Biopesticides Registration Improvement Course

Management of Submissions Policy (MOSP) for Pest Control Product Applications in Canada

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Outline

- Background
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- Submission Categories
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Management of Submissions Policy (MOSP) - Background

- In Canada, pursuant to the *Pest Control Products Act,* no person can manufacture, possess, handle, store, transport, import, distribute or use a pest control product that is not registered under the *Pest Control Products Act*, except as otherwise authorized under the Act or unless specifically exempted by the *Pest Control Products Regulations*.

- Purpose: To outline the method by which Health Canada's Pest Management Regulatory Agency (PMRA) manages applications and material submitted for the notification, research, registration, and amendment of pest control products

Management of Submissions Policy (MOSP)- Principles

- Predictability
  - Sets timelines for examination of submissions
- Quality of Submission
  - Ensures to the extent possible that all required submission/data components are present
- Fairness
  - Submissions are handled chronologically within each MOSP category based on date of receipt
- Workflow Management
  - Categorizes applications with a balance between the amount of evaluation work required and the need for priority.

Management of Submissions Policy (MOSP) – Submission Categories

- Category A
  - New technical grades of active ingredients (TGAI) and related products
  - Major new uses for registered active ingredients (e.g., addition of a new Use Site Category to the use pattern of a registered active ingredient)
- Category B

-New pest control product registrations (active ingredient is registered) within the same Use Site Category

-Amendment of existing product registrations where data are required

E.g.,

-Changes in product chemistry

-Changes in labelling (e.g., use pattern expansion within the same use site category)

-Conversion or renewal of conditional registration

Management of Submissions Policy (MOSP) – Submission Categories (cont'd)

- Category C:
  - No data required (e.g., minor changes to formulation)
  - New products based on precedent, with no changes to registered use pattern
- Category D:

  -Import for manufacture and export

  -User requested minor use label expansion (URMULE)

  -Master copy

  -Private label

  -Renewal / Discontinuation
- Category E:
  - Research Authorization

Management of Submissions Policy (MOSP) – Process

1) Verification:
   - To ensure that non-data elements, including the appropriate application form, fee form, fee, and e-index, have been provided

2) Screening:
   - To ensure that format, data and fee requirements are met

3) Review:
   - Science evaluation of the data, the health and environmental risks, and the value of the pest control product
     - Identification of any deficiencies to the applicant
     - Review of product labels

   -Decision-making process
     - Conditional registration
     - Full registration (if new active ingredient or major new use, public consultation is required).

Management of Submissions Policy (MOSP) – Process (cont'd)

4) Public Consultation (as required) via Proposed Regulatory Decision (PRD) document* (usually 45 days)

5) Registration Decision (RD) document – Comments received as a result of public consultation are taken into consideration before making a final decision*

6) Label Verification/Issuance of Registration Certificate

**new active ingredients and major new uses*

Management of Submissions Policy (MOSP) – Timelines

- MOSP performance timelines for each submission category can be found in PRO2010-05, *Revised Management of Submissions Policy*

- Within each MOSP category, there are further subdivisions (for example, submission subcategories, submission types, etc.) that may have shorter performance timelines

Management of Submissions Policy (MOSP) – Timelines (cont'd)

Category A Submission Performance Timelines in Number of Calendar Days (includes new active ingredients, import MRLs on new active ingredients and major new use registration)

Category Subdivision	Verification	Screening	Review	Public Consultation	Decision	Verification of Final Label
Conventional Chemical	7	45	550	45	45	45
Reduced-Risk Chemicals*, Other Biopesticides, NSCLP**	7	45	450	45	45	45
Microbials	7	45	365	45	45	45
SCLP***	7	45	180	45	45	45
URMUR*****	7	45	365 or 180	45	45	45
Joint Reviews	30		Negotiated	45	45	45
Program 914	7	45	Negotiated (<365 days)	45	45	45
Import MRL****	7	45	550			45

* Reduced-risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides.*

** Non Straight Chain Lepidopteran Pheromone

*** Straight Chain Lepidopteran Pheromone

**** Reduced-risk timelines don't apply to import MRLs

*****User Requested Minor Use Program

Management of Submissions Policy (MOSP) – Timelines (cont'd)

Category B Submission Performance Timelines in Number of Calendar Days (includes new formulations, changes in current formulations, new hosts and/or pests added to existing products, renewal or conversion of conditional registration, new source of currently registered active ingredient, emergency registrations and changes in rates and methods of application)

