



NAFTA Technical Working Group on Pesticides

UPDATED PROCEDURES FOR JOINT REVIEW OF MICROBIALS AND SEMIOCHEMICALS

July 17, 2002

The Canadian Pest Management Regulatory Agency (PMRA) and the United States (U.S.) Environmental Protection Agency (EPA) have established a process for the joint review of pest control products in which the new active ingredient is a microbial or an arthropod semiochemical (including pheromones). The procedure entails a joint pre-submission consultation to establish specific data requirements for the product; the proposed use pattern must be common to both countries. The attached document describes processes and timelines for the registration of products that applicants nominate for joint review. This document replaces all earlier documents on the Joint Review of microbials and semiochemicals.

The PMRA and the EPA are committed to joint reviews and worksharing of pesticide evaluations on a regular basis. Joint reviews will increase the efficiency of the registration process, facilitate simultaneous registration in Canada and the U.S., and increase access to new pest management tools in both countries. Efficient worksharing requires a shared understanding of the responsibilities of each agency, as well as common procedures and time frames.

International liaisons for microbials and semiochemicals are:

Wendy Sexsmith
Chief Registrar
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
Ottawa ON K1A 0K9
Canada
(613) 736-3704
(613) 736-3707 (fax)

Janet Andersen
Director
Biopesticides and Pollution Prevention
Division (7511C)
OPP-EPA
1200 Pennsylvania Ave., NW
Washington DC 20460
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(703) 308-8712
(703) 308-7026 (fax)



Requests for joint pre-submission consultation for a new microbial or semiochemical pesticide should be submitted in writing to the following contacts. Similarly, data packages to support a microbial or semiochemical pesticide submission, prepared according to the pre-submission consultation agreement, should be submitted to the following:

Lisa Lange
Project Manager
Executive Director's Office
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
Ottawa ON K1A 0K9
Canada
(613) 736-3760
(613) 736-3707 (fax)

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1200 Pennsylvania Ave., NW
Washington DC 20460
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(703) 308-8712
(703) 308-7026 (fax)

For inquiries regarding joint review, contact:

PMRA Information Service:
1-800-267-6315 or (613) 736-3799

EPA Biopesticides and Pollution Prevention Division:
Brian Steinwand (Steinwand.Brian@epa.gov)
(703) 308-8712 or (703) 305-7973



INTRODUCTION

The purpose of this document is to inform registrants and other interested groups about the process for joint review of proposed microbial or semiochemical pesticides by the Canadian Pest Management Regulatory Agency (PMRA) and the United States (U.S.) Environmental Protection Agency (EPA) for consideration for simultaneous registration in both Canada and the U.S. For pre-registration testing (research permits, experimental use permits, or notification for small-scale testing), please contact individual countries.

A pest control product must meet the following general prerequisites to be considered for a joint review of data submitted in support of registration:

- C the active ingredient is a microbial agent or a semiochemical for control of arthropods;
- C a complete database is available;
- C the proposed use pattern and formulation type are the same for both countries; and
- C the active ingredient is unregistered in both countries, at time of application.

Definitions:

Microbial: a naturally occurring or genetically modified micro-organism including fungi, bacteria, viruses, and 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 are allomones, kairomones, pheromones, and synomones.

STEP I: Joint Pre-Submission Consultation

A joint pre-submission consultation is generally required to establish joint data requirements for a specific product or the type of information required to support a data waiver. Proponents of microbial or semiochemical pesticides that meet the general prerequisites for joint review (above) will initiate a joint pre-submission consultation, by submitting to both agencies an information package that includes:

1. a cover letter requesting a joint pre-submission consultation regarding data requirements; the applicant must identify a company contact in each country;
2. formal letters consenting to consultation between the EPA and the PMRA, including confidential business information, during joint review (contact either agency for model letters) and agreeing to public announcement of the submissions;



3. a draft label;
4. a list specifying contents of the proposed product, including active ingredient and formulants;
5. short summaries of available data regarding efficacy, safety to the environment and human health, and any scientific rationales regarding waivers from the submission of data that the proponent would like to include in the formal submission;
6. for microbial products only: the identity of the organism and its survival parameters, the manufacturing methods, information regarding any potential health or environmental issues, and the protocols of studies that will be submitted to support registration if these differ from the standardized protocols described in the guidelines; and
7. for semiochemical products only: as much chemistry information (as described in the registration guidelines) as possible and a description of the manufacturing methods.

