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**Pest Control Products Regulations** 

Vol. 139, No. 46 — November 12, 2005

Statutory authority

Pest Control Products Act

Sponsoring department

Department of Health

# REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

# Description

Pest control products are regulated in Canada under the federal *Pest Control Products Act* (PCPA). A new PCPA was given Royal Assent on December 12, 2002, and will be brought into force once the existing *Pest Control Products Regulations* have been revised (revised PCPR). Other supporting regulations will follow shortly afterwards. These regulations include the *Review Panel Regulations*, the *Pest Control Products Adverse Effects Reporting Regulations*, the *Pest Control Products Sales Information Reporting Regulations*, the revised *Agriculture and Agri-Food Administrative Monetary Penalties Regulations Respecting the Pest Control Products Act and Regulations*, the *Pest Control Product Safety Information Regulations*, and the revised fees regulations. The new PCPA will replace the existing PCPA. The revised PCPR will replace the existing PCPR.

Under both the current and new PCPA, pest control products must be registered by the Minister of Health before they can be used in Canada. A pest control product may not be registered or may not continue to be registered unless its health and environmental risks and its value have been determined to be acceptable by the Minister. The existing PCPR

contain provisions describing the registration process requirements, storage, display, packaging, sampling, import and detention, distribution, prohibitions respecting use, the types of pest control products exempt from the Act, the types of pest control products exempt from registration as well as definitions of terms used throughout the Regulations. Health Canada's Pest Management Regulatory Agency (PMRA) administers the PCPA and Regulations on behalf of the Minister.

The new PCPA modernizes and strengthens pest control product legislation and makes the registration system more transparent. In order to ensure that the objectives of the new Act are met, the existing PCPR must be revised. The revisions being proposed to the existing PCPR aim at implementing the new PCPA while minimizing the economic impacts or burden on businesses. The proposed revised PCPR will be structured in a very similar manner to the existing PCPR, although the language will be simplified, where possible, using plain language. The revised PCPR will continue to include provisions describing definitions of terms used in the Regulations, types of pest control products that are exempt from the Act or from registration, procedures detailing the registration process, including provisions relating to labelling requirements for products, packaging, storage and display, distribution, import, sampling and detention.

The proposed revisions to the PCPR can be broadly categorized into three areas:

- ensuring coherence with the new PCPA;
- clarifying and modernizing provisions in the Regulations, where appropriate; and
- formalizing established procedures and practices into regulations, thereby providing them with legal status.

Many of the proposed revisions to the PCPR are necessary to establish coherence with the new PCPA. These revisions include removing provisions from the Regulations that are now in the new PCPA to avoid duplication, removing provisions that are obsolete, removing provisions that are not within the mandate of the PCPA and Regulations, and adding provisions based on new authorities in the new PCPA. Examples of these revisions for coherence are described in the various sections below.

The proposed revisions to the PCPR also provide an opportunity to clarify and modernize provisions where appropriate. The revised PCPR have been updated to reflect a modern regulatory approach. To achieve this, plain language has been used throughout the Regulations and definitions have been added to the Regulations, allowing provisions within the Regulations to be simplified.

Revisions to the PCPR also provide for the formalizing of established procedures and practices into regulations, thus providing legal status and ensuring better compliance. Three areas are affected in this way:

- temporary/conditional registration;
- Own Use Import (OUI); and
- research.

Details on these areas proposed for formalizing into the Regulations are discussed in sections 14 and 15, sections 37 to 45, and sections 46 to 72 respectively.

# Proposed revised PCPR

These proposed revised Regulations would revoke and replace the existing PCPR. The following is a description of each section of the proposed revised PCPR and includes, where applicable, a reference to the corresponding section of the existing PCPR to which revisions are proposed. An explanation is also provided as to whether the proposed revisions relate to ensuring coherence with the new PCPA, clarifying and modernizing the Regulations or formalizing established procedures and practices into the Regulations.

# Section 1

Section 1 contains definitions of terms used in the revised Regulations. Terms introduced in the Act are defined in the Act and these definitions also apply to the Regulations. This section replaces section 2 of the existing Regulations. The revisions in this section reflect establishing coherence with the new PCPA by using wording that is consistent with that in the new Act. Section 1 also addresses revisions for clarification and modernization, with emphasis on using plain language and concise definitions to simplify the Regulations. Revisions will include clarifying certain definitions, removing definitions that are either currently included in the new PCPA or no longer used, as well as adding definitions to simplify the Regulations.

Definitions to be clarified would include "display panel," "principal display panel," and "secondary display panel." Others would be revised to reflect terminology in the new PCPA or current plain language drafting conventions, e.g. "registration certificate," "device," and "seed."

A number of definitions would be removed, as they are now included in the new PCPA, e.g. "active ingredient," "biotechnology," "control product" (changed in the new PCPA to "pest control product"), and "registrant." In other cases, the term is no longer used, e.g. "assessed or evaluated," "Director General," "Plant Industry Directorate," and "Regional Pesticide Officer"; or it is no longer considered necessary to define the term, e.g. "applicant," "organism," and "residues," so these would also be removed.

It is also proposed to add definitions for the following terms in order to simplify the wording of the relevant provisions: "antimicrobial agent," "approved label," "CAS registry number," "cooperator," "domestic animal," "experimental label," "foreign product," "marketplace label," "microbial agent," "pheromone," "research," "research establishment," "research notification certificate," "research site," "researcher," "semiochemical," and "validity period."

# Section 2

Section 2 would prescribe a device, an adjuvant and a safener to be pest control products.

Devices used in pest control are included in the scope of the existing PCPA but are not covered by the definition of "pest control product" in the new PCPA, which refers to a product that consists of its active ingredient, formulants and contaminants. However, the new PCPA does include authority to prescribe other things to be pest control products. Prescribing a device to be a pest control product would allow current practices respecting

devices used in pest control to continue.

Adjuvants (products added to a pesticide to enhance its effectiveness) and safeners (products either added to or used in conjunction with a pesticide to prevent damage to the crop) would also be prescribed to be pest control products when they are added to or used with a pest control product. Products added to a pesticide are included in the scope of the existing PCPA. Products used in conjunction with a pesticide should be regulated in the same way, as the health and environmental risks that they pose are the same.

This is a new section of the revised PCPR, proposed to maintain coherence with the associated authority in the new PCPA to prescribe other things to be pest control products [subsection 2(1), definition of a "pest control product"].

