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# Overview of Biopesticide Regulation in Canada

**Canadian Fertilizer Products Forum**

**October 14, 2009**

**Ottawa**

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Canada



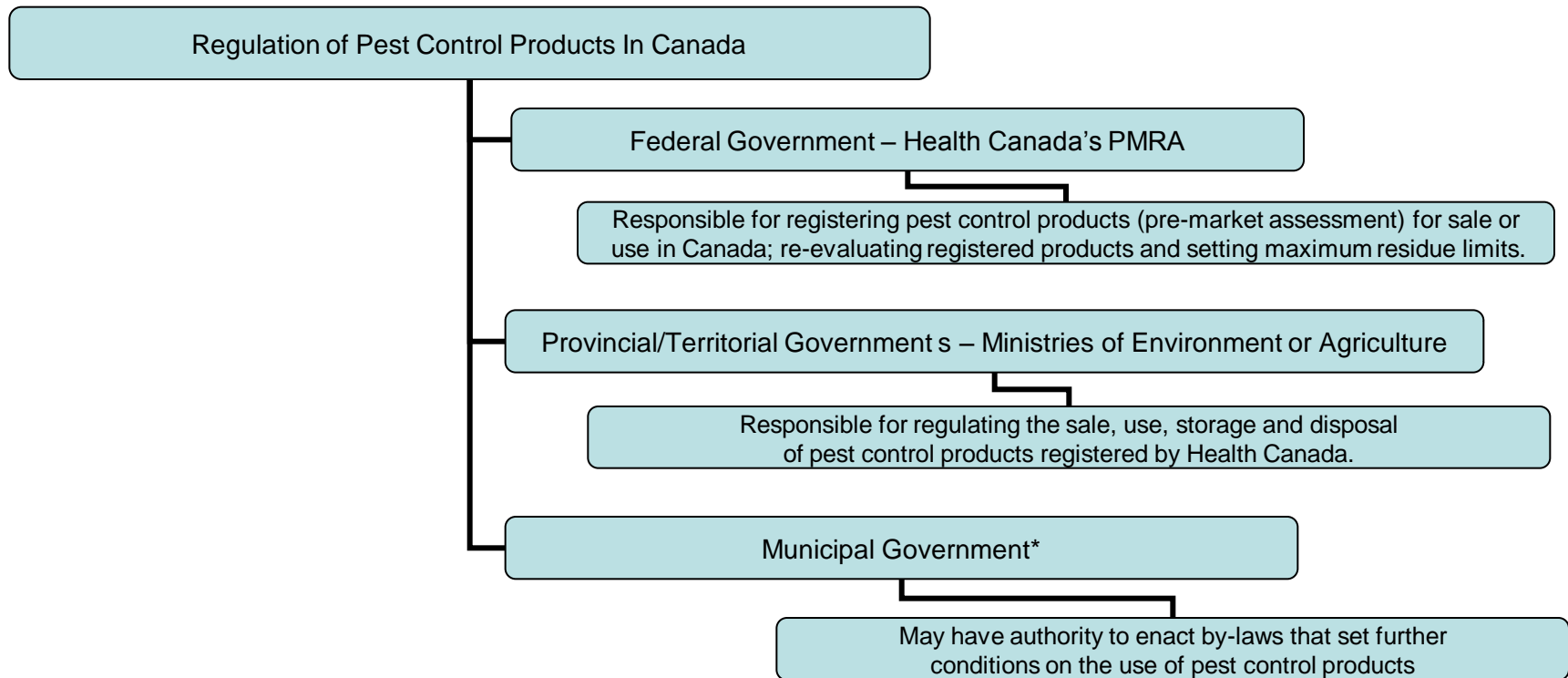
## Scope of Presentation

- PMRA mandate under the Pest Control Products Act
- PMRA structure and pesticide regulatory system
- Regulating biopesticides
- Perspectives on microbial pesticides – safety and efficacy testing/information requirements
- Pesticide-Fertilizer (Supplement) – the dual claim regulatory challenge





# Regulation of Pest Control Products in Canada





## ***Pest Control Products Act (PCPA)***

- PMRA's mandate is to administer the *PCPA* which regulates products that are manufactured, or used as a means for directly or indirectly controlling, destroying, attracting/repelling a pest for mitigating or preventing its injurious, noxious or troublesome effects [s. 2(1)]
- In accordance with the *Pesticide Residue Compensation Act* (PRCA) and the *Food and Drug Act* (FDA)
- Prevent unacceptable risks to people and the environment from the use of pest control products [s. 4(1)]
  - “acceptable”: reasonable certainty that no harm to human health, future generations, or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration





## ***Pest Control Products Act (PCPA)***

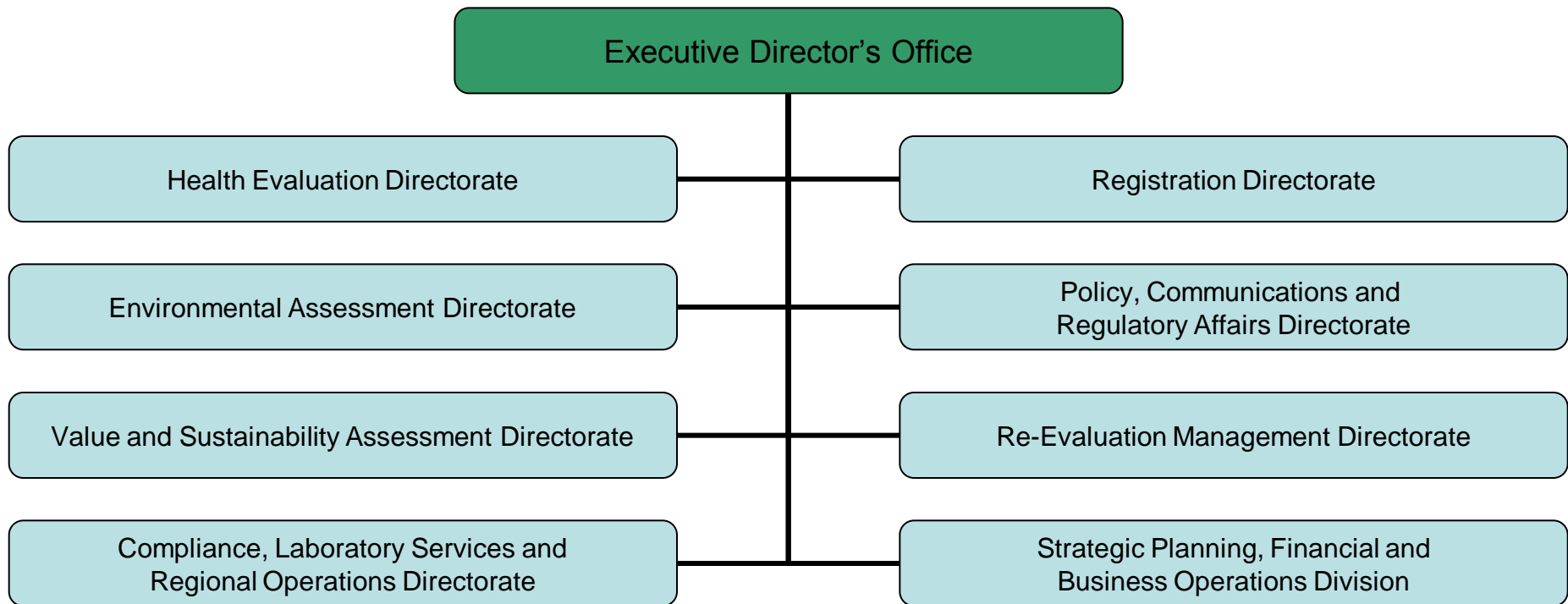
### **Types of Pest Control Products:**

- A product; e.g., trapping device
- A substance; e.g., chemical, biochemical
- An organism; e.g., microbial agents, including bacteria, fungi, viruses
- A product/organism/substance derived through biotechnology





## Pest Management Regulatory Agency





## Health Evaluation Directorate

- Human health risk assessments
  - Toxicological hazard, including infectivity/pathogenicity for microbials
  - Dietary/food residue exposure
  - Occupational/bystander exposure
  - Establish Maximum Residue Limits (not generally for microbials and biochemicals)
- Incident reporting
- Science policy development





## Environmental Assessment Directorate

- Evaluates data on the environmental toxicology of products, as well as their environmental fate
  - Microbial pesticides are evaluated by HED, but EAD retains authority and responsibility for environmental risk assessments
- Provides expertise on environmental hazards, risk assessments and risk mitigation
- Science policy development





## Value and Sustainability Assessment Directorate

- Value assessments (efficacy, crop tolerance, benefits, resistance management, etc.)
- Use information in marketplace
- Risk reduction and transition strategies development (IPM, SPM)





## Overview Of Submission Process

- Receipt, verification, and screening
  - Loading into databases
  - Required elements addressed and adequate
    - Cover letter
    - Application
    - Specification forms, fees
    - Letters of access
    - Labels
    - Data, rationales, waiver requests
    - Verify purpose and category, precedents?
  - Deficiencies?