While it is not necessary to submit detailed scientific studies with the pre-submission consultation package, data supporting statements included in the summaries of the package must be included in the formal submission package.

The data requirements that are established during a joint pre-submission consultation will be considered valid for up to 24 months.

Activities and Time Frames for Pre-Submission Consultations

Activity			Responsible	Calendar days
1	Receipt and assignment	Information package to Wendy Sexsmith (PMRA) and Janet Andersen (EPA)	applicant	15
		Review teams, science team lead and administrative co-ordinators assigned	EPA, PMRA	
		Eligibility check		
		EPA notifies applicant, request received	EPA	0
2	Review and interagency discussion	Both agencies review information package and develop a draft data requirements in tabular format. Agencies exchange requirements, consult on issues, set data requirements (phone, fax or E-mail)	EPA, PMRA	65
3	Final consultation agencies/applicant	Between agencies and applicant, finalize data requirements, provisional worksharing agreement, and lead agency	EPA, PMRA	80



Activity			Responsible	Calendar days
4	Notification of applicant	Applicant is notified of joint data requirements for the proposed use pattern (letter; copy PMRA).	EPA	90

STEP II: Receipt, Screening, and Announcement of Formal Submissions

Applicants of products that meet the general prerequisites (above) for joint review must submit simultaneously to the PMRA and the EPA:

1. the same formulation type, packaging, and use pattern;
2. a common data package, including U.S. and Canadian labels, to both countries;
3. a package complete with forms, fees, and format required by each agency. Both agencies will accept a submission that is in a complete Organisation for Economic Co-operation and Development (OECD) dossier format;
4. a Comprehensive Data Summary or a Summary Dossier containing Tiers II and III in OECD format;
5. a written request for a joint review; refer to date and file number of pre-submission consultation. Letters should identify a company contact in each country. If the technical and end-use submissions are from different applicants, indicate who is “lead applicant”; and
6. a letter permitting exchange of data and reviews, including confidential business information, between the PMRA and the EPA and agreeing to public announcement regarding the submission.

Activities and Time Frames for Receipt, Screening and Announcement of Submissions

Activity			Responsibility	Calendar days
1	Receipt	Application to register technical product and end-use product with required supporting data package	applicant	0
2	Login	Receipt of submission by the PMRA and the EPA	EPA, PMRA	7
		Acknowledgment of receipt of submission to applicant	EPA, PMRA	



Activity			Responsibility	Calendar days
3	Data screen	Submission is screened for completeness, with reference to requirements established in pre-submission consultation.	PMRA	52
	Communication of screening decision	PMRA coordinates consultation with EPA on adequacy of submissions and confirms the pre-submission agreement on worksharing and lead agency. Review team members are confirmed in each agency. Lead agency prepares mutually acceptable letter to registrants in both countries on acceptability of the submission.	PMRA	
	Public announcement	Lead agency prepares mutually acceptable announcement of joint review (product name). In Canada the announcement is via the PMRA web site; in the U.S., via creation of public docket/repository (three days).	EPA, PMRA	

To be eligible for joint review, a candidate must meet all prerequisites and clear the data screen. If any of these criteria is not met, deficiencies will be explained in the joint letter sent by the lead agency. If the applicant can address all deficiencies by providing supplementary information to both agencies within 45 days of the date of the letter, the clock starts again at zero and Step II is repeated. If the applicant is unable to correct noted deficiencies within this time frame, submissions will be administratively withdrawn by both agencies. Review of submissions will not begin in either agency until public announcement is completed (Activity 3, above).

