Regulatory Directive DIR2012-01

Guidelines for the Registration of Non-Conventional Pest Control Products

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1.0 Introduction

Pest control products can be registered in Canada only if their use poses no unacceptable risks to human health or the environment and has value. As with all pest control products, Health Canada's Pest Management Regulatory Agency (PMRA) further reduces any risks that pesticides may pose through policies that encourage the development and implementation of innovative, sustainable pest management strategies.

On 28 October 2010, the PMRA published for consultation Regulatory Proposal PRO2010-06 *Guidelines for the Registration of Non-Conventional Pest Control Products.* Comments received from stakeholders were considered in establishing this Regulatory Directive. Since first piloting the PRO2007-02, *Guidelines for the Registration of Low-Risk Biochemicals and Non-Conventional Pesticides,* approaches have been refined in consideration of comments received from government, industry and grower groups, and from insights gained during the pilot. The revised approach recognizes that non-conventional products may not fit well into a registration framework that was developed for 'conventional' pesticides with well-defined chemistries and molecular structures.

The varied nature of these types of products can make it challenging to define a specific mode of action, to identify the active components of a mixture or to delineate a specific level of efficacy/value. This directive outlines a regulatory approach for non-conventional products with favourable risk profiles that allows innovation and flexibility assessing whether they have value and whether they pose any unacceptable risks to human health or the environment.

A wide range of non-conventional pest control products may be considered for review under this directive. Certain biopesticide products (microbials, semiochemicals and pheromones) have unique information requirements, as outlined in Regulatory Proposal PRO2002-02, *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals* and Regulatory Directive DIR2001-02, *Guidelines for the Registration of Microbial Pest Control Agents and Products*. This regulatory directive does not replace these documents.

Products eligible for consideration under this directive must have some, but not necessarily all, of the following characteristics:

- Low inherent toxicity to non-target organisms. Products with low inherent toxicity to humans and other non-target organisms would be expected to have minimal environmental and health risks even if exposure is extensive (N.B. Substances with chronic toxicity, genotoxicity, carcinogenicity, neurotoxicity or immunotoxicity, cause reproductive or developmental effects, metabolize into compounds of toxicological concern or are anticipated to bioaccumulate are not eligible for review under this directive);
- Low potential for their use to result in significant human or environmental exposure. When exposure is negligible, risks may be minimal even if the product has some inherent toxicity;
- Not persistent in the environment;

- Already widely available to the public for other uses, with a history of safe use under conditions posing equivalent potential for exposure to humans and the environment;
- Pesticidal action that is not the result of toxicity to the target organism, for example, products that work by attracting, repelling, desiccating or smothering pests; or
- Unlikely to select for pest resistance.

Substances eligible for review under this directive could include, but are not limited to:

- Food items, extracts, preservatives or additives (for example, crushed garlic, garlic powder, table salt, citric acid) ;
- Plant extracts and oils (for example, vegetable or mineral oils);
- Commodity chemicals that have a range of non-pesticidal uses (for example, acetic acid);
- Fertilizer or other plant growth supplements, commonly used in the agricultural sector (for example, mineral salts, such as sodium, and potassium salts of phosphorus acid); or
- Inert materials (for example, diatomaceous earth).

2.0 Information Requirements

The PMRA will assess the eligibility of products for review under this directive on the basis of all the evidence available. Applicants should submit a detailed rationale explaining why they believe their product is eligible for review under this directive. This should include details of the proposed use pattern and label claims, and as much scientific evidence as possible on the characterization of the components, toxicity, exposure and environmental fate.

The PMRA supports a tiered and flexible approach to information requirements and recognizes that the information needed to make a regulatory decision should be commensurate with the level of anticipated risks. As for all pest control products, the PMRA will require applicants to provide sufficient information to assess that a product has value and will not pose unacceptable risks to human health or the environment. Applicants are encouraged to make use of the presubmission consultation process described in Section 3.1 to help determine what information is needed.

Relevant data could be related to either pesticidal or other uses, and could include published literature or original studies. Where they exist, submission of regulatory reviews conducted in other countries is encouraged. In some cases, data requirements may be waived on the basis of a scientifically valid rationale. For example, a long history of exposure to humans or the environment could form the basis of a request to waive some data requirements, especially if the historical routes and levels of exposure are similar to what would result from the proposed uses of the product. Detailed guidance on waiver requests is provided in Appendix I.