# Section 3

Section 3 would exempt from the new PCPA products that are exempt from the existing PCPA (sections 3 and 4 of the existing PCPR). This includes devices, other than those listed in a schedule to the Regulations, products subject to the *Food and Drugs Act* such as veterinary drugs and disinfectants as well as products imported for personal use in very small quantities. The monetary value of the small quantities has been increased from \$10 to \$100 to reflect the current value of these quantities.

The revisions proposed in this section reflect revisions to clarify and modernize the Regulations. This is achieved mainly by the use of plain language and, aside from increasing the monetary value of small quantities of pest control products imported for personal use, the revisions do not introduce any changes.

# Section 4

Section 4 would exempt from registration certain products that are exempt from the requirement to be registered under the new PCPA (sections 5 and 5.1 of the existing PCPR). This includes active ingredients, if they are used only in products registered before 1984 as, prior to 1984, active ingredients did not require registration, only end use products. However, such active ingredients, which are of limited numbers, are subject to re-evaluation. A number of other types of products, such as swimming pool and spa chemicals and certain devices, are also included in this section, provided that they meet certain labelling and other conditions set out in a schedule to the Regulations. Products imported under the own use import program or for use in research would continue to be exempt from registration; the substantive provisions to specify the conditions for these exemptions are found in sections 37 to 45 for own use import and sections 46 to 72 for research, described hereafter.

Section 4 would also exempt from registration a pest control product that is manufactured only for export, provided that it contains a registered active ingredient. This exemption is not included in the existing PCPR because the manufacture of an unregistered pesticide is not prohibited under the existing PCPA, as it is under the new PCPA. Exempting pesticides intended for export from the requirement to be registered would allow current practices respecting these products to continue.

Revisions contained in this section provide for maintaining coherence with the new PCPA

(exempting a product manufactured only for export), clarifying and modernizing provisions (mainly by using plain language) and formalizing established procedures and practices into the Regulations (own use import and research).

## Section 5

Section 5 is proposed as a new section to clarify wording contained in provisions of the Regulations, specifically those relating to labelling. Descriptions of current product class designations for pest control products ("DOMESTIC," "COMMERCIAL," "RESTRICTED" and "MANUFACTURING") would be set out in this section. Under the existing PCPR, references are made to "domestic" and "restricted" but not to "commercial" or "manufacturing" and nowhere in the existing PCPR is a complete description for either "domestic" or "restricted" classes provided.

This section is proposed to clarify and modernize the Regulations. The addition of this section will provide for further transparency by clearly describing all four product classes and will also provide for clarification of other provisions within the revised PCPR. The proposed descriptions do not introduce any changes to the current descriptions.

# Section 6

Section 6 would set out the information that is required to accompany an application to register or amend the registration of a pest control product. This includes information about the applicant and the product, including details about the product's composition, specifications and packaging. This section is equivalent to sections 7 and 10 of the existing PCPR but has been updated and revised to reflect current application requirements more accurately. An example of this is the proposed change that applicants submit an electronic copy of the proposed label as opposed to paper copies.

The revisions to this section provide for clarifying and modernizing the Regulations to reflect current practices. As such, the changes proposed should not pose a negative impact.

## Section 7

As in the existing PCPR (section 6.1), section 7 would require the registrant to make an application to amend the registration of a pest control product if requested to do so by the Minister. This is an administrative procedure that normally follows a re-evaluation or special review.

This section reflects a revision to clarify and modernize the Regulations by making use of plain language.

#### Section 8

Section 8 would set out the data requirements for applications to register or amend the registration of a pest control product, which are the test data that must be generated through scientific studies to demonstrate that the health and environmental risks as well as the value of the product are acceptable. This section is equivalent to section 9 in the existing Regulations but has been updated to reflect current practices respecting the

assessment of the risks and value of pesticides. For example, more comprehensive data with respect to dietary risk assessment have been specified.

This section reflects revisions for the purposes of clarifying and modernizing the Regulations. The proposed revisions are in keeping with current practices.

## Section 9

Section 9 would be a new provision in the revised PCPR, required to ensure coherence of the Regulations with the new PCPA. Under the new PCPA, the Minister may consider additional information from a source other than an applicant or registrant during the evaluation process. Should the Minister do so, provisions are proposed to be added to the revised PCPR to allow the applicant or registrant access to this additional information, while preserving its confidential nature.

#### Section 10

Section 10 would be a new provision in the revised PCPR, required for coherence with the new PCPA. This section would provide for evaluation reports to contain references to any information the Minister considers when making decisions respecting registrations, amendments, re-evaluations or special reviews.

#### Section 11

As under the existing PCPR (section 11), section 11 would require an applicant, upon request, to provide a sample of the pest control product and its technical grade active ingredient as well as a laboratory standard for the active ingredient.

This section provides for clarification and modernization of the Regulations by using plain language. No changes have been made in this section.

## Section 12

As under the existing PCPR [subsection 13(3)], section 12 would require the Minister to issue a certificate of registration when a pest control product is registered, which would show its registration number and would set out its conditions of registration. Other provisions in section 13 of the existing PCPR that relate to the registration of pest control products would be deleted because they have been moved to the new PCPA. Subsection 42(2) of the new PCPA describes information that must be contained in the Register; included in this subsection are the requirements from section 13 of the existing PCPR.

This section provides for clarification and modernization of the Regulations by using plain language. As well and as described above, revisions are required to ensure coherence with the new PCPA.

#### Section 13

Section 13 is a new provision in the revised PCPR, added to clarify the Regulations. This section would clearly describe the maximum validity period of a pest control product's

registration. The term "validity period" would be defined in section 1 of the revised PCPR.

This section provides for clarifying and modernizing the Regulations.

Sections 14 and 15

Sections 14 and 15 would specify requirements respecting the registration of a pest control product that is conditional upon the submission of confirmatory data. These sections are equivalent to section 17 of the existing Regulations but with revisions to ensure coherence with authorities under the new PCPA.

Instead of the term "temporary registration" that is used in the existing PCPR, the term "conditional registration" would be used. As with temporary registrations, conditional registrations would be granted when there are confirmatory data requirements but a determination has been made that the risks and value of the pesticide are acceptable, and limitations are placed on the duration of the registration. Under the existing PCPR, temporary registrations cannot exceed one year but often must be renewed because it is not possible to generate and review the outstanding data within a year. Under the revised PCPR, the validity period of a conditional registration would reflect the time needed to generate the data to a maximum of three years. Once the data requirements had been fulfilled, the validity period could be extended for a period of two years, during which the data would be evaluated. A possible further extension of the validity period could occur, allowing for consultation to take place in accordance with section 28 of the new PCPA, if that section applies. Once a registration decision is reached, it would be subject to notice of objections where section 35 of the new PCPA applies and placing of information in the Register [paragraphs 42(2)(c) to (e)].

