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Canada

Determining the Value of Pest Control Products in Canada

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Outline

- Purpose of the presentation
- Canadian regulatory framework
- Canadian considerations for “low risk” products
- Value assessment in Canada
- Case studies
- Challenges
- Lessons learned – managing the challenges
- Conclusion

Purpose of the Presentation

Provide some insight and awareness of the Canadian pesticide regulatory system and how value is considered and evaluated for “low risk” active substances.

Canadian Regulatory Framework

- Health Canada's Pest Management Regulatory Agency is responsible for the regulation of pest control products in Canada under the authority of the *Pest Control Products Act* (PCPA).
- Primary objective under the act is to prevent unacceptable risks to people and the environment from the use of pest control products
- Other objectives of the *PCPA* are to:
  - Ensure that pest control products have acceptable value
  - Support sustainable pest management
  - Facilitate access to pest control products, especially those associated with lower risk
  - Encourage public awareness of pest control products

Scope of Products Registered at PMRA

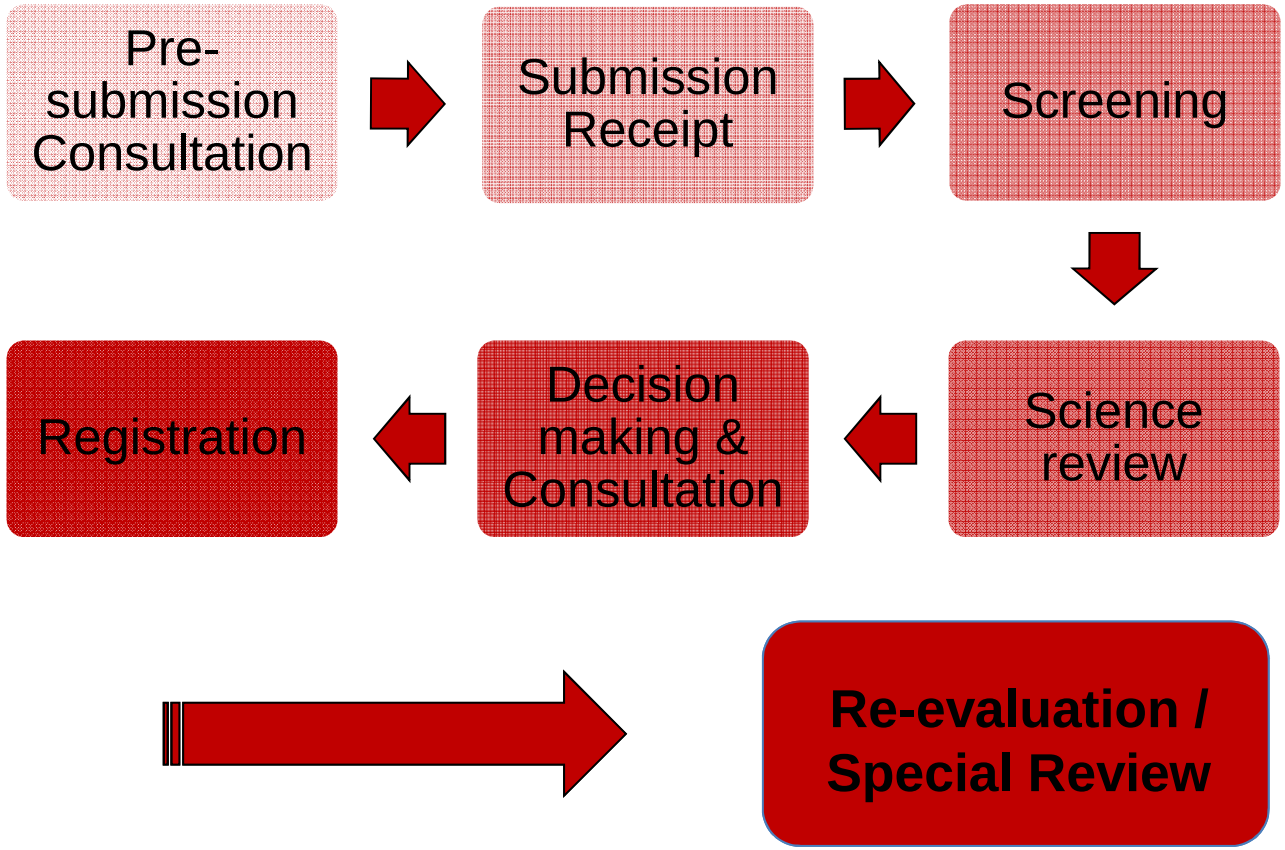
Product Types

- Insecticides, insect repellents
- Herbicides
- Fungicides
- Algicides
- Devices to control rodents & insects
- Rodenticides
- Antifouling agents
- Biopesticides

