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Value Assessment of Biopesticides – Use History and Consideration of Benefits

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Scope of Presentation

- PMRA's approach to value assessment of biopesticides
- Use History
- Consideration of Benefits
- Helpful Tips
- Pre-submission Consultation





Pest Control Products Act (PCPA)

Prevent unacceptable risks to people and the environment from the use of pest control products

- 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





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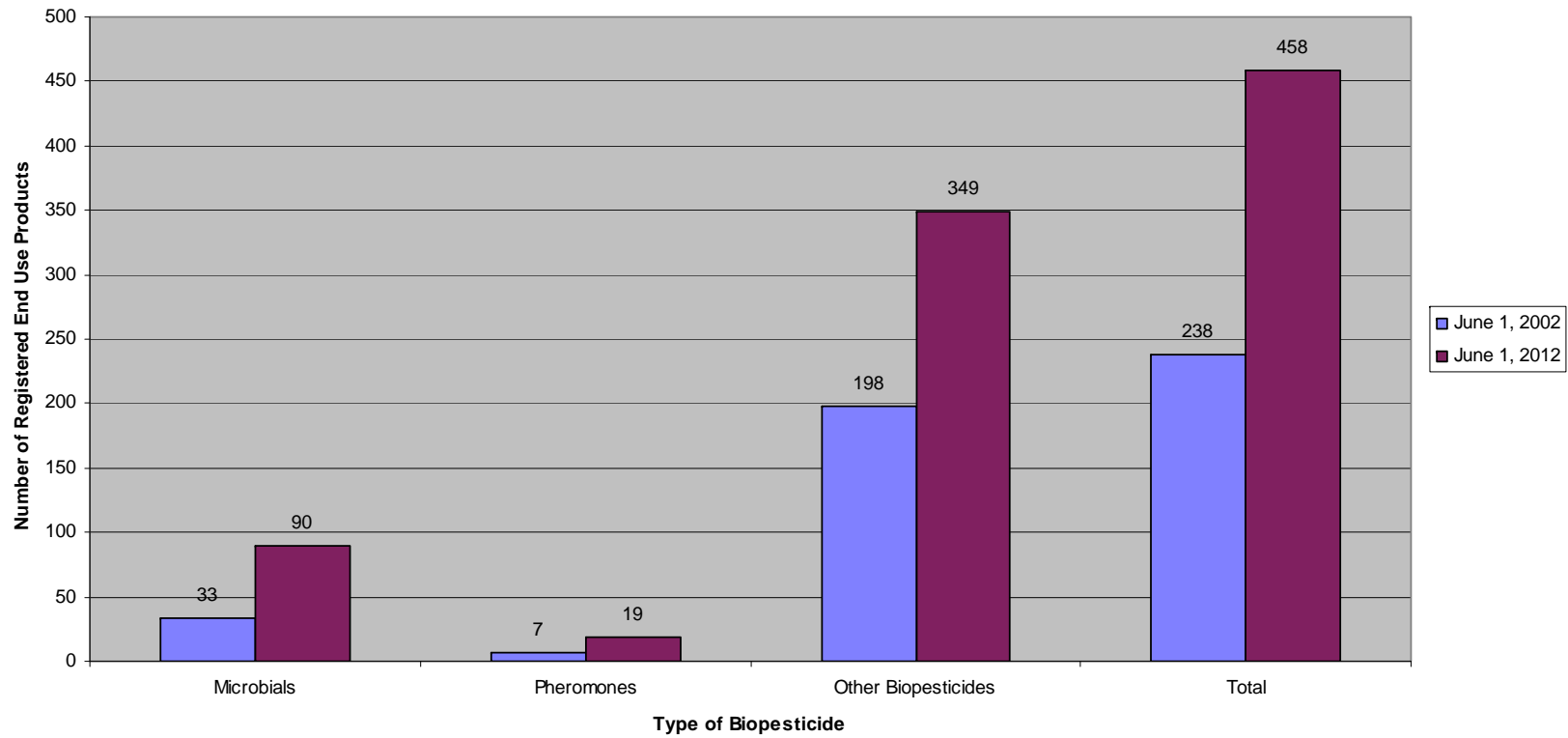
Pest Control Products Act (PCPA)

“...only pest control products that are determined to be of acceptable value are approved for use in Canada.”





Number of Biopesticide End Use Products Registered as of June 1, 2002 and June 1, 2012 (Microbials, Pheromones, Other Biopesticides Including Non-Conventionals Except for Devices)





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





Biopesticide regulation in Canada

- Reduced data requirements
- Shorter review timelines
- May be exempt from cost-recovery fees
- EPA, OECD formatted applications are acceptable





Traditional Assessment of Value

- Efficacy and Crop Tolerance
 - Data from trials, rationales for extrapolation
 - Use of foreign data
 - Generally case by case : need to address factors affecting performance (e.g. climate, soil, pest susceptibility, etc.)