Prior to initiating any original testing, applicants should consult the PMRA on proposed protocols, particularly those that may deviate from internationally recognized guidelines.

At any point during the PMRA assessment, additional information may be requested if the available information is inadequate or if potential risks are identified.

2.1 Information Required for Product Chemistry

The applicant must provide enough information on both the technical grade active ingredient and the end-use product to characterize the product composition. The identity of any impurities of toxicological or environmental concern suspected to be present in a product must be disclosed regardless of concentration. For non-conventional products that contain a mixture of active components, the applicant may opt to only register one technical product comprised of all ingredients in the mixture, instead of registering each active component separately.

2.2 Information Required for Assessment of Risk to Human Health

2.2.1 Toxicology Information

Toxicology information is required to assess the hazard of a product to human health. This information, combined with information on exposure, forms the basis of the human health risk assessment. Certain uses may require more supporting information than others. For example, a personal insect repellent may require significantly more toxicology information than a product that is not applied directly to the skin.

The applicant must provide sufficient toxicology information on the technical active ingredient and end-use formulated products to show that they pose low acute and chronic risks. Products must not be genotoxic, carcinogenic, neurotoxic or immunotoxic, cause reproductive or developmental effects, metabolize into compounds of toxicological concern or be anticipated to bioaccumulate. In addition, products should not have the potential to cause unintended adverse effects to companion animals.

2.2.2 Occupational and Bystander Exposure Information

An initial assessment of potential occupational and bystander exposure during and following application of a product will be based on the proposed use pattern and the draft labels. Information required includes:

- Description of typical practices for individuals applying the product, such as the amount of active ingredient handled and the site, timing, and method of mixing/loading and application.
- Description of the type, frequency and duration of any activities where post-application exposure could occur.
- Description of the potential for exposure to bystanders, particularly in nearby residential communities, schools or recreational areas.

2.2.3 Dietary Exposure Information

The requirement for dietary exposure information depends on the toxicological profile of the product and its use. If a product is to be applied to food or feedstuff, the applicant must show that any anticipated residues of the parent compound or any metabolites will not pose a toxicological concern. Crop residue data will usually be required if residues of toxicological concern in excess of natural background levels are likely to occur on a consumable commodity.

2.3 Information Required for Assessment of Risk to the Environment

The information required to assess potential risks to non-target aquatic and terrestrial organisms will primarily depend on the proposed use, which usually determines in which environmental media (soil, water, sediment, air) non-target organisms could be exposed. The applicant must provide information to show the product poses low acute risks to any non-target aquatic or terrestrial organisms likely to be exposed.

2.4 Information Required for Assessment of Value

In the *Pest Control Products Act*, value of a pest control product means "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's:

a) efficacy;
b) effect on host organisms in connection with its intended use(s); and
c) health, safety and environmental benefits and social and economic impact."

The applicant must provide evidence that a product has value for the proposed uses claimed on the label. This could include information from experimental trials, published studies, scientific rationales, a product's use history in another jurisdiction and analysis of the product's potential benefits. In most cases, efficacy data requirements for non-conventional products will be less than for conventional pest control products and the establishment of a lowest effective rate will not be needed. The PMRA recognizes that some non-conventional products may not be as efficacious as conventional products and, if a product is not effective enough to support a standard use claim, a lower level claim such as "reduces damage, reduces annoyance, reduces innoculum, reduces populations, suppresses symptoms or may inhibit" may be acceptable. Applicants are encouraged to submit any information describing the value of the product as a pest management tool, in addition to its efficacy.

Products like personal insect repellents, sanitizers and pool bactericides, where the pests controlled may pose a concern to public health, may not be eligible for reduced value/efficacy data requirements or reduced use claims.

3.0 Submission Process

3.1 Presubmission Consultation

Applicants are encouraged to request a presubmission consultation with the Agency, particularly if they are not familiar with the Canadian regulatory system or need assistance in determining specific information requirements. The main objectives of a presubmission consultation are to determine the following before making an actual application for registration:

- Whether the proposed product and technical grade active ingredient(s) are eligible for review under this directive; and
- What information is required to support the health, environment and value evaluations.

