed
  - Included a wide distribution for comments (07/2013)
  - Final version now in preparation
  - Expect submission 2014 for OECD approval
- Field Rotational Crop Guidance

OECD Expert Group on Minor Uses (EGMU)

- Chaired by Alan Norden, Australia (APVMA)
- 3 areas of work
  - Cooperation Activities
  - Technical Activities
  - Policy Activities

OECD Expert Group on Minor Uses (EGMU)

- Cooperation Activities
  - Collection and Maintenance of Minor Use Baseline Information
  - Collaborative data generation- address minor use gaps, collate data exchanges and pilot minor uses for data generation and exchange.
  - Conduct joint reviews to encourage registration of minor uses
  - Data sharing on minor uses
  - Expand involvement beyond OECD countries

OECD Expert Group on Minor Uses (EGMU)

- Technical Activities
  - Generation of data and implement smart use of residue and efficacy data.
  - Efficacy and crop safety data – review of guidelines developed by EPPO and identify any gaps.
  - Align activities with reduced risk principles and enhance IPM implementation for minor uses.

OECD Test Guideline Program

- A collection of the most relevant internationally agreed testing methods used by governments, industry and independent laboratories to assess the safety of chemical products.
- They are primarily used in regulatory safety testing to support labeling and product registration.
- Test Guidelines are not data requirements, which are the prerogative of national authorities.
- Data generated using OECD test guidelines must be accepted by OECD member countries under the Mutual Acceptance of Data (MAD) Council decision

OECD Test Guideline Program

- Structure:

- US National Coordinator (NC), Christine Olinger, is housed in OPP/HED, and coordinates all test guideline activities across US Government
- NC works closely with the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM) on new methods
- National Coordinators met in April 2014 and approved 15 new/updated test guidelines and guidance documents, and declined to approve three.
- Twenty proposed projects were approved for inclusion on the 2014 WNT workplan

OECD Test Guideline Program: Recent Trends

- Increased development of *in vitro* and *ex vivo* methods to replace acute toxicity methods
- Integration of the OECD Adverse Outcome Pathway program into the Test Guideline Program
- Development of Guidance Documents on Integrated Approaches to Testing and Assessment (IATA) to incorporate 21st Toxicology Principles
- Larval Honeybee TG approved in 2013; additional pollinator work is in the TG workplan

OECD Test Guideline Program: Websites

- OECD Test Guideline Program
  - http://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicalsandrelateddocuments.htm
- OECD Adverse Outcome Pathway Program
  - http://www.oecd.org/env/ehs/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm
- OECD Activity on Endocrine Disruptors
  - http://www.oecd.org/env/ehs/testing/oecdworkrelatedtoendocrinedisrupters.htm

OECD Task Force on Biocides (TFB)

- **Objectives**
  - **Attain a harmonized regulatory approach.**
  - **Increased efficiency in the registration of biocides for both governments & industry.**
  - **Help countries to reduce risks associated with biocides use.**
- **Structure**
  - **14 member countries; representatives from the European Commission; observers from the biocide industry, i.e., European Chemical Industry Council (CEFIC) and American Chemical Council (ACC)**
  - **TFB Chair, Jennifer McLain (Deputy Director, Antimicrobials Division)**
  - **Reports directly to the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology**
  - **Work closely parallels the work on agricultural pesticides**

OECD Task Force on Biocides (TFB): Activities

Areas of Focus

- **Harmonization of methods for efficacy testing to ensure the validity of label claims**
- **Harmonization of physical/chemical test methods**
- **Harmonization of exposure assessment approaches**
- **Identifying effective biocide risk reduction measures**
- **Work sharing**

Highlights of Work Programme for 2013-2016

- **Proposal for work sharing - development of OECD dossier guidance for biocides, i.e. harmonised templates for dossier submission as well as an approach for joint reviews**
- **Development of OECD guidance (details - next slide)**
- **Survey on performance standards and label claims for hard surface biocides**
- **Aggregate exposure/risk of biocides for human health. Survey and case studies that illustrate assessment approaches in OECD countries**
- **OECD Emission Scenario Documents**
- **Survey on integrated pest management (IPM) for residential & public health disinfectants**

OECD TFB: Guidance Documents & Test Guidelines

Under Development

- **Quantitative method for Tier 1 evaluation of antibacterial activity of porous and non-porous antibacterial treated materials**
- **Guidelines on physical/chemical properties (density and viscosity)**
- **Guidance on the validation of analytical methods and on the storage stability of products**
- **Guidance on the efficacy of insecticides against bed bugs**

Recent Publications

- **Guidance Document for Demonstrating Efficacy of Pool and Spa Disinfectants and Field Testing**
- **Guidance Document on Assays for Testing the Efficacy of Baits against Cockroaches**
- **Guidance Document on the Testing of Efficacy of Baits, for Indoor Use, Against Garden Ants**
- **Guidance Document on Quantitative Methods for evaluating the activity of Microbicides used on hard non-porous surfaces (bactericidal, mycobactericidal, fungicidal and virucidal methods).**
- **Test Guideline on Determination of pH, Acidity and Alkalinity**
- **Revised Emission Scenario Document for Wood Preservatives**

