



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

Introduction to Biopesticide Joint Review Process

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Biopesticide Joint Review Process

- ◆ Requirements to be eligible for a joint review:
 - ❖ new active ingredient to both countries
 - ❖ microbial or arthropod semiochemical
 - ❖ proposed use pattern must be common to both countries
- ◆ EPA and PMRA are committed to joint reviews and worksharing of pesticide evaluations on a regular basis
- ◆ 12 month review period (contingent upon completeness of application package)



Advantages of Joint Reviews

- ◆ Increase efficiency of registration process
- ◆ facilitate simultaneous registration in US and Canada
- ◆ increase access to new pest management tools in both countries



Requests for Joint Presubmission Consultation

- ◆ Requests should be submitted in writing to:
 - ❖ Janet Andersen, Director
 - ❖ Biopesticides and Pollution Prevention Division, EPA
 - ❖ 703-308-8712

 - ❖ Wendy Sexsmith, Chief Registrar
 - ❖ Pest Management Regulatory Agency
 - ❖ 613-736-3707



Products Eligible for Joint Review

- ◆ To be eligible for a joint review, the product must meet the following requirements:
- ◆ the active ingredient is a microbial agent or a semiochemical for control of arthropods;
- ◆ a complete data base is available;
- ◆ proposed use pattern and formulation type are the same for both countries; and
- ◆ 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 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.



Joint Presubmission Consultation

- ◆ Critical step in the joint review process (scientific teams established, decision on lead agency made, time frames discussed and established)
- ◆ required to establish joint data requirements or the information required to support a data waiver
- ◆ applicant must submit an information package 90 days prior to the joint presubmission consultation



Joint Presubmission Consultation

- ◆ Information required for a joint presubmission consultation:
 - ❖ cover letter requesting joint presub, must identify a company contact in each country
 - ❖ formal letter consenting to consultation between EPA and PMRA and agreeing to public announcement
 - ❖ draft label
 - ❖ list of contents (including active ingredient and formulants)
 - ❖ short summary of available data (efficacy, environment, human health, and scientific waivers)



Joint Presubmission Consultation

- ◆ Information required for a joint presubmission consultation (cont'd):
- ◆ Microbial products only:
 - ❖ identity of organism and survival parameters
 - ❖ manufacturing methods
 - ❖ info regarding potential health or environmental issues
- ◆ Semiochemicals:
 - ❖ applicable chemistry
 - ❖ manufacturing methods



Joint Presubmission Consultation

- ◆ Next Steps:
- ◆ Each agency reviews information package, drafts data requirements
- ◆ Agencies work together to finalize data requirements and develop harmonized data tables
- ◆ Applicant notified of joint data requirements for proposed use pattern at joint presubmission consultation



Joint Review Process

- ◆ Applicants that meet the requirements for joint review must submit simultaneously to the PMRA and the EPA:
 - ❖ the same formulation type, packaging and use pattern;
 - ❖ common data package to both countries (including U.S. and Canadian labels);
 - ❖ 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;



Joint Review Process

- ◆ Applicants that meet the requirements for joint review must submit simultaneously to the PMRA and the EPA:
 - ❖ a Comprehensive Data Summary or a Summary Dossier containing Tiers II and III in OECD format;
 - ❖ a written request for a joint review;
 - ❖ a letter permitting exchange of data and reviews between PMRA and EPA; must agree to public announcement of submission.



Joint Review Process

- ◆ A candidate must meet all prerequisites and clear the data screen to be eligible for a joint review
- ◆ If any criteria are not met, deficiencies will be explained in a joint letter sent by the lead agency
- ◆ Deficiencies must be addressed in 45 days
- ◆ If deficiencies not addressed within 45 days, submission will be administratively withdrawn by both agencies



Review of Data and Decision

- ◆ Each agency commences review of data elements for which it is responsible for the primary review
- ◆ Each agency conducts preliminary reviews for deficiencies to validate the ‘reviewability’
- ◆ 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



Review of Data and Decision

- ◆ Submissions successfully determined 'reviewable' following preliminary review move immediately to full assessment
- ◆ Evaluators complete reviews (includes waivers) and draft evaluation reports/ data evaluation records; exchange and discussion of individual reports for peer review, as completed



Review of Data and Decision

- ◆ Agencies conduct parallel risk assessment
- ◆ Conference call between agencies to harmonize risk assessment
- ◆ Agencies negotiate a proposed decision
- ◆ Agencies prepare final review and risk assessment documents
- ◆ Product Labels reviewed, Joint label established
- ◆ Joint review announcement made to Public



Review of Data and Decision

- ◆ Agencies prepare formal document/letters
- ◆ Lead agency sends letter of “agreement in principle” to applicant
- ◆ Each agency communicates decision to applicant for registration follow-up
- ◆ The required consultation in support of the regulatory decisions will be prepared as mandated in the two agencies.



References

- ◆ For further information on Biopesticides:
- ◆ Procedures for Joint Review of Microbials and Semiochemicals
- ◆ EPA web site:
<http://www.epa.gov/biopesticides/biopesticides>
- ◆ PMRA web site: <http://www.hc-sc.gc.ca/pmra-arla/>

