Agriculture and Agri-Food Canada
Agriculture et Agro-alimentaire Canada

Food Production and Inspection Branch
Direction générale, Production et inspection des aliments

Plant Industry Directorate
Direction de l'industrie des produits végétaux

Pro93-05

Regulatory Proposal

Research Permit Guidelines for Microbial Pest Control Agents

Memorandum to Registrants R-90-02 proposed requirements for field trials with naturally occurring microbial pest control agents. The comments and suggestions received were taken into consideration and the original document has been revised and expanded to include genetically modified microorganisms. This Regulatory Proposal is the result.

The subject matter has been discussed at several meetings and workshops. Major recommendations from these workshops and meetings have been incorporated into this Regulatory Proposal. However, some recommendations have not been adopted, because those views have not been shared by all federal agencies with different mandates concerning pesticide regulation.

Health Canada developed the data requirements relating to human health safety. Environment Canada developed the data requirements relating to environmental fate and toxicology. The data requirements relating to characterization and specification were developed jointly.

You are invited to review and comment on this Regulatory Proposal. Recommendations or comments with factual written documentation would be appreciated. Comments should be submitted within 60 days of the date of this document to:

Pest Management Regulatory Agency
Health Canada
2250 Riverside Drive
A.L. 6606D1
Ottawa, Ontario
K1A 0K9

(publié aussi en français)

November 25, 1993

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Canada

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1.0 Introduction

Microbial agents used for pest control are subject to regulation under the *Pest Control Products (PCP) Act and Regulations*.

Microbial pest control agents can provide a more specific (narrow spectrum) method of pest control and are perceived to be an environmentally acceptable alternative to chemical pesticides. However, careful testing and evaluation are necessary to ensure that the products meet the requirements of safety, merit and value.

Certain information is required to support a research program, to ensure the safety of the users and the safe introduction of a microbial agent to the environment. The data requirements outlined in this document were specifically developed to address the characteristics of microbial pest control agents (for example, limited host range/narrow spectrum, or ability to multiply and disseminate). Further explanation of requirements are found in the *Registration Guidelines for Microbial Pest Control Agents* (Pro93-04).

Because microbial pest control agents include diverse groups of microorganisms, not all studies or data requirements in the guidelines may be appropriate for a specific microorganism. Applicants should consider the unique characteristics of their microorganism when determining specific data requirements and protocols, and are encouraged to consult with the federal reviewing agencies **before** testing commences. In addition, **waivers for certain data requirements may be granted when accompanied by sound scientific rationale**.

2.0 Definitions

- **Active ingredient or microbial pest control agent**: Microbial entity (organism and any associated metabolites) to which the effects of pest control are attributed.

- **Cooperator**: Any individual, corporation or institution not engaged in control product research that has agreed to use or allows the use of a control product on a site owned or operated by the individual, corporation or institution.

- **Ecozones**: Large and very generalized ecologically distinctive areas based on interplay of landform, water, soil, climate, flora, fauna and human factors. The boundaries between the ecozones should be viewed as transitional areas, rather than discrete lines of demarcation.

- **Genetically engineered microorganism**: Microorganism modified through *in vitro* alterations of genetic material.

- **Genetically modified microorganism**: Microorganism modified through alterations of genetic material (includes genetically engineered microorganism).

- **Indigenous**: Isolated from or previously used in the ecozone(s) of intended use.

- **Microbial Pest Control Agent (MPCA)**: Refers to the active ingredient or to the microbial entity to which the effects of the pest control can be attributed. Includes bacteria, algae, fungi, protozoa, viruses, mycoplasmae or rickettsiae and related organisms.

- **Microbial Pest Control Product (MPCP)**: Refers to the end-use product (with or without formulants or additives).

- **Residues**: The number of microbial organisms or identifiable parts thereof. Alternatively, where appropriate, may relate to a measurable quantity of a representative chemical component or metabolic by-product of the microbial pest control agent.

- **Technical active ingredient**: Material which incorporates an active ingredient, and is produced on a commercial or pilot scale for the manufacturing of microbial pest control products.

3.0 Guidelines for Field Trials

Field Trial Size	Terrestrial (ha)	Aquatic (ha)	Forestry (ha)
Small	up to 10	up to 1	-
Medium	10-1,000*	1+	up to 3,000
Large	1,000-5,000*	-	-

* or 10% of the total national crop, whichever is smaller

Note: Larger areas may be permitted in special cases, such as testing products for control of migratory insects or avian pest species. In these situations the applicant is required to justify the request.

In order to carry out field trials, it is necessary to:

1. Complete a Notification of Pesticide Research (Appendix 1) or Application for Research Permit form (Appendix 2).

2. Provide an experimental label (see Section 4 of this Guideline).

3. Report results of all work carried out.

A Notification or Application for Research Permit is required for all field testing of MPCA's. This includes testing with:

- new (unregistered) active ingredient;
- new source of currently registered active ingredient;
- new products or formulations containing currently registered active ingredient; or
- new use(s) for a currently registered product, such as rate change, new targets, or new mixing instructions.

