



NAFTA Technical Working Group on Pesticides  
Grupo de Trabajo Técnico del TLCAN sobre plaguicidas  
Groupe de travail technique de l'ALENA sur les pesticides

# PMRA Submission Process for Microbials and Semiochemicals

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# Introduction to Biopesticide Regulation

- ◆ Facilitate Risk Reduction through improved access to biopesticides
  - ❖ Microbials
  - ❖ Pheromones and other semiochemicals



# Definitions

- ◆ **Microbial:** a naturally occurring or genetically modified micro-organism including fungi, bacteria, viruses or other micro-organisms.
- ◆ **Semiochemical** - a message-bearing substance produced by a plant or animal, or a synthetic analogue of that substance that evokes behavioural response in individuals of the same or other species. Some examples of semiochemicals include allomones, kairomones, pheromones and synomones.



# Category A Biopesticides

- ◆ Pheromone: new technical grade active ingredient (TGAI) and associated End-use products (EP);
- ◆ Microbial: new Microbial Pest Control Agent (MPCA) and associated Microbial Pest Control Product (MPCP);
- ◆ major new use;
  - ❖ 18 months
- ◆ includes User Requested Minor Use Registrations (URMURs)
  - ❖ 12 months
- ◆ no cost recovery fees for microbials and semiochemicals



# Category B Biopesticides

- ◆ Submissions to amend or to register products that represent a change to the registered use-pattern of an active ingredient within a given use-site category
- ◆ 12 months



# Getting Started: Presubmission Consultation

- ◆ Registrant should submit an information package to PMRA at least 45 days prior to the consultation
- ◆ presubmission consultation package should include the following:
  - ❖ cover letter requesting presubmission consultation
  - ❖ draft label



# Getting Started: Presubmission Consultation

- ◆ presubmission package (cont'd):
  - ❖ list of contents of proposed product (active ingredient, formulants)
  - ❖ short summaries of available data (efficacy, environment, human health) and any waivers requested
  - ❖ particularly important for non-pheromone, non-microbial products



# Getting Started: Presubmission Consultation

- ◆ presubmission package (cont'd):
  - ❖ Microbials: identity of organism and survival parameter, manufacturing method, potential health or environmental issues
  - ❖ Semiochemicals: relevant chemistry information, manufacturing methods
- ◆ Critical for these products



# Getting Started: Presubmission Consultation

- ◆ For information on setting up a presubmission consultation, contact:
  - ❖ Stephane Lavigne 613-736-3584 or [Stephane\\_Lavigne@hc-sc.gc.ca](mailto:Stephane_Lavigne@hc-sc.gc.ca)
  - ❖ Presubmission and Consultation Coordination Section



# Ensuring a Complete Biopesticide Submission

- ◆ Covering Letter (purpose, content)
- ◆ Forms (application, application fees form, specification form, if appropriate)
- ◆ Draft Label
- ◆ Documentation (letters of confirmation, support, agent, certification, etc.)



# Ensuring a Complete Biopesticide Submission (cont'd)

- ◆ Index to Submitted Data/Studies
- ◆ Data/Studies
- ◆ Foreign Reviews, if appropriate

**INCOMPLETE SUBMISSIONS WILL NOT GO FORWARD**



# Registration Requirements Category A Biopesticides

- ◆ Data requirements established during a joint pre-submission consultation will be considered valid for up to 24 months



# Data Codes (DACOs) - Pheromones

## ◆ Straight-Chained Lepidopteran Pheromones (SCLPs):

- ❖ a group of pheromones consisting of unbranched aliphatics having a chain of nine to eighteen carbons, containing up to three double bonds, ending in an alcohol, acetate or aldehyde functional group.
- ❖ characteristic of most known pheromones produced by members of the order Lepidoptera, including moths and butterflies.