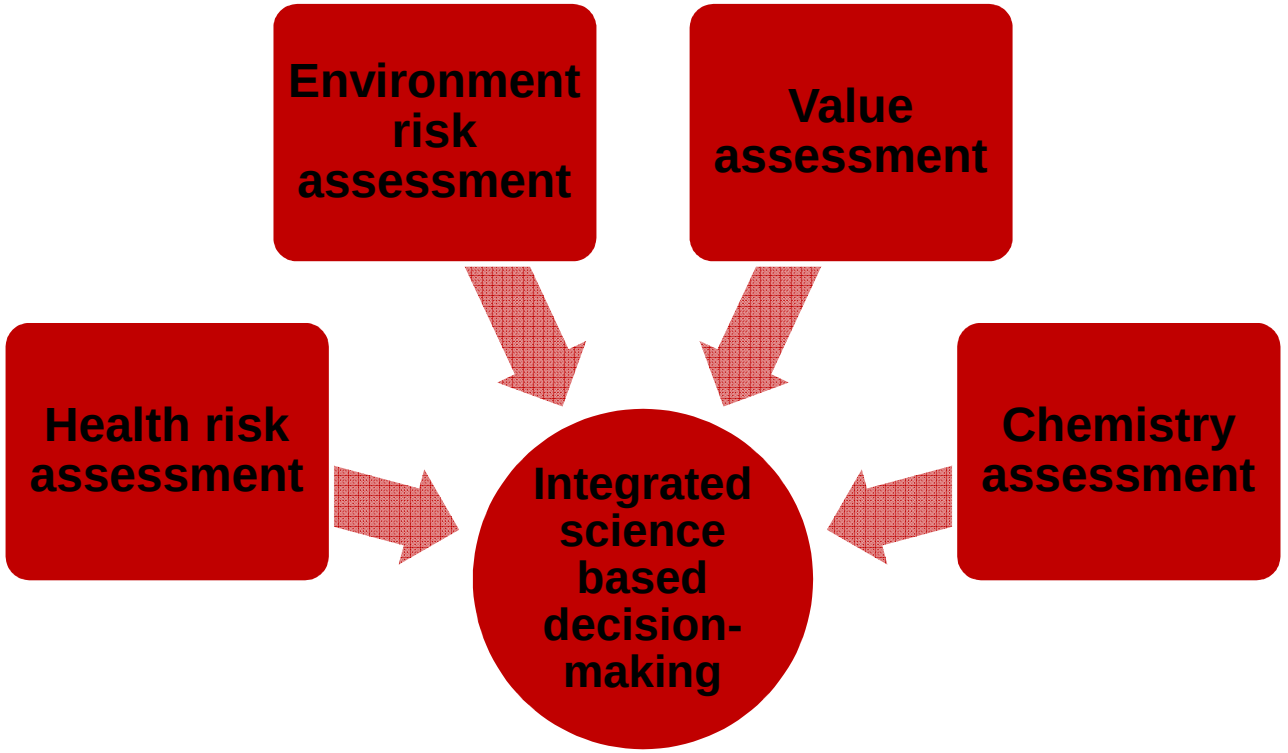
Use Categories

- Agriculture
- Forestry
- Lumber
- Aquaculture
- Inside homes
- Urban landscapes (golf courses, playgrounds, parks)
- Institutions/structures e.g., schools, hospitals, apartments

