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Agri-Food Canada

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# Canadian Minor Use Program and MRL Activities

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Canada

# Pest Management Centre's Activities

- Who we are
- Pest Management Centre Activities
  - Pesticides Risk Reduction Program
  - Minor Use Pesticides Program
- International Collaborative Efforts
  - Joint work sharing with the U.S. IR-4 Project
  - Opportunities through International Collaboration



# PMC's Purpose and Vision

- The PMC uses scientific knowledge and expertise to improve pest management practices for the benefit of all Canadians and the environment. We respond to grower needs by providing specific pest management solutions that foster competitiveness, sustainable crop production and environmental stewardship.
- PMC vision:
  - An internationally recognized centre of excellence and catalyst for innovation and competitiveness, dedicated to sustainable pest management.

# What is a Minor Use?

In Canada a “minor use pesticide” is defined a pesticide use for which the anticipated volume of sales is not high enough for a manufacturer to justify the costs to register and sell the product in Canada.

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Canada accounts for **less than 3%** of world pesticide sales.

Canada accounts for **less than .06%** of world minor use pesticide sales.

# Importance of Minor Use Crops to the Canadian Economy

Preliminary findings by AAFC Economic Analysis:

- \$1 million increase in farm sales of fruits and vegetables will create 10 jobs in the fruits and vegetable industry and a total of 19 jobs to the economy.
- The program is expected to increase farm receipts per hectare due to reduced incidence of pests.
- Minor use pesticides program is expected to increase economic activity and employment.
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- Easier access to minor use pesticides will reduce the unit cost and help Canadian producers to compete in both domestic and export markets.
- The availability of new minor uses could reduce potential environmental damage and human health.
- It is expected that the net present value of the program is positive and the benefit cost ratio is greater than 1.

# PMC Partnerships

## PMC:

- Facilitates priority setting process
- Carries out field trials
- Write submissions

## IR-4:

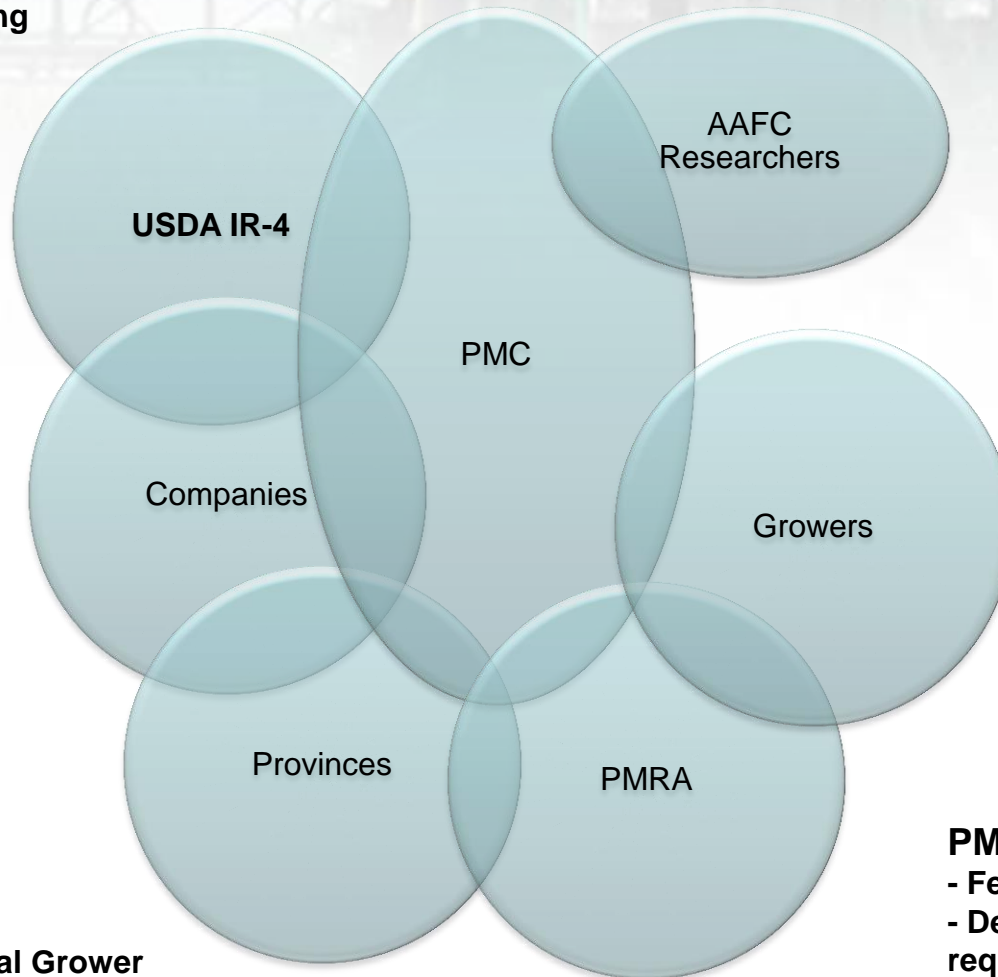
- Work with PMC to facilitate North American Registrations