Appendix 3 provides a quick reference to information that may be required for a particular product or active ingredient. Researchers are encouraged to consult with the Plant Industry Directorate, Agriculture and Agri-Food Canada early in the application or notification process to discuss data requirements.

3.1 Notification

Small scale field trials with active ingredients or registered products which meet the following criteria require only notification to the Plant Industry Directorate.

- The MPCA is indigenous to the ecozone of intended use.
- The field test will be carried out on property owned or operated by the research institution.
- The method of application is restricted to ground equipment.

For trials which meet these criteria, a Notification Form (Appendix 1) outlining the following information must be submitted at least 30 days prior to the commencement of research:

- Binomial name of the microbial pest control agent
- Product name or identifiers
- Validation of the indigenous nature of the active ingredient which would constitute either:
    - details on the geographical location of the site of original isolation of the MPCA proposed for testing (i.e., proof that the MPCA occurs in the ecozone of intended use); or

- details on the previous history of use of the test organism or product in the ecozone of intended use.

- Name and address of the supplier of the test product

- Name and address of responsible researchers

- Experimental information, including:

  - location and site of the trial
  - size and number of test plots
  - host and target pest species (binomial and common names)
  - timing, rate and method of application, and
  - concentration of the MPCA in the test product.

If insufficient space is available on the form, provide separate documentation numbered according to the sections on the form.

The following specific conditions MUST be observed:

- The research institution must ensure the safety of its employees or seek guidance regarding safety procedures;

- Good laboratory practices and appropriate quality control procedures must be followed; and

- Food and feed crops from all treated sites must NOT be sold, and must not be used for consumption, unless written authorization has been obtained from the Food Directorate, Health Canada, under the authority of the *Food and Drugs Act*.

A copy of the notification should also be provided to the provincial pesticide regulatory officials having jurisdiction over the research area (see Section 7).

Note: Further information may be required on a case-by-case basis to determine if the proposed research meets the criteria for notification.

Notification is subject to review and audit and the regulatory authority may limit the size of the plot, the number of sites, or disallow research if it does not comply with the terms and conditions as outlined in this guideline document.

3.2 Research Permit

For any field trials which do not meet the criteria for Notification, a federal Research Permit is required prior to initiating the trial.

Requirements/Procedures:

- The research coordinator should complete and sign the Application for Research Permit (AGR1182);

  The Latin and common names of the microbial pest control agent(s) should be reported in box #3 of the Application for Research Permit form.

  Note: When applying for testing of a single agent/product or new use at multiple sites, a single application, including all proposed treatment locations, should be made.

- The Application for Research Permit must be submitted at least three (3) months prior to the date of the proposed field trial for previously reviewed or registered active ingredients and products, and at least six (6) months for new active ingredients. This will allow sufficient time for adequate review. Incomplete applications received after the above time periods cannot be assured of timely service.

- Four (4) copies of the complete application package are required for non-food uses; six (6) for food uses. The complete packages must be submitted to the Product Management Division, Plant Industry Directorate. Forms are available from the Directorate or from regional offices of the Food Production and Inspection Branch (see Appendix 4 for addresses).

- A Product Specification Form (AGR1168) must be submitted with the Application for Research Permit.

4.0 Labels

Labels for experimental uses are required for all control products. Copies of the labels must be available to all researchers and cooperators before experimental tests are initiated. Draft labels must also accompany all Applications for Research Permits. The accepted experimental labels must be attached to the container(s) used during the test(s). Seven (7) copies of the experimental labels should be submitted with the Application for Research Permit. Labels should be legibly typed in English and/or French, and be representative of procedures for the intended research project or be a supplement to currently registered product labels.

Supplemental labelling (used in connection with a registered product label) shall include any information which is not on, or differs from, the current label. Those items indicated below with an

asterisk (*) must always be included. This supplementary labelling shall be accompanied at all times by a copy of the most recent registered product label. Questions about labels should be referred to the Product Management Division, Plant Industry Directorate. Labels must include the following information where applicable and available:

1.* "For Experimental Use Only" statement
2.* Research Permit or Notification Number issued under the *Pest Control Products Act*
3.* "Not for sale. Not for distribution to any person other than a researcher or cooperator" statement
4.* name, brand or trademark of the product
5.* name and address of the manufacturer
6. net contents
7.* ingredient statement (guarantee)
8. hazard warnings and precautions
9. "KEEP OUT OF REACH OF CHILDREN" statement
10. "READ THE LABEL BEFORE USING" statement
11. 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:
    - crop(s) or site(s)
    - pest(s)
    - dilution and application rates
    - method of application
    - timing of application
    - pre-harvest intervals
16. personal protective equipment
17. limitations (if any)
18.* Any other information necessary to ensure safe and effective use of the product for research purposes

5.0 Data Requirements

5.1 Agent Specifications and Characteristics (Part 2 of *Registration Guidelines for Microbial Pest Control Agents*, Pro93-04)

Scientific literature, ecological data, descriptions of organism and habitat, appropriate laboratory tests on pest control product(s) as well as the following information (where applicable):

5.1.1 New Active Ingredients

- name (binomial and common); an identification from an independent authority is desirable;
- taxonomic and morphological description, species, strain, serotype, phage type, drug resistance, biochemical and plasmid profile, as relevant;
- binomial and common name of the target species;
- name and address of the supplier of the test product;
- information on any relationship to any known pathogen;
- mode of action of active ingredient on pest (if available);
- description of the native habitat and ecological range of the microbial pest control agent in Canada;
- production methods (these methods should be made available to the Plant Industry Directorate by the manufacturer or the researcher. Source of the inoculum for the production strain to be tested must be given);
- descriptions of isolation substrate (leaf, root, etc.); and methods of isolation and culture;
- quality control information on the test product.

