



## Regulatory Directive

### Chemical Pesticides Research Permit Guidelines

The purpose of this regulatory directive is to inform registrants, researchers and other interested groups and agencies of revisions to Regulatory Directive Dir93-22, *Chemical Pesticides Research Permit Guidelines*. The revisions do not involve changes to the data requirements. Some procedures have been modified to reflect current practices of the Pest Management Regulatory Agency (PMRA), and parts of the text have been revised to improve clarity.

Research is essential to the development of pest control products. The scientific and technical information needed to evaluate the effectiveness and safety of a product can be provided only by well-documented research. The *Pest Control Products Act* (PCPA) provides opportunity for research to be conducted under conditions set forth in the Pest Control Products Regulations (PCPR).

This guideline pertains to research with conventional chemical pesticides only. For research involving pheromones and other semiochemicals, or microbial pest control agents, please consult Regulatory Directive Dir97-02, *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals* and Regulatory Proposal Pro93-05, *Research Permit Guidelines for Microbial Pest Control Products* (or subsequent revisions), respectively.

This regulatory directive replaces Regulatory Directive Dir93-22, of the same title, dated October 28, 1993.

*(publié aussi en français)*

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## 1.0 Definitions

The following terms are defined for the purpose of these research permit guidelines.

- **Cooperator:** any individual, corporation or institution not engaged in pesticide research who has agreed to use or allows the use of a pesticide for research purposes on a site owned or operated by that individual, corporation or institution.
- **Crops:** includes all agricultural crops and forest resources.
- **Food use:** includes crops intended for human consumption, feed use, and application in food storage or food handling areas, as defined in the *Food and Drugs Act*.
- **New use:** involves addition of new use site categories or commodities, change in application methods (e.g., change from ground to aerial application), increase in application rate, or other significant changes of the use.
- **Research:** tests, trials, or experiments carried out to generate new data or confirm results drawn from other studies, as required pursuant to Section 9 of the PCPR, to support registration of a pesticide.
- **Researcher:** any person employed by a research establishment who is responsible for using or supervising the use of a pesticide for research purposes.
- **Research establishment:** any public or private corporation or institution or part thereof whose employees are engaged in research pertaining to chemical pesticides.
- **Structural pest control:** includes, but is not limited to, pest control in houses, apartments, hotels, motels and vehicles.

## 2.0 Application for Research Permits

### 2.1 General

Anyone can apply for a research permit, for example, a company officer or a researcher. However, trials should be conducted by trained personnel employed by private industry, government, universities or other recognized research establishments.

When a number of research permit applications involving the same pesticide product are expected from various sources, the PMRA may ask the pesticide company to coordinate the requests through a *single* application for permit to include all proposed treatments at all

locations. This type of coordination is especially important when questions on the basic supporting data package make it desirable to limit quantities of a product used for research. Applications for research permits should include the following (see Appendix III for details):

- C covering letter;
- C completed Application for Research Permit form;
- C completed Control Product Specification form;
- C draft experimental label;
- C research plan (including site information, list of cooperators, etc., if applicable);
- C supporting data and information; and
- C completed Application Fees form and the appropriate fee.

Application for Research Permit, Control Product Specification, and Application Fees forms are available from headquarters, or the regional managers of the PMRA. Instructions for completing and submitting requests are included with the forms. Applications should be submitted to the Agency and should include sufficient information to allow scientific assessment of individual research proposals. Researchers applying for research permits should seek the cooperation of the chemical company concerned and ensure that an experimental label is submitted with the application.

All submissions concerning research should be sent to:

Submission Management and Information Division  
Pest Management Regulatory Agency  
Health Canada (A.L. 6605E1)  
2250 Riverside Drive  
Ottawa, Ontario, K1A 0K9

## 2.2 Purpose of Research

The applicant must clearly state the purpose of the proposed research.

## 2.3 Site Information

When making an application, the applicant must provide the most exact location possible for the treatment site.

For forest or water applications, maps and/or locations of the areas being considered must be provided. Maps must be marked with labelled lines of latitude and longitude and a scale bar. Detailed maps and/or locations must be supplied to the PMRA preferably at the time of submission of application, but no later than one month prior to the planned treatment date, so

that final concerns can be addressed by the Agency. Failure to provide these test location details may result in refusal of the permit.

For sites other than forests and waters, maps may not be required on condition that the test plot is at least 100 metres for ground applications, and 500 metres for aerial applications, away from environmentally sensitive areas such as forests, water bodies and wetlands (including sloughs). However, the site locations and a list of cooperators, if any, should be provided to the Agency at the time of application for the permit. If this is not possible, the information should be provided, as soon as available, to the Agency *and* the PMRA's regional managers for the region where the research will be conducted (see Appendix VII for address).

### 3.0 Date of Application

To allow time for processing, applicants are requested to advise the PMRA of their research intentions as early as possible before the date of the intended trial, but no later than the time frame specified below. If the time frame is not met, then the research permit may not be granted in time for the trials to be conducted.

|                               |          |
|-------------------------------|----------|
| New Active Ingredients        | 180 days |
| Registered Active Ingredients | 90 days  |
| Notification                  | 30 days  |

Note: Regulatory Proposal Pro 96-01, *Management of Submission Policy*, dated June 7, 1996, had proposed different time frames. After consultation with the industry, the Agency has decided to follow the original time lines as stated above.

### 4.0 Limitations and Data Requirements for Research Permits

There are three basic divisions of research\*:

- a) new use (new crop, rates, animal host, application method, tank-mix, etc.) for registered products;
- b) new formulation and/or new uses for an active ingredient that is currently in a registered product; and
- c) new active ingredients. This group is subdivided further into three categories according to type of personnel involved, total area, and available data.