Active Ingredient Review Life Cycle

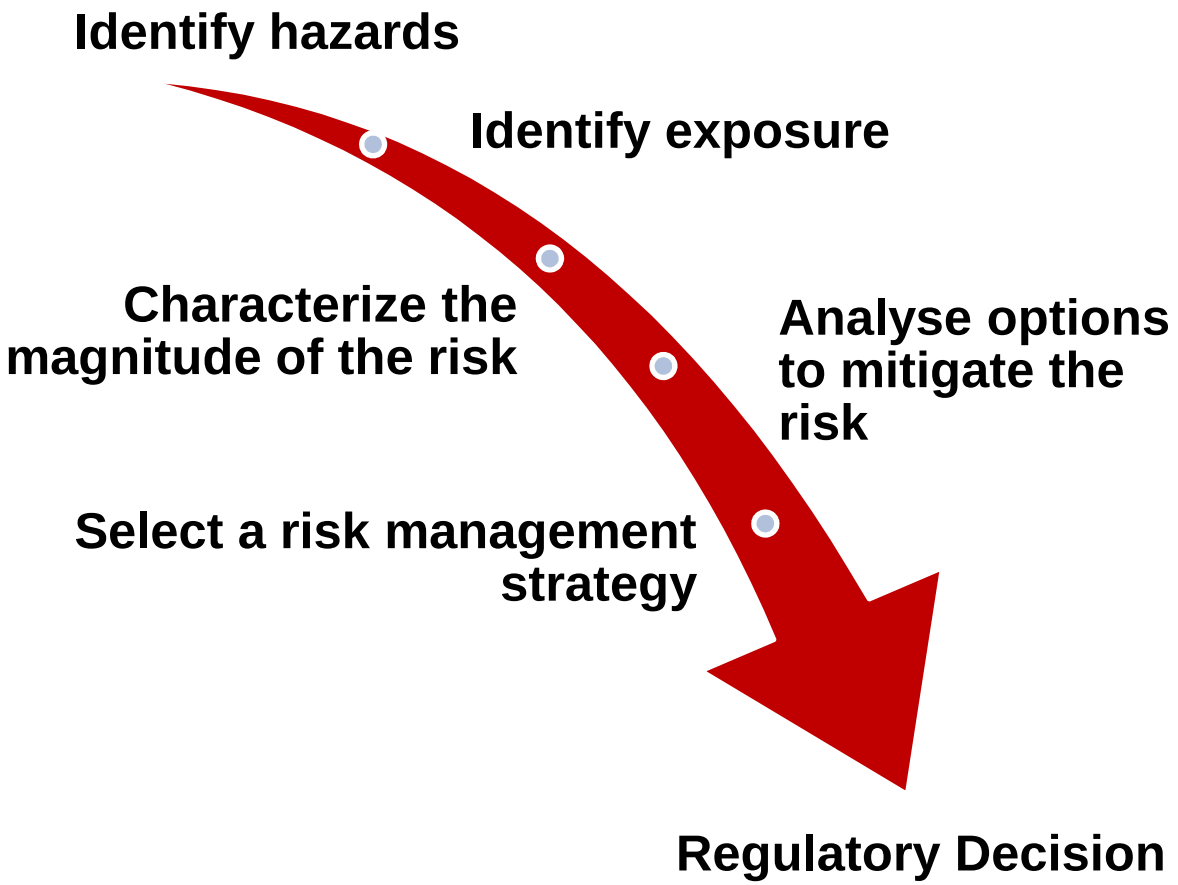


Science Review Process



Science-based Risk Management Decision-Making

- Based on scientific assessment and management of risks



Canadian Considerations for “Low Risk” Products

In Canada, biopesticides are generally considered to be of lower risk; however, there is no working definition of “low risk”.

Types of biopesticides include:

1. **Microbials**
   - Naturally occurring and genetically modified bacteria, algae, fungi, protozoa, viruses, and related organisms

2. **Pheromones/semiochemicals**
   - Naturally occurring chemicals used for communication by insects

3. **Biochemicals (non-conventional chemicals)**
   - Naturally occurring substances (other than pheromones/semiochemicals) representing diverse chemistries, including, botanical essential oils, plant extracts, commodity chemicals, food ingredients, preservatives, inert materials, certain inorganic salts used as fertilizers

Products considered as non-conventionals must have some, but not all, of the following characteristics:

- Low inherent toxicity to non-target organisms
- Low potential for use to result in significant human or environmental exposure
- Not persistent in the environment
- Widely available to the public for other uses with history of safe use
- Pesticidal action that is not the result of toxicity to the target organism (eg., repellents, desiccants, smothering)
- Unlikely to select for pest resistance

Value Assessment According to the Legislation….