Category Subdivision	Verification	Screening	Review	Public consultation	Decision	Verification of Final Label
Conventional Chemical	7	45	365	NA		45
Reduced-Risk Chemicals*, Other Biopesticides, NSCLP**	7	45	300	NA		45
Renewal or Conversion of Conditional Registration ****	7	45	365	45	45	45
Microbials	7	45	180	NA		45
Pheromones – SCLP***	7	45	180	NA		45
New MRL for previously assessed active****	7	45	365	NA		45
Emergency use (Priority) Reduced-Risk*, Other Biopesticides, NSCLP**	7	45	300	NA		45
Emergency use (Priority) Conventional Chemicals	7	45	365	NA		45
Emergency use (Priority) for microbials and SCLP***	7	45	180	NA		45

* Reduced risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides.*

** Non Straight Chain Lepidopteran Pheromone

*** Straight Chain Lepidopteran Pheromone

**** The reduced-risk timelines don't apply in this case

Management of Submissions Policy (MOSP) – Timelines (cont'd)

- Submissions with Negotiated Timelines:
  - Joint Reviews
    - Evaluation of new pesticides (active ingredients and new uses) at the same time in numerous jurisdictions/ countries while meeting country specific requirements
    - Workload is split among participating regulatory authorities, reviews of data are exchanged and peer-reviewed
    - As timelines are negotiated in advance of application, there is the potential for review timelines to be expedited.
  - Program 914
    - Allows for the expedited review of "technology gap" active ingredients which meet certain qualifying criteria, e.g., availability of US and/or other OECD data reviews; active identified on the Grower Priority Database (GPD)
    - Criteria for Program 914 eligibility discussed in advance of application submission.

Management of Submissions Policy (MOSP) – Proposed Revisions

- Amendments were recently proposed to the MOSP to make the submission management process more efficient (Regulatory Proposal 2010-05: *Revised Management of Submissions Policy*)

- Proposed changes include:
  - Streamlining process (e.g., removing some deficiency loops in those cases where deficiencies have been identified; Use of separate Notice of Deficiencies by science evaluation streams)
  - Label verification and review to be done in parallel with the science review
  - Option of renegotiation of review timeline

- Follow-up Regulatory Directive being prepared for publication

Considerations

- Fees
  - Certain products are exempt from most application fees except label fees ($262), including:
    - Microbials
    - Arthropod pheromones and other semiochemicals
    - Plant extracts (foods)
    - Food Grade active ingredients
    - Naturally occurring substances (e.g., essential oils) used as personal insect repellents
    - Invertebrate biological pest control agents

Considerations (cont'd)

- Fee Reductions
  - Fee reductions are available to facilitate access to the Canadian market of new, low sales volume/niche products.

    - Application Fees: Reduced application fees are based on the first three years of projected sales of the product(s) (the application fee may be reduced by up to 90%). The applicant has to apply for the fee reduction and supply the PMRA with sufficient evidence to support the application for the reduced fee.

    - Maintenance Fees: An annual maintenance fee of $2,690.00 is charged per registered product (i.e., per *Pest Control Products Act* Registration Number) for the right to manufacture or sell a product in Canada. There are reduced fees for products with sales of less than $89,667.00. The reduced fee is 3% of sales down to a minimum fee of $75.00.

Challenges

- Main Challenge: Quality of Submissions

NOTE: Pre-submission Consultation service offered at no cost by the PMRA

- Provides regulatory advice to applicants/registrants prior to the submission of an application to register or amend a pest control product.
- May be used as a mechanism for obtaining advice on a study protocol
- Recommended for:
  - new registrants with limited experience with the Canadian pesticide regulatory system
  - products that may qualify as low-risk biochemical / non-conventional pesticides (e.g., essential oils, food grade actives)
  - products that contain active ingredients under re-evaluation
- Mandatory for microbial applications /Joint Review requests/potential Program 914 candidates

References

- Revised Management of Submission Policy (PRO2010-05)
  - http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/_pro2010-05/pro2010-05-eng.php
- Guidance on Selecting the Correct Category for Pest Control Product Submissions
  - http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_decisions/reg2003-01/index-eng.php
- Category C Guidance Document
  - http://www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/prod/_memo-note/registrants-titulaires-eng.php
- Requirements for Submitting Data Index, Documents and Forms (DIR 2006-05)
  - *http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir2006-05/index-eng.php*
- Guidance Document on Pest Control Product Cost Recovery Fees
  - *http://www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/prod/cost-cout-eng.php*
- Pre-submission Consultation Process
  - *http://www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/pre-consult/index-eng.php*
- Grower Priority Database

  http://www.uscanadagrowerprioritydatabase.com

  http://www.cfa-fca.ca/cfa-gp/home_eng.php