



# International Initiatives

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# International Work is Essential to Achieving OPP Goals

- International marketplace
- Impact on U.S. health and environment.
- International acceptance of safer products.
- Opportunities to collaborate on international fora



# OPP International Goals

## ☐ **Goal #1: Strengthening Protection**

- Strengthen food safety, public health and environmental protection, domestically and globally

## ☐ **Goal # 2: Enhance Regulatory Decisions through Collaboration**

- Improve science base and enhance regulatory efficiency by leveraging scientific and regulatory resources with the international community

## ☐ **Goal # 3: Conserve Resources**

- Conserve resources of U.S. consumers, growers, and industry stakeholders through more efficient and coordinated regulatory processes

## ☐ **Goal # 4: Minimize Barriers**

- Minimize international trade issues related to pesticide regulatory requirements & facilitate trade and fair competition



# Collaborative Engagement

- ❑ **MRLs**: Codex Alimentarius; Codex Committee on Pesticide Residues (CCPR); WTO SPS Committee
- ❑ **OECD**: Global Joint Reviews; Working Group on Pesticides; Registration and Risk Reduction Steering Groups; Expert Groups; Test Guideline Program; Task Force on Biocides; Biopesticides Steering Group
- ❑ **NAFTA**: Technical Working Group on Pesticides, Regional Coordination Council (RCC)



## MRLs: Harmonization

- Crop groups
  - Promote harmonization
  
- Regulatory harmonization
  - Median vs. maximum value
  - Statistical approach
  - [GlobalMRL.com](http://GlobalMRL.com)
  
- Global Zoning Projects
  - Comparison of residue levels



# MRLs: Codex Alimentarius Commission (CAC); Codex Committee on Pesticide Residues (CCPR)

- ❑ Food safety standards.
  
- ❑ U.S. priorities
  - Ensure timely adoption of MRLs.
  - Sound science.
  - Promotes consumer health and fair trade practices.



# Global Initiatives through OECD

- Working Group on Pesticides
- Task Force on Biocides
- Biopesticides Steering Committee



# OECD: Working Group on Pesticides

- ❑ The WGP helps governments co-operate in assessing and reducing risks of agricultural pesticides. Programs strive to improve the efficiency of pesticide control, share the work of pesticide registration and reevaluation, reduce risks to human health and the environment, and minimize trade barriers.
- ❑ Focuses on agricultural pesticides (chemical and biological) used for plant protection in agriculture and related areas. Non-agricultural pesticides are dealt with separately (Biocide Programme).

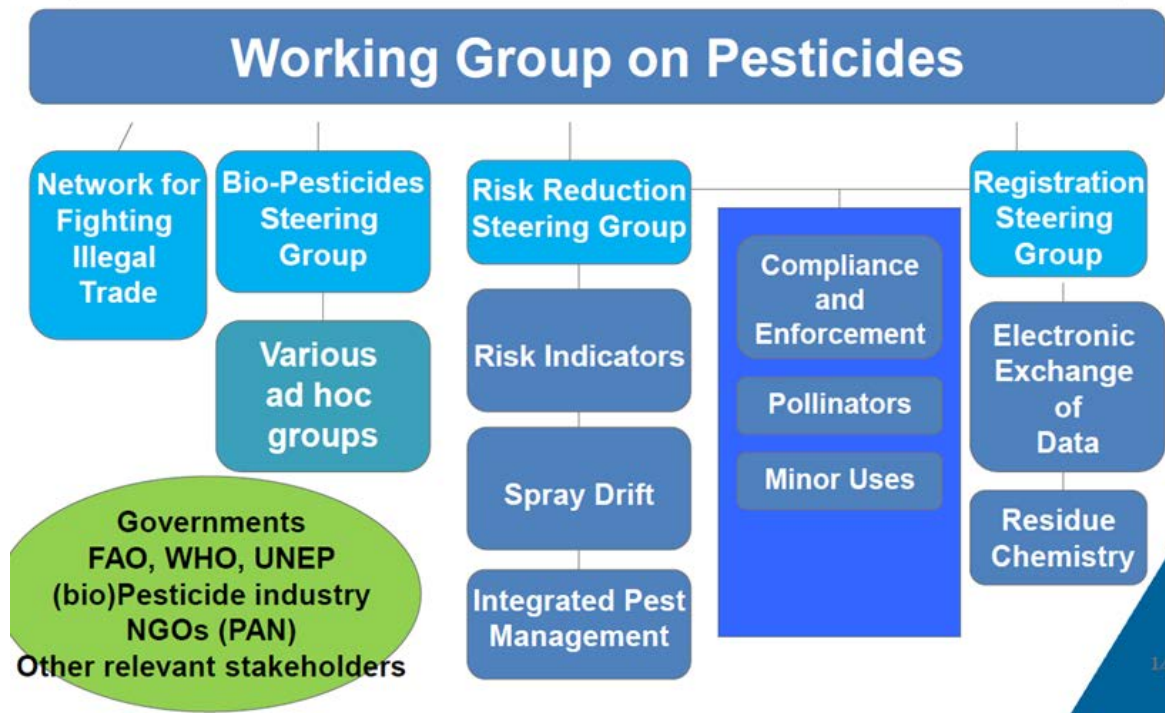




# OECD: Working Group on Pesticides



## OECD Pesticides Programme Structure





# OECD: Working Group on Pesticides

- ❑ U.S. Priorities to facilitate Pesticide Registration
  - Streamline joint review processes
  - Facilitate bio-pesticides registration
  - Develop tools for work sharing
  - Facilitate electronic exchange of data and exchange of reviews - maintain the GHSTS (Global Harmonised Submission Transport Standard)
  - Facilitate minor use registration



# Global Joint Review

- ❑ Twenty-seven Joint Reviews for new active ingredients have been completed since 2007.
- ❑ Currently there are seven global/NAFTA joint reviews ongoing for new active ingredients.
  - Cyclaniliprole – insecticide (AU, CA, US)
  - Pyriofenone – fungicide (CA, US)
  - Tioxazafen – nematocide (CA, MX, US)
  - Pydiflumetofen – fungicide (CA, MX, US)
  - Tolpyralate – herbicide (CA, US)
  - Triflumezopyrim – insecticide (CDPR, CA, US)
  - Rinskor – herbicide (US, CN)
- ❑ Seventeen new active ingredient global/NAFTA joint reviews are scheduled for submission in 2015 - 2019.