# Data Codes (DACOs) - Pheromones

## ◆ Data requirements for SCLPs:

◆ Part	0	Index
	1	Label
	2	Product Chemistry - TGAI
	3	Product Chemistry - EP
	4	Toxicology (TGAI and EP)
	5	Exposure
	6	Metabolism
	10	Value/ Efficacy
	12	Foreign Reviews, if applicable



# Data Codes (DACOs) - Pheromones

- ◆ Data requirements for non-SCLPs:
  - ❖ Parts 0 to 6
  - ❖ 7 Food, Feed and/or Tobacco Residue
  - ❖ 8 Environmental Chemistry and Fate
  - ❖ 9 Environmental Toxicology
  - ❖ 10 Value/ Efficacy
  - ❖ 12 Foreign Reviews, if applicable
- ◆ DACOs apply to studies, screening forms, waiver requests, previously submitted studies, foreign reviews



# Data Codes (DACOs) - Microbials

## ◆ Data requirements for microbials:

◆ Part	0	Index
	1	Label
	2	Product Characterization and Analysis
	4	Human Health and Safety
	5	Exposure
	6	Metabolism
	8	Environmental Fate
	9	Environmental Toxicology
	10	Value/ Efficacy
	12	Foreign Reviews, if applicable



# Organization of Submission Package

## ◆ Envelope

- ❖ Covering Letter, Forms, Fee, Documentation
- ❖ 3 Hard (Paper) Copies of Label
- ❖ Diskette of Index and Label

## ◆ Binders

- ❖ Data Parts, Screens, Waiver Requests, Foreign Reviews, Comprehensive Summaries
- ❖ Labeled on the Front and Spine
- ❖ Table of Contents, Tabs (DACOs)



# Organization of Submission Package (cont'd)

## ❖ Summary Binder 1

- ◆ Part 0 Index
- ◆ Part 1 Label
- ◆ Summaries of Parts 4, 5, 6, 7, 8, 9, 10
- ◆ MSDSs

## ❖ Data Parts as Required

- ◆ Binder 2 - Product Chemistry/ Characterization (if applicable)
- ◆ Only One Part per Binder



# Submission Screening

## ◆ Screening ensures:

- ❖ submission is organized and formatted correctly
- ❖ submission is complete [All the required (R) data elements are present]
- ❖ early identification to applicants of deficiencies

## ◆ Screening occurs:

- ❖ at beginning of process (45 days)



# General Screening Procedure

- ◆ Pre-submission consultation (data requirements established)
- ◆ Assign submission number
- ◆ Detailed Screen
  - ❖ non-data components
  - ❖ draft label
  - ❖ index
- ◆ Check for presence/ absence of required supporting data



# General Screening Procedure (cont'd)

- ◆ Consider “Letter of Screening Deficiencies”
- ◆ Advise applicant of deficiencies and screen response
- ◆ Forward to relevant science divisions and Data Management



# Label

- ◆ Electronic and hard (paper) copy of proposed draft label in Canadian format
- ◆ Refer to Handbook, PCP Regulations
- ◆ Will be reviewed during screen
  - ❖ primary panel
  - ❖ secondary panel



# A Complete Category B Submission

- ◆ Covering Letter (purpose, content)
- ◆ Forms (application, specification, if applicable)
- ◆ Draft Label
- ◆ Documentation (letters of confirmation, support, agent, certification, etc.)



# A Complete Category B Submission (cont'd)

- ◆ Index to Submitted Data/Studies
- ◆ Data/Studies
- ◆ Foreign Reviews

**INCOMPLETE SUBMISSIONS WILL  
NOT GO FORWARD**



# Classes of Category B Submission

- B1. Changes to Product Chemistry of a Technical Grade Active Ingredient (TGAI) product or Integrated System Product (ISP)
- B2. Changes to Product Chemistry of an End-Use, or Manufacturing-Use, Product
- B3. Changes to Product Labeling
- B4. Extension or Conversion of Temporary Registration
- B5. New Product, use



# Registration Requirements for Category B Biopesticides

- ◆ Dependent on purpose of submission in relation to registered products.
- ◆ Presubmission consultation
- ◆ Extension/conversion of temporaries depend on condition of registration



# Common Screening Deficiencies

- ◆ Indices not submitted (paper and electronic) or formatted incorrectly (electronic).
- ◆ Data Requirements (DACOs) not adequately addressed by data, request for waiver or citation of previously submitted data.
- ◆ Material Safety Data Sheets (MSDS) not submitted



# Common Screening Deficiencies

## ◆ Labels

- ❖ missing/incorrect basic requirements.
- ❖ not all labeling components submitted.
- ❖ electronic labels not formatted properly.