- In Canada, the PCPA says: ".. the Minister considers that the health and environmental risks and the **value** of the pest control product are **acceptable** after any required evaluations and consultations have been completed, the Minister shall register the product or amend its registration in accordance with the regulations.."

- In EU, Regulation 1107 says:

"A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements: (a) it shall be **sufficiently effective**;…"

Canadian Legal Framework: What is Value??

Value of a pest control product is:

- Its actual or potential contribution to pest management
- Takes into account its conditions and proposed conditions of registration
- Includes:
  1. product's efficacy,
  2. its effect on host organisms or use sites with which it is to be used, and
  3. health, safety and environmental benefits and social and economic impact.

→ The value of a pest control product includes a consideration of the anticipated user groups' expectations.

Approach to Value Assessments of Pesticides

- Flexible approach to fulfill data requirements
- Consideration of non-traditional sources of information (rationales, use history, benefits, grower priority)
- Weight of evidence approach
- Less reliant on trial data than previously, although efficacy assessment is still a core component
- Streamlined approaches to proposed minor uses that meet certain criteria
- Rate justification in lieu of lowest effective rate

What are the components of a value assessment?

- Product performance
  - Efficacy (level of control; rate justification; application methods, etc.)
  - Non-safety adverse effects (crop tolerance, safety to rotational crops, effects on use sites)

- Consideration of benefits
  - Resistance management
  - Risk reduction
  - Sustainability and compatibility with IPM
  - Social and economic impact
  - Health, safety and environmental benefits

What efficacy information may be provided?

- Use history
- Results of research trials
- Scientific rationales
- Published information – scientific literature, recommendations from crop production guides

What benefit information may be provided?

- Resistance management
  - Survey of alternatives
  - 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
- Social and economic impact
  - How proposed use impacts Canadian competitiveness
  - Addresses grower identified priorities
- Health, safety and environmental benefits
  - Statements about value of the product to the user (e.g. controls a poisonous weed or mycotoxin)

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)
- Impact of the use on managing resistance (e.g. product provides a new mode of action)
- Addresses pest management needs identified by users
- Proposed use results in yield benefit

Level of Pest Control Claims on Labels

- Driven by available commercial standards and expectations of the market.

- All types of products are eligible for:
  - **Control** - a consistent level, in general, ≥80%
  - **Suppression** - a consistent level that is less than full control, in general ≥60%
  - **Top Growth Control (herbicides)** – consistent reduction of weed top growth in the year of treatment.

- Claims generally reserved for biopesticides (aka “low-risk”) products:
  - **Partial Suppression** - less than suppression, in general <60%
  - **Reduces damage** – damage reduced, not consistent
  - **May reduce numbers of** – pest numbers reduced, but not consistent

Value – Overall Conclusions

- Conventional and biopesticide products can fulfill value data requirements in the same manner
- Weight of evidence approach for biopesticides may rely more on benefit information than efficacy
- Level of control for conventional and biopesticide products evaluated on the same scale
- Label claim will accurately reflect the level of control a user can expect
  - Claims less than suppression and control generally reserved for biopesticide products

Bottom line:

➢ Information must demonstrate that the product is sufficiently effective at a level that is acceptable to the intended users.

Case Studies

Product Background

- Microbial bait insecticide formulated with spores of a microsporidial pathogen
- Takes 3 to 6 weeks from infection to death of the insect, and will multiply and pass from infected insect to infected insect.
- The product was proposed for suppression of grasshoppers and Mormon crickets in crop and rangeland, applied by hand, ground, or air at a rate of at least 1.12 kg per hectare

Submitted Value Information

- A variety of information was submitted, including published journal articles, grasshopper control handbooks, organic crop surveys, and integrated pest management information.
- No efficacy studies were submitted which tested the product.
  - However, several published articles were submitted which tested the active ingredient. Many of these were relatively old (1970s and 1980s).
- Submitted studies indicated that use of the product against grasshoppers or Mormon crickets may potentially suppress, at best, grasshopper populations over a long period of time.
- The product requires a relatively long period of time to develop in and debilitate the host, and spreads slowly through the population.
  - Therefore does not readily infect other grasshoppers other than through cannibalism.