If the microorganism to be tested has been genetically modified (either by classical or rDNA techniques), the information outlined in Section 2.7.1 of the *Registration Guidelines for Microbial Pest Control Agents* (Pro93-04): *Origin, Derivation and Identification of Microbial Active Ingredient(s)* must be submitted for all parents (host(s) and/or donor(s)) used in the process.

For a microorganism derived through recombinant nucleic acid technology, the information outlined in Section 2.7.3 of the *Registration Guidelines for Microbial Pest Control Agents* (Pro93-04) *Characterization of Active Ingredient Strains Derived Through Recombinant DNA (and related) Technologies* must be submitted.

5.1.2 New Formulations, New Uses, New Sources

- Information on changes to any of the characteristics listed in 5.1.1 (such as agent specifications, characteristics, formulation) that could affect host or geographic range, quality control, infectivity, and pest controlled.

- Information on new production methods of formulation, if applicable.

5.2 Human Health Safety Testing (Part 3 of *Registration Guidelines for Microbial Pest Control Agents*, Pro93-04)

Field trials of genetically modified and naturally occurring microorganisms are subject to the same data requirements. Genetically modified organisms do not trigger additional human health safety and bystander exposure testing unless the nature of the active ingredient or the mode of application of the formulation indicates a need for additional testing.

5.2.1 New Active Ingredients

The applicant should supply information concerning mammalian and/or human pathogenicity or other significant health effects either noted in the literature or determined during the research phase (especially for hypersensitivity and/or allergenic reactions).

1) **Small-scale field trials** (which require a research permit, Section 3.2)

- Infectivity and/or toxicity study* with active ingredient. Tests should be conducted with a single dose of active ingredient intravenously (I.V.) for bacteria and viruses and intraperitoneally (I.P.) for fungi and protozoa.

  *** WAIVER**: in cases where scientific evidence and rationale indicate that risks from exposure to humans are minimal, the infectivity and/or toxicity test requirements may be waived. Applicants may request such a waiver if they provide the necessary scientific evidence and rationale.

- Other tests may be required on a case-by-case basis.

- Appropriate safety equipment should be worn to avoid exposure.

- If the material is to be used by cooperators, testing for dermal irritation, eye irritation and dermal sensitivity may be required.

  These studies may not be required for products limited to use by experienced researchers and staff using appropriate protective equipment.

2) **Medium scale field trails**

- An acute I.V. or I.P. test.

- An additional infectivity and/or toxicity study may be required depending on nature of the ingredients and the mode of application of the formulation.

- if the material is to be used by cooperators, testing for dermal irritation, eye irritation and dermal sensitivity may be required.

  These studies may not be required for products limited to use by experienced researchers and staff using appropriate protective equipment.

3) **Large-scale field trials**

- Full toxicology data package as specified in part 3 of Regulatory Proposal Pro93-04, *Registration Guidelines for Microbial Pest Control Agents.*

5.2.2 New Formulations, New Uses, New Sources

- Depending on the formulation or changed exposure due to new uses and area of testing, additional infectivity and/or toxicity tests may be required on a case-by-case basis.

  Applicants may consult with the Environmental Health Directorate, Health Canada for information on protocols for specific tests (see Appendix 5 for address).

5.3 Food and Feed Residue Studies (Part 5 of the *Registration Guidelines for Microbial Pest Control Agents* Pro93-04)

Residue data applies only to crops used for food or feed.

Sale of treated food is subject to regulation under the *Food and Drugs Act*. Crops harvested from treated plots or sites may not be sold for food or feed purposes or disposed of through commercial channels without written authorization of the Food Directorate, Health Canada (see Appendix 5 for address).

Waivers may be possible depending on the nature of the organism and the use pattern. A scientific rationale and appropriate supporting data must accompany applications for waivers.

5.3.1 New Active Ingredients

1) **Small-scale field trials** (which require a research permit, Section 3.2)

Residue data are not required to perform a small-scale field trial. The trial itself may be used as an opportunity to gather such data. Testing is done on a crop destruct basis only. Treated crops are intended for experimental use only; must not be used for food or feed and must be disposed of in an approved manner. Depending on the use pattern, a waiver of the crop destruct requirement may be possible in some instances.

If the intention is to sell any treated food or feed, residue data may be required, depending on product type and proposed food uses.

2) **Medium-scale field trials**

If the intention is to sell any treated food or feed, residue data may be required, depending on product type and proposed food uses.