## ◆ Chemistry Data not organized/labeled according to Canadian format (DACOs).

## ◆ Submission Format/ Organization in General does not follow proper criteria.



# Common Screening Deficiencies

- ◆ Incorrect Data Codes (DACOs) used to identify studies.
- ◆ Requests for Data Waivers do not include adequate scientific rationale.
- ◆ Table of Contents not included for each data binder.
- ◆ Tabs separating studies not labeled or incorrectly labeled (according to DACO).
- ◆ Responses to Letters of Deficiencies not formatted correctly (separated by DACO) and insufficient copies submitted.



# Common Screening Deficiencies

- ◆ Responses to Letters of Deficiencies not provided within 45 day period.
- ◆ Specification Form is incomplete, incorrect or missing.
- ◆ Application Form is incomplete or incorrect.
- ◆ No Canadian Agent



# Common Screening Deficiencies

- ◆ Insufficient copies of data/information submitted.
- ◆ Missing or illegible pages.
- ◆ Consolidated response (to all deficiencies) not provided.
- ◆ Letter of Confirmation of source of supply for technical product not provided.

**NOTE:** Most of these deficiencies could be avoided if

applicants read the information provided by the  
PMRA



before



submitting applications and had

# Preliminary Review

- ◆ PMRA conducts preliminary review for deficiencies to validate ‘reviewability’ of the file:
  - ❖ have data requirements been properly interpreted?
  - ❖ are data waiver requests supportable?
  - ❖ are non-standard test protocols acceptable?
- ◆ Applicants have 90 days to respond to deficiencies identified during the preliminary review (ie: clarification/additional data)
  - ❖ the review process and the clock stops
- ◆ Responses proceed through a second data screen plus preliminary review



# Evaluation

- ◆ Submissions successfully determined 'reviewable' following preliminary review move immediately to full assessment/ evaluation
- ◆ Evaluators complete reviews (includes waivers) and draft evaluation reports/ data evaluation records.



# Regulatory Decision

- ◆ Final review completed
- ◆ Risk Assessment conducted
- ◆ Regulatory document [Regulatory Note or Proposed Regulatory Decision Document (PRDD)] may be released for public comment
- ◆ Final Label Review conducted
- ◆ Certificate of Registration issued (may be temporary registration)



# Biopesticide Documents: Pheromones

- ◆ PMRA is updating Regulatory Directive 97-02 (Guidelines for Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals)
  - ❖ incorporating input from 1999 OECD Pheromone workshop held in Ottawa
- ◆ will be published as a proposal early 2002



# Biopesticide Documents: Microbials

- ◆ New PMRA Regulatory Directive (DIR2001-02) replaces 1998 proposal
- ◆ Directive published March 2001



# Other Relevant Documents

- ◆ Regulatory Proposal 96-01: Management of Submissions Policy, published June 1996
  - ❖ Defines submission types and process of handling submissions
- ◆ Regulatory Proposal 98-02: Organizing and Formatting a Complete Submission for Pest Control Products, published February 1998
- ◆ Regulatory Directive 98-05: Chemical Pesticides Research Permit Guidelines, published May 1998



# Other Relevant Documents

- ◆ Regulatory Directive 99-05: User Requested Minor Use Registration (URMUR), published April 1999
- ◆ Regulatory Directive 2001-01: User Requested Minor Use Label Expansion (URMULE), published February 2001
- ◆ Registration Handbook

