

US EPA ARCHIVE DOCUMENT



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

## **Environmental Assessment: Data requirements, scientific waiver building**

**Valerie Hodge**

Environmental Assessment Directorate (EAD)

Pest Management Regulatory Agency



Health      Santé  
Canada     Canada



## Overview

- Sources of Information for Non-Conventional Pest Control Products, including Microbials, Pheromones and other Semiochemicals
  - Pre-submission Consultation
- Data Requirements
- Environmental Risk Assessment
- How to Address Information Requirements
- Areas for Improvement



## Sources of Information

- Guidelines for the Registration of Non-Conventional Pest Control Products, PRO2010-06
- Guidelines for the Research and Registration of Products Containing Pheromones and Other Semiochemicals, PRO2002-02



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## Sources of Information

- Guidelines for the Registration of Microbial Pest Control Agents and Products, DIR2001-02



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## Pre-Submission Consultation

- Strongly encouraged, particularly for new applicants
  - Will determine if the product/active ingredient is eligible for review under the guidelines for non-conventional pest control products; also for pheromones and other semiochemicals
  - Will determine what information is required (i.e., what concerns need to be addressed)
  - An opportunity to request guidance on building a successful submission package



## Environmental Data Requirements *Non-Conventionals*

- Tiered and flexible
- Dependant on proposed use
  - This will determine in which environmental media (soil, water, sediment, air) non-target organisms could be exposed (e.g., indoor uses – limited environmental data would be needed; conventional and non-conventional)
- Must show that the use of the product would pose low acute risks to any non-target aquatic or terrestrial organisms likely to be exposed





## Acute Toxicity *Non-Conventionals*

- Terrestrial

- Through the use of your product, could this substance cause adverse effects to beneficial insects and other organisms in the soil or on plants; could birds be harmed if they were to consume this substance on various food items

- Arthropods - bees, predators, parasites
- Birds
- Plants





## Acute Toxicity *Non-Conventionals*

- Aquatic (freshwater, marine)
  - If this substance reached an aquatic habitat through spray drift or runoff, could it cause adverse effects to aquatic organisms
    - Invertebrates (*Daphnia*, other organisms)
    - Fish (cold water, warm water)
    - Plants (algae, duckweed, pondweed)





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## Environmental Fate *Non-Conventionals*



It is important to understand the environmental chemistry and fate of the active ingredient

- Reference to existing studies, reviews or summaries are acceptable
- More information may be required





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## **Environmental Risk Assessment** *Non-Conventionals*

- Pest control products can be registered in Canada only if their use poses no unacceptable risks to human health or the environment and has value
- PMRA follows a risk assessment process similar to the U.S. EPA



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## **Environmental Risk Assessment** *Non-Conventionals*

- An assessment of risk may be quantitative or qualitative
- If as a result of the environmental assessment other concerns are raised, more information may be requested
  - Chronic toxicity data
  - Reproductive studies



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# How to Address Information Requirements

## *Non-Conventionals*

- Scientific data/study for one or more species in each group



# How to Address Information Requirements

## *Non-Conventionals*

- For example:
  - PMRA Data Code 9.5 Acute toxicity to fish: Provide information for one of the following to address this concern -
    - 9.5.2.1 cold water fish (e.g., rainbow trout)
    - 9.5.2.1 warm water fish (e.g., bluegill sunfish)
    - 9.5.2.3 other freshwater fish species
    - 9.5.2.4 marine/estuarine fish species



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# How to Address Information Requirements

## *Non-Conventionals*

- Scientific data/study for one or more species in each group
- Relevant information regarding other uses of this substance where there may be environmental exposure
- Original guideline studies, published data or research, existing foreign reviews or summaries
- Reference data codes for each piece of information (also see USC Tables, PMRA website)



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# How to Address Information Requirements

## *Non-Conventionals*

### – Foreign Reviews

- Submission of foreign reviews is encouraged
- To discuss the acceptability of a foreign review document/publication for your submission, please consult with the PMRA



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# How to Address Information Requirements

## *Non-Conventionals*

- Waiver request with a scientifically-based rationale and supporting documentation
- Examples (also provided in PRO2010-06):
  - Surrogate data, bridging
  - Describe origin of substance (i.e., naturally occurring)
  - Explain if there is a long history of use with similar exposure to the environment
  - Describe how method/site of application of product minimizes direct exposure



## Data Requirements *Pheromones and Other Semiochemicals*

- Reduced and tiered
  - Non-toxic, target-specific mode of action, natural occurrence
  - Generally effective at very low rates, comparable to levels that occur naturally
  - Generally volatile, and dissipate rapidly
  - SCLPs are of low toxicity to mammals





## Data Requirements *Pheromones and Other Semiochemicals*

- Tier I Data for TGAI: Acute toxicity
  - Where a semiochemical, including SCLPs, is broadcast or sprayed:
    - Freshwater invertebrate acute toxicity study
    - Freshwater fish acute toxicity study
  - In addition, for products other than SCLPs:
    - Avian acute oral toxicity study
    - Avian dietary toxicity study
  - If hazards are demonstrated, data from subsequent tier(s) will be required



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## **Data Requirements** *Pheromones and Other Semiochemicals*

- Environmental Chemistry and Fate
  - Required for semiochemicals that will be used outdoors
  - For SCLPs, sufficient data have been received
    - No further data are needed



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## Area(s) for Improvement

- Ensure that information is relevant and sound





## Area(s) for Improvement

- Organize the submission of data, information, waivers, rationales
  - This will make it easier to see that everything has been addressed
  - Cite data codes where possible





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## Area(s) for Improvement

- Clearly indicate how the product will be used
  - Sometimes labels submitted for presubmission consultations are sparse
  - Indoor, outdoor; residential, agricultural
  - This is the basis for determining potential exposure



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## Area(s) for Improvement

- The big picture
  - Understanding why a particular piece of information has been requested makes it easier to put together a response
  - Ask questions
  - Thank you for attending this course





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# Questions?