A presubmission consultation is also an opportunity to request guidance in building a successful submission package for a product. For example, draft labels for the technical grade and formulated product(s) are requirements for every submission, regardless of the type of use or application. Although labels vary in their complexity, they must clearly show how the product is to be used and for what purpose. The PMRA can provide tips to prospective applicants on creating product labels. A fully searchable database of registered labels is available on the Pesticides and Pest Management portion of Health Canada's website, which can be used as examples for creating a product label. An example of a draft label has also been included in this document (Appendix III).

Applicants can request a consultation through the presubmission webpage (http://www.hc-sc.gc.ca/cps-spc/pest/registrant-titulaire/pre-consult/index-eng.php) or by contacting the PMRA at pmra-arla_presubs@hc-sc.gc.ca. An information package containing as much information as possible about the technical grade active ingredient, the product and the proposed uses should be submitted as the first step in the consultation. The information package must include a cover letter with the following information:

- A draft label outlining the proposed performance claims, directions for use, crops or use sites, target pests and application rates (how will this product be used and for what pests);
- A completed Statement of Product Specification Form (a list of all the ingredients in the product and their proportions or amounts, such information is kept confidential);
- A brief description of manufacturing information (specific details on how the product is made; such information is kept confidential); and
- A rationale and supporting evidence explaining why the product is eligible for review under this directive (based on the considerations outlined earlier in this document).

If applicable, the package should also include:

- International regulatory status; and
- Other relevant information, such as summaries of other available evidence on the health and environmental risks and value.

The PMRA's advice will be based on the information package that has been provided. If an applicant wishes, he/she may request a meeting to discuss the results of a presubmission consultation. This is generally scheduled two to three weeks after the PMRA's initial advice has been communicated to the applicant. During this meeting, the applicant may discuss his/her submission with scientific and technical staff at the PMRA about information requirements or administrative issues.

Subsequent to a presubmission consultation, the information requirements for the specified product(s) and use pattern will be communicated to the applicant. A copy of this consultation document must be enclosed with the submission to initiate the registration process. It is recommended to verify the validity of the information requirements if the application for registration is made later than the two-year period following the closure of the presubmission consultation process as requirements may change.

If it is determined that the proposed product is not eligible for an evaluation under this directive, the applicant will be notified as soon as possible and referred to the conventional review stream.

3.2 Submission of Information for Regulatory Decision Making

Details on how to prepare a submission package to register a product can be found in Regulatory Directive DIR2006-05, *Requirements for Submitting Data Index, Documents and Forms*. All information requirements identified during the presubmission consultation must be addressed, using appropriate information from scientifically valid sources such as studies or requests for waivers based on scientific rationales. Only complete submissions will be considered for review by the Agency. If the applicant did not make use of the presubmission consultation process, the PMRA will assess eligibility for review under this directive early in the review process and will notify the applicant of any additional data requirements.

Due to the variability of composition and diverse conditions of use, it is anticipated that registration will continue to be the route most commonly used for non-conventional products. However, as with conventional pesticides, non-conventional products are eligible for exemption from registration for research purposes as described in Regulatory Directive DIR98-05, *Chemical Pesticides Research Permit Guidelines*, under Schedule II of the *Pest Control Products Act*, and for the Own-Use Import Program, subject to compliance with prescribed conditions.

3.3 Performance Timelines and Fees

The performance timeline for submission review of products under Regulatory Directive DIR2012-01, *Guidelines for the Registration of Non-Conventional Pest Control Products* will be similar to the timelines presented in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides*.

Some of the products reviewed under this directive will be eligible for fee exemption or reduced fee status as described in the PMRA's *Guidance Document on Pest Control Product Cost Recovery Fees*. The applicant is responsible for providing a written rationale as to why their product should be considered for a fee exemption or reduced fee status.

Appendix I

Guidance on Preparing Waiver Requests for Information Requirements

1.0 Toxicology

Toxicology data waiver requests must be science-based and should include supporting documentation. They can be based on one or more of several premises as outlined in the example below. All relevant toxicity information should be submitted, including Material Safety Data Sheets and Technical Bulletins.

Sample Waiver Request Format for Toxicity Data Requirements

Waiver Request Justification:
The waiver request is based on [*one or more of*] the following rationales.