A conditional registration could be renewed but would be subject to the public consultation provisions under the new PCPA upon renewal.

According to current practice, when a pesticide is granted a temporary registration, a Regulatory Note is published to describe the risk and value assessments conducted, the confirmatory data requirements and the rationale for the registration decision. When the confirmatory data requirements have been fulfilled and the pesticide is proposed for full registration of up to five years, the public is consulted on the proposed decision through publication of a Proposed Regulatory Decision Document. In order to continue this practice, the mandatory public consultation provisions of the new PCPA, if applicable, would not apply when a conditional registration was initially granted. A Regulatory Note would be published as is currently done and the detailed reports of the risk and value evaluations would be made available to the public in accordance with the new PCPA. When the pesticide was proposed for full registration or if the conditional registration was proposed to be renewed, continued or reinstated after the initial three-year validity period, the provisions for public consultation would apply. Following the consultation, certain new provisions in the new PCPA would also apply, that is, the public would have the opportunity to file a notice of objection and the test data would be available for viewing by the public in a reading room.

Sections 14 and 15 reflect revisions to ensure coherence with the new PCPA and to formalize established procedures and practices into regulations.

Section 16

Section 16 would specify requirements respecting the renewal of pesticide registrations, including the renewal of conditional registrations discussed in sections 14 and 15 noted above. This section would be equivalent to section 14 of the existing Regulations but with revisions to account for conditional registrations and current administrative practices.

Revisions to this section reflect clarifying and modernizing the Regulations, mainly by using plain language but also by providing for the electronic submission of the approved label when renewing. This section also incorporates revisions reflective of formalizing established procedures and practices for conditional registrations.

# Section 17

Section 17 would be a new provision in the revised PCPR, required to ensure coherence of the Regulations with the new PCPA. Under the new PCPA, the Minister may consider information from a source other than a registrant during the re-evaluation or special review process. Should the Minister do so, provisions are proposed within the revised PCPR to allow the registrant access to this additional information while preserving its confidential nature. This section is similar to section 9 but pertains specifically to reevaluation and special reviews.

#### Section 18

Section 18 would specify requirements respecting the registration of a pesticide for the emergency control of a seriously detrimental infestation. This section is equivalent to section 17 of the existing Regulations. An emergency registration could not exceed one year and could not be renewed. If, however, in cases of recurring emergency situations, a request for an emergency registration may be made and if it is justified, an emergency registration may be granted.

This section is an example of revisions to clarify and modernize the Regulations by making use of plain language and incorporating a reference to the validity period, proposed in section 13. As well, revisions to ensure coherence with the new PCPA are proposed.

#### Section 19

As under the existing PCPR (sections 47 and 48), section 19 would set out standards for pest control products. The requirement that every pest control product conform to the specifications and bear the label contained in the register would be removed, as this requirement is now in the new PCPA. The requirement for products to have a uniform composition would be removed, as this requirement can be included in the conditions of registration specified by the Minister under the new PCPA. The requirements regarding the active ingredients 2,4,5-T and fenoprop would be removed, as they are no longer registered. The requirement regarding contaminants in pest control products containing the active ingredient trifluralin would remain.

Revisions proposed in this section ensure coherence with the new PCPA and clarify and modernize the Regulations.

#### Section 20

As in the existing PCPR (section 42), section 20 would provide that the Minister may require a product to be denatured by means of colour, odour or other means in order to ensure that its presence would be recognized. For example, treated seed may be coloured to indicate the presence of a pest control product.

This section is an example of clarifying and modernizing the Regulations by using plain language.

## Section 21

Section 21 would clarify the intent in the existing PCPR [paragraph 51(*c*)] to prohibit any words or expressions that imply that the Government is promoting, endorsing or recommending the use of a pest control product.

Sections 22 to 32

Sections 22 to 32 would set out the requirements for the labelling of registered pest control products. These sections are equivalent to sections 27 to 41, 50 and 51 of the existing PCPR.

Provisions for bilingual labelling and for prohibiting the representation of a pest control product as a treatment, preventive or cure for a disease of humans or animals are centralized in these sections of the revised PCPR.

The information that would be required to be shown on a product's principal and secondary display panels would continue to be specified in the Regulations.

The requirement to show on domestic products a statement "keep out of the reach of children" is proposed as a new requirement under the Regulations but such a statement is in keeping with current practice normally carried out as a condition of registration. The change will increase transparency.

The revised PCPR would specify the normal requirements for pest control product labels, but subsection 8(2) of the new PCPA provides authority for the Minister to approve labels that deviate from these Regulations. This authority allows labelling requirements to be tailored to the wide range of registered pest control products. The Regulations themselves indicate certain ways in which the normal labelling requirements may be varied, for example, by permitting information that would normally be shown on the principal or secondary display panel to appear in a leaflet or brochure.

Another change being proposed is the removal of the Notice to Buyer provision (section 37 of the existing PCPR). Since the intent of this statement relates to the contractual agreement between the pest control product registrant and the user of the product, it is felt that such a provision is not appropriate under these Regulations. Also, such a contractual matter is under provincial jurisdiction and should not be addressed in a federal regulation. A portion of this provision would be added to the Notice to User statement [paragraph 26(2)(g) of the revised PCPR], namely "The user assumes the risk to persons or property that arises from any such use of this product."

The revisions proposed in sections 22 to 32 reflect revisions to ensure coherence with the new PCPA and to clarify and modernize the Regulations. The revisions proposed are not expected to pose negative impacts.

Section 33

As in the existing PCPR (section 46), section 33 would set out the requirements for the construction of packages for pest control products.

Section 33 represents revisions for clarifying and modernizing the Regulations by using plain language and, as a result, no changes to the intent of the requirements have been introduced.

Section 34

As in the existing PCPR (section 43), section 34 would set out the requirements for storage and display of pest control products.

Section 34 represents revisions for clarifying and modernizing the Regulations by using plain language and, as a result, no changes to the intent of the requirements have been introduced.

Section 35

As in the existing PCPR (section 44), section 35 would require that the conditions of registration relating to the distribution of a pest control product be shown on the documents accompanying the shipment.