Current Approach to Value

- Broader definition of value
- More flexible approach to fulfill data requirements
- Several possible sources of information
- Weight of evidence approach
- Facilitate access to new and effective tools





Value assessment of biopesticides

- Includes assessment of a product's
 - Efficacy
 - Effect on host organisms (a.k.a. host and rotational crop tolerance)
 - Compatibility with current management practices
 - Contribution to resistance management
 - Social and economic impact
 - Health, safety and environmental benefits





What does “value” mean?

- Does it work? → Efficacy
- Is there a potential for phytotoxicity? → Non-safety Adverse Effects
- Are there other advantages from the proposed use? → Consideration of Benefits





What types of information can be provided to demonstrate that the product works?

- Efficacy trials
- Use History
- Scientific Rationales
- Published scientific papers
- Other

A combination of these types of information may be submitted.





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Efficacy : Is there evidence that shows the product will work as stated on the label?





Efficacy Trials

- Appropriate treatments that reflect the proposed use pattern
 - Application rate/s
 - Crop/site
 - Test product and commercial standard
 - Controls
 - Application interval
 - Number of applications
 - Application method





Efficacy Trials, continued

- Appropriate assessment parameter/s
- Appropriate statistical analysis of trial results
- Adequate pest pressure
- Sufficient number of trials for consistency of results
- Sufficient information on non-safety adverse effects
- Efficacy Summary Table
- Information on mode of action
- Justification for the proposed rate





Use History

- May be used to define the use pattern when efficacy database is not complete or unavailable.
- Particularly useful for label expansions.
- Consider for uses and active ingredients that have been registered in a foreign country.
- Intent is to leverage the experience of commercial use in other countries.





When is use history information appropriate?

- Proposed use is currently registered and adopted in a country with a pesticide regulatory system broadly comparable to Canada (eg. OECD)
- Little or no efficacy and crop tolerance data available to support the proposed use in Canada
- Scientific rationale is not appropriate as there is no basis on which to form a scientific argument





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What are the components of use history information?

- Comparison of proposed use pattern with the use pattern registered in a foreign jurisdiction (Table 1)
- Information on acceptable efficacy and crop safety (Table 2)
- Validation statement from technical expert/s (Table 3)





Agricultural Use History Template

Table 1. Comparison of the proposed and foreign registered use pattern

	Proposed Canadian Use	Foreign Registered Use ¹	Related Canadian Registered Use ²
Active ingredient			
Product			
Formulation type			
Guarantee			
Host/Crop			
Pest			
Rate (g ai/ha or g ai/1000 L water)			
Spray Volume (L/ha)			
Adjuvant (name & rate)			
Number of applications			
Timing of Application			
Re-application interval			
Application method (broadcast, aerial, directed)			
How long has the use been registered			

¹ Provide a copy of the foreign registered label in PDF format.

² If available, provide details of a Canadian registered use pattern(s) that is/are related to the proposed pattern.

³ As expressed for greenhouse and ornamental uses.





Table 1. Comparison of proposed and foreign registered use pattern: Important elements

- Active ingredient
- Product name
- Formulation type
- Guarantee
- Host/Crop
- Pest
- Application rate
(g ai/ha or g ai/1000 L)
- Spray Volume
- Adjuvant (name and rate)
- Number of applications
- Timing of applications
- Re-application interval
- Application method
- How long the use has been registered





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Table 1. Comparison of proposed and foreign registered use pattern (continued)

- Complete required information in the appropriate columns in Table 1
- Include information on related use if product is registered in Canada
- Address any differences between the proposed use pattern and the foreign registered use pattern
- Provide copy of the foreign label (pdf format)





Table 2. Crop tolerance and efficacy considerations (if more space required, attach a separate sheet)

Author: Name: _____
 Title: _____
 Contact Information (p hone and email): _____

Describe the context of the use history information	Describe the efficacy and/or crop tolerance of this product as observed in a scenario related to the proposed use:	
	Efficacy	Crop tolerance
1. Describe the use pattern and application scenario (e.g., rate, crop, number of applications, etc.)		
2. What is the level of a) control (efficacy) and b) crop tolerance (adverse effects)? If adverse effects are noted, please outline the conditions (e.g. high than normal temperatures, excessive rain fall)		
3. Is the level of control or crop tolerance consistent?		
4. Does it meet expectations?		
5. How does it compare with industry standards or untreated controls?		
6. Over what period of time are effects of the treatment observable (e.g., days or weeks)?		
7. Geographic range of use (e.g., across multiple northern states)		
To what level has industry adopted this product? If there has been little adoption, why not?		
Contribution to pest management systems?		
Additional information		





Table 2. Crop tolerance and efficacy considerations

- Provides a record of experience with the product relating to efficacy and crop tolerance
- Information will contribute to weight of evidence for the proposed use
- Rationales required if there are deviations from proposed use (e.g. different crop, different rate, etc.)