Increased environmental exposure to the active ingredient, due to use of the end-use product, will be minimal: Describe levels of naturally occurring substance in environment/use site. Address whether it is ubiquitous in nature and provide information on its geographical distribution and sources; from where it has been isolated (for example, soil, plants/crops/vegetables/fruits, insects, streams, ponds, lakes, etc.). Describe its environmental fate and/or degradation rate and/or formation of metabolites and metabolite fate/degradation. Discuss the extent to which the proposed use pattern will increase the active ingredient above background levels and estimate the time it will take to return to background levels.

No evidence of toxicity and/or no adverse effects: Conduct an extensive literature search of key databases (for example, TOXLINE®, Biological Abstracts, CHEMTOX® [Hazardous and Regulated Chemicals Database]) on the active ingredient and its metabolites to ascertain whether there are any acute, short-term and chronic toxicity data available on humans and/or other mammals (for example, rodents). If little or no public data/information is available on the toxicity of the active ingredient to be registered, then data may be submitted on chemically equivalent or similar substances with an accompanying explanation why the surrogate data should be considered representative of the toxicological effects expected of the active ingredient.

Proposed label uses mitigate/eliminate human exposure: Discuss proposed label use sites (for example, outdoor food/non food, greenhouses, etc.) and rate/timing of application, application methods (for example, spray, dip, soil incorporation, ground boom, aerial, etc.) and their effects on limiting human exposure, if applicable. Address measures to minimize/eliminate direct exposure to humans (workers and bystanders), as well as whether timing of application precludes direct/indirect exposure to humans.

References Cited: Rationales should be supported by references. Cite references by number in brackets in order of mention in the text as if it were in a published technical journal article. Provide full references in this section at the end of the waiver request.

2.0 Environmental Exposure/Environmental Toxicology

Environmental data waiver requests must be based on a scientific rationale and should include supporting documentation. Some examples are as follows:

Rationale	Supporting documentation
• Toxicity to the non-target organism or environmental fate can be described by surrogate data	• Surrogate data (for example, bridging information based on a similar chemical) that describes potential environmental toxicity or fate of the proposed pesticide, and a rationale supporting the validity of extrapolating from the surrogate data to the proposed pesticide.
• Increase in non-target organism exposure to the active will be negligible	• Describe levels of naturally-occurring substance in environment/use site. Give geographical distribution and sources. Has it been isolated from soil, plants, crops, vegetables, fruits, insects, streams, ponds or lakes? Describe environmental fate/degradation rate including formation of metabolites and their fate/degradation, if applicable.
• There is no evidence of toxicity or adverse effects to the non-target organism at relevant exposure levels, demonstrating a long history of safe exposure	• For natural or existing substances that have a history of environmental exposure, a literature search demonstrating that there is no information indicating toxicity or adverse effects on the non-target organism can be submitted. Indicate which databases were searched and the search terms (year range, active name, synonyms, metabolites, etc.) The results or a summary of the results of the literature search should be submitted. Non-target organism exposure of natural/existing substance must also be estimated and compared to the proposed use.
• Proposed label uses mitigate or eliminate exposure	• Describe how method of application minimizes direct exposure to the non-target organism. Describe how timing of application precludes direct or indirect exposure to the non-target organism. Discuss proposed label use sites and rate/timing of application, application methods and their effects on limiting drift/runoff, if applicable. Give degradation rates of active ingredient in days/weeks/months, if available. Would runoff or overspray result in effects not seen from naturally occurring levels?

Appendix II

Directions for Creating a Draft Label

Basic label requirements are outlined below. For more detailed information on the preparation of product labels, refer to the list of references under Policies, Guidelines and Codes of Practice, Labeling of Products, on the Health Canada website: http://www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/publi-regist/codes-eng.php.

Principal Display Panel

1. Product Name

- Must match name on the application form
- Should be specific to the product and be descriptive of its physical form and purpose
- Should not be misleading or contain unacceptable or scientifically unsupportable claims.

2. Class Designation

- Based on intended use and potential hazards
- Must match class indicated on application form
- Usually only one class designation accepted per product (there are some exceptions with combined commercial and manufacturing, commercial and restricted, etc.)
- Class designation must be one of the following:

    - DOMESTIC
    - COMMERCIAL (AGRICULTURAL, INDUSTRIAL or INSTITUTIONAL)
    - RESTRICTED
    - MANUFACTURING

- Domestic class products must include the following statement on the primary panel:

    KEEP OUT OF REACH OF CHILDREN

3. Precautionary Symbols and Words

- If this information is required, poison, flammability, explosive and corrosive hazard symbols and signal words must appear on the label.