3) **Large-scale field trials**

Further residue data may not be required if previous assessments have not indicated a cause for concern. If significant safety questions exist involving food crops, large-scale field trials may only be permitted on a crop destruct basis.

5.3.2 New Uses, New Formulations, New Sources

Depending on the new use, new host or formulation changes, residue testing may be required. When required by the Food Directorate, Health Canada, residue data must be accompanied by detailed protocols of the detection methods employed. This should include the sensitivity, specificity, reliability and practicality of the methods. It is recommended that microbial populations of the pest control agent be monitored before and after application, during the test, and at harvest.

Applicants must consult the Food Directorate, Health Canada for further information on residue testing requirements.

5.4 Environmental Fate and Environmental Toxicology (Parts 6 and 7 of the *Registration Guidelines for Microbial Pest Control Agents* Pro93-04)

5.4.1 New Active Ingredients

1) **Small-scale field trials**

The information requirements (IR) for field trials of microbial pest control agents are determined by following the scheme depicted in Appendix 6.

IR I: For microorganisms indigenous to the ecozone of intended use (see Appendix 7):

- Notification category (refer to section 3.1).

IR II: For genetically modified microorganism indigenous to the ecozone of intended use:

- Information in IR I (refer to section 3.1), plus
- Quality control information for test product (5.1.1)

IR III: For microorganisms not indigenous to the ecozone of intended use but indigenous to continental Canada/U.S:

- All relevant information in IR II, plus
  - Documented geographical range of microbial pest control agent
  - Documented geographical range of target and known affected non-target organisms
  - Comprehensive literature review on taxonomically closely related microorganisms with respect to:
    - Effects on target and non-target organisms
    - Persistence and dispersal in the environment

IR IV: For microorganisms not indigenous to continental Canada/U.S. but claimed to be identical to an indigenous microorganism in continental Canada/U.S:

- All relevant information in IR III, plus
- Verification of the taxonomic equivalence (down to epithetic level which distinguishes pathogen from other related pathogen) of the microbial pest control agent and the indigenous microorganisms.

IR V: For microorganisms not indigenous to continental Canada/U.S. and not identical to indigenous microorganism in continental Canada/U.S:

- All relevant information outlined in Parts 2 and 7 of the *Registration Guidelines for Microbial Pest Control Agents* (Pro93-04).

2) **Medium and Large-scale Field Trials**

For all types of MPCA's, the information required in IR V should be submitted for evaluation. Laboratory data on the fate of the MPCA in the area of the field trial will be required for all MPCA's which demonstrate poor host specificity or significant effects on non-target organisms of environmental or economic importance.

The applicant should submit any data from small-scale field trials which may be useful in determining the environmental effects of the MPCA.

5.4.2 New Uses, New Formulations, New Sources

- generally no further requirements other than registration of original product or active ingredient.

- if there is a possibility of some significant effect(s) caused by the formulation change or the new use pattern (such as increased persistence or toxicity), this should be indicated and additional testing may be required.

5.5 Site Description, Experimental and Safety Protocols

5.5.1 Provide exact location (including latitudes and longitudes) for each field trial. For forest and water applications, maps of the area must be provided. Maps may be requested for some other applications. Provide descriptions of habitat(s) for locations of proposed field trials and adjacent habitat(s). Failure to provide details on test location(s) may result in refusal of the permit.

5.5.2 Provide experimental design.

5.5.3 Describe introductory protocol:

1) formulation to be tested (identification and quantification of active ingredients and other constituents);
2) total quantity to be used;
3) method of introduction including rate(s), frequency and (where applicable) duration of application; and
4) crop or animal husbandry practices that may enhance dispersal (such as plans for mechanical disruption of soil or irrigation).

5.5.4 Provide site safety procedures which include:

1) a description of procedures to reduce public access to research sites (the site should be posted with sign(s) indicating that an experimental test is in progress);
2) a description of safety procedures on site and during transportation;
3) contingency plans (for example, method to eliminate organism if required);
4) protocols for cleanup of application equipment and product container(s); and
5) Researchers and the pest control product companies are responsible for the safe disposal of unused products. Any unused product should be returned to the manufacturer.

5.5.5 Monitoring procedures may be required on a case-by-case basis.

5.6 Analysis of Formulation for Purity and Identification of Contaminants and By-Products

Requirements outlined in Section 2.9 of the *Registration Guidelines for Microbial Pest Control Agents*, Pro93-04, should be consulted for quality control.

5.7 Additional Information

Manuscripts and reports that would aid in efficient and effective review should also be supplied. Where scientific literature is referenced in support of a research permit, copies of the original papers must be supplied.

5.8 Data Submission and Handling

Four (4) copies of the complete application package are required for non-food uses and six (6) copies for food uses must be submitted to the Plant Industry Directorate, Agriculture and Agri-Food Canada.

Previously submitted data will be considered but must be accurately referenced and identified. An index (Part 0, Pro93-04) should be supplied with the application.

6.0 Submission Review Procedures

After receipt of the application, the Plant Industry Directorate distributes relevant data for review and comment to advisory groups. Addresses of advisory groups are listed in Appendix 5.