## Overview Of Submission Process (cont'd)

- Preliminary Review
  - Forward to review divisions (if necessary) for preliminary review
    - Conditionally required elements
    - Study acceptability
    - Value and chemistry reviews done early
    - Deficiencies
- Evaluation
  - Reviews and peer reviews of all disciplines
  - Risk assessments and label statements verified/revised
  - Coordination, integration of science assessments, labels
  - Regulatory document preparation (final reviews, consultation documents)





## Overview Of Submission Process (cont'd)

- Decision-Making and Certificates
  - SMC for new actives (major new uses); emergency requests
  - Value, risk and risk management considerations





# Reduced-Risk Initiative

- Defines “reduced-risk” pesticides and “biopesticides”
- R-R designation granted to actives given such status by the U.S. EPA following select criteria and rationales
- Adopts a definition for biopesticide that is consistent with that of U.S. EPA
  - Microbials, pheromones (SCLPs, Non-SCLPs), biochemicals
  - Does not include transgenic plants (regulated in Canada under Seeds Act by Canadian Food Inspection Agency)



## Regulatory Directive

DIR2002-02

### The PMRA Initiative for Reduced-Risk Pesticides

The purpose of this regulatory directive is to inform applicants, provinces and territories, user groups, and other interested parties that the North American Free Trade Agreement (NAFTA) Joint Review Programs for Reduced-Risk Pesticides will be extended by the Pest Management Regulatory Agency (PMRA) to include submissions made to the PMRA only. The program is designed to encourage pesticide manufacturers to apply for Canadian registration of reduced-risk products that are currently available in the United States (U.S.) Canada will use the same criteria as the U.S. Environmental Protection Agency (EPA) to determine eligibility of chemicals for the reduced-risk program and recognize the U.S. EPA's biopesticide designation, thus further harmonizing the approaches between the two countries. Through this program, the PMRA will also commit to shorter review timelines for products that have been shown to qualify as a reduced-risk chemical or biopesticide.

The reduced-risk or biopesticide designation does not mean reduced from normal data requirements or no data requirements. In addition, any product submission with a reduced-risk or biopesticide designation will undergo a thorough evaluation and risk assessment. The expedited review times given to reduced-risk products will not compromise Canadian safety standards in any way. As with all pesticides, registration will only be considered if the proposed product meets current health and environmental safety standards..

*(publié aussi en français)*

May 31, 2002

This document is published by the Submission Coordination and Documentation Division, Pest Management Regulatory Agency. For further information, please contact:

Publications Coordinator  
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# Reduced-Risk Initiative

- Establishes expedited review timelines for major submission categories (e.g., new and major amendments, label expansions, etc.)
  - New actives: 12 mos. (MPCAs); 6 mos. (SCLPs); 15 mos. (other)
  - 5-6 mos. (MPCAs, PHEs) or 10 mos. (other) for minor use label expansions within existing registered categories
- Further reduction in performance standards possible for EPA-registered products with complete data bases and available EPA reviews (DERs, etc.)



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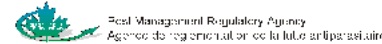
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# Microbials

- Data requirements harmonized with U.S. EPA's for new actives and associated end-use products
- Tiered data requirements covering product characterization, human health, environment and value (efficacy)
- Exempt from cost-recovery fees
- Accept EPA, OECD formatted submissions
- No barriers to working together with EPA's Biopesticides and Pollution Prevention Division on NAFTA Joint Reviews
  - Conducted 6 NAFTA Joint Reviews with harmonized risk assessments and decisions, and numerous joint pre-submission meetings with prospective applicants; currently conducting 2 NAFTA JRs



## Regulatory Directive

DIR2001-02

### Guidelines for the Registration of Microbial Pest Control Agents and Products

This directive outlines the requirements for the registration of microbial pest control agents and products proposed for pest management in Canada at this time. The Canadian data requirements are essentially harmonized with the United States Environmental Protection Agency. Microbial pest control agents are naturally occurring or genetically modified microorganisms, including bacteria, algae, fungi, protozoa, viruses, mycoplasmae or rickettsiae, and related organisms.

Several regulatory proposals, including PRO98-01, *Guidelines for the Registration of Microbial Pest Control Agents and Products*, dated January 30, 1998 and PRO93-05, *Research Permit Guidelines for Microbial Pest Control Agents*, dated November 25, 1993, invited comments on proposed registration requirements for microbial pest control agents. Approximately 65 detailed comments on PRO93-05 were received from interested parties in the biotechnology, agri-food and forestry sectors, and eight comments were received on PRO98-01 and incorporated as appropriate.