# OECD Task Force on Biocides

- ❑ Attain a harmonized regulatory approach.
- ❑ Increase efficiency in the registration of biocides for both governments and industry.
- ❑ Reduce risks associated with biocides use.
- ❑ Partners: 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)
- ❑ Work closely parallels the work on agricultural pesticides.



## OECD TFB: US Priorities

- US proposal for work sharing
- OECD guidance document on Bridging/Waiving of Acute Studies
  - US/Canada lead
- Guidance Document on Quantitative Methods for Evaluating the Activity of Microbicides used on Hard Non-porous Surfaces
- Tier 2 Quantitative method for evaluating antibacterial activity of porous and non-porous antibacterial treated materials and label claims
- Efficacy methods for insecticides – priority for bed bugs
- Special sessions to exchange information and identify areas for future harmonization
  - 2015 Treated Articles
  - 2016 Dietary Risk Assessment



# OECD Biopesticides Steering Committee

- ❑ BPSG helps member countries to harmonize the methods and approaches used to assess biological pesticides (includes microbials and pesticides EPA classifies as biochemicals, including pheromones, semiochemicals, and plant extracts/botanicals).
- ❑ It is focused on developing guidance for submission and evaluation of test data and other issues related to risk assessment.



## OECD BSC: U.S. Priorities

- ❑ Developing guidance documents for risk assessment of microbial secondary metabolites, storage stability testing for microbial pesticides, and assessment of equivalence of microbial active ingredients.
- ❑ Updating guidance documents on risk assessment of semiochemicals and botanicals.
- ❑ Risk assessment of microbial secondary metabolites
  - The guidance document is still draft
  - US and Canada rely on testing to identify issues of concern; many OECD countries believe that that is not sufficient.
- ❑ Sensitization potential of microbial pesticides and the role of sensitization testing for informing regulators on PPE requirements for labels.



# OECD Test Guideline Program

- ❑ Update on documents approved since the April 2016 WNT Meeting
  - 4 new test guidelines approved
  - 10 test guidelines updated (2 co-lead by U.S.)
  - 7 supporting documents approved (2 led or co-led by U.S.)
  - 12 new projects approved
  
- ❑ Other activities
  - Coordinate with ICCVAM
  - Endocrine Disruptors





# NAFTA Technical Working Group on Pesticides

- 2016-2021 Strategic plan
  - Facilitate trade
  - Encourage joint reviews
  - Cooperate on science and regulatory issues



# NAFTA Technical Working Group on Pesticides

## Joint Reviews

## Pollinator Protection

- Two products approved for the Varroa mite
- Opportunity for US, CAN and MX to work together to protect the Monarch butterfly

## MRLs

- Importance of regulatory cooperation on MRLs
- Codex Forum is an international forum for MRLs



# U.S.-Canada Regulatory Cooperation Council (RCC)

- ❑ Regulatory Cooperation Council (RCC) built on the success of NAFTA initiatives; it was implemented in 2011. The RCC seeks to advance the US and Canadian regulatory relationships across multiple sectors to further transparency, alignment, and coordination.
- ❑ For OPP, initial efforts included initiatives to remove obstacles to, and encourage joint submission of, use-expansions and fully aligned labels, and to develop joint guidelines and aligned data collection processes and procedures for residue trials.
- ❑ Current projects continue to build on the initial progress and include: joint IT solutions, joint product chemistry reviews, and pollinator protection.
- ❑ EPA is working with PMRA to develop initiatives for the next phase of RCC work.



# Regulatory Cooperation Council (RCC)

- ❑ Early successes
  - Increased cooperation and joint submissions
  - Developed joint guidelines
  - Aligned processes for residue trials
  
- ❑ On-going efforts
  - IT solutions
  - Product chemistry reviews
  - Pollinator protection



# Other Opportunities and Technical Assistance

- Asia-Pacific Economic Cooperation (APEC)
- Chemical, commodity, and country specific assistance
- International visitors and bilateral assistance



# Other Bilateral Technical Cooperation and Assistance Projects: Overview

- ❑ Wide range of diverse activities with international partners, from long term involvement in joint reviews of chemicals to informational briefings with visitors interested in learning about the U.S. pesticide regulatory system.
- ❑ Strategic choice to focus on relatively few priority bilateral efforts (NAFTA, RCC) with most potential for direct benefit to OPP's work and strategic goals



## Other Initiatives

- ❑ Work closely with USDA/FDA on chemical, commodity, and country specific issues as they arise and provide technical support.
- ❑ Examines protocols received by USDA/FAS for grants to support data generation and research towards resolving MRL issues.
  - These have included protocols from tree fruit, caneberry, blueberry, cranberry, tree nut producers in the U.S.
- ❑ Assist, where possible, with getting U.S. exports into foreign markets



# Summary

- Many opportunities
- Continuing to make progress on international harmonization initiatives
- Success depends on coordination across various US Federal Agencies, other national authorities, International Organizations, and stakeholders
- Stakeholder initiatives complement government initiatives