\*Note: Limitations and conditions for research permits for antimicrobial pesticides and products for greenhouses, domestic/residential areas (including lawns and gardens), industrial

premises, food handling areas or for structural pest control or fumigation, will be determined on a case-by-case basis.

Table 1 outlines the general limitations on research permits (Appendix I).

Figure 1 and Table 2 outline the general data requirements for research permits under different situations (Appendices IIA and IIB).

Table 3 specifies the number of copies of information required for research permit submissions (Appendix III).

Data requirements may be discussed with the appropriate Agency division(s) responsible for evaluating the request prior to submission of research permit applications to avoid unnecessary delays in the review process. Trade Memoranda T-1-245, *Guidelines for Developing a Pesticide Toxicology Database*, and T-1-255, *Guidelines for Determining Environmental Chemistry and Fate of Pesticides*, and Regulatory Directive Dir93-07a, *Guidelines for Efficacy Assessment of Chemical Pesticides* (or any replacement documentation) should be consulted.

## **5.0 Data Submission and Handling**

Data required to support a research project must be organized according to instructions provided in Regulatory Proposal Pro98-02, *Organizing and Formatting a Complete Submission for Pest Control Products*. Sufficient copies must be submitted for distribution to the reviewers. Consult Table 3 (Appendix III) for information regarding the number of copies required.

Data submitted to support research permits may also be used to support future submissions for registration by reference to either the research permit or submission number. The applicant must clearly indicate that the data submitted are to be used for the research permit and retained for registration purposes. Previously submitted data may also be considered in support of research trial requests, if such data have been submitted according to the regulatory guidelines and are referenced in the research permit request.

## **6.0 Research Records and Data Reporting**

Records must be kept of all quantities of pesticides used in a research program, cooperator(s) involved, trial location(s), method(s), and data generated as a result of research, whenever pesticides are distributed for research purposes. These records are to be made available to the Agency upon request. Data generated as a result of research permits are to be reported in a scientific manner and, submitted in accordance with instructions for data submission. Refer to research permit numbers or permit submission numbers in all correspondence.

## 7.0 Labels for Research Uses

Labels are required for all chemical pesticides to be tested under a research permit or notification in lieu of permit. These labels must be submitted with the research permit request and research notifications. It is the responsibility of the supplier of the pesticides and the research permit applicant to provide these labels to all researchers and cooperators before experimental work is initiated. All people handling this product must be able to produce this label for inspection. The information included on these labels will depend on the use under investigation. Labels must be typed and legible, and represent the intended research project.

Labels for experimental products should include the following information where applicable:

- 1) the statement: EXPERIMENTAL USE ONLY;
- 2) the Research Permit Number, or the Notification Number, issued under the PCPA;
- 3) the statements: Not for sale. Not for distribution to any person other than a researcher or cooperator.;
- 4) the name, brand, or trademark of the product, and type of formulation;
- 5) the name and address of the manufacturer;
- 6) the net contents;
- 7) the ingredient statement (guarantee);
- 8) hazard warnings and precautions, including proper personal protective equipment and re-entry intervals (see item #3 of General Limitations, Appendix IV, for restrictions on re-entry);
- 9) the KEEP OUT OF REACH OF CHILDREN statement;
- 10) the READ THE LABEL BEFORE USING statement;
- 11) the Notice to User statement;
- 12) disposal and decontamination methods (for unregistered products, the label should indicate that any unused product should be returned to the manufacturer);
- 13) first aid and toxicological information;
- 14) environmental hazards;
- 15) directions for use, including information on:
  - a) crop(s) or site(s)
  - b) pest(s)
  - c) dilution and application rates
  - d) method of application
  - e) timing of application
  - f) number of applications per crop season
  - g) pre-harvest intervals; and
- 16) any other information necessary to ensure safe and effective use of the product for research purposes.

NOTE: Items 1 to 10 above should be on the front panel of the label. In addition, the PMRA may add any use limitations, terms and conditions to the label.



For research involving a registered product, a supplemental label will be accepted in conjunction with the approved version of the registered product label. The supplemental label shall include items 1 to 5, 7 to 10, 13, 15 and 16 as outlined above. Both the supplemental label and the registered product label must accompany pesticide containers at all times.

The number of copies of the label, including the supplemental label, required for review is outlined in Table 3 (Appendix III). Additional copies should be submitted for distribution to the regional offices of the PMRA for the regions where the research will be conducted.

## **8.0 Review Procedure for Research Permit Applications**

- 8.1 The applicant should submit an appropriate number of copies of the application and any necessary supporting data to the Agency. The applicant should also submit a copy of the application to the provincial pesticides regulatory officials having jurisdiction over the research area.
- 8.2 The Agency will verify the application and, if acceptable, will review the submitted information. If deficiencies are identified, the applicant will be asked to submit all of the requested information in a specified time frame. If there is no response, or if the response is incomplete or inadequate, the submission is withdrawn and returned to the applicant at the applicant's expense. If related data have been submitted previously, please make reference to such data by submission number (and the study number or report number where applicable) in the research permit application. The Agency may also request comments by the provincial regulatory officials when appropriate (when research permit submissions involve restricted uses that would require provincial permits, e.g., forest and/or aquatic sites).
- 8.3 Based on the review by the Agency and comments received from the provincial regulatory officials (where appropriate), a decision regarding the application is made and forwarded to the applicant.
- 8.4 Copies of approved permits are sent to the applicant and the regional offices of the PMRA for the regions where the research will be conducted. When the research involves food use and the PMRA has approved subsequent sale of the treated commodity, PMRA will notify the Canadian Food Inspection Agency of the food use under research, at the following address:

Dairy Fruit and Vegetable Division  
Canadian Food Inspection Agency  
59 Camelot Drive  
Nepean ON  
K1A 0Y9

The applicant is responsible for notifying provincial governments and applying for their permits if this is a requirement in the province where the research takes place. Appendix VI contains addresses of relevant provincial officials.