(publié aussi en français)

March 30, 2001

This document is published by the Submission Management and Information Division, Pest Management Regulatory Agency. For further information, please contact:

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## New Guidelines for Biochemicals and other Non-Conventionals

- *Guidelines for the Registration of Biochemicals and Other Non-Conventional Pest Control Products* will be published this winter, replacing PRO2007-02
- Streamlined registration process for a wide range of non-conventional pesticides, including biochemicals, plant oils and extracts, commodity chemicals, devices
- Products included under reduced-risk initiative
- Characteristics of biochemical pesticides defined and very similar to U.S. EPA's definition

Regulatory Proposal

PRO2007-02

### Guidelines for the Registration of Low-Risk Biochemicals and Other Non-Conventional Pesticides

This Regulatory Proposal outlines the requirements being proposed by Health Canada's Pest Management Regulatory Agency (PMRA) for registering low-risk biochemicals and other non-conventional pesticides.

This proposal is being distributed for information and comment. Please review this document and provide your written comments within 60 days of the date of publication of this Regulatory Proposal to Publications.

(publié aussi en français)

1 October 2007

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## New Guidelines for Biochemicals and other Non-Conventionals

- Tiered information requirements for human health and environmental fate and effects (similar to U.S. EPA 40 CFR 158 & 172, Data Requirements for Biochemical Pesticides, Subpart U, 2006)
- Lays out submission process
- Review timelines (12-15 months)
- Cost-recovery fees (not all products exempted, but fee reductions possible)
- Regulatory Directive finalized; no change in data/information requirements

Regulatory Proposal

PRO2007-02

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## The Value Data Package (Part 10)

- **Product label**
- **Efficacy and value report**
  - **Mode of action**
  - **Description of the pest problem**
  - **Efficacy trials (use pattern; appropriate rates; adequate disease pressure)**
  - **Non-safety adverse effects**
  - **Contribution to sustainability (IPM; resistance management)**
- **Efficacy Summary Table**
  - **Spreadsheet format**
  - **Required information (pathogen; rate; number of applications; assessment parameters; etc.)**
  - **Templates available**





## Value data package: Challenging issues

### Use pattern

- many crops
- use of blanket claims

### Mode of action

- Usually very general information provided
- Detailed information required related to type of claim, e.g., SAR, competition, antibiosis, parasitism

### Use of scientific rationales

- Applicability of trial conditions to Canadian conditions
- Extrapolations across crops and pests





## Value data package: Challenging issues

### Performance claims

- Use standard product claim (control, suppression, partial suppression)
- Short term vs. long term effects

### Efficacy trials

- Variability in performance
- Many formulations tested
- Lack of standardization between trials
- Various assessment parameters
- Wide rate spectrum





# Solutions

## Effective rate vs. Lowest Effective Rate

- Dose response, lab data

## Level of performance

- Base level
- Benefit to the users
- Define new types of claims

## Better use of rationales

## Improved guidance to registrants to provide pertinent background information on commercial expectations





# Solutions

## Pre-submission consultations

- Essential for smaller companies
- Improves submission quality
- Allows for discussion of appropriate performance standard
- Manage expectations

## Develop efficacy guidelines for biopesticides

- Rationale
- Extrapolation
- New performance claim definitions
- Long term effect





## PMRA-CFIA Regulatory Overlaps

### Multi-ingredient products with dual claims

- Products containing two or more ingredients with distinct functions subject to regulation under the *Pest Control Products Act* and *Fertilizers Act*.
  - Fertilizer-pesticides (e.g., combination products for lawn and turf uses; PMRA intends to uncouple)
  - Supplement-pesticides (e.g., Wilson Roots Liquid Root Stimulator with Fungicide)
- CFIA and PMRA exploring regulatory options on dual claims and submission file/information sharing





## PMRA-CFIA Regulatory Overlaps

### Single ingredient products with dual claims

- Products consisting of a single ingredient (either chemical or microbial) that exhibits dual activity are subject to regulation under the PCPA and FA
  - (a) Pesticide and a Fertilizer
    - Corn gluten meal
    - Salts of phosphorus acid
  - (b) Pesticide and a Supplement
    - Gibberellic acid
    - *Bacillus subtilis* strains for disease control and plant growth promotion
- PMRA and CFIA exploring options to allow dual claims on a single product label; file/information sharing; workshare/joint reviews to facilitate dual/simultaneous registrations under PCPA and FA





- Questions?
- Comments