Section 35 represents revisions for clarifying and modernizing the Regulations by using plain language and, as a result, no changes to the intent of the requirements have been introduced.

Section 36

As in the existing PCPR (section 55), section 36 would set out requirements for import declarations to accompany shipments of pest control products when they are imported into Canada. Other provisions relating to the handling of import declarations by customs officers in sections 56 and 57 of the existing PCPR would be deleted because the conduct of customs officers is regulated under other federal legislation.

The revisions proposed in section 36 provide for clarifying and modernizing the Regulations.

Sections 37 to 45

Sections 37 to 45 would set out the requirements for the existing Own Use Import (OUI) program [paragraph 5(1)(*d*), subsection 5(3), and section 5.1 of the existing PCPR]. The

intent of the revisions is to ensure coherence of the revised PCPR with the new PCPA while clarifying certain aspects of the program. No significant program changes are proposed in the revisions, but a comprehensive review of the program is planned during fiscal year 2005-2006.

The objective of the OUI program is to allow a person to import for their own use a less expensive foreign product that is equivalent to a registered product. This program is restricted to agricultural products. Under this program, an unregistered product may be imported from a foreign country for the importer's own use if it has been demonstrated that the foreign product is equivalent to a product that is registered in Canada under the PCPA. The imported product must bear an additional label that conforms with the approved label of the registered product.

Under the existing PCPR, provisions provide for the exemption from registration a foreign product, providing that the foreign product meets the criteria specified as well as the criteria for determining equivalency. To maintain coherence with the new PCPA, it is proposed that the authority of section 41 of the new PCPA be used to allow the Minister to authorize the use of any unregistered pest control product or a specified purpose. The Regulations would also formalize details currently found in guidance documents in order to ensure that the processes for determining equivalency and obtaining authorization to import the equivalent foreign product can be adequately controlled.

Proposed provisions relating to OUI would describe the process for determining equivalency and detail how to obtain an OUI certificate (that is, approval to use a foreign product).

One revision proposed within these Regulations relates to a screening criteria for a foreign product. Under the current PCPR, a foreign product considered under the OUI program cannot contain a formulant on List 1 of the Lists of Inert Pesticide Ingredients of Toxicological Concern issued by the United States Environmental Protection Agency [subparagraph 5(1)(d)(i) of the existing PCPR]. Under the revised PCPR, this screening criteria for formulants would reference the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*. This List, including background information on the inception of the List, can be found on PMRA's Web site (www.pmra-arla.gc.ca/english/pdf/noi/noi2005-01-e.pdf). As well, the List and an explanatory note will be published in the near future in the *Canada Gazette*, Part II.

Also proposed within the provisions for determining equivalency are requirements respecting a price differential of 10 percent. This price differential pertains to the processing of an application to determine equivalency.

The revisions proposed in sections 37 to 45 provide for formalizing established procedures and practices into regulations. Such formalization also involves ensuring coherence with the new PCPA.

Sections 46 to 72

Sections 46 to 72 pertain to research using pest control products. These sections are equivalent to paragraph 5(1)(b) of the existing PCPR and reflect the formalization of established research procedures and practices into the Regulations. These provisions will ensure that the objective of research (i.e. generating the test data that must accompany

an application for the registration of a pest control product or for the amendment of a product's registration) can be met while providing for better compliance.

Using the authority in section 41 of the new PCPA, sections 46 to 72 would set out the provisions for allowing the use of an unregistered pest control product or allowing an unregistered use of a registered pest control product to conduct research and to attach conditions to the authorization to ensure that the use does not pose unacceptable health or environmental risks.

The revised PCPR would also provide exemptions from the requirement to obtain authorization to conduct research in certain circumstances that are currently in practice. In some circumstances, confirmation that the specified criteria for exemption are met would have to be obtained in the form of a research notification; in other circumstances, the research would be exempt from the requirements to obtain authorization or confirmation (notification).

The criteria are currently found in guidance documents but must be included in these Regulations in order to guide properly the exercise of the Minister's authority. The criteria are based on the degree of risk involved with the research and provide for proposed research to fall into one of the three research categories currently used in practice (authorization, notification or exemption). For example, exempt research cannot involve the aerial application of a pest control product and must be carried out on limited areas of land or water.

Research conducted under notification cannot involve aerial application but could be carried out on larger areas of land or water, when compared to exempted research. Where there is higher potential risk, an authorization is required and the application must include certain specified information that would enable the Minister to determine whether potential risks would be acceptable.

One of the proposed criteria relates to a pest control product containing a formulant that is on the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.* In keeping with formalizing established procedures and practices, products proposed for research containing a formulant that is on this list or a formulant that is not a component of a registered pesticide would not be permitted under notification or exemption and could only be considered under an authorization. This List, including background information on the inception of the List, can be found on PMRA's Web site (www.pmra-arla. gc.ca/english/pdf/noi/noi2005-01-e.pdf). As well, the List and an explanatory note will be published in the near future in the *Canada Gazette*, Part II.

The revised PCPR would also indicate the requirements that are currently in guidance documents for posting of signs at research sites, labelling of products used in research, material safety data sheets, record keeping, importation, disposal of unused product and sale of treated crops, in order to ensure that these provisions can be adequately enforced.

The revisions proposed in sections 46 to 72 provide for formalizing established procedures and practices into regulations. Such formalization also involves ensuring coherence with the new PCPA.

Section 73

As in the existing PCPR (section 52), section 73 would set out certain requirements relating to the sampling of pest control products by an inspector.

The revisions proposed in this section involve clarifying and modernizing the Regulations by using plain language and reflecting terminology of the new PCPA.

## Section 74

As in the existing PCPR [subsection 53(2)], section 74 would require an inspector to attach a detention tag to at least one package of a pest control product in a lot that has been seized. Other provisions relating to detention in sections 53 and 54 of the existing PCPR would be deleted because they have been moved to the new PCPA.

The revisions to this section provide for ensuring coherence with the new PCPA.

Sections 75 to 77

Sections 75 to 77 would contain requirements related to transition, repealing the existing PCPR and coming into force of the revisions to the PCPR.

#### Schedule 1

As in the existing PCPR, Schedule 1 would list the devices that are not exempt from the PCPA.

The revisions contained in this schedule reflect clarification and modernization of the Regulations by using plain language.

#### Schedule 2

As in the existing PCPR, Schedule 2 would specify the requirements for pest control products that are exempt from registration under the new Act. The exemption for treated feed has been clarified to specify that the pest control product must be registered for the purpose of mixing with feed.