For this system to function, research programs must be planned well in advance and applications must be submitted early.

## **9.0 Research Permit Exemptions**

Research permits are not required under the PCPA if the pesticide is used for small scale research according to the conditions and limitations outlined in Appendix IV.

Precautionary measures against exposure (including proper personal protective equipment and re-entry intervals) and worker education are essential (see General Limitations for notifications and exemptions under Appendix IV for more details).

Note that food uses of treated crops are also regulated by the *Food and Drugs Act* and Regulations. Treated crops must not be sold for human consumption or for feed for meat or dairy animals, or for chickens or other fowl that supply eggs for human consumption, unless the residues conform with the existing maximum residue limits (MRLs) as defined in Division 15 of the Food and Drugs Regulations. If the treated crop is intended for food or feed use without an appropriate existing MRL, a research permit is required and no exception is allowed.

## **10.0 Notification in Lieu of Permit**

Notification is designed to speed up procedures and only applies to small and medium scale research involving (a) new active ingredient in an area of 5 to 50 ha of the crop under research on premises owned or operated by the researcher; (b) new active ingredient in an area of 1 to 5 ha of the crop under research on premises not owned or operated by the researcher; and (c) currently registered active ingredient in an area of 10 to 50 ha of the crop under research, regardless of whether or not the land for the research is owned or operated by the researcher. More details and limitations are outlined in Appendix IV.

Note that food uses of treated crops are also regulated by the *Food and Drugs Act* and Regulations. Treated crops must not be sold for human consumption or for feed for meat or dairy animals, or for chickens or other fowl that supply eggs for human consumption, unless the residues conform with the existing maximum residue limits (MRLs) as defined in Division 15 of the Food and Drugs Regulations. If the treated crop is intended for food or feed use without an appropriate existing MRL, a research permit is required and no exception is allowed.

Under these conditions and limitations, a research permit under the PCPA will not be required. However, the Agency must be notified of the research according to the following terms and procedures:

- (1) The researcher, or the pesticide company involved, must *notify* the Agency of the research plan using a standard notification form (Appendix V). Copies of the form can be obtained from the Agency or the regional managers of the PMRA. The form must be received by the Agency at least 30 days prior to the treatment.
- (2) Experimental label and product specification form requirements are the same as those for a research permit (see Table 3, Appendix III).
- (3) Sufficient copies of the notification should be submitted to the Agency for distribution to the evaluation divisions and the PMRA regional offices involved (Table 3, Appendix III indicates the number of copies required to review, but does not include copies for the regional offices). A copy of the notification should also be provided to the provincial pesticide regulatory officials having jurisdiction over the research area.
- (4) Research record and data reporting requirements are the same as those for research under a permit.
- (5) Precautionary measures against exposure (including proper personal protective equipment and re-entry intervals) and worker education are essential (see General Limitations for notifications and exemptions under Appendix IV for more details).
- (6) The Notification in Lieu of Permit option is subject to review and audit (see Section 19) and is considered a privilege that can be revoked if any misuse is determined.

NOTE: The Agency may limit the size of the plot, the number of sites and/or disallow research if it does not comply with the terms and conditions as outlined in this regulatory directive.

## **11.0 Provincial Permit**

Certain provinces may require a provincial permit to conduct any research with pesticides, whether the research is conducted under a federal permit or a federal exemption of research permit. It is the responsibility of the researcher to contact the provincial regulatory officials for such a permit as early as possible to allow sufficient time for approval.

Regardless of whether or not a provincial permit is required, the applicant of a federal research permit should submit a copy of the research permit application or notification in lieu of permit to the provincial pesticide regulatory officials having jurisdiction over the research area. Where appropriate (when research permit submissions involve restricted uses that would require provincial

permits, e.g., forest and/or aquatic sites), the provincial regulatory officials will be given the opportunity to make comments to the Agency for consideration.

## **12.0 Importation of Pesticides for Research Purposes**

Quantities of product required for research must be reported on the research permit application or the notification in lieu of permit. Section 55 of the *PCP Regulations* permits the importation of a pesticide for research purposes provided that the product is accompanied by a declaration of importation. However, quantities of imported products in excess of the amount necessary for the proposed research are subject to detention.

## **13.0 Disposal of Unused Products**

Researchers and the pesticide companies are responsible for the safe disposal of unused products. Any unused product should be returned to the manufacturer.

## **14.0 Sale of Products Under Research**

Pesticide products that are not registered under the PCPA and Regulations should not be sold for research purposes. For a currently registered product, it should not be sold for the unregistered uses under research. This policy is designed to promote safe use by limiting product availability only to those doing genuine research.

## **15.0 Sale and Use of Foods Treated Under Research**

The sale of all food crops and livestock that have been treated with any agricultural chemical is subject to the Food and Drugs Act and Regulations. For food residue and safety assessment, relevant information (see Appendix II) should be submitted to the Agency for review. Treated crops from research sites must not be sold for food or feed, and meat (including meat byproducts and fat), milk and eggs that contain residues as a result of research must not be sold for food, unless (1) written authorization has been obtained from the Agency, or (2) the residues conform with the existing MRLs as defined in Division 15 of the Food and Drugs Regulations.