7.0 Provincial Permits and Reviews

Certain provinces may require a provincial permit to conduct any research with pesticides, whether the research is conducted under a federal permit or a notification of research. 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 for a federal research permit should submit a copy of the Application for Research Permit, or Notification, to provincial pesticide regulatory officials having jurisdiction over the research area (see Appendix 8 for addresses). Where appropriate, the provincial officials will be given the opportunity to make comments to the Plant Industry Directorate, Agriculture and Agri-Food Canada for consideration within 30 days of receipt of the application.

8.0 Importation for Research Purposes

An import permit is required to import microbial pest control agents which are not registered in Canada. Applications for Import Permit are available from:

Pest Management Regulatory Agency
Health Canada
2250 Riverside Drive
A.L. 6606D1
Ottawa, Ontario
K1A 0K9
Tel: (613) 736-3592
Fax: (613) 736-3666

9.0 Sale of Product Under Research Permits

Control products which are not registered under the *PCP Act and Regulations* will not be eligible for sale under a research permit. For a currently registered product, it is not permissible to sell that product for the unregistered uses under research. This policy is designed to promote safe use by limiting product availability only to those doing genuine research. Any use of the research privilege for test marketing or for operational programs with an unregistered product or unregistered use is considered a violation of the *PCP Act*.

10.0 Records and Data Reporting

Records of the distribution and storage of all quantities of experimental microbial pest control agents and environmental releases must be kept and supplied to the Plant Industry Directorate upon request. Data generated as a result of field trials must be submitted, when requested, to the Plant Industry Directorate. Research Permit Numbers or Permit Submission Numbers should be on all correspondence.

11.0 Advertising

There are concerns that advertising of pest control products under research may lead to misuse of the product. Advertising that creates a false or misleading impression is considered a violation of Section 4 of the *PCP 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.

12.0 Posting of Research Areas

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

13.0 Audit

All field research programs are subject to auditing by staff of the Plant Industry Directorate and the Regional Pesticide Program officers of Agriculture and Agri-Food Canada for compliance with the terms and conditions set out in this guideline document and in the research permit approval process. The researchers must provide any information requested for audit purposes.

14.0 Impact Analysis

An impact analysis has been conducted on the proposed guidelines. Please refer to accompanying document for the full text.

Health Canada Santé Canada

NOTIFICATION OF PESTICIDE RESEARCH
Under the Pest Control Products Act

AVIS DE RECHERCHE SUR UN PESTICIDE
[illegible]

NOTE: TYPE OR PRINT CLEARLY. LEAVE SHADED AREAS BLANK

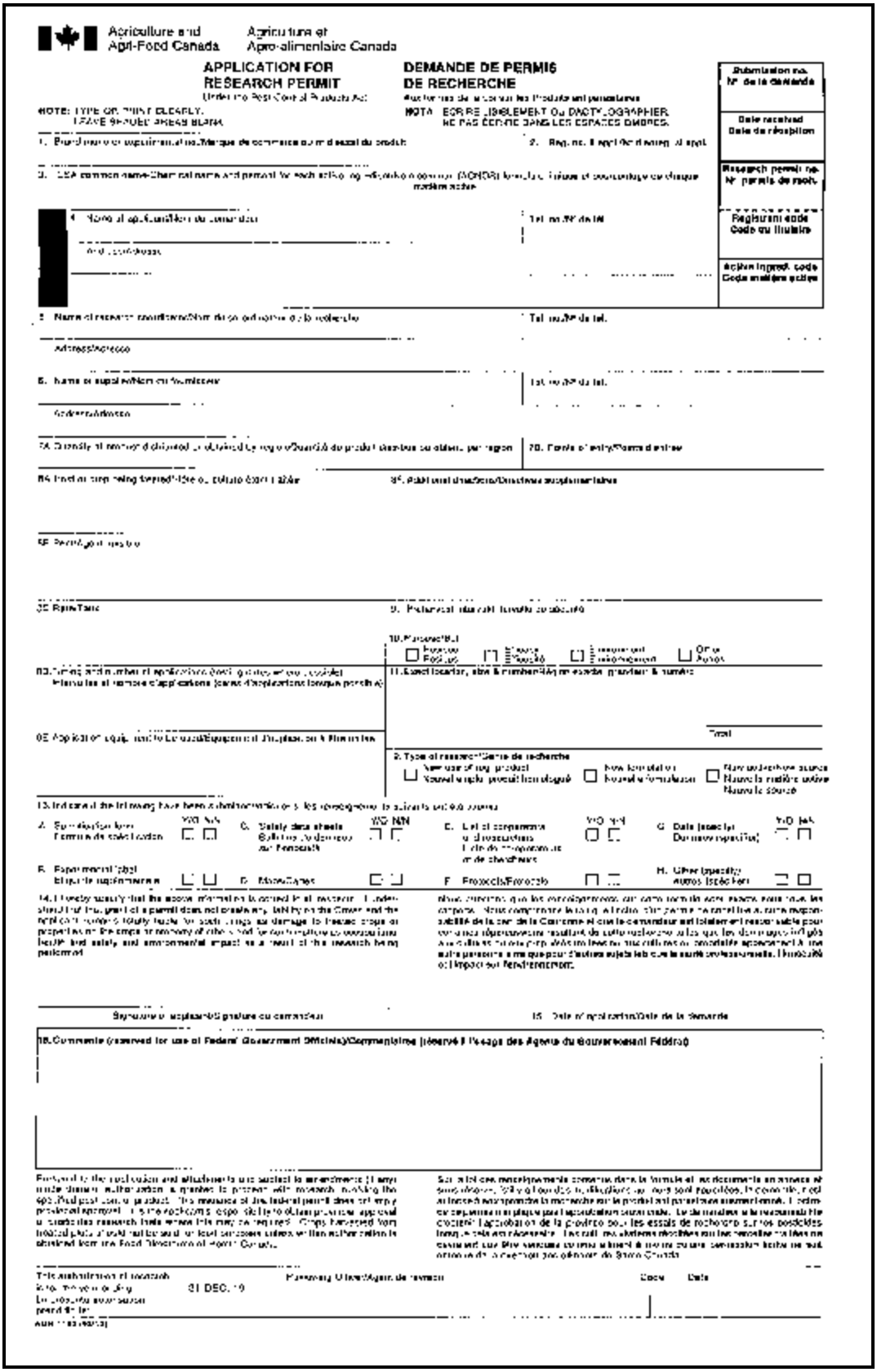
NOTA: ÉCRIRE LISIBLEMENT OU DACTYLOGRAPHIER. NE PAS ÉCRIRE DANS LES ESPACES OMBRÉS.

