

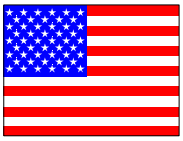

# NAFTA Technical Working Group on Pesticides

## UPDATED PROCEDURES FOR JOINT REVIEW OF CHEMICAL PESTICIDES

The Canadian Pest Management Regulatory Agency (PMRA), and the United States Environmental Protection Agency (EPA), in cooperation with Mexico's Comisión Intersecretarial para el Control del Proceso y Uso de Plaguicidas y Sustanicas Tóxicas (CICOPLAFEST) have established a process for the joint review of pest control products that contain conventional chemical pesticides. This document describes the acceptance criteria, processes and time lines for the joint review of Group 1 Reduced Risk Joint Reviews, Group 2 Non-Reduced Risk NAFTA Priority Joint Reviews, and Group 3 Negotiated Joint Reviews. The procedure entails a joint pre-submission process to ensure a clear understanding of the entire joint review process and data requirements; the proposed uses and use patterns, formulation, and label must be common to all countries. The attached document describes the processes and time lines for the application and registration decision of products that applicants nominate for joint review. This document replaces all earlier documents on the *Procedures for the Joint Review of Reduced Risk Pesticides*.

While the ultimate goal is to conduct joint reviews and share the work of pesticide evaluations among all NAFTA countries, currently joint reviews and workshares are only taking place on a routine basis between EPA and PMRA on a routine basis. Joint reviews increase the efficiency of the registration process, facilitate simultaneous registration in participating countries and increase access to new pest management tools in participating countries. Efficient worksharing requires a shared understanding of the responsibilities of each agency, as well as common procedures and time frames.

International liaisons for conventional chemical pesticides are:


Chief Registrar
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
Ottawa, ON, Canada
K1A 0K9

(613) 736-3705
(613) 736-3707 (fax)

Director
Registration Division (7505C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC, 20460 USA

(703) 305-5447
(703) 305-6920 (fax)

Director General
Secretaria de Salud
Subsecretaria de Regulacion y Fomento Sanitario
Direccion General de Salud Ambiental
Mariano Escobedo 366
Colonia Casa Blanca, CP 11570
Mexico D.F.

General inquiries regarding the joint review process and requests for joint pre-submission consultation for a new conventional chemical pesticide should be submitted in writing to the following contacts.

| Canada | United States | Mexico |
|---|---|---|
| Lisa Lange<br>Executive Director's Office<br>Pest Management Regulatory Agency<br>Health Canada<br>2720 Riverside Drive<br>Ottawa, ON K1A 0K9 Canada<br><br>(613) 736-3760 (voice)<br>(613) 736-3707 (fax)<br>Lisa_Lange@hc-sc.gc.ca | Terri Stowe<br>Registration Division (7505C)<br>U. S. Environmental Protection Agency<br>Office of Pesticide Programs<br>Registration Division (7505C)<br>Ariel Rios Building<br>1200 Pennsylvania Ave., NW<br>Washington, DC 20460 USA<br><br>In person: 1921 Jefferson-Davis Hwy., Room 713S, Crystal Mall 2, Arlington, VA USA<br><br>(703) 305-6117 (voice)<br>(703) 305-6920 (fax)<br>stowe.terri@epa.gov | Hector Murguia Romero<br>CICOPLAFEST<br>Dirección de Riesgos Radiológicos<br>Dirección General de Salud Ambiental<br>Piso 4 Col. Anzures<br>Delegación Miguel Hidalgo<br>Mexico, D.F.<br>C.P. 11590<br><br>52 52 50 46 84 (voice)<br>52 52 55 45 58 (fax)<br>hmurguia@mail.ssa.gob.mx |

Data packages for a conventional chemical pesticide submission that have been prepared according to the pre-submission consultation agreement should be submitted to the following:

| Canada | United States | Mexico |
|---|---|---|
| Submission Coordination and Documentation Division<br>Pest Management Regulatory Agency<br>Health Canada<br>2720 Riverside Drive<br>Ottawa, ON<br>K1A 0K9 Canada | U. S. Environmental Protection Agency<br>Office of Pesticide Programs<br>Document Processing Desk<br>Mail Code 7504C<br>Ariel Rios Building<br>1200 Pennsylvania Ave., NW<br>Washington, DC 20460 USA<br><br>In person: Room 266A, Crystal Mall 2, 1921 Jefferson-Davis Hwy., Arlington, VA 22202 USA | Director General<br>Secretaria de Salud<br>Subsecretaria de Regulacion y Fomento Sanitario<br>Direccion General de Salud Ambiental<br>Mariano Escobedo 366<br>Colonia Casa Blanca, CP 11570<br>Mexico D.F. |