The revisions contained in this schedule reflect clarification and modernization of the Regulations by using plain language.

# Schedule 3

As in the existing PCPR, Schedule 3 would depict precautionary symbols and signal words to be used on pest control product labels.

The revisions contained in this schedule reflect clarification and modernization of the Regulations by using plain language.

# Provisions no longer applicable to the revised PCPR

A number of sections of the existing PCPR would be removed, as they are either no longer applicable or are covered by provisions in the new PCPA. The following describes those sections and specifies whether they have been moved to the new PCPA or deleted in their entirety:

- Short Title (section 1) removed, as short titles are no longer included in regulations;
- Certificate of designation of inspector (section 2.1) the authority to designate inspectors was moved to the new PCPA (section 45, new PCPA);
- Registration of control products required (section 6) the requirement for pest control products to be registered was moved to the new PCPA (section 6, new PCPA);
- Resident agents (section 8) The requirement for registrants who do not reside
  in Canada to designate a Canadian representative was moved to the new PCPA
  (section 62, new PCPA);
- Expiry date (section 15) This provision provided an expiry date of December 31, 1980, for products registered before 1978 and is no longer needed;
- Discontinuation (section 16) The provisions respecting discontinuation of the sale of a registered pest control product by the registrant were moved to the new PCPA (section 22, new PCPA);
- Refusal to register (section 18) The provisions respecting the denial of registration applications were moved to the new PCPA (Subsection 8(4), new PCPA):
- Re-evaluation (sections 19 and 20) The provisions for re-evaluating registered pest control products were moved to the new PCPA (sections 16 and 17, new PCPA);
- Boards of Review (sections 21 to 25) The provisions respecting Boards of Review were replaced by provisions in the new PCPA for the reconsideration of major registration decisions by review panels (section 35, new PCPA). The provisions in the Act will be supplemented by proposed new regulations to be published separately for comment in the *Canada Gazette*, Part I;
- Records (section 26) This section will be replaced by the proposed Pest Control Products Sales Information Reporting Regulations; a proposal was published for comment in the Canada Gazette, Part I on March 27, 2004;
- Prohibition respecting use [subsection 45(1)] The requirement that users of a
  pest control product comply with the directions on the label was moved to the
  new PCPA [subsection 6(5), new PCPA];
- Value of active ingredient in a product (section 49) Requirements respecting
  the composition and value of pest control products were moved to the new
  PCPA;
- Schedule IV The requirements in this schedule have been moved to section 4
  of the proposed revised PCPR, with some clarification.

All revisions proposed above are necessary to ensure coherence with the new PCPA.

#### **Alternatives**

In December 2002, the new PCPA received royal assent. The new PCPA will strengthen Canada's safeguards against the risks to people and the environment from using pest control products. Canadians will have access to more information and new opportunities

for input into major pest control product registration decisions. In order for the new PCPA to come into force, the *Pest Control Product Regulations* require revision to maintain cohesion with the new PCPA and provide the regulatory framework for many authorities in the new PCPA.

The revisions being proposed do not introduce new policy or procedural changes in how pest control products are regulated under the current framework, so as to minimize the economic impacts or burden on businesses while allowing the new PCPA to come into force.

The revisions to the PCPR provide for ensuring coherence with the new PCPA, modernizing and clarifying provisions in the Regulations, where appropriate, and formalizing established procedures and practices into regulation. Such revisions are supportive and consistent with the objectives of the new PCPA.

# Benefits and costs

Since the revisions being proposed do not introduce new policy or procedural changes in how pest control products are regulated under the current framework, it is expected that the revised PCPR would have no economic impacts or pose additional burden on businesses.

Together with the PCPA, the revised PCPR will provide for a more transparent federal pest management regulatory system that will afford greater human health and environmental protection from the use of pest control products; the cost to Government for the infrastructure (e.g. a reading room where public can see information used in registering products) needed to implement the new PCPA's transparency requirements is already planned for.

The new PCPA will strengthen human health and environmental protection, make the registration system more transparent and strengthen post-registration controls on pest control products.

It was determined through a strategic environmental assessment that this regulatory initiative would result in no potential environmental impact.

## Consultation

The revisions to the Regulations are being proposed to bring the new PCPA into force. Extensive consultation took place during the development and passage of the new PCPA. The resulting new PCPA and proposed revised PCPR reflect the results of such extensive consultation. Where established procedures and practices are formalized in the revised PCPR, these areas have been consulted on previously. In the case of formalizing the research program into the revised PCPR, consultation is reflected in regulatory directives and regulatory proposals, upon which the research provisions proposed in the revised PCPR are based.

The public and the stakeholders were recently informed of the specific proposal through a presentation made at the Pest Management Advisory Council's (PMAC) meeting of June 6, 2005, and a Notice of Intent published on PMRA's Web site on June 13, 2005. PMAC

is a multi-stakeholder group that fosters communication and dialogue among stakeholders and with PMRA, and provides advice to the Minister of Health on policies and issues relating to the federal pest management regulatory system.

Following the publication of the Notice of Intent, two inquiries were received and responses were provided. The inquiries requested clarification on wording used in the Notice of Intent, specifically in relation to the formalization of the research program, and responses provided confirmation that no new impacts were being introduced, as established procedures and practices for research would continue to apply.

# Compliance and enforcement

The PMRA promotes, verifies and enforces compliance with the PCPA through compliance promotion programs, inspections, both monitoring and surveillance, and investigations. Compliance promotion programs aim to educate, facilitate and promote compliance while monitoring programs assesses the level of compliance of selected users, distributors and registrants of pest control products with specific terms and conditions of registration and re-evaluations and the provisions of the PCPA and Regulations. Surveillance inspections are planned to target specific individuals or groups for follow-up on previous findings or concerns. Investigations are conducted in response to specific complaints or suspected violations.

Available enforcement response actions when investigations are conducted include product detention, denial of product entry into Canada, education (written and oral), administrative monetary penalties or warning under the *Agriculture and Agri-Food Administrative Monetary Penalties Act* (AMPs) and prosecutions under the PCPA. The goal of any enforcement response is to achieve and maintain continuing compliance. Since the majority of the regulated community will comply with the law if they understand it, many violations are dealt with and corrected using education as a means to address non-compliance situations and behaviour.

In general, compliance with the PCPA and Regulations is achieved through a network of PMRA regional officers and Canadian Food Inspection Agency (CFIA) inspectors across Canada. PMRA regional staff also have formal agreements providing a basis to collaborate with provincial pest control product regulatory officials in investigations and in the development and delivery of programs.