## Companies:

- Develops new technologies
- Determines product eligibility based on market

## Provinces:

- Coordinate regional Grower needs
- Make emergency and Provincial MU submissions



## AAFC Researchers:

- Conduct Research on grower priorities
- Compile data supporting new MU submissions

## Growers:

- Demonstrate needs
- Choose priorities

## PMRA:

- Federal regulator
- Determines data requirements
- Reviews submissions



# Although the roles of the PMC are quite different than those of HC's PMRA, we work closely together

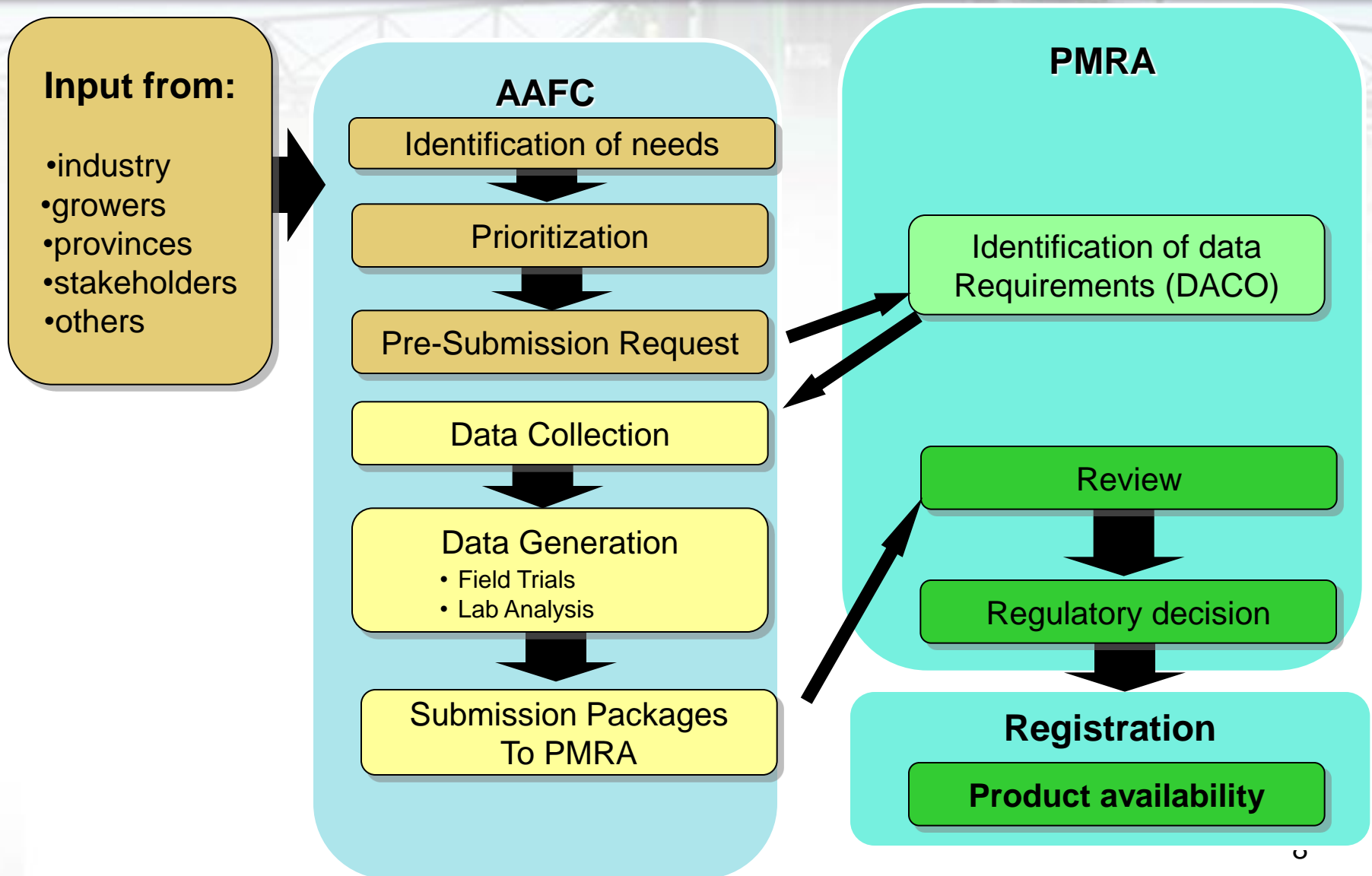
## PMC Roles

- Work with stakeholders to identify key pest management issues
- Generate data and regulatory submissions for new minor uses
- Implement projects which will enhance environmental stewardship
- Improve access to pesticides to help growers compete in global and markets
- By providing field & lab data contributes to regulatory policy decisions / changes

## Pest Management Regulatory Agency Roles

- Federal regulator and registrar of pesticides
- Develops, delivers and enforces federal pesticide policies and guidelines
- Evaluates pesticide registration proposals
- Promotes sustainable pest management
- Looks to improve regulatory process to improve efficiency

# Minor Use Registration Process





# Canadian Biopesticides and Minor Use Pesticides Priority Workshops

- **PMC 10<sup>th</sup> Anniversary – 2013 Priority Workshops**
- **41 grower-chosen priorities selected (48 projects)**
- **8 Biopesticides priorities**
- **PMC collecting data and preparing Pre-submission requests**
- **Trials will begin during 2014 growing season**