    (Refer to the *Checklist of Labeling Requirements for Pest Control Products* referenced in Schedule 3 of the Pest Control Products Regulations.)

4. READ THE LABEL BEFORE USING Statement

- If the product labeling includes a brochure or pamphlet, the following statement must appear on the label:

READ THE LABEL AND BROCHURE BEFORE USING

5. GUARANTEE Statement

- The guarantee on the label must match that on the product specification form and both of these are to reflect the concentration of the active ingredient(s).

6. Registration Number

- The registration number on the label must match the one assigned.
- This number must appear as follows:

REGISTRATION NUMBER XXXXX PEST CONTROL
PRODUCTS ACT

- If the product is domestic class and size is a limiting factor, the number may appear as follows:

REG. NO. XXXXX P.C.P. ACT.

7. Net Contents

- Must be expressed in metric units (imperial measure may appear in brackets after the metric measure).
- Liquids are expressed in millilitres (mL) or litres (L), and solids or pressurized products are expressed in grams (g) or kilograms (kg).

8. Registrant Name

- The name is defined as the Company in which the name of the product is registered, must match the information in box 6 of the application form.
- Can be the name only, the name and a postal address, the name and an Internet address, or the name and an e-mail address

9. Name and Full Postal Address of a contact in Canada

- The contact name, postal address and phone number can be the same or different than that of the Registrant.
- If the Registrant and the public inquiries contact name are the same, one set of information can fulfill both provisions but must include a phone number.

- Public inquiries contact name and address:
    - for a Registrant in Canada: address must be in Canada.
    - for a Registrant in the U.S.: address must be in Canada or the U.S.
    - for a Registrant NOT in Canada or the U.S.: address must be in Canada.

NOTE: For domestic class products of very small size, points 5, 6, 7, 8 and above can appear on the secondary display panel.

Secondary Display Panel

1. DIRECTIONS FOR USE

- Must include complete information on application rates, how to apply the product, and any use limitations. For technical or manufacturing products, the standard DIRECTIONS FOR USE statement is as follows:

> To be used only in the manufacture of a pesticide which is registered under the *Pest Control Products Act*. Read Technical Bulletin for formulation details.

(Please note that the word “pesticide” can be replaced with insecticide, herbicide, fungicide, etc.)

2. PRECAUTIONS

- Must include information on any significant hazard relating to handling, storage, display, or distribution of the product, and how to alleviate such hazards.
- Must include any significant hazard relating to human health, wildlife, or the environment that may result from the use of the product, along with instructions on how to alleviate such hazards.
- Non-domestic class products must include the following statement:

> KEEP OUT OF REACH OF CHILDREN

Domestic class product may also include this statement under Precautions as well as on the Primary panel.

- Manufacturing use products (for example, TGAI or Manufacturing concentrates) must include the following statement:

> PREVENT ACCESS BY UNAUTHORIZED PERSONNEL

3. FIRST AID

- A clear and concise statement of practical first aid measures will be required in cases where the product could pose a hazard as the result of accidental contact with skin or eyes, or ingestion or inhalation. Regulatory Directive 2007-01, *First Aid Labeling Statements*, contains guidance on labeling statements.

4. TOXICOLOGICAL INFORMATION

- The TOXICOLOGICAL INFORMATION portion of the label contains information to assist medical care givers in treating symptoms associated with exposure to the product, this will include antidotes and remedial measures, description of the symptoms and a list of any components that may affect the treatment.
- If there is no antidote or remedial measures, the default statement is:
  Treat symptomatically

5. STORAGE STATEMENT

- Must include information on appropriate storage conditions (for example, temperature range and light restrictions) and any other relevant information aimed at ensuring product stability, performance and safety. May be included under PRECAUTIONS or may be under a separate heading of its own, near the DISPOSAL section.

6. DISPOSAL

(a) Products of DOMESTIC class designation must present the following on the label:

> Do not reuse empty container. Dispose of empty container with household garbage.

(b) For products of COMMERCIAL class designation, use the following statements for liquid products:

1. Rinse the emptied container thoroughly and add the rinsings to the spray mixture in the tank.
2. Follow provincial instructions for any required additional cleaning of the container prior to its disposal.
3. Make the empty container unsuitable for further use.
4. Dispose of the container in accordance with provincial requirements.
5. For information on the disposal of unused, unwanted product and the cleanup of spills, contact the provincial regulatory agency or the manufacturer.