## INTRODUCTION

The purpose of this document is to inform applicants and other interested parties about the process for joint review of proposed conventional chemical pesticides by the Canadian Pest Management Regulatory Agency (PMRA), the United States (US) Environmental Protection Agency (EPA), and Mexico's CICOPLAFEST, for consideration for simultaneous review and registration in participating countries. Please note a joint review may be proposed for two of the three NAFTA countries. For pre-registration testing (research permits, experimental use permits or notification for small-scale testing), please contact individual countries.

A new chemical pesticide submission must meet the following general prerequisites to be considered for a joint review of data submitted in support of registration:

1. The proposed new active ingredient must be unregistered in all participating NAFTA countries at time of application; for products with multiple active ingredients, registered active ingredients must have been evaluated under the U.S. EPA Food Quality Protection Act (FQPA);

2. Proposed uses, use patterns and formulation type common to all countries;

3. A complete data base (including efficacy data), labels for all countries, and a label comparison review comparing the key components of the labels (e.g.: same % active ingredient, same formulation type, signal words, etc.)

4. Applicant to provide a written request to each country for joint review authorizing free exchange of reviews and other information on the chemical among the Agencies

Submissions for joint review must fall under one of the following groups:

1) Group 1 - Reduced Risk Chemicals

   This group includes new chemical pesticides that meet the EPA criteria for a reduced risk pesticide. EPA's reduced-risk program encourages the development, registration and use of lower risk pesticide products which would result in reduced risks to human health and the environment when compared to the existing pesticide alternatives.

   Group 1A Joint Reviews (Reduced Risk Chemicals) contain products with only one active ingredient and a maximum of two end-use products. Chemicals in this group will usually have a 12-month time line for evaluation and decision after passing the PMRA and EPA screens.

   Group 1B Joint Reviews (Reduced Risk Chemicals) contain products with more than one active ingredient and two end-use products or more. Chemicals in this group will have time lines of 18 to 24 months for evaluation and decision after passing the PMRA and EPA screens.

2) Group 2 - Non-Reduced Risk Chemicals that are NAFTA Priorities

   This group contains non-reduced risk chemicals that are considered NAFTA priorities, e.g., organophosphate (OP) and methyl bromide alternatives. Chemicals in this group will usually have an 18-month schedule for evaluation and decision after passing the PMRA and EPA screens.

3) Group 3 - Negotiated Joint Review Chemicals

This group contains chemicals which do not meet the criteria for Group 1 or 2. Chemical submissions eligible for consideration at this time include those with: electronic data submission components (including electronic versions of labels), OECD formats, and multiple active ingredients. Chemicals in this group will have negotiated time lines of 18 to 24 months for evaluation and decision after passing the PMRA and EPA screens.

Please note: all time frames mentioned begin only when the submissions are in Step III.

**Definitions:**
The term joint review refers to a formal process with specific time lines where the workload is split up between the countries, the reviews of data are exchanged, peer reviewed and a cooperative risk assessment is undertaken with the goal of a harmonized and simultaneous registration decision.

Another form of review is called work share, which can include ad hoc exchanges of information as well as the structured division of work and collaboration on decisions of mutual interest. Worksharing can include exchange of information about new active ingredients, new uses and reassessment of older pesticides.

**STEP I: Joint Pre-Submission Consultation**

A joint pre-submission consultation is required to establish joint data requirements for a specific chemical and to ensure common understanding of the approach and process. Applicants of pesticide chemicals that meet the above general prerequisites for a joint review must request a joint pre-submission consultation meeting with the appropriate NAFTA Joint Review Coordinators listed above. Applicants must provide four copies of the pre-submission consultation package containing the information listed below to the participating regulatory agencies at least 45-days prior to the consultation. A pre-submission consultation will be held with the participating regulatory agencies and company representatives from each country, either in person or by conference call.

During a pre-submission consultation exploration of the potential for the use of crop groupings for residue chemistry and efficacy to facilitate minor use registrations is encouraged. In addition, registrants are encouraged to consider the development and submission of a NAFTA label in order to facilitate movement of jointly registered products from one country to another.

