

Value Assessment of Biopesticides at the PMRA

OECD Expert Group on Biopesticides
Seminar – Different Aspects of Efficacy Evaluation of Biopesticides
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Overview

- Biopesticide Definitions
- Value requirements
 - Efficacy and crop tolerance
 - Level of control
 - Benefits
 - Weight of evidence
- Resources

Biopesticide Definitions

- Three types/classes of biopesticides defined and regulated by PMRA
 - Microbials (Regulatory Directive DIR2001-02)
 - Bacteria, fungi, viruses, protozoa
 - Pheromones and other Semiochemicals (Regulatory Proposal PRO2002-02)
 - Natural and synthetically derived
 - Arthropod and non-arthropod
 - Non-conventional Chemical Pesticides (Regulatory Directive DIR2012-01)
 - Naturally-occurring substances with:
 - Low hazard/toxicity to mammals (including humans) and other non-target organisms
 - Not persistent in the environment
 - Non-toxic mode of action against pest
 - Low potential for resistance development

Value Assessment: Legal Framework

- Value of a pest control product (per Pest Control Products Act):
 - Actual or potential contribution to pest management
 - Takes into account conditions and proposed conditions of registration
 - Includes:
 - product's efficacy,
 - its effect on host organisms or use sites with which it is to be used, and
 - health, safety and environmental benefits and social and economic impact.

Value Information: Efficacy and Crop Tolerance

- Lab, field trials
 - Application rates: include the proposed rate/rate range
 - Treatments: include controls (-/+), proposed treatment.
- Use history information
 - Registered in a foreign jurisdiction
 - Similar product
 - Similar use pattern
- Published scientific literature
 - Needs to align with the proposed Canadian use pattern
- Scientific rationales
- Crop tolerance is mainly of concern for herbicides

Value Information: Level of Control

- Label claims need to be supported
- Herbicides and fungicides:
 - Control (80-100%)
 - Suppression (60-80%)
 - Partial Suppression (30-60%) (non-conventional products only)
 - Other lower claims for biopesticides: e.g., may inhibit, reduces inoculum, etc.
- Insecticides:
 - Control (consistent reduction in pest numbers or damage to acceptable levels)
 - Suppression (consistent reduction in pest population)
 - Other lower claims for biopesticides: e.g., reduces damage, reduces populations, etc.

Value Information: Benefits

- Social and economic impact
 - How proposed use impacts Canadian competitiveness
 - Impact of the proposed use on marketability of the crop
 - Addresses grower identified priorities
- Health, safety and environmental benefits
 - Does not refer to information provided for the human health or environmental risk assessment
 - Statements about value of the product to the user (e.g. controls a poisonous weed; reduces the formation of harmful mycotoxins in diseased plants)

Value Information: Benefits

- Resistance management
 - Survey of alternatives
 - Resistance management label statements (DIR2013-04)
 - Recommendations and guidance from resistance action committees
- Risk reduction
 - Potential of a product to replace a product being phased out due to re-evaluation
- Sustainability and compatibility with IPM
 - Viability of a product's use in an IPM program
 - Studies demonstrating integration into pesticide spray programs

Determining Value Through Weight of Evidence

- Consideration of all information provided to support the proposed use.
- Each component of value may weigh in differently depending on the situation.
- Flexibility in the consideration of level of control provided by the product (e.g. products demonstrating suppression or partial suppression of pests may still be considered to have value in an IPM system).
- Value must be acceptable, and is considered independent of health or environmental risks.

Resources

- Documents
 - Guidelines for the Registration of Microbial Pest Control Agents and Products (DIR2001-02)
 - Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals (PRO2002-02)
 - Value Assessment of Pest Control Products (DIR2013-03)
 - Pesticide Resistance Management Labelling Based on Target Site/Mode of Action (DIR2013-04)
 - Value Guidelines for New Plant Protection Products and Label Amendments
 - Guidelines for the Registration of Non-Conventional Pest Control Products (DIR2012-01)

Thank you!

Questions?