STEP III: Review of Data and Decision

Following completion of Step II, each agency commences review of data elements for which it is responsible for the primary review, according to the worksharing agreement.

Both countries will cooperate to conduct preliminary reviews for deficiencies to validate the “reviewability” of the file, asking the following questions:

- C Have data requirements been properly interpreted?
- C Are data waiver requests supportable?
- C Are non-standard test protocols acceptable?

Should the preliminary review process identify the need for clarification or additional data, applicants will have 90 days to respond, during which time the review process and the clock both stop. If the necessary information is received within 90 days, the clock starts again at zero of



Step II, i.e., a second data screen plus preliminary review. Candidates that are successfully established as “reviewable” following the preliminary review move immediately to full assessment.

Activities and Time Frames for Review of Data and Decision

Activity		Responsible	Calendar days	
			Microbials	Pheromones
1	Review commences	EPA, PMRA	0	0
2	<p>Canada to complete review of product efficacy. Complete chemistry and microbial characterization data review to be conducted. Preliminary review for deficiency of all other data parts to be conducted.</p> <p>Evaluators exchange reviews, discuss need for additional information. If required, lead agency sends letter-of-deficiency to applicant.</p> <p>Evaluators in each agency complete assigned reviews (including waivers) and draft evaluation reports / data evaluation records; exchange and discussion of individual reports for peer review, as completed. If required, lead agency sends letter of deficiency to applicant.</p>	EPA, PMRA according to worksharing agreement	260 (120 days for efficacy, characterization, and preliminary review of deficiencies)	120*
3	Agencies conduct a parallel risk assessment, conference call between agencies to harmonize risk assessment, and develop a proposed decision; prepare final review and risk assessment documents.	PMRA EPA	350	180
4	Preparation of formal document/letters. Lead agency sends letter of “agreement in principle” to applicant. Each agency communicates decision to applicant for registration follow-up.	PMRA EPA	365	185

Summary: Log in seven days, screening 45 days
 Review and decision, 365 days (microbial submissions)
 Review and decision, 185 days (pheromones and other semiochemicals)

*Caveat: a longer timeframe will be required if the substance is not a straight chain lepidopteran pheromone (SCLP), a toxicity issue is raised for the formulation, or an occupational or food residue risk assessment is triggered.

The required consultation in support of the regulatory decisions will be prepared as mandated in the two agencies.



Appendix: Data Requirements

The data requirements for microbials and semiochemicals, including pheromones, in the U.S. and Canada are essentially harmonized, except in the area of efficacy. The documents providing information on protocols and data requirements for the registration of these products can be found at:

1. U.S. EPA 40CFR 158.690 Biochemical Pesticides Data Requirements, and U.S. EPA 40CFR 158.740 Microbial Pesticides Data Requirements, both at <http://www.epa.gov/pesticides/biopesticides/guidelines/series885.htm>
2. OPPTS Harmonized Test Guidelines, at http://www.epa.gov/OPPTS_Harmonized/
3. OPPTS Harmonized Test Guidelines — Biochemicals Test Guidelines, at http://www.epa.gov/docs/OPPTS_Harmonized/880_Biochemicals_Test_Guidelines
4. OPPTS Harmonized Test Guidelines — Microbials Test Guidelines, at <http://www.epa.gov/pesticides/biopesticides/guidelines/biochem2.htm>
5. Canada PMRA Guidelines for the Registration of Microbial Pest Control Agents and Products, DIR2001-02
<http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir2001-02-e.pdf>
6. Canada PMRA Guidelines for the Research and Registration of Pheromone Pest Control Products and Other Semiochemicals, DIR97-02
<http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9702-e.pdf>

For further information on Biopesticides at the EPA see
<http://www.epa.gov/biopesticides/biopesticides>

For further information on the PMRA see
<http://hc-sc.gc.ca/pmra-arla/>