**Prioritize**

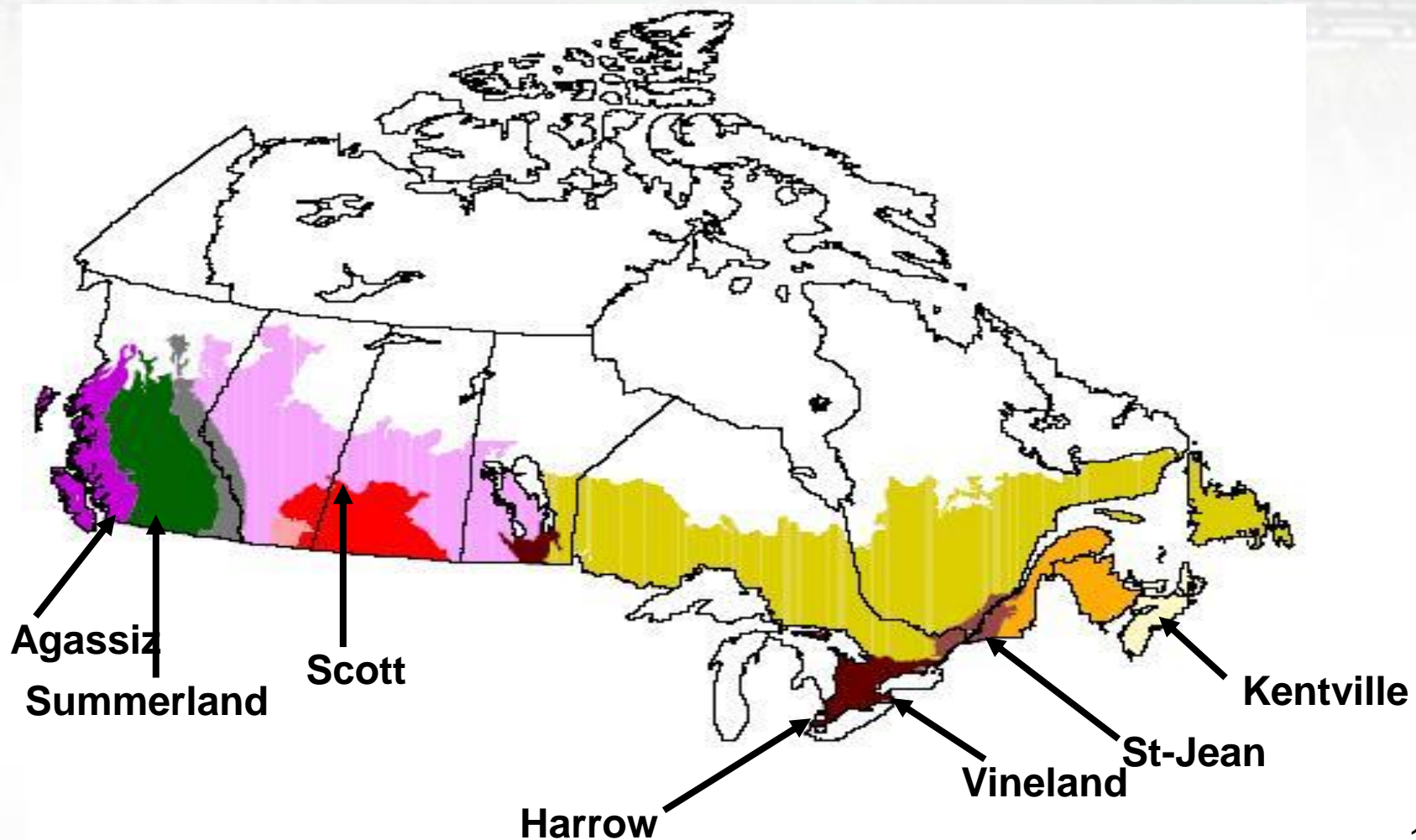


**Plan and Conduct Trials**



**Analyze**

# AAFC Research Centres involved in Minor Use Field Trials



# Minor Use Achievements 2003 - 2013

- 906 projects undertaken including 49 new projects from 2013 Workshop
- 472 projects completed and submitted to PMRA & Registrants
- 333 Registrations
- Over 1238 new uses
- Most recent submissions to PMRA:

• 2007-2008	49
• 2008-2009	45
• 2009-2010	77 (includes backlog)
• 2010-2011	83 (includes backlog)
• 2011-2012	62 (includes backlog)
• 2012-2013	65 (includes backlog)
–	74 registrations
–	+261 new uses
- 2013-2014 5

# Background

## Harmonization = Increased Competitiveness

- Pesticides in Canada regulated by HC's PMRA
  - Under the authority of PCPA
- Harmonization of pesticide regulations is beneficial:
  - Results in faster decisions by regulators
    - Speedier access to new and effective crop protection tools
  - Reduces trade barriers through harmonized MRL's
    - Opens markets to Canadian growers
  - Contributes to simultaneous registration of new uses
    - “technology gap” doesn't increase
  - Canada's high health and safety standards not compromised
- Push for increased regulatory harmonization
  - Minister's mandate letter
  - RCC initiative seek greater regulatory harmonization

# North America Activities and Collaboration

- Working closely with the U.S.D.A. IR-4 Project to maximize harmonized pesticide registrations and MRLs for the U.S. and Canada.
  - 18 Joint projects in 2013
  - Use of crop groupings
  - Collaborative efforts on biopesticides