Table 2. Crop tolerance and efficacy considerations: Important elements

- Author, title and contact information
- Context of use history information
- Description of product efficacy and crop tolerance
 - Use pattern
 - Level of control
 - Non-safety adverse effects (phytotoxicity)
 - Consistency of pest control or phytotoxic reactions
 - Industry expectations regarding pest control
 - Comparison with industry standards or untreated controls





Table 2. Crop tolerance and efficacy considerations : Important elements

- Description of product efficacy and crop tolerance (continued)
 - Period of time effects of the treatment are observed (days, weeks, etc.)
 - Geographic range of use
- Level of adoption by industry
- Contribution to pest management systems
- Additional Information





Table 3. Use history validation information

Identification:	Name	
	Title	
	Contact information (phone and email)	
Do you agree with the observations identified in Table 2 regarding the use history of this product? If not, why?		
What is your experience with the end-use product/active ingredient – have you used the product yourself or directly observed its use?		
How many times have you observed the efficacy and/or crop tolerance of this product?		
What is your experience with the commodity and production system (why do you consider yourself qualified to validate the use history)?		

¹This row is required ONLY when the validator (author of Table 3) is different from the author of Table 2





Table 3. Use history validation

- To be completed by individual with direct experience with the foreign registered use
- Confirms information provided in Table 2
- Technical experts – extension personnel, university researchers, agricultural department officials-should clearly identify their experience with the product





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Important!

- Summarize the use history information in the Value Summary document





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Are there additional advantages that could result from the proposed use?

- Consideration of benefits an integral part of the value assessment
- Explain why the proposed use is needed
- Explain how and to what extent registration of the proposed use will benefit Canadian users
- Type of information and level of detail will vary





Consideration of Benefits

- Important elements
 - Survey of alternatives
 - Compatibility with current management practices, Including IPM
 - Resistance management
 - Social and economic impact
 - Health, safety and environmental benefits





Consideration of Benefits: Survey of Alternatives

- List of currently registered products registered for the proposed use
- Important to denote which are conventional pesticides and non-conventional pesticides
- Useful to identify those that can be used for organic production





Consideration of Benefits: Compatibility with Current Management Practices

- Describe how proposed use can be integrated into the crop production system
- Describe its role as a component of an integrated pest management system
- Operational trials, when available, could be useful
- Studies demonstrating pesticide spray programs





Consideration of Benefits: Resistance Management

- Describe how proposed use contributes to resistance management
- New mode of action (rotational partner/tank mix partner)
- Reports of resistance to the active ingredient
- Baseline sensitivity and resistance monitoring results, where available

Analysis of resistance risk is an integral part of the value assessment!





Consideration of Benefits: Social and Economic Impact

- Describe economic impact of proposed use
 - Crop losses attributable to pest
 - Effects of marketability of the crop
 - Cost-benefit analysis of pesticide application/s
 - Reduction of additional crop production costs (e.g. drying costs for grain)
 - Proposed use identified as a priority in the Canadian Grower Priority Database or at the Canadian Minor Use Priority Setting Workshop
 - Potential to replace a use proposed for phase out





Consideration of Benefits: Health, Safety and Environmental Benefits

- Examples of benefits
 - Controls a toxic plant (e.g. giant hogweed)
 - Manages a plant disease harmful to humans or animals (e.g. ergot, fusarium head blight)
 - Controls an invasive species
 - Addresses limitations in existing methods of control (duration of control; conditions of use- long REI)
 - Alternative to active ingredient being phased out
 - Alternative mode of action for resistance management





Scientific Rationales

- Science-based explanation for a proposed use when no efficacy trials or use history information is provided
- Useful for extrapolation of uses
- List of crops is required for crop group extrapolation





Helpful Tips

- ✓ Request for a pre-submission consultation
 - Improves submission quality
 - Allows for discussion of appropriate assessment parameters
 - Manage expectations
- ✓ Identify the biopesticide's intended uses and design appropriate trials
- ✓ Make effective use of scientific rationales and use history information
- ✓ Include appropriate benefit information
- ✓ Consult appropriate guidelines and directives
- ✓ Communicate with the PMRA





What is required for a pre-submission consultation?

- Proposed product label
- Information relevant to the applicant's questions on the value data requirements (e.g. trial protocols)
- List of questions regarding the value assessment





Relevant Documents

- DIR 2001-02, Guidelines for the Registration of Microbial Pest Control Agents and Products
- PRO2002-02, Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals
- PRO2010-06, Guidelines for the Registration of Non-Conventional Pest Control Products
- PRO2010-07, Value Guidance – Benefit Information and Use History





PMRA contacts

- Pre-submission consultation (Richard Kenny; Martha Farkas)
- Value Assessment (VSAD-appropriate section head)
- Health and Environmental Risk Assessments (Dr. Brian Belliveau)





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Thank you!

Questions?



<http://www.hc-sc.gc.ca/cps-spc/pest/index-eng.php>