## **16.0 Pesticide-Fertilizer Combinations**

When the proposed research involves pesticide-fertilizer combinations, the Fertilizer Section of the Plant Products Division, Food Inspection Directorate, Canadian Food Inspection Agency, 59 Camelot Drive, Nepean, Ontario, K1A 0Y9, must be consulted following the procedures outlined below:

- (1) When the pesticide component alone would require a research permit:
  - C the applicant will provide a copy of the Pesticide Research Permit Application to the Fertilizer Section of the Plant Products Division; and
  - C approval of the application will be dependent upon the reviews of both the fertilizer and the pesticide components.
- (2) When the pesticide component falls into the notification category:
  - C the company or researcher will copy the notification to the Fertilizer Section of the Plant Products Division for information.
- (3) When the pesticide component alone does not need a permit or notification:
  - C the Fertilizer Section of the Plant Products Division does not require any information.

## 17.0 Advertising

There are concerns that advertising of pesticides under research may lead to misuse of the product. Advertising or any information release that creates a false or misleading impression is considered a violation of Section 3 of the PCPA and Section 36 of the *Competition Act*. All information must be consistent with the labelling of the control product being tested, and must not leave the impression that the product being tested has been fully evaluated and accepted for uses other than research.

## 18.0 Posting of Research Area

All field research activities, including those that do not require a permit, must have appropriate warning signs posted adjacent to the treated site.

The following must be observed in posting the warning signs:

- C The primary message must be:

PEST CONTROL EXPERIMENTAL SITE,  
DO NOT ENTER WITHOUT AUTHORIZATION,  
CONTACT

\_\_\_\_\_ AT \_\_\_\_\_  
(Contact name) (Telephone No.)

- C A contact name, such as the researcher or a local representative, and phone number must appear on the sign.
- The sign should include the research permit number or notification number, where applicable.
- C The sign should be visible, legible, and posted at the point(s) of entry.
- C The sign must be installed immediately before the product is applied, and remain in place until the crop has been harvested or as long as data are being collected.
- C Company names, colours and logos may be used if desired. The name of the product(s) may appear but must be smaller than the primary message.
- C Provinces may require additional information.

## **19.0 Inspections**

All research programs including those under research permit, notification in lieu of research permit, and research permit exemptions, are subject to inspections by staff of the Agency for compliance with the terms and conditions set out in this regulatory directive. Researchers will be required to provide any information that may be requested pertaining to the research that will allow the inspector to ensure that the conditions of research have been properly met.

Please direct any inquiries regarding this Regulatory Directive to:

Submission Management and Information Division  
Pest Management Regulatory Agency  
Health Canada (A.L. 6605E1)  
2250 Riverside Drive  
Ottawa ON K1A 0K9



## Appendix I: Summary of Limitations of Research Permits<sup>1</sup>

| Permit Limitations  | Registered Product, New Uses | New Formulation or New Uses for Active Ingredient Used in a Registered Product | New Active Ingredient <sup>2</sup>            |   |   |
|---|------------------------------|--|---|---|---|
|   |                              |  | Category 1                                    | Category 2  | Category 3  |
| Type of Personnel   | No limitation                | No limitation  | Researcher only                               | Researcher and Cooperator   | Researcher and Cooperator   |
| Cumulative area per year (by all researchers for all purposes)        | Case-by-case                 | Case-by-case   | Case-by-case, but generally small plot trials | Up to 100 ha or 10% of total national crop area, whichever is less, or a limited number of industrial sites | Up to 5000 ha <sup>3</sup>  |
| Plot size (total area treated with the test pesticide per trial site) | Case-by-case                 | Case-by-case   | Case-by-case < 5 ha <sup>4</sup>              | Up to 20 ha or 20% of any one field or plantation, whichever is less <sup>4</sup>                           | Up to 40 ha or 20% of the area of that crop grown on the establishment where the research takes place, whichever is less <sup>4</sup> |

<sup>1</sup> Limitations on Research Permits for antimicrobial pesticides and products for greenhouses, domestic/residential areas (including lawns and gardens), industrial premises, food handling areas or for structural pest control or fumigation, will be determined on a case-by-case basis.

<sup>2</sup> Data requirements for each category are given in Figure 1 and Table 2.