The pre-submission consultation package should include the following:

1. A cover letter which contains the following: the type of joint review (Group 1A, 1B, 2, or 3) being requested, a request for a joint pre-submission consultation with all participating agencies which gives several proposed dates/times for the meeting and any audio-visual equipment needs (including conference call phone lines), the lead company contact person and a company contact person for each participating country;

2. A formal letter consenting to consultation among participating agencies, including confidential business information, and agreeing to public announcement of the submissions;

3. Chemical/ Product Description: name of chemical, type of pesticide (e.g., fungicide), chemical structure, formulation types (e.g., dust), proposed uses (including country-specific uses and rotational crops), use patterns (e.g., foliar), application methods (e.g., aerial), and the international regulatory status. If available at the time of the meeting, then provide draft country-specific and NAFTA labels for each participating country, a label comparison review comparing the key components of the labels (e.g., same % active ingredient, same formulation type, signal word, etc.).

**Activities and Time Frames for Pre-Submission Consultations**

| Activity | | | Responsible | Calendar days |
|---|---|---|---|---|
| 1 | Consultation Package | Consultation package submitted simultaneously to appropriate agencies at least 45-days prior to meeting | Applicant | 45 |
| 2 | Receipt by agencies and eligibility check | Each agency reviews consultation package and discuss data requirements and issues via phone, fax or E-mail | Participating Agencies | 30 |
| 3 | Pre-submission consultation meeting | Applicant notified by agencies of date and time of pre-submission consultation meeting at least 15-days prior to meeting; | Participating Agencies | 15 |
| | | Meeting held | Applicant and participating agencies | 0 |
| 4 | Applicant notified of results | Agencies notify applicant of results of meeting within 90-days | Lead Agency* | 90 days after meeting |

* Note: Government will determine the lead Agency (e.g.., EPA or PMRA) and the review teams and assignments.

**STEP II: Receipt, Screening, Label Review, and Reduced Risk Assessment**

To be eligible for joint review, a chemical pesticide must meet all prerequisites and clear all administrative and data screens in the participating agencies. Reduced-risk, OP and methyl bromide alternative chemicals must also clear the EPA Reduced Risk, OP/Methyl Bromide Alternative Assessment and appeals process (where applicable), before review activities will commence in any country. If any of these criteria are not met, work by all participating agencies will stop and applicants will be given 45 days to provide supplementary information to address the deficiencies. If applicants can not correct the deficiencies within this time frame, the submission will be rejected as a NAFTA Joint Review candidate. If the upgraded submission is received within 45 days, the participating agencies will determine if the deficiencies were adequately addressed. If the submission is acceptable, then a new target decision date will be determined and the applicant will be notified of acceptance into the Joint Review program and the new target decision date. Another data screen and/or reduced risk assessment is done before review activities will begin.

Applicants of chemical pesticides that meet the general prerequisites (above) for joint review must submit simultaneously to the reviewing agencies (e.g. PMRA and EPA):

1. the same formulation type, packaging, uses and use pattern;

2. a common data package, for example including US and Canadian labels if those two countries are the participating countries, to all countries along with an index using table that can be obtained from international coordinators that includes the crosswalk for Canadian DACO, EPA guidelines, and OECD point;

3. a package complete with forms, fees, and format required by each agency. EPA and PMRA 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’;

6. a letter permitting exchange of data and reviews, including confidential business information (CBI), between the participating agencies (and if appropriate, the State/Provincial and non-NAFTA country agencies) and agreeing to public announcement with regard to the submission.

7. for Group 1 Reduced Risk Chemicals only: a rationale supporting the definition of a Reduced Risk Chemical (refer to the US EPA Pesticide Registration Notice PR 97-3 and PR 98-7).

8. For Group II Non-Reduced Risk NAFTA Priorities involving an organophosphate or methyl bromide alternative: a rationale supporting these alternatives must be submitted (refer to the US EPA Pesticide Registration Notices 98-7 and 95-4, respectively).