The "Compliance and Enforcement Policy Guideline" describes the measures used by the PMRA to promote and enhance fair treatment of the regulated community, and the role of PMRA inspectors. The Guideline is available on the PMRA Web site at www.hc-sc.gc.ca/pmra-arla/english/pdf/bgr/bgr\_b9801-e.pdf.

# Contact

Francine Brunet, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Health Canada, Address Locator 6607D1, 2720 Riverside Drive, Ottawa, Ontario K1A 0K9, (613) 736-3678 (telephone), (613) 736-3659 (fax), pmra\_regulatory\_affairs-affaires\_reglementaires\_arla@hc-sc.gc.ca (email).

# PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council proposes, pursuant to subsection 67(1) of the Pest Control Products Act (see footnote a), to make the annexed Pest Control Products Regulations.

Interested persons may make representations with respect to the proposed Regulations within 30 days after the date of publication of this notice. All such representations must cite the Canada Gazette, Part I, and the date of publication of this notice and be sent to Francine Brunet, Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency, Department of Health, Address Locator 6607D1, 2720 Riverside Drive, Ottawa, Ontario K1A 0K9 (fax: (613) 736-3659; e-mail: pmra\_ regulatory affairs-affaires reglementaires arla@hc-sc.gc.ca).

Persons making representations should identify any of those representations the disclosure of which should be refused under the Access to Information Act, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa, October 31, 2005

DIANE LABELLE Acting Assistant Clerk of the Privy Council

## PEST CONTROL PRODUCTS REGULATIONS

# INTERPRETATION

**Definitions 1.** (1) The following definitions apply in these

Regulations.

"Act" "Act" means the Pest Control Products Act.

« Loi » "antimicrobial agent" "antimicrobial agent" means a non-agricultural pest

« agent antimicrobien » control product that is manufactured, represented, distributed or used as a means to directly or indirectly control or destroy the following on or in inanimate objects, industrial processes and

systems, surfaces, water and air:

(a) micro-organisms; and

(b) organisms that are not vascular plants and that

cause fouling. "approved label" "approved label" means a label that meets the

> conditions of registration relating to the label as specified by the Minister and that is placed in the

Register.

"CAS registry number"

« étiquette approuvée »

« numéro d'enregistrement CAS »

"CAS registry number" means the identification number that is assigned to a chemical substance by the Chemical Abstracts Service Division of the

American Chemical Society.

"common chemical name" « nom chimique commun »

"conditional registration"

« homologation conditionnelle »

"cooperator"

« collaborateur »

"device" « *dispositif* » "display panel"

« aire d'affichage »

"domestic animal"

« animal domestique »

"equivalency certificate"
« certificat d'équivalence »

"experimental label" « étiquette

de stade expérimental »

"foreign product" « produit étranger »

"marketplace label"

« étiquette de marché »

"metric unit"

« unité métrique »

"microbial agent"

« agent microbien »

"own use"

« approvisionnement personnel »

"own-use import certificate" « certificat d'importation pour approvisionnement personnel »

"common chemical name", with respect to an active ingredient of a pest control product, means the name set out in International Standard ISO 1750-1981 (E/F), entitled *Pesticides and other agrochemicals* — *Common names*, published by the International Organization for Standardization, as amended from time to time.

"conditional registration" means a registration to which section 14 applies.

"cooperator" means an individual, a corporation or an unincorporated entity, or part of one, that agrees to use or allows the use of a pest control product for research purposes on a site owned or operated by it.

"device" means an article, an instrument, an apparatus, a contrivance or a gadget.

"display panel" means the part of the label that is affixed to the container, wrapping, covering or holder in which a pest control product is wholly or partly contained, placed or packed. It does not include any brochure or leaflet that accompanies the product.

"domestic animal" means an animal that is under the control of humans and dependent on them for its survival.

"equivalency certificate" means a certificate issued under subsection 39(7) with respect to a foreign product.

"experimental label" means a label that is for use during research.

"foreign product" means a pest control product that is registered in a country other than Canada.

"marketplace label" means the approved label and any added graphic design or symbol that relates to the pest control product.

"metric unit" means a unit of measurement set out in Schedule I to the *Weights and Measures Act*.

"microbial agent" means a pest control product whose active ingredient is a micro-organism. It includes any metabolites and toxins produced by the micro-organism.

"own use", with respect to an imported foreign product, means that the product is imported by or on behalf of the holder of an own-use import certificate for the holder's own use.

"own-use import certificate" means a certificate issued under section 41.

"pheromone" « *phéromone* »

"principal display panel" « aire d'affichage principale »

"registration certificate"
« certificat d'homologation »

"research" « recherche »

"research authorization certificate" « certificat d'autorisation de recherche »

"researcher" « *chercheur* »

"research establishment"
« établissement de recherche »

"research notification certificate" « certificat d'avis de recherche »

"research site" « site de recherche »

"secondary display panel" « aire d'affichage secondaire »

"seed"

« semence »

"pheromone" means a semiochemical that is produced by an individual of a species and that affects the behaviour of other individuals of the same species.

"principal display panel" means the part of the display panel that is visible under normal conditions of display for sale.

"registration certificate" means a certificate issued under section 12 that states that the pest control product named in it is registered under the Act.

"research" means tests that are carried out to generate test data in support of an application for registration of a pest control product or an application to amend a registration, using a pest control product that contains an unregistered active ingredient, using an unregistered pest control product that contains a registered active ingredient or using a registered pest control product in a manner or for a use that is not specified in the conditions of registration.

"research authorization certificate" means a certificate issued under subsection 50(2) that states that the pest control product named in it may be used in conducting research.

"researcher" means an individual who is employed by or who provides service to a research establishment and who is responsible for using or supervising the use of a pest control product for research purposes.

"research establishment" means an individual, a corporation or an unincorporated entity, or part of one, that is engaged in research that pertains to a pest control product.

"research notification certificate" means a certificate issued under section 54 that confirms that proposed research meets the criteria set out in section 53.

"research site" means an area that is treated or to be treated with a pest control product for the purpose of conducting research.

"secondary display panel" means the part of the display panel other than the principal display panel.

"seed" means a generative part of a plant that is used for propagation purposes. It includes true seeds, seed-like fruits, bulbs, tubers and corms but does not include whole plants or cuttings.

