



NAFTA Technical Working Group on Pesticides  
Grupo de Trabajo Técnico del TLCAN sobre plaguicidas  
Groupe de travail technique de l'ALENA sur les pesticides

# Overview of PMRA National and International Activities on Biopesticides

Biopesticides Registration Workshop

November, 2001

Washington, DC

Wendy Sexsmith

Chief Registrar

PMRA, Canada

# PMRA: responsibilities

- ◆ regulation of pesticides at national level
- ◆ health and environmental protection, value
- ◆ premarket assessment and registered products, proposing MRLs under Food and Drugs Act
- ◆ compliance
- ◆ sustainable pest management



# Overview: what are we trying to achieve?

- ◆ **Goal: Facilitate Risk Reduction through Improved Access to Reduced Risk Products including microbials and pheromones**
- ◆ **Integrated Review Process**
- ◆ **Expedited review process e.g. specific timelines for all submissions**



# Overview - Goal:

- ◆ Remove regulatory barriers
- ◆ Maintain health and environmental protection
- ◆ Facilitate access to reduced risk products
- ◆ Simultaneous access
- ◆ Facilitate worksharing and exchange of reviews



# Overview - Mechanisms:

- ◆ Mechanism in North America:
  - ❖ NAFTA Technical Working Group on Pesticides
  - ❖ Risk Reduction Subcommittee
  
- ◆ Mechanism in OECD member countries:
  - ❖ OECD Working Group on Pesticides



# Harmonized Approaches:

- ◆ Common approaches to doing business that allow a submission to be accepted for review in another jurisdiction
- ◆ does not mean identical
- ◆ Vision: North American Initiative
  - ❖ Routine Worksharing
  - ❖ North American market



# Harmonized Approaches:

- ◆ Common approaches to:
  - ❖ data requirements and study protocols
  - ❖ submission and review formats
  - ❖ risk assessment
  - ❖ regulatory decision making



# Harmonized Approaches:

- ◆ OECD: Impetus for Work on Biopesticides
  - ❖ 1994 - Ongoing work under NAFTA
  - ❖ 1996 - OECD interest in harmonization of data requirements for microbials and pheromones; develop safer pest control products
  - ❖ 1998 - OECD/FAO IPM workshop recommendation
  - ❖ Risk Reduction Steering Group



# Pheromones: OECD

- ◆ Canada - lead
- ◆ 1994 initiated work on pheromones - US/ Canada work
- ◆ OECD guidance document on data requirements for pheromones to be published July 2001
- ◆ data requirements are 90% harmonized
- ◆ EU will adopt guidance



# Pheromones: Canada

- ◆ PMRA is updating Regulatory Directive 97-02 (Guidelines for Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals)
- ◆ incorporating input from 1999 OECD pheromone workshop held in Ottawa
- ◆ will be published as a proposal in late 2001



# Microbials: OECD

- ◆ Building on U.S./Canada work
- ◆ OECD guidance document on data requirements to be published in late 2001
- ◆ 80% harmonized



# Microbials: Canada

- ◆ New PMRA Regulatory Directive replaces 1998 proposal
- ◆ Directive published March 2001
- ◆ Essentially harmonized with U.S. EPA requirements



# OECD: Next Steps

- ◆ OECD Biopesticides Steering Group - Canada is Chair
- ◆ work on universal dossier and monograph initiated for pheromones and microbials
- ◆ share information on registrations/possible future worksharing
- ◆ review status of data requirements in 3 years and coordinate other related work



# NAFTA: TWG Partners

- ◆ CICOPPLAFEST (consortium of Mexican agencies)
- ◆ EPA (Office of Pesticide Programs)
- ◆ PMRA (Health Canada)



# NAFTA: Ultimate Goal

- ◆ A North American market for pesticides
- ◆ Routine joint reviews and work sharing



# Risk Reduction Subcommittee

## ◆ Subcommittee co-chairs:

- ◆ Janet Andersen, USA
- ◆ Wendy Sexsmith, Canada
- ◆ Rosio Alatorre, Mexico

## ◆ Work on Biopesticides is situated in this subcommittee



# Vision for Future:

- ◆ Single submission for North America - operational; closer links with Europe
- ◆ simultaneous access to pesticide products
- ◆ increased efficiency, better use of existing resources



# Report on Progress:

## ◆ Joint Review Products Registered:

- ❖ Pheromone: Bedoukian/3M 9-dodecenyl acetate MEC for Eastern Pine Shoot Borer - Forestry, July 1999
- ❖ Microbial: BioTepp *Cydia pomonella* GV, Virosoft CP4 for codling moth on apples, July 2000



# Report on Progress:

## ◆ JR Products under Review:

- ❖ BioTepp *Mamestra configurata* npv, Virosoft BA3 for bertha army worm on canola
- ❖ Plant Products *Pseudozyma flocculosa* Sporodex WP biological fungicide for Powdery mildew on greenhouse roses and English cucumbers
- ❖ Mycologics *Chondrostereum* bioherbicide for hardwood control



# Report on Progress

- ◆ many others in presubmission stage
- ◆ pilot second entry pheromone being considered
- ◆ looking for pilot Joint Review for biochemical



# Report on Progress:

- ◆ URMUR (User Requested Minor Use Registration) products registered in Canada using foreign reviews (12 month review):
  - ❖ 3M/ Bedoukian pheromone for black headed fireworm/cranberries
  - ❖ Kemira Mycostop biofungicide
  - ❖ 1 +2 microbial and 1+1 pheromone in system



# Achievements:

- ◆ Universal dossier and monograph initiated for pheromones and microbials through OECD
- ◆ pilot OECD microbial dossier submission
- ◆ progress on NAFTA label for biopesticides
- ◆ JR program (microbials -12 months for review and pheromones - 6 months for review/under consideration) is operational



# Achievements (cont'd):

- ◆ Revised procedures to be published shortly
- ◆ New active ingredient and complete data base; presubmission consultation
- ◆ exchange of reviews/worksharing ongoing/URMUR



# Achievements (cont'd):

- ◆ Harmonize data requirements and guidelines:
  - ❖ data requirements for registration harmonized for pheromones and microbials
  - ❖ test guidelines harmonized for pheromones and microbials - Canada accepts U.S. test guidelines



# Achievements (cont'd):

- ◆ 22 microbial and pheromone products registered in Canada in 2000-2001
- ◆ 35 microbial and pheromone products currently in the system



# Next Steps

- ◆ further harmonization activity
- ◆ pilots
- ◆ label
- ◆ OECD formats
- ◆ closer links with EU
- ◆ always...improve communication



# Summary:

- ◆ Countries are working together in the area of pesticide regulatory harmonization for biopesticides and risk reduction
- ◆ harmonization is working - most of Canada's new microbials are coming in through the JR process



# Main Websites:

## ◆ PMRA Site:

❖ <http://www.hc-sc.gc.ca/pmra-arla>

## ◆ EPA Site:

❖ <http://www.epa.gov>

## ◆ OECD Site:

❖ <http://www.oecd.org>