1. Brand name or experimental no./Marque de commerce ou n° d'essai du produit
2. [illegible]
3. CSA common name or Chemical name and percent for each active ingredient/Nom commun (ACNOR) 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.
Address/Adresse
5. Name of researcher or research coordinator if different from 4/Nom du chercheur ou du collaborateur de recherche si différent de la case 4 — Tel. no./N° de tél.
Address/Adresse
6. Name of supplier/Nom du fournisseur — Tel. no./N° de tél.
Address/Adresse
7A. [illegible]
7B. [illegible]
7C. Rate and total estimated quantity of product to be used/Dose et quantité totale estimée de produit à utiliser
7D. Timing and number of applications (listing dates where possible)/Calendrier et nombre d'applications (dates des essais si possible)
7E. Application equipment to be used/Type de [illegible]
7F. Additional directions/[illegible]
8. [illegible]
9. Purpose of research/But de la recherche
Residue/Résidus — Efficacy/Efficacité — Environment/Environnement — Other (specify)/Autres (préciser)
10. Exact location, size and number of plots/Endroit, superficie et nombre exacts des parcelles
Total Area (ha)/Superficie totale (ha)
11. Type of research/Type de recherche
New use of reg. product/Nouvel usage d'un produit homologué — New formulation or New source/Nouvelle formulation ou Nouvelle source — New active/Nouvelle matière active
12. Indicate if the following have been submitted/[illegible]
A. Specification form/Formule de spécifications Y/O N
B. Experimental label/Étiquette de produit expérimental Y/O N
C. List of cooperators and researchers/[illegible] Y/O N
D. Maps/Cartes
E. [illegible]
F. Other (specify)/Autres (préciser)
13. [illegible] Yes/Oui No/Non
14. [illegible]

Signature of the Notification Agent/Signature de l'agent chargé des avis de recherche — Date of Notification/Date de l'avis

15. [illegible]

[illegible]



Agriculture and Agri-Food Canada / Agriculture et Agro-alimentaire Canada

APPLICATION FOR RESEARCH PERMIT
Under the Pest Control Products Act

DEMANDE DE PERMIS DE RECHERCHE
Aux termes de la Loi sur les produits antiparasitaires

NOTE: TYPE OR PRINT CLEARLY. LEAVE SHADED AREAS BLANK.
NOTA: ECRIRE LISIBLEMENT OU DACTYLOGRAPHIER. NE PAS ECRIRE DANS LES ESPACES OMBRES.

Submission no. / N° de la demande
Date received / Date de réception
Research permit no. / N° permis de recherche
Registrant code / Code du titulaire
Active ingredient code / Code matière active

1. Brand name or registration no. / Marque de commerce ou n° d'essai du produit
2. Reg. no. if applicable / N° d'enr. s'il y a lieu
3. USA common name / Chemical name and percent W/W each active ingredient (ACNOR) / Nom usuel aux É.-U. / Nom chimique et pourcentage de chaque matière active
4. Name of applicant / Nom du requérant
Tel. no. / N° de tél.
Address / Adresse
5. Name of responsible person / Nom de la personne responsable
Tel. no. / N° de tél.
Address / Adresse
6. Name of supervisor / Nom du superviseur
Tel. no. / N° de tél.
Address / Adresse
7A. Quantity of material required / Quantité de produit dont on a besoin
7B. Form of entry / Forme d'entrée
8A. Proposed starting date / Date prévue du début
8B. Proposed duration / Durée prévue
8C. Purpose / But
9. Proposed use pattern / Mode d'emploi proposé
10. Province(s) / Province(s)
11. Exact location, site & number / Endroit exact, parcelle & numéro
Total
12. Type of research / Genre de recherche
13. Indicate if the following have been submitted / Indiquer si les renseignements suivants ont été soumis
14. I hereby certify that the above information is correct to the best of my knowledge. I understand that the granting of a permit does not preclude any liability by the Crown and the applicant for damage to persons, crops, damage to treated crops or property or the expense or necessity of other control measures resulting from the use of the product. I will be responsible for safety and environmental impact as a result of this research being performed.