"semiochemical" « écomone »

"validity period" « période de validité »

Definition of "common chemical name"

Prescribing

Exemption from application of Act

"semiochemical" means a message-bearing chemical that is produced by a plant or an animal, or a synthetic analogue of such a chemical, that evokes a behavioural response in individuals of the same or another species.

"validity period" means the period specified under paragraph 8(1)(c) of the Act.

(2) For the purpose of the application of the definition "common chemical name" in subsection(1), the common chemical name "carboxin" is to be read as "carbathiin" wherever it appears in the Standard referred to in that definition.

# PRESCRIBED PEST CONTROL PRODUCTS

- **2.** For the purpose of paragraph (*c*) of the definition "pest control product" in subsection 2(1) of the Act, the following are prescribed to be pest control products:
- (a) a device that is manufactured, represented, distributed or used to directly or indirectly control, destroy, attract or repel a pest or to mitigate or prevent the injurious, noxious or troublesome effects of a pest; and
- (b) a compound or substance that is added to or used with a pest control product to enhance or modify the product's physical or chemical characteristics or to modify an effect on host organisms in connection with which the product is intended to be used.

# EXEMPTION OF CERTAIN PEST CONTROL PRODUCTS

- **3.** (1) The following pest control products are exempt from the application of the Act:
- (a) a pest control product that is a device of a type not described in Schedule 1;
- (b) a pest control product that is subject to the *Food* and *Drugs Act* and that is used only
  - (i) to control arthropods on or in humans or animals, if the pest control product is to be administered directly and not by topical application, or
  - (ii) during the cooking or processing of food for humans to preserve the food;
- (c) a pest control product that is used to control viruses, bacteria or other micro-organisms in premises in which food is manufactured, prepared or kept for sale;
- (d) a pest control product that is used to destroy or inactivate viruses, bacteria or other microorganisms in order to treat, mitigate or prevent disease in humans or animals, except in respect of its use in a swimming pool or spa;
- (e) except in respect of its uses as a preservative

for wood or other material, as a slimicide or in a swimming pool or spa, a pest control product that is used both to

- (i) destroy or inactivate viruses, bacteria or other micro-organisms in order to treat, mitigate or prevent disease in humans or animals, and
- (ii) reduce the level of viruses, bacteria or other micro-organisms that cause mould, mildew, odour or disease in humans or animals; and
- (f) a pest control product, other than an organism, that is imported into Canada primarily for use by the importer in or around the home, if the quantity being imported is not more than 500 g or 500 mL and the value of the quantity imported is not more than \$100.
- (2) A pest control product that is exempt under paragraph (1)(c), (d) or (e) is exempt only in respect of any use described in that paragraph.

**EXEMPTION FROM REGISTRATION** 

- **4.** (1) Subject to subsection (2), a pest control product is exempt from the application of subsection 6(1) of the Act if it is
- (a) an active ingredient that is used only in the manufacture of a registered pest control product that was registered on January 1, 1984, or was registered after January 1, 1984 and the application for its registration was received by the Minister on or before that date, and the active ingredient meets the relevant conditions of registration of the registered pest control product;
- (b) a pest control product
  - (i) that is of a type described in Schedule 2 and that meets the applicable conditions set out in that Schedule, and
  - (ii) the active ingredient of which is registered under the Act;
- (c) a pest control product that is manufactured only for export from Canada and that contains an active ingredient that is registered in Canada;
- (d) a pest control product that is imported under an own-use import certificate; or
- (e) a pest control product that is imported for the purpose of conducting research in accordance with sections 46 to 72.
- (2) A pest control product is not exempt from the application of subsection 6(1) of the Act if it is an active ingredient that is used in a pest control product of a type described in Schedule 2.

Exemption for named uses only

Exemption — unregistered pest control products

No exemption

Use in manufacture only

Designation

Contents

(3) A pest control product that is exempt from registration under paragraph (1)(a) may not be used for any purpose other than the manufacture of a registered pest control product.

## PRODUCT CLASSES

- **5.** The following are the classes of pest control products:
- (a) "DOMESTIC", if the pest control product is to be distributed primarily to the general public for personal use in or around their homes;
- (b) "COMMERCIAL", if the pest control product is to be distributed for use in commercial activities that are specified on the label;
- (c) "RESTRICTED", if the pest control product is one for which the Minister, out of concern for its health or environmental risks, has set out additional information to be shown on the label concerning essential conditions respecting the display, distribution or limitations on use of, or qualifications of persons who may use, the product; and (d) "MANUFACTURING", if the pest control product is to be used only in the manufacture of a pest control product or a product regulated under the

# APPLICATION FOR REGISTRATION

**6.** (1) An application to register or amend the registration of a pest control product must include all of the following information:

Feeds Act or the Fertilizers Act.

- (a) the applicant's name, address and signature or, if the application is made by a representative of the applicant, both the representative's and applicant's name and address and the representative's signature;
- (b) the name and address of the place of manufacture of the pest control product;
- (c) the product name referred to in paragraph 26(1)(a);
- (*d*) the product type referred to in paragraph 26(1)(*b*);
- (e) in the case of
  - (i) a chemical pest control product that is an active ingredient, its chemical name, common chemical name and CAS registry number, its percentage of the total weight of the product in which it is contained, the name of each contaminant that it contains, and each contaminant's percentage of its total weight, (ii) a chemical pest control product other than an active ingredient, the chemical name, common chemical name and CAS registry number of each active ingredient in the product, each active ingredient's percentage of the total weight of the product, and the

registration number of each active ingredient or other pest control product used to manufacture the product, and (iii) any other pest control product, any specifications that are relevant to its health or environmental risks or value;

- (f) in the case of a pest control product that contains one or more formulants, the name and CAS registry number of each formulant, the name and address of the supplier of each formulant, each formulant's percentage of the total weight of the product, and the purpose of each formulant in the product;
- (g) the size, type and specifications of the package in which the pest control product is to be distributed: and
- (h) the guarantee statement described in paragraph 26(1)(h).
- (2) The applicant must include an electronic copy of the proposed label with every application to register a pest control product and with any application to amend the registration of a pest control product that would result in a change to the label.
- (3) The applicant must include with every application to register or amend the registration of a pest control product a statement signed by the applicant certifying that the information in the application is accurate and complete.
- 7. If the Minister requests a registrant to amend the registration of a pest control product, the registrant must make an application to amend the registration.
- **8.** In addition to the information required by section 6, the applicant must provide the Minister with any other information that the Minister may require to evaluate the health and environmental risks and the value of the pest control product, including, if relevant to the product and its conditions or proposed conditions of registration, the results of scientific investigations respecting any of the following:
- (a) the efficacy of the pest control product for its intended purpose;
- (b) the risks posed by the pest control product and its derivatives to humans or animals that may be exposed to it, including when it is manufactured, handled, stored, transported or distributed or during or after its use or disposal in accordance with its conditions or proposed conditions of registration; (c) the effect of the pest control product and its derivatives on host organisms in connection with which it is intended to be used;
- (d) the effect of the pest control product and its

