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

Biopesticides Registration Improvement Course

Overview of Health Canada's PMRA Biopesticide Regulatory Activities

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Health
Canada

Santé
Canada



Presentation Overview

- PMRA introduction
- PMRA Mandate and Legislative Framework
- Reduced risk pesticides and Biopesticides
- Directives and Proposals
- Overview Of Submission & Decision Making Process
- Facilitating Pesticide Risk Reduction



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Pest Management Regulatory Agency





Health Canada PMRA - Mandate

- Primary objective under the *Pest Control Products Act (PCPA)* PCPA is to prevent unacceptable risks to people and the environment from the use of pest control products [s. 4(1)]
- Other objectives of the *PCPA* include:
 - Ensure that pest control products have acceptable value
 - Support sustainable pest management
 - Facilitate access to pest control products, especially those which support lower risk
 - Encourage public awareness of pest control products



Pest Control Products Act (PCPA)

- PCPA commits the PMRA to support pesticide risk reduction
 - **Increased** efforts to support sustainable pest management practices
 - **Facilitating** the registration of lower risk products
 - **Supporting** Canadian pesticide users in gaining quicker access to newer, safer pesticides so they can be competitive in international markets



Reduced-Risk and Biopesticides

- PMRA adopts a definition for biopesticide that is consistent with that of U.S. EPA*
- Does not include transgenic plants (regulated in Canada under Seeds Act by Canadian Food Inspection Agency)
- Establishes shortened review timelines for major submission categories (e.g., new and major amendments, label expansions, etc.)*
- Further reduction in performance timelines may be possible for EPA-registered products with complete data bases and available EPA reviews (DERs, etc.)*

* Taken from *The PMRA Initiative for Reduced-Risk Pesticides*
– DIR2002-02, May 31, 2002



Microbials

- *Guidelines for the Registration of Microbial Pest Control Agents & Products*
 - DIR2001-02, March 30, 2001
- 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 most cost-recovery application fees
- Accept EPA, OECD formatted submissions
- Working together with EPA's Biopesticides and Pollution Prevention Division on Joint Reviews



Pheromones/Semiochemicals

- *Guidelines for the Research & Registration of Pest Control Products Containing Pheromones & Other Semiochemicals*
 - PRO2002-02, September 25, 2002
- Harmonized with U.S. EPA data requirements in 40CFR158 Subpart U (biochemicals)
- Exempt from most cost-recovery application fees
- Will be updated in the near future
- Some regulatory challenges still to be resolved and will be addressed, e.g., arthropod traps used for mass trapping
- 12-15 month registration review timeline for Non-SCLPs; 6 mos. for SCLPs



Non Conventional Pest Control Products

- *Guidelines for the Registration of Non Conventional Pest Control Products*
 - PRO2010-06, October 28, 2010
- Approach recognizes these products may not fit well into a registration framework that was developed for conventional pesticides with well-defined chemistries and molecular structures
- The varied nature of these types of products can make it challenging:
 - to define a specific mode of action
 - to identify the active components of a mixture or
 - to delineate a specific level of efficacy/value
- Regulatory approach of products with favourable risk profiles that is based on innovative and flexible approaches to assessing:
 - whether they pose any unacceptable risks to human health or the environment
 - whether they have value



New Approach to Value

- *Value Guidance – Benefit Information and Use History*
 - Regulatory Proposal PRO2010-07, November 17, 2010
- More flexible approach to fulfill the value requirements for registration of pest control products
- New approach aims to facilitate access to new and effective crop protection tools
- Information other than the efficacy may be used to determine acceptable value for the purpose of the registration of a pest control product
 - may include evidence of a product's use history in another country as well as analysis of the potential benefits of a product



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Overview Of Submission & Decision Making Process

- Receipt via eSubmission, verification, and screening
 - Required elements addressed and adequate
- Preliminary Review
 - Study acceptability and deficiencies determined
- Evaluation
 - Reviews and peer reviews of all disciplines
 - Risk assessments and label statements verified/revised
- Decision-Making and Certificates
 - Science Management Committee makes final decisions on registration of new active ingredients as well as major new uses of existing registered actives; emergency registration requests
 - Value, risk and risk management considerations (establish conditions of registration, risk mitigation measures, etc.)
 - Public consultation on decisions for new active ingredients and major new uses
 - Label Verification/Registration Certificate issued



Working with Stakeholders to Facilitate Pesticide Risk Reduction

- Facilitate access to lower risk pesticides and the strategic development of pest control tool boxes that include a variety of options that allow for IPM to be implemented
- Support PMRA's mandate to reduce the risk associated with pesticides, and in doing so:
 - Support the Canadian user and commodity groups
 - Provide support internal activities



Areas of Focus for PMRA Risk Reduction Program

- Strategy Development
 - **PMRA/Agriculture & Agri-Food Canada (AAFC)
Pesticide Risk Reduction Program**
 - **Increasing the Availability and Adoption of
Biopesticides**
 - Transition Strategies to replace products lost through re-evaluation
 - Risk Reduction Strategies for Non-Agriculture sectors
- Resource for PMRA staff, user groups, registrants and academia



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PMRA/AAFC Joint Pesticide Risk Reduction Program

- Joint initiative between
 - Pest Management Regulatory Agency, Health Canada
 - Pest Management Centre, Agriculture and Agri-Food Canada
- **Focus** on working collaboratively with AAFC to reduce the risk associated with the use of agricultural & ornamental pesticides by providing pesticide regulatory support in complement to the research support and focus of alternative practices provided by AAFC
- **External Engagement:** Work in partnership with AAFC and commodity stakeholders in the identification of lower risk and biopesticide options, identification of stakeholder priorities, development of Crop Profiles and pest strategy documents, preparation for pre-submission consultation meetings and research authorization applications, etc.



Biopesticides Program

- Project under NAFTA
- **Goals:**
 - Identify existing trade irritants and unilateral registration of biopesticides
 - Promote registration through joint review, work share and other regulatory processes (*e.g.* minor use registrations)
 - Identify and pursue opportunities to increase biopesticide adoption by users
- **Focus** on supporting the submission of registration applications and adoption of biopesticides by users
- **External Engagement:** Support and collaborate with user group stakeholders, registrants and AAFC through the identification of biopesticide options, pre-submission consultations, biopesticide efficacy and adoption trial design and applications for registration



Questions?



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