For products of COMMERCIAL class designation, use the following statements for solid products:

1. Thoroughly empty the contents of the container into the application device.
2. Make the empty container unsuitable for further use.
3. Dispose of the container in accordance with provincial requirements.
4. For information on the disposal of unused, unwanted product and the cleanup of spills, contact the provincial regulatory agency or the manufacturer.

(c) Products of technical or manufacturing class designation must present the following on the label:

> Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and clean up of spills, contact the manufacturer or the provincial regulatory agency.

7. NOTICE TO USER

The Notice to User statement presented below is required on all COMMERCIAL, RESTRICTED and MANUFACTURING class products.

> This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product

Appendix III

SAMPLE DRAFT LABEL

PRINCIPAL PANEL

PEST AWAY
Flowable Herbicide

DOMESTIC

READ THE LABEL BEFORE USING

KEEP OUT OF REACH OF CHILDREN

GUARANTEE: *active ingredient*..... X g/L

REGISTRATION NO: XXXXX PEST CONTROL PRODUCTS ACT

[Precautionary symbols and signal words (if appropriate)]

Net Contents: 1 L

[Company Name]
Postal Address
City, Province, Postal Code

[Lot Number (if required)]
[Expiry Date (if required)]

SECONDARY PANEL

NOTICE TO USER: This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label. The user assumes the risk to persons or property that arises from any such use of this product.

DOMESTIC USE: For use against dandelions in lawns.

DIRECTIONS: Treat when plants are growing. Do not mix with any other materials. Spray foliage at rate of 100 mL/m^2. Spray uniformly over all plant surfaces to be treated.

PRECAUTIONS: KEEP OUT OF REACH OF CHILDREN. Avoid contact with skin, eyes and clothing. Wash with soap and water after use.

FIRST AID:

If swallowed (assumes no petroleum distillates in the product)	Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person.
If on skin or clothing	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15–20 minutes. Call a poison control centre or doctor for treatment advice.
If inhaled	Move person to fresh air. If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control centre or doctor for further treatment advice.
If in eyes	Hold eye open and rinse slowly and gently with water for 15–20 minutes. Remove contact lenses, if present, after the first 5 minutes then continue rinsing eye. Call a poison control centre or doctor for treatment advice.

Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

TOXICOLOGICAL INFORMATION: Treat symptomatically.

STORAGE: Store at temperatures between 0°C and 15°C. Store container upright and keep tightly closed when not in use.

DISPOSAL: Do not reuse empty container. Dispose of empty container with household garbage.

Appendix IV List of Relevant Publications

Submission Formatting

Regulatory Directive DIR2006-05, *Requirements for Submitting Data Index, Documents and Forms*

Guidelines for General Guidance and Background

Regulatory Directive DIR2007-02, *First Aid Labeling Statements*

Regulatory Directive DIR2005-01, *Guidelines for Developing a Toxicological Database for Chemical Pest Control Products*

Regulatory Directive DIR2003-04, *Efficacy Guidelines for Plant Protection Products*

Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides*

Regulatory Directive DIR2001-02, *Guidelines for the Registration of Microbial Pest Control Agents and Products*

Regulatory Directive DIR98-05, *Chemical Pesticides Research Permit Guidelines*

Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*

Regulatory Directive DIR98-03, *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products*

Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*

Regulatory Directive DIR98-01, *Good Laboratory Practice*

Regulatory Directive DIR93-17, *Assessment of the Economic Benefits of Pesticides*

Regulatory Proposal PRO2002-02, *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals*

Regulatory Proposal PRO96-01, *Management of Submissions Policy*

Trade Memorandum T-1-255, *Guidelines for Determining Environmental Chemistry and Fate of Pesticides*

Guidance Document on Pest Control Product Cost Recovery Fees

Checklist of Labeling Requirements for Pest Control Products

North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides, *Updated Procedures for Joint Review of Microbials and Semiochemicals*

NOTE: The above documents may be revised in the future. When a revised or final document is issued, the title may be slightly modified and there will be a new reference number. Applicants should contact the PMRA or refer to the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra to determine whether any of the listed references have been superseded by more recent or final versions.