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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

Value Assessment: Data requirements and the new value approach

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Health
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Canada



Value of biopesticides

- Product's actual or potential contribution to pest management
- Considers efficacy, effect on host organisms, health, safety and environmental benefits, social and economic impact



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Biopesticide regulation in Canada

- Information requirements and assessment efforts commensurate with expected level of risk
- Development and implementation of innovative, flexible, weight-of-evidence approaches to health, environment and value assessments



Value

- Efficacy
- Non-Safety Adverse Effects
- Contribution to Sustainability
- Health, Safety and Environmental Benefits
- Social and Economic Impact



Value approach

- Considers information other than trial reports
- Leverage experience gained in other countries
- Consists of use history information and benefit analysis
- Applicable to most pesticide uses except those that directly relate to public health
- Decisions made on weight of evidence approach



Types of efficacy information

- Efficacy trial data
- Use history in a foreign jurisdiction



Use History

- Information from foreign jurisdictions indicating acceptable efficacy and crop safety
- Valuable in situations where efficacy and crop safety data are insufficient or on occasion, unavailable
- May reduce, supplement or, in some cases replace efficacy trials



Use history information may be used if:

- Product/use fully registered in a country with comparable pesticide regulatory system
- Proposed uses in Canada and foreign jurisdiction are comparable
- Product is used under commercial conditions
- Level of performance of the product can be documented



Use History Information: Components

- Comparison of use pattern
 - Formulation, application rate, application timing, number of applications
 - Conditions of use
 - * how often the product is recommended
 - * level of user adoption (% crop treated)
 - * estimates of crop injury or product failure
 - * performance level (control, suppression, etc.)



Use History Information: Components

- Use history analysis
 - To be provided by technical experts
 - Explains experience and familiarity with the product
 - Describes use pattern and level of adoption by users
 - Provides observed level of performance and how it meets user expectations
 - Discusses product's contribution to pest management



Use History Information: Components

- Additional information and rationales
 - Product failure reports
 - Remedial actions or changes to use directions
 - Market information (product adoption and sales)
 - Rationale to explain differences in use pattern



Benefit Analysis

- Explains why the proposed use is needed
- Explains how and to what extent registration of the proposed use will benefit Canadian users
- Type of information and level of detail required will vary



- What is the benefit of the proposed use?
 - Control of pests causing widespread or sporadic damage
 - Limitations in existing methods of control such as duration of control, conditions of use (long REI)
 - Need for alternatives to support resistance management
 - Need for alternatives to replace older actives being phased out



When should use history and benefit information be submitted?

- Efficacy and non-safety adverse data insufficient or not available
- Useful for providing context to support a regulatory decision
- Include under DACO 10.1 Value summary



Resources: value approach

- PRO2010-07, Regulatory Proposal, Value Guidance – Benefit Information and Use History



Questions?



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