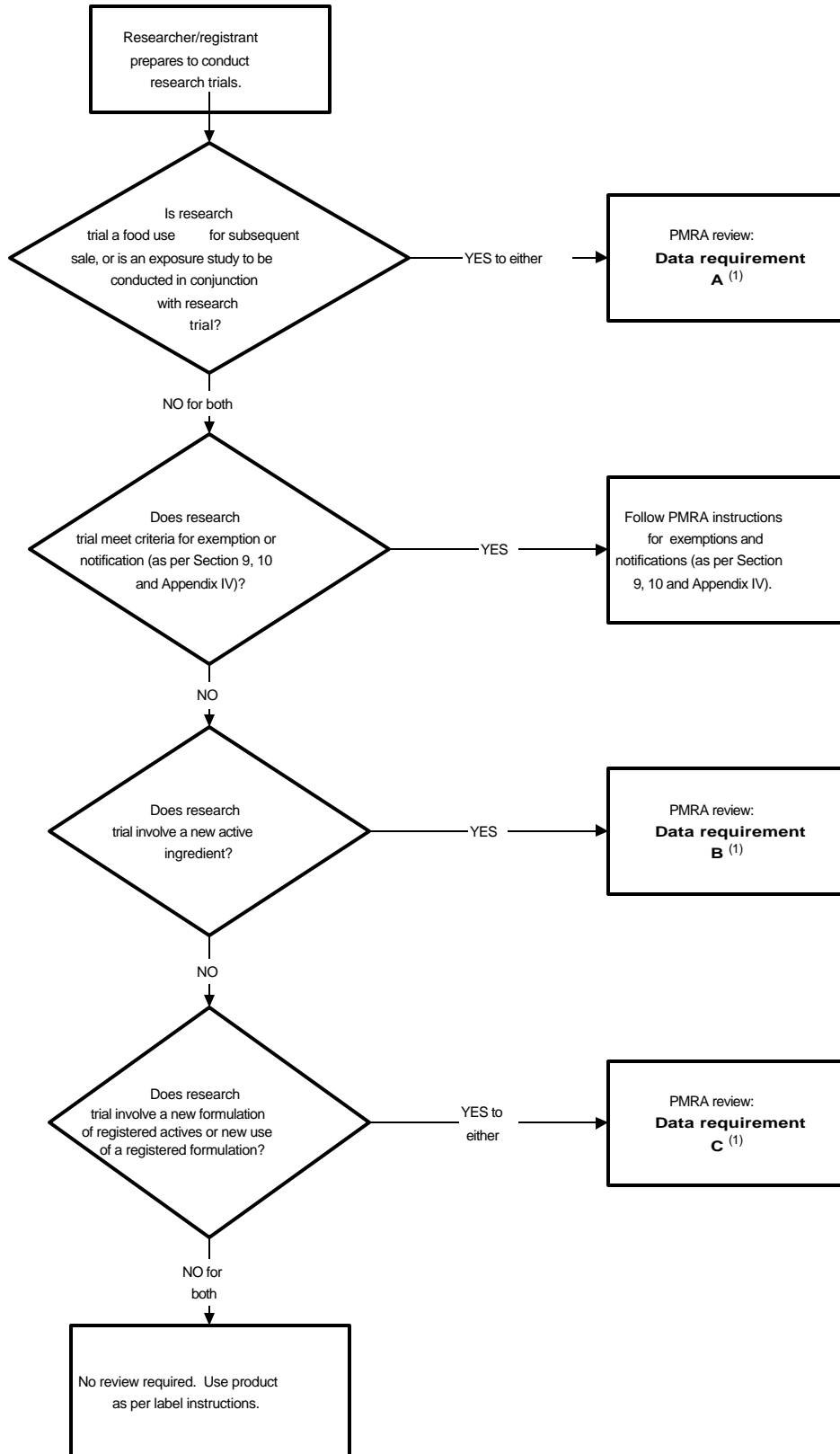
<sup>3</sup> The size of trial must be justified by the applicant.

<sup>4</sup> Exceptional circumstances may be considered on a case-by-case basis.





## Appendix IIA: Scheme of Data Requirements for Research Permits



(1) Refer to Table 2 (following page) for description of data requirements A, B, and C.



## Appendix IIB: Summary of Data Requirements for Research Permit Applications

| Data Requirements   | A<br>(e.g., for subsequent sale of treated crops as food, or for exposure studies to be conducted in conjunction with research trial)   | B<br>(e.g., for new actives)   | C<br>(e.g., for a new formulation of a registered active, or new use(s) of registered formulation)  |
|---|---|--|---|
| <b>Product Information</b>  | Required <sup>1</sup>   | Required <sup>1</sup>  | Required <sup>1</sup>   |
| <b>Toxicology</b><br>- Any of the required studies that have been previously submitted to the PMRA should be cited and referenced instead.<br>- Toxicology studies for antimicrobial products for non-food use will be evaluated on a case-by-case basis. | 1) Acute studies for technical and formulation<br>2) Two teratogenicity studies<br>3) 90-day feeding in two species<br>4) Mutagenicity<br>5) Toxicokinetics<br>6) Chronic/ oncogenicity and reproduction (interim reports as minimum)<br>7) Short-term study of appropriate duration and route of administration for exposure assessment<br>8) Any other available toxicity studies | <b>Category 1:</b> Acute studies for technical<br><b>Category 2:</b> above plus Acute studies for formulation<br><b>Category 3:</b> above plus summaries of the following:<br>2) Two teratogenicity studies<br>3) 90-day feeding in two species<br>4) Mutagenicity<br>5) Toxicokinetics<br>6) Chronic/oncogenicity and reproduction (interim reports as minimum)<br>7) Short-term study of appropriate duration and route of administration for exposure assessment<br>8) Any other available toxicity studies | <i>For new formulation of a registered active:</i><br>1) Acute studies for new formulation<br>2) Toxicology data listed in <b>Data Requirement B</b> , if these have not been previously submitted to the PMRA<br><br><i>For new use of registered formulation:</i><br>1) Toxicology data listed in <b>Data Requirement B</b> , if these have not been previously submitted to the PMRA |
| <b>Metabolism and Residue Chemistry</b>   | Required <sup>2</sup>   | Not required   | Not required  |

<sup>1</sup> Includes label, specification forms and Material Safety Data Sheets (MSDSs). (MSDSs not required for registered products). Chemistry data are required for new active ingredients and new source of active ingredients (if these data have not been previously submitted to the PMRA). Precautionary measures to reduce exposure to workers should be prominently displayed on the experimental label along with the statement FOR EXPERIMENTAL USE ONLY on the primary display panel.

<sup>2</sup> Necessary if treated food is to be used for human consumption or if feed is to be used for meat or dairy animals, or for chickens or other fowl that supply eggs for human consumption. Residue and metabolism data must be provided if no data for a similar crop and under a similar use-pattern were submitted.

| <b>Data Requirements</b> | <b>A</b><br><b>(e.g., for subsequent sale of treated crops as food, or for exposure studies to be conducted in conjunction with research trial)</b> | <b>B</b><br><b>(e.g., for new actives)</b> | <b>C</b><br><b>(e.g., for a new formulation of a registered active, or new use(s) of registered formulation)</b> |
|--------------------------|---|--|--|
| <b>Exposure</b>          | Conditional <sup>3</sup>  | Conditional <sup>3</sup>                   | Conditional <sup>3</sup>   |
| <b>Environment</b>       | Conditional <sup>4,5</sup>  | Conditional <sup>4</sup>                   | Conditional <sup>5</sup>   |

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<sup>3</sup> Exposure assessment may be required depending on the toxicology profile and use-pattern. Requirements for personal protective equipment and other exposure reduction measures will be assessed during the PMRA review. If an occupational exposure study is to be conducted in conjunction with research permit, prior consultation with the Health Evaluation Division (HED) regarding study protocol is recommended. Proposed precautionary measures against exposure and worker education are essential components of the research permit application.