Je déclare solennellement que les renseignements ci-dessus sont exacts, pour autant que je sache. Je comprends que la délivrance du permis ne dégage la responsabilité de la part de la Couronne et de l'demandeur ni totalement ni partiellement pour tout dommage causé aux personnes, aux récoltes traitées ou aux biens ou pour les dépenses ou la nécessité d'autres mesures de lutte résultant de l'emploi du produit. Je serai responsable de la sécurité et de l'impact sur l'environnement de la recherche effectuée.

Signature of applicant / Signature du demandeur
15. Date of application / Date de la demande
16. Comments (reserved for use of Federal Government Officials) / Commentaires (réservé à l'usage des Agents du Gouvernement Fédéral)
Tele authorization of research / Autorisation de recherche par téléphone
Reviewed by / Examiné par
Date
Date authorized / Date autorisée
31 DEC. 19

Data and Information Requirements for Applications for Research Permits for Microbial Pest Control Agents

Data	New Uses for Currently Registered Products	New Formulation or New Sources of an Active Ingredient	New Active Ingredient
Label[1]	Conditional	Yes	Yes
Research Permit Form[2]	Conditional	Yes	Yes
Product Specification Form[2]	Conditional	Yes	Yes
Safety Testing[3]	Conditional[3]	Conditional[3]	Yes
Residues and Metabolism[4]	Conditional[4]	Conditional[4]	Conditional[4]
Environment	Conditional[5]	Conditional[6]	Yes
Experimental Information[7]	Yes	Yes	Yes

[1] - as per section 4
[2] - as per section 3.2
[3] - as per section 5. Data will be reviewed by Health Canada when required.
[4] - as per section 5.2. Conditional on review and use of treated crop for feed or food.
[5] - data may be required for use in a new ecozone or for an increase in an application rate.
[6] - data may be required for adjuvants which increase infectivity/toxicity or persistence/ multiplication of the MPCA.
[7] - as per section 3.1

Regional Pesticide Program Officers
— Agriculture and Agri-Food Canada —

Address letters to: Regional Pesticide Program Officer at appropriate address below:

Atlantic

Agricultural Inspection Directorate
Food Production & Inspection Branch
Agriculture and Agri-Food Canada
P.O. Box 6088
Moncton, N.B. E1C 8R2
506-851-7671

Midwest

Food Production & Inspection Branch
Agriculture and Agri-Food Canada
269 Main Street
Winnipeg, Man. R3C 1B2
204-983-8662

Quebec

Dir. Gen. de la production et de l'inspection des aliments
Agriculture et Agro-alimentaire Canada
Complexe Guy Favreau
200, boul René Lévesque Ouest
Tour Est - Suite 1002-I
Montréal (Québec) H2Z 1Y3
514-283-8888

Alberta

Food Production & Inspection Branch
Agriculture and Agri-Food Canada
Room 747, Harry Hays Bldg.
220-4th Avenue, S.E.
Calgary, Alta. T2G 4X3
403-292-4106

Ontario

Food Production & Inspection Branch
Agriculture and Agri-Food Canada
174 Stone Road W.
Guelph, Ont. N1G 4S9
519-837-9400

British Columbia

Food Production & Inspection Branch
Agriculture and Agri-Food Canada
620 Royal Avenue
P.O. Box 2523
New Westminster, B.C. V3L 5A8
604-666-0741

Federal Advisors

Health Canada

Workplace Substances and Pesticides Division
Environmental Health Directorate
Environmental Health Centre
Tunney's Pasture
Ottawa, Ont.
K1A 0L2
613-957-1852

Bureau of Chemical Safety
Food Directorate
Health Canada
Tunney's Pasture
Ottawa, Ont.
K1A 0L2
613-957-1825