Value of the product – Benefit Consideration

- The active ingredient has little effect on beneficial and other non-target organisms
- Can be used in organic production
- The product may be useful in environmentally sensitive areas where conventional insecticides cannot be used and reliable, immediate control is not critical.

Supported Label Claims

- **May provide suppression** of grasshopper and Mormon crickets in crop and rangeland; apply by hand, ground, or air at a rate of at least 1.12 kg per hectare.

Additional statements were required based on the submitted information:

- This product must be consumed by the target pest in order to be effective. Consumption of a higher number of spores per grasshopper will increase product efficacy and decrease the amount of time required to kill the grasshoppers. If greater efficacy or faster population reduction is required, multiple applications or a higher rate are advisable to increase the amount of bait available to each grasshopper.
- Due to the nature of this product (i.e., microsporidial pathogen), efficacy may be affected by such factors as weather, grasshopper population densities, and insect migration.

Non-Conventional Herbicide on turf

Proposed use:

- The plant derived compound inhibits germination of smooth crabgrass and dandelion seed (prior to weed emergence) on turf
- 9.7 kg product/100m^2 for lawns with weeds or 4.85 kg product/100 m^2 for lawns without weeds
- Apply in spring and again in late summer/early fall

Challenges of submitted information

Inappropriate study protocols or evaluation methods:

- Did not test the proposed use pattern
- Used an inappropriate control that did not include fertilizer to match the nitrogen in the product
- Assumption that weed populations were even across each trial site
- Did not indicate if established weeds were removed to prevent inclusion in the assessments (pre-emergence control only)
- Inappropriate assumption that crabgrass and dandelion seedbank was even across each trial site, i.e., no seeding of weeds to minimize variation among treatment plots
- Use of other unspecified pesticides, which may have included herbicide(s)

Value Approach

A weight of evidence approach was used to assess value:

- “organic” alternative to conventional turf herbicides
- combats two important lawn weeds
- despite shortcomings of study design and protocols efficacy was observed
  - greenhouse study: product inhibited smooth crabgrass and dandelion (tested rates were 3.3-10x that of the maximum proposed)
  - field studies: some inhibition of these weeds, although degree was variable and often at sub-suppression levels (<60%)
- - demonstrated safety to Kentucky bluegrass turf

Conclusions

- claim reduced to “may inhibit seed germination”
- only supported the higher rate
- for use only on turf comprised mainly of Kentucky bluegrass
- to be used only in a sound turf management program

What are our challenges?

Label	• Unrealistic claims proposed • Too broad, unclear directions for use
Efficacy	• Proposed use pattern not evaluated in package • Poor experimental design • Weak treatment effect
Benefits	• Applicants may not take advantage of all ways to satisfy value • Expectations of use sector not clear
Submission Quality	• May be poorly organized and explained • Variable quality information • Too much / too little information

Lessons Learned: Managing Challenges

- During pre-submission consultations for biopesticide products, value data requirements are thoroughly outlined as guidance for applicants
- Value often driven by benefits, but the label claim represents the efficacy that can be reasonably anticipated
- Adjustment of label claim to reflect the level of control to be expected
  - Manages stakeholder expectations
- Accept scientific rationales built on broader assumptions than what would be acceptable for conventional chemicals in order to retain claims on labels
- Remove proposed uses from labels when value cannot be determined (no benefit or no efficacy)

The biggest changes to the way we look at value for biopesticides:

1. A product with low or inconsistent control may still have value provided that it meets a need for a stakeholder group.
2. Shifting from a reliance on trial data to consideration of benefits in order to satisfy the weight of evidence approach to value.
3. Accepting that the rate itself is less important than establishing that the product works.

Reference Documents

- DIR2012-01: Guidelines for the registration of Non-Conventional Pest Control Products
  - http://www.hc-sc.gc.ca/cps-spc/alt_formats/pdf/pubs/pest/pol-guide/dir2012-01/dir2012-01-eng.pdf
- DIR2013-03: Value Assessment of Pest Control Products
  - http://www.hc-sc.gc.ca/cps-spc/alt_formats/pdf/pubs/pest/pol-guide/dir2013-03/dir2013-03-eng.pdf
- Value Guidelines for New Plant Protection Products and Label Amendments (to be published)