OECD Expert Group On Electronic Exchange of Pesticide Data (EGEEPD)

- Expert Group on Electronic Exchange of Pesticide Data (EGEEPD)
  - Members: Regulatory authorities from OECD countries and European Commission, and experts from pesticide industry
  - Co-chaired by PMRA and OPP
  - Tasked with developing a common method for electronic submission of documents to regulators
  - Globally harmonized format for electronic submissions – Globally Harmonized Submission and Transport Standard (GHSTS)
    - Consists of multiple components – some completed, others under development
    - Can transport associated text files, spreadsheets, PDF, and XML data files
    - Supports OECD Harmonized Templates (OHTs) and Table of Contents (ToC)

OECD Expert Group On Electronic Exchange of Pesticide Data (EGEEPD)

- Recent Publication
- GHSTS format specification published May 28
  - Provides conceptual and technical description of all GHSTS components
  - Provides technical specifications for 4 completed components
    - Schema definition
    - Format specification
    - Pick list XML schema definition
    - Table of contents XML schema definition
  - ENV/JM/MONO(2014)9
  - http://www.oecd.org/officialdocuments/displaydocument/?cote=ENV/JM/MONO(2014)9&doclanguage=en

OECD Expert Group On Electronic Exchange of Pesticide Data (EGEEPD)

- Implementation strategy document currently under development
  - Designed to help regulatory authorities and industry adopt and implement GHSTS standard
  - Includes proposed procedures for approving modifications and updates to GHSTS components
- Viewer component currently under development
  - Provides user interface for reviewing submission package
- Coordinate with other OECD expert group to update related standards (e.g., OHTs and ToCs)
- OPP and PMRA to integrate GHSTS submission standard into electronic submission process

Codex Committee on Pesticide Residues (CCPR)

- CCPR Meeting May 2014 held in Nanjing, China:
- Pre-meeting delegation meetings: CCPR Chair and FAO/WHO Secretariats; QUAD countries (Canada, NZ, Australia; EU; Latin American countries.
- Side meetings: China and Korea
- MRL Advancement: 343 MRLs for 32 pesticides were advanced to Step 8 for adoption by the Codex Alimentarius Commission (CAC) at the July 2014 meeting; 11 pesticides were new active ingredients.
- 46 MRLs were held and not advanced.

CCPR Initiatives

- Revision of Codex Classification of Animal Food and Feeds (aka Crop Grouping)
  - Currently four vegetable groups waiting for finalization of the revision of all vegetable groups before further advancement towards adoption: Brassica (Cole or Cabbage); Head Cabbages and Flowerhead Cabbages; Leafy Vegetables (including Brassica Leafy Vegetables); Stalk and Stem Vegetables; Root and Tuber Vegetables.
  - Fruit Group has been adopted.
- Work Group on Minor Uses and Specialty Crops re-established to complete workto determine the minimum number of field trials needed for risk assessment to support the establishment of Codex MRLs fo minor uses and specialty crops. on defining number of field trials required for minor crops by JMPR.

CCPR Initiatives

- Nomination and Prioritization of Compounds to be considered by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR)
  - Nominations for 2015: 12 new pesticides; New uses for 20 pesticides; 6 existing compound re-evaluations.
  - Nominations for 2016: 12 new pesticides; New uses for 19 pesticides.
  - 2015 and 2016 at current capacity.
- US Delegation has lead many efforts over the past decade to increase the capacity of the JMPR; possibility of an additional meeting is under consideration.
- Funding is an issue; US EPA and USDA have provided majority of funding in the past.

Bilateral Initiatives

- Japan:
  - Sharing of US EPA reviews to support MRLs on Positive List
  - Global joint review partner
- Brazil:
  - Participation in global joint reviews
- China:
  - ICAMA and EPA continue cooperation workshops and high level delegation meetings.

Bilateral Initiatives

- Taiwan:
  - Sharing of reviews that support MRLs
  - Hosting for training.
  - Priority list provide May 2014. Used Grower Priority Data Base to determine priorities.
- Korea:
  - Minor Use Symposium in November 2013
  - Continued cooperation with Korean Ministry of Food and Drug Safety on MRLs. Rural Agricultural Development Agency participating in joint reviews.
- European Union:
  - Work with EU member states in OECD and Codex.
  - Some participation on joint reviews of new active ingredients.
  - Work on specific MRL issues.

Other Initiatives

- Work closely with USDA /FAS on chemical/commodity/country issues that arise and provide technical support.

- Work with commodity groups on chemical/commodity issues.

Summary

- Individual initiatives all have same goal and build on each other.
- Much progress made on international harmonization initiatives.
- Multiple initiatives pursued.
- Success depends on coordination across various US Federal Agencies, other national authorities, international organizations, and stakeholders.
- Stakeholder initiatives compliment government initiatives.

- THANK YOU FOR YOUR ATTENTION!

- QUESTIONS