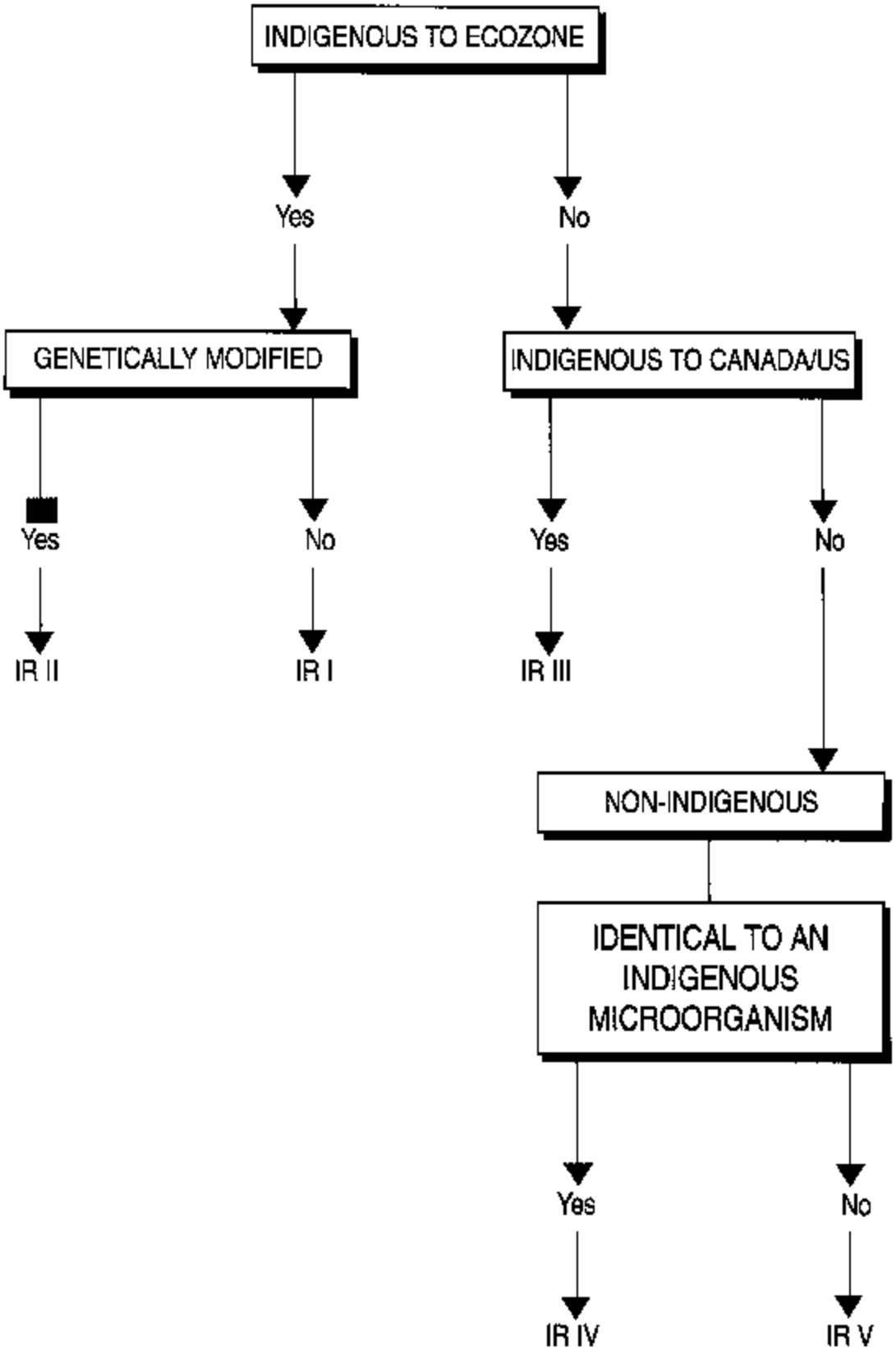
Environment Canada

Pesticides Division
Commercial Chemicals Branch
Environment Canada
Ottawa, Ont.
K1A 0H3
819-953-3450

Natural Resources Canada

Forest Pest Management Institute
P.O. Box 490
Sault Ste. Marie, Ont.
P6A 5M7
705-949-9461

Environmental Information Requirements



Ecozones

Provincial Regulatory Offices

Newfoundland

Pesticides Control Branch
Newfoundland Dept. of Environment and Lands
Box 8700
St. John's, Nfld.
A1B 4J6

Prince Edward Island

Fish and Wildlife Division
Dept. of Community Affairs
Box 2000
Charlottetown, P.E.I.
C1A 7N8

Nova Scotia

Nova Scotia Environment
Box 2107
Halifax, N.S.
B3J 3B7

New Brunswick

Operations Branch
N.B. Environment
Box 6000
Fredericton, N.B.
E3B 5H1

Quebec

Gestion et controle des pesticides
Ministere de l'environnement
3900, Marly, boite 68
Ste-Foy (Québec)
G1P 3W8

Ontario

Hazardous Contaminants and Coordination
Branch
Ontario Environment
135 St. Clair Avenue, West
Suite 100
Toronto, Ont.
M4V 1P5

Manitoba

Technical Services Branch
Manitoba Department of Agriculture
911 Norquay Building
Winnipeg, Man.
R3C 0V8

Saskatchewan

Soils and Crops Branch
Saskatchewan Agriculture and Food
Room 133, 3085 Alberta Street
Regina, Sask.
S4S 0B1

Alberta

Waste and Chemicals Division
Alberta Environment
9820-106 Street
Edmonton, Alta.
T5K 2J6

British Columbia

Pesticide Control Branch
B.C. Environment
780 Blanshard Street
Victoria, B.C.
V8V 1X5