<sup>4</sup> For new active ingredients, laboratory data for Parts 8 and 9 (see DACO Table, Regulatory Proposal Pro98-02, *Organizing and Formatting a Complete Submission for Pest Control Products*) for all field uses, are required.

<sup>5</sup> Prior to approval of research permits, laboratory studies of environmental chemistry and fate, environmental toxicology and/or field studies may be requested by the environmental reviewers if, following their review of a research permit application, significant environmental exposure is expected as a result of, for example:

- a) direct application to bodies of water, forest sites and woodlands;
- b) application within 100 m of federal, provincial, or municipal protected forests, lands or waters or other areas particularly sensitive to environmental impact and wildlife exposure, for example, prairie sloughs; and
- c) new active ingredients involving application methods that present a possibility of significant drift.

### Appendix III: Number of Copies of Information Required for Research Permit Submissions

| PART NO. | DATA/INFORMATION  | TOTAL NO. OF COPIES |
|----------|---|---------------------|
| 0<br>1   | Application form <sup>1</sup><br>Application Fees form (1 copy only)<br>Specification form <sup>1</sup><br>Cover Letter <sup>1</sup><br>Index <sup>2,4</sup><br>Label <sup>2,3,4</sup><br>Summaries <sup>4</sup><br>Material Safety Data Sheet (MSDSs) <sup>4</sup> | 7*                  |
| 2        | Chemistry   | 2                   |
| 4        | Toxicology  | 2                   |
| 6        | Metabolism  | 2                   |
| 7        | Residue   | 2                   |
| 8        | Environmental Chemistry and Fate  | 2                   |
| 9        | Environmental Toxicology  | 2                   |

<sup>1</sup> One original plus photocopies

<sup>2</sup> One electronic copy as well as hard (paper) copies in the prescribed format are required.

<sup>3</sup> Two additional paper copies of the label are required and should be submitted loosely, i.e., not in binders but with the non-data submission components.

<sup>4</sup> These items are to be combined in the Summary Binder

\* This is the maximum number of copies required for a full review by all concerned groups. The number of copies can be reduced if a full review is not required, e.g., test with existing formulation (no new chemistry) and non-food uses.



## Appendix IV: Summary of A) Exemption from Requirements for Research Permits and, B) Notification Requirements for Exempted Research

| Limitations  | New Active Ingredient   |  | Active Ingredient in Currently Registered Product (New Source, New Formulation, New Uses)                                      |
|--|---|--|--|
|  | Researcher (no cooperator participation)  | Researcher (no cooperator participation)   |  |
| Type of Personnel  | Researcher (no cooperator participation)  | Researcher (no cooperator participation)   | Research with cooperator participation   |
| Premises   | Owned or operated by the research establishment                                       | No limitation <sup>1</sup>   | No Limitation  |
| a) Exemption: Total area per year per establishment <sup>2</sup>                   | Up to 5 ha of the crop under research on establishment where the research takes place | Up to 1 ha or 5% of total area of crop under research on establishment where the research takes place, whichever is less | Up to 10 ha or 20% of total area of the crop under research on establishment where the research takes place, whichever is less |
| b) Notification <sup>3</sup> : Required when total area per year per establishment | > 5 ha to 50 ha   | >1 ha to 5 ha  | >10 ha to 50 ha  |

<sup>1</sup> On land not owned or operated by the research establishment; the land supplier does not participate in the research operation.

<sup>2</sup> If the research is carried out on several locations by any one establishment, the total accumulated area is subject to the area limitations outlined in the table. If the pesticide company is doing the research, each company is considered one establishment.

<sup>3</sup> Follow Notification Procedures as outlined in Section 10, and observe the General Limitations outlined in the following page.



**General Limitations** (for exemption and notification)

1. No application to bodies of water, including sloughs, or where runoff water may remove residues from the treatment premises.
2. Food uses of treated crops are also regulated by the *Food and Drugs Act* and Regulations. Treated crops must not be sold for human consumption or for feed for meat or dairy animals, or for chickens or other fowl that supply eggs for human consumption, unless the residues conform with the existing maximum residue limits (MRLs) as defined in Division 15 of the Food and Drugs Regulations. If the treated crop is intended for food or feed use, without an appropriate existing MRL, a research permit is required and no exception is allowed.
3. The researcher assumes the responsibility for worker and bystander safety. Protective measures and education must be employed to minimize exposure to workers and bystanders during and post application. Personal protective equipment should include the following as a minimum: during mixing/loading, application, clean-up and repair wear coveralls over normal work clothing, goggles or face shield, and chemical-resistant gloves. Re-entry into treated areas within 48 hours must be restricted. Individuals may re-enter treated areas within 48 hours if at least four hours have passed since application and long clothing and protective gloves are worn.
4. New formulations and new uses with potential to increase worker exposure above the existing formulations and uses are not suitable for exemption or notification. New uses with potential to increase worker exposure include those that involve a major change in use-pattern or within a use-pattern, significant changes in application methodology, or bystander access. Advice should be requested from the Occupational Exposure Assessment Section, Health Evaluation Division.
5. The exemption and notification options do not apply to antimicrobial products, and products for research in greenhouses, domestic/residential areas (including lawns and gardens), industrial premises, food handling areas, or for structural pest control or fumigation.