  - Joint projects for the Ornamental sector
  - Global Residue Studies (tomato, blueberry, validation of CG8)
  - Work on Invasive species
  - RCC Initiative
- Memorandum of Understanding (MOU) between IR-4 and AAFC/PMC.



# Canada/U.S. Regulatory Cooperation Council

## RCC – Crop Protection Products initiative

Objective: Facilitate access to products and uses in both countries and align MRL/tolerances through 4 action items:

1. Encourage Joint Submission of Use Expansions and Fully Aligned Labels'
  - Address the technology gap for Canada and trade irritants for both countries
  - Pilot project undertaken involving PMC, IR-4 and company in the US and Canada
  - Data submitted from PMC/IR-4, import tolerance requests from company in the US and in Canada, Crop group expansions added
  - Results: registration of CG 03-07, 13-07 B, 13-07G, import tolerance for sweet corn and tropical fruits, and CG expansion for CG 8-10 and 11-10
  - Dietary Risk assessment aligned, MRL/tolerances are harmonized, accomplished in 15 months
  - Challenges: trial differentiation, MRL statistical method for small data set
  - Next step: Evaluation of the process



# Canada/U.S. Regulatory Cooperation Council

## 2. Develop Joint Guidelines for Residue Trials

- Objective that each country/agency accepts the other's review; resulting in concurrent, aligned decisions

## 3. Address Obstacles to Joint Registration

- Eliminate regulatory obstacles preventing the joint submission and registration of pest control product applications into the US and Canada.