9. For All Groups: labels should incorporate the pesticide mode of action classification and labeling recommendations as described in the voluntary resistance management guidelines based on mode of action (refer to US EPA Pesticide Registration Notice PR 2001-5 and Canada PMRA DIR 99-06, respectively).

| Activities and Time Frames for Receipt, Screening and Announcement of Joint Reviews Accepted | | | | |
|---|---|---|---|---|
| Activity | | | Responsibility | Calendar days |
| 1 | Receipt | Application to register technical product and end-use product(s) with required supporting data package submitted to participating agencies | Applicant | 0 |
| 2 | Login | Receipt of submission by the participating agencies | Participating Agencies | 7 |
| | | Acknowledgment of receipt of submission to applicant | Participating Agencies | |
| 3 | Screening of submission for completeness | Each participating agency will screen the submission for completeness based on their country-specific requirements (including the requirements established in the pre-submission consultation) as follows: | Participating Agencies | 45 |
| | | PR 86-5 administrative screen, label comparison review, and if appropriate - reduced risk, methyl bromide and OP alternative assessments | EPA | |
| | | Completeness (Level B) Screen | PMRA | |
| 4 | Interagency Consultation/ Coordination | Agencies will decide on adequacy of submission. If adequate, the target decision date, work split, and draft review schedule are determined. | Participating Agencies | |
| 5 | Public Announcement | Agencies prepare announcement of joint review. | Participating Agencies | |

**STEP III: Review of Data and Decision**

Following completion of Step II, each agency reviews their assigned data according to the work split agreement. If additional deficiencies/data gaps are identified during the review of the data, then the applicant will have 90 days to submit additional information to adequately address them. If the information is received within 90 days and adequately addresses the deficiencies/data gaps, then the review will continue. However, depending on the nature of the deficiencies/data gaps, additional review time may be required and therefore, a new target decision date given. **The participating countries will be responsible for their country-specific regulatory decision consultation and documentation processes.**

The participating countries will cooperate to conduct preliminary reviews for deficiencies to validate the 'reviewability' of the file:

- have data requirements been properly interpreted?
- are data waiver requests supportable?
- are non-standard test protocols acceptable?

| **Activities and Time Frames for Review of Data and Decision** | | | | |
|---|---|---|---|---|
| Overall Performance Standards (days) | | | | |
| Activity | Group 1A Reduced-Risk | Group 1B Reduced-Risk | Group 2 Non Reduced Risk | Group 3 Negotiated |
| Login, Screening, Reduced Risk assessment, label comparison review | 52 | 52 | 52 | 52 |
| Review, Decision | 365 | 550 to 730 | 550 | 550 to 730 |

## Appendix 1: References

The documents providing information on protocols and data requirements in the U.S. and Canada for the registration of chemical pesticides are referenced below.

Potential applicants should familiarize themselves with the appropriate documents of each country regarding data requirements and protocols of required studies for each country. Appropriate guidelines and data requirements can be found on the PMRA and EPA web sites at:
PMRA: http://www.hc-sc.gc.ca/pmra-arla
EPA: http://www.epa.gov/pesticides

**Guidance for applicants preparing a Reduced Risk Rationale is available in:**

- U.S. EPA Pesticide Registration Notice PR 97-3, Guidelines for Expedited Review of Conventional Pesticides under the Reduced-Risk Initiative and for Biological Pesticides http://www.epa.gov/opppmsd1/PR_Notices/pr97-3.html

**Guidance for applicants preparing a Organophosphate (OP) Alternative designation rationale is available in:**

- U.S. EPA Pesticide Registration Notice PR 98-7, Changes to Registration Priority System Involving Organophosphate (OP) Alternatives and Reduced Risk Candidates http://www.epa.gov/opppmsd1/PR_Notices/pr98-7.html

**Guidance for applicants preparing a Methyl Bromide Alternative designation rationale is available in:**

- U.S. EPA Pesticide Registration Notice PR 95-4, Changes to Registration Priority System Involving Organophosphate (OP) Alternatives and Reduced Risk Candidates http://www.epa.gov/opppmsd1/PR_Notices/pr95-4.html

**Guidance for Organization for Economic Cooperation and Development (OECD) dossier format:**

- OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances, available at http://www.oecd.org/ehs/PestGD03.htm

**Guidance for Voluntary Resistance Management Labeling:**

- U.S. EPA Pesticide Registration Notice PR 2001-5, Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling http://www.epa.gov/opppmsd1/PR_Notices/pr2001-5.pdf

- Canada PMRA Regulatory Directive DIR 99-06, Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action http://www.hc-sc.gc.ca/pmra-arla/english/pdf/dir/dir9906-e.pdf

For further information on the EPA see http://www.epa.gov/
For further information on the PMRA see http://www.hc-sc.gc.ca/pmra-arla/

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