**NOTIFICATION OF  
PESTICIDE RESEARCH**

Under the Pest Control Products Act

NOTE: TYPE OR PRINT CLEARLY.  
LE AVEZ SHADHDARHARSI HANK.
**AVIS DE RECHERCHE  
SUR UN PESTICIDE**

En vertu de la Loi sur les produits antiparasitaires

NOTE: ÉCRIRE LISIÈREMENT OU DACTYLOGRAPHIÉ.  
NE PAS ÉCRIRE DANS LES ESPACES OMBRÉS.

|   |  |   |  |  |
|---|--|---|--|--|
| 1. Brand name or experimental no./Marque de commerce ou n° d'essai du produit   |  | 2. Reg. no. if appl. N° d'immat. s'il y a lieu  |  | Submission No.<br>N° de la demande<br><br>Notification no.<br>N° de l'avis de recherche<br><br>Date received<br>Date de réception<br><br>Active ingredient code<br>Code matière active |
| 3. CSA common name or Chemical name and percent for each active ingredient/Nom commun (ACNON) ou formule chimique et pourcentage de chaque matière active   |  |   |  |  |
| 4. Name of Notification Agent/Nom de l'agent chargé des avis  |  | Tel. no./N° de tél.   |  | Date received<br>Date de réception<br><br>Active ingredient code<br>Code matière active  |
| Address/Adresse   |  |   |  |  |
| 5. Name of researcher or research coordinator / Nom du chercheur ou du collaborateur  |  | Tel. no./N° de tél.   |  |  |
| Address/Adresse   |  |   |  |  |
| 6. Name of supplier/Nom du fournisseur  |  | Tel. no./N° de tél.   |  |  |
| Address/Adresse   |  |   |  |  |
| 7A. Host or crop being treated/Hôte ou culture traité   |  | 7F. Additional directions/Directives supplémentaires  |  |  |
| 7B. Pest/Organisme nuisible   |  |   |  |  |
| 7C. Rate and total estimated quantity of product to be used<br>Dose et quantité totale estimées de produit à utiliser   |  | 8. Preharvest interval/Délai d'attente avant récolte  |  |  |
| 7D. Timing and number of applications (listing dates where possible)<br>Calendrier et nombre d'applications (dates des essais si possible)  |  | 9. Purpose of research/But de recherche<br><input type="checkbox"/> Residue <input type="checkbox"/> Efficacy <input type="checkbox"/> Environment <input type="checkbox"/> Other (specify):<br><input type="checkbox"/> Résidus <input type="checkbox"/> Efficacité <input type="checkbox"/> Environnement <input type="checkbox"/> Autres (préciser)  |  |  |
| 7E. Application equipment to be used/Type de matériel d'application   |  | 10. Exact location, size and number of plots/Endroit, superficie et nombre exacts des parcelles<br><div style="text-align: right;">Total Area (ha)<br/>Superficie totale (ha)</div>   |  |  |
| 12. Indicate if the following have been submitted/Indiquer si les renseignements suivants ont été soumis  |  | 11. Type of research/Type de recherche<br><input type="checkbox"/> New use of reg. product <input type="checkbox"/> New formulation or New source <input type="checkbox"/> New active<br><input type="checkbox"/> Nouveau usage d'un produit <input type="checkbox"/> Nouvelle formulation ou Nouvelle source <input type="checkbox"/> Nouvelle matière active  |  |  |
| A. Specification form<br>Formulaire de spécifications <input type="checkbox"/> Y <input type="checkbox"/> N<br>E. Experimental label<br>Étiquette du produit expérimental <input type="checkbox"/> Y <input type="checkbox"/> N<br>C. List of cooperators<br>and researchers<br>Liste des chercheurs<br>et collaborateurs <input type="checkbox"/> Y <input type="checkbox"/> N<br>D. Maps/Cartes <input type="checkbox"/> Y <input type="checkbox"/> N<br>F. Other (specify)<br>Autre (préciser) <input type="checkbox"/> Y <input type="checkbox"/> N |  | 13. Indicate whether the land for the research is owned or operated by the research establishment/Indiquer si les terrains où sera effectuée la recherche appartiennent à l'établissement de recherche ou s'ils sont exploités par ce dernier :<br><input type="checkbox"/> Yes/Oui <input type="checkbox"/> No/Non   |  |  |
| 14. I hereby specify that the above information is correct in all respects. I understand that permission to undertake the research does not create any liability on the Crown and the researcher remains totally liable for such things as damage to treated crops or properties or the crops or property of others and for such matters as occupational health and safety and environmental impact as a result of the research being performed. I will ensure that the researcher and I will observe the limitations and requirements that:            |  | Je certifie, par la présente, que les renseignements ci-dessus mentionnés sont corrects sur tous les plans. Je comprends que l'autorisation de mener des recherches n'est pas donnée en aucune façon et que le chercheur assume toutes les responsabilités comme les dommages aux cultures ou aux propriétés traitées ou à ceux de autres personnes, ainsi que l'impact sur l'hygiène et la sécurité au travail, sur l'environnement et pourra respecter vos recherches effectuées. Je m'assurerai que le chercheur et moi-même observeront les restrictions et les conditions suivantes :  |  |  |
| 1. no application to bodies of water including sloughs and wetlands, or when run off water may bring pesticide residues out of the treatment premises.<br>2. crops harvested from treated plots will not be sold or used for food purposes unless the residue conform with the existing maximum residue limits (MRLs) under the Food and Drugs Regulations; and<br>3. it is the researcher's responsibility to notify the provincial pesticide regulatory officials of the research program and obtain provincial approval when this may be required.   |  | 1. si vous appliquez sur des plans d'eau, ouverts, y compris les mares vaseuses ou les zones humides, ou dans les endroits où les eaux de ruissellement pourraient transporter des résidus de pesticides à l'extérieur des lieux traités<br>2. les récoltes récoltées des parcelles traitées ne seront pas vendues comme aliments à moins que les taux de résidus ou les concentrations soient conformes aux limites maximales de résidus (LMR) existantes en vertu de la Loi sur les aliments et drogues; et<br>3. le chercheur est responsable d'avertir les agents provinciaux chargés du programme de recherches sur les pesticides et d'obtenir l'approbation provinciale s'il y a lieu. |  |  |
| Signature of the Notification Agent/Signature de l'agent chargé des avis de recherche   |  | Date of Notification/Date de l'avis   |  |  |