## 4. Align Data Collection Processes/Procedures for Residue Trials

- PMC and IR-4 to work together on the alignment of the approach to the generation of residue data so that each country/agency accepts this data.

# International Activities and Collaboration

- Participation in the NAFTA TWG on Pesticides, in the Global Minor Use Summit I and II, in the CODEX meeting, OECD Expert Group on Minor Use forum, OECD IPM Workshop, International IPM Symposium
- Involvement with CABI, US IPM Centres, US IR-4 Biopesticides Program, Biopesticides Industry Alliance
- Memorandum of Understanding (MOU) between AAFC and Brazil.
  - A work plan is being developed to assist ANVISA focussing on project prioritization, data generation and establishing a GLP framework.
- Memorandum of Understanding (MOU) between AAFC and China.
  - Work plan developed to help in the establishment of a Minor Use Program

# Benefits of Harmonization

- For example: Development of a successful Brazilian Minor Use initiative brings economic potential to both countries
  - Future conduct of joint projects; data sharing
  - Determining variabilities in growing zones with respect to pesticide residues helps fast track establishment of harmonized MRLs.
  - Harmonized MRLs opens trade opportunities
  - Work sharing initiatives and joint reviews results in greater efficiencies

# Summary: MRL Harmonization

- At the NAFTA level:
  - Through Canada / US / Mexico Joint Review submissions by companies
  - Through Minor Use Joint Review Initiative implemented by IR-4, PMC, PMRA and EPA
  - RCC
- At the International level:
  - Through the Global Joint Reviews
  - PMC and IR-4 involvement early in the development of new compounds
  - More minor uses attached to the first Tier submission
  - Participation in Global Residue studies

# Elements of a Successful Model

- **Grassroots/business motivate change:**
  - Leadership from private sector to educate, and demonstrate need
- **Policy Decision:**
  - Decision-makers - recognition of public policy need to resolve issue
  - Demonstrate the public benefits increased Government role.
- **Budget:**
  - adequate spending authorities to prioritize, initialize and implement grower-selected solutions.
  - budget is targeted for Minor Use work and regulatory body for evaluation and regulatory decision. (example; PMC and PMRA)
- **Professional Staff**
  - Placement of highly specialized, highly skilled & highly motivated personnel.
- **Identify and utilize partnerships expertise:**
  - Maximize public and non-public sector potential, achieve stakeholder buy-in
- **Tangible Results – linked to Government Strategic Outcomes**
  - Achieving realistic targets, continual re-evaluation of better ways to achieve results
- **Governance / Accountability to stakeholders, taxpayers, AND, partners**
  - Joint Management Committee (example PMC/PMRA/TB)
  - Advisory Committee, Technical Working Groups
- **Outreach** activities/regular dialogue with growers

# Communications

- Website
  - By monthly updates
  - **WEB SITE:**
  - **WWW.AGR.GC.CA/PRRMUP**
- Newsletter
  - Quarterly updates
  - Distributed through List Server and grower organizations
- List Serv
  - Each time a Minor Use project is registered / labelled
  - Each time a Risk Reduction fact sheet is completed / published or a Risk Reduction project is completed
  - **PMC-CLA-L-subscribe-request@www.agr.ca**





# The Way Forward

- Be available to countries who wish to establish MU programs like in the US (IR-4) and in Canada (PMC).
- Increase number of joint projects with IR-4 and other country MU programs.
- Enhance relations with Registrants to encourage partnership early in the development process of new actives for minor uses / specialty crops.
- Continue work under the Regulatory Cooperation Council to facilitate equal access to products and uses in Canada and the US, and align MRLs wherever possible in order to avoid technology gaps
  - Identifying mechanisms to encourage applications for joint reviews that include increased number of minor uses
  - Potential for more Canada/U.S. cooperation on joint work to collect data and evaluate regulatory submissions
- Cooperation with China, Brazil

# THANK YOU!