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## **Appendix VI:      Addresses of Provincial Pesticide Regulatory Officials**

### **Newfoundland/Terre Neuve**

Pesticides Control Section  
 Newfoundland Dept. of Environment & Labour  
 Box 8700  
 St. John's NF A1B 4J6  
 Tel: (709) 729-3395; Fax: (709) 729-1930

### **Prince Edward Island/Ile du Prince Edouard**

Pesticide Regulatory Program  
 P.E.I. Agriculture and Forestry  
 Box 306  
 Kensington PE COB 1M0  
 Tel: (902) 836-8925; Fax: (902) 836-3161

### **Nova Scotia/Nouvelle Ecosse**

Environmental Management & Support Services  
 N.S. Dept. of the Environment  
 5151 Terminal Road, 5th Floor  
 P.O. Box 2107  
 Halifax NS B3J 3B7  
 Tel: (902) 424-2534; Fax: (902) 424-0503

### **New Brunswick/Nouveau Brunswick**

Technical Approvals  
 N.B. Environment  
 Box 6000  
 Fredericton NB E3B 5H1  
 Tel: (506) 453-7945; Fax: (506) 453-2390

### **Québec**

Division des Pesticides  
 Ministère de l'Environnement et de la Faune  
 Édifice G, étage 8, bte 26  
 675 boul. René Levesque Est  
 Québec QC G1R 5V7  
 Tel: (418) 521-3829 x 4806  
 Fax: (418) 528-1035

### **Ontario**

Pesticides Section  
 Ontario Environment  
 135 St. Clair Ave. West, Suite 100  
 Toronto ON M4V 1P5  
 Tel: (416) 327-5442; Fax: (416) 327-2936

### **Manitoba**

Environmental Management,  
 Pesticide Approvals  
 Manitoba Environment  
 123 Main Street, Suite 160 Via Station  
 Winnipeg MB R3C 1A5  
 Tel: (204) 945-7067; Fax: (204) 945-5229

### **Saskatchewan**

Sustainable Production Branch  
 Saskatchewan Agriculture & Food  
 Room 133, 3085 Alberta Street  
 Regina SK S4S 0B1  
 Tel: (306) 787-8061; Fax: (306) 787-0428

### **Alberta**

Pesticide Management Branch  
 Alberta Environmental Protection  
 5th Floor, Oxbridge Place  
 9820 -106 Street  
 Edmonton AB T5K 2J6  
 Tel: (403) 427-5855; Fax: (403) 422-5120

### **British Columbia/Colombie Britannique**

Pollution Prevention and Remediation Branch  
 Ministry of Environment, Lands & Parks  
 P.O. Box 9342, Stn Prov. Park  
 Victoria BC V8W 9M1  
 Tel: 250-387-9951; Fax: 250-387-9935

**Northwest Territories/Territoires de Nord  
Ouest**

Environmental Protection Service  
Resources, Wildlife & Economic Development  
Government of the Northwest Territories  
600-5012 50th Ave.  
Yellowknife NT X1A 3S8  
Tel: (403) 873-7654; Fax: (403) 873-0221

**Yukon**

Standards and Approvals  
Environmental Protection  
Yukon Renewable Resources  
Box 2703  
Whitehorse YT Y1A 2C6  
Tel: (403) 667-5610; Fax: (403) 393-6205

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**Appendix VII: PMRA Regional Offices****Atlantic**

Regional Manager  
Pest Management Regulatory Agency  
1081 Main Street  
P.O. Box 6088  
Moncton NB E1C 8R2  
TEL: 506-851-7671  
FAX: 506-851-2689

**Québec**

Regional Manager  
Pest Management Regulatory Agency  
2001 University,  
7ième étage  
Montréal QC H3A 3N2  
TEL: 514-283-8888  
FAX: 514-283-1919

**Ontario**

Regional Manager  
Pest Management Regulatory Agency  
174 Stone Road, West  
Guelph ON N1Q 4S9  
TEL: 519-837-9400  
FAX: 519-837-9773

**Manitoba**

Regional Manager  
Pest Management Regulatory Agency  
613-269 Main Street  
Winnipeg MB R3C 1B2  
TEL: 204-983-8662  
FAX: 204-983-8022

**Saskatchewan**

Regional Manager  
Pest Management Regulatory Agency  
Room 300 Walter Scott Bldg.  
3085 Albert Street,  
P.O. Box 8060  
Regina SK S4P 4E3

TEL: 306-780-7123  
FAX: 306-780-5177

**Alberta**

Regional Manager  
Pest Management Regulatory Agency  
Room 654, Harry Hays Bldg.  
220 - 4Th Ave. S.E.  
Calgary AB T2G 4X3  
TEL: 403-292-4106  
FAX: 403-292-6629

**British Columbia**

Regional Manager  
Pest Management Regulatory Agency  
Room 202, 620 Royal Avenue  
P.O. Box 2523  
New Westminster BC V3L 5A8  
TEL: 604-666-0741  
FAX: 604-666-6130