Electronic copy of label

Certification

When Minister requests amendment

Additional information required

- derivatives on representative species of organisms not targeted by its intended use;
- (e) the degree of persistence, retention and movement of the pest control product and its derivatives in the environment, including the degree to which the pest control product and its derivatives may leach or dislodge from things treated with the product;
- (f) acceptable methods of analysis for detecting the components and measuring the specifications of the pest control product;
- (g) acceptable methods of analysis for detecting and determining the amount of the pest control product and its derivatives in human food, animal feed and the environment when the product is used in accordance with its conditions or proposed conditions of registration;
- (h) appropriate methods for detoxifying or neutralizing the pest control product in water, air or soil, or on any surface;
- (i) appropriate methods for disposing of the pest control product and its empty packages;
- (j) the stability of the pest control product under normal conditions of storage and display;
- (*k*) the compatibility of the pest control product with other pest control products with which it is recommended to be, or is likely to be, mixed;
- (I) the effect of mixing the pest control product or using it simultaneously with other pest control products on its value and the health and environmental risks associated with its use;
- (*m*) the chemical and physical properties, or the species or strain and biological properties, of the pest control product, its composition, and specifications and processes for its manufacture, including quality control processes;
- (n) the fate of the pest control product in humans or animals exposed to it, including the identity and quantity of all the major metabolites and other derivatives that result from its use;
- (o) the residues of the pest control product and its derivatives that may remain in or on human food or animal feed after its use in accordance with its conditions or proposed conditions of registration;
- (p) the risks posed to humans or animals exposed to the pest control product or its derivatives through their diet or drinking water when the product is used in accordance with its conditions or proposed conditions of registration;
- (q) the effect of storing and processing, including post-market processing, human food or animal feed in relation to which the pest control product was used on the dissipation or degradation of the pest control product and any of its derivatives;

Additional information — affidavit and contents

- (r) the proposed maximum residue limits for the pest control product and its derivatives in or on human food or animal feed; and
- (s) the fate of the pest control product and its derivatives in subsequent crops of human food or animal feed.
- **9.** (1) When, in the context of an application for registration or to amend a registration, the Minister considers confidential information under paragraph 7(6)(b) of the Act, the applicant must be given access to that information by the Minister for the purpose of making representations under that paragraph with respect to the information, if the applicant submits to the Minister an affidavit made under oath or a statutory declaration under the Canada Evidence Act made before a commissioner for oaths or for taking affidavits that
- (a) identifies the information to which access is given;
- (b) acknowledges that the access is given only for the purpose of enabling the applicant to make representations to the Minister with respect to the information:
- (c) states that the applicant will not copy the information, make it available to any other person or use it for any other purpose; and
- (d) states that the information will be returned to the Minister when the stated purpose has been met.
- (2) The applicant to whom access is given to confidential information under subsection (1) may not use the information for any purpose other than to make representations under paragraph 7(6)(b) of the Act with respect to the information, and may not make the information available to any other person or use it for any other purpose.

Return of confidential information

(3) Confidential information to which access is given under subsection (1) must be returned to the Minister by the applicant as soon as they have made their representations with respect to the information.

Reference in Register

No copying or other use

**10.** For the purpose of subsection 42(4) of the Act, evaluation reports that are placed in the Register under paragraph 42(2)(f) of the Act must include a reference to information placed in the Register under paragraph 42(2)(e) of the Act.

Samples on request

- 11. On application to register or amend the registration of a pest control product, the applicant must, if requested by the Minister, provide the Minister with a sample of
- (a) the pest control product;
- (b) the technical grade of its active ingredient; and
- (c) the laboratory standard of its active ingredient.

Registration certificate

**12.** When a pest control product is registered or a registration is amended under section 8 of the Act, the Minister must issue a registration certificate that bears the registration number of the pest control product and sets out any conditions of registration specified by the Minister.

# VALIDITY PERIOD

Maximum validity period

13. Subject to subsection 14(6), the validity period with respect to a pest control product must end no later than December 31 in the fifth year after the year in which the product is registered.

## CONDITIONAL REGISTRATION

Valid up to three years

14. (1) Despite section 13 and subject to subsection (2), if a notice is delivered to the registrant under section 12 of the Act when a pest control product is registered or the registration of a pest control product is amended under subsection 8(1) of the Act, the registration becomes a

conditional registration and

(a) the validity period must end no later than December 31 in the third year after the year in which the product is registered or the registration is

amended: and

(b) subsections 28(1) and 35(1) and paragraphs

42(2)(c) to (e) of the Act do not apply.

Further notices under section 12 of the Act

(2) When a notice is delivered to the registrant under section 12 of the Act in relation to the reinstatement of an expired conditional registration or the continuation of a conditional registration after the evaluation of data, paragraph (1)(a) applies.

Amendment

(3) Paragraphs (1)(a) and (b) apply to an amendment of a conditional registration.

Exemption

(4) Despite subsection 81(2) of the Act, paragraph 42(2)(f) of the Act applies to all registrations referred to in that paragraph if a registration decision of a type described in paragraph 28(1)(a) of the Act has been made and the validity period

has been fixed.

No extension

(5) Subject to subsections (6) and (7), the validity period of a conditional registration may not be

extended.

Automatic extension

(6) The validity period of a conditional registration is extended for a period of two years when the registrant complies with the requirements of the notice delivered under section 12 of the Act.

Extension for consultation

(7) The Minister may extend the validity period for a period of sufficient duration to allow the Minister to carry out the consultation required by section 28 of the Act, if the application to amend or renew is made before the end of the validity period.

Expanded scope of section 14 associated products

**15.** (1) Paragraphs 14(1)(*a*) and (*b*) apply to the registration of any pest control product that contains an active ingredient in respect of whose registration a notice has been delivered under section 12 of the Act.

Extended scope of section 14 associated active ingredients

(2) Paragraphs 14(1)(a) and (b) apply to the registration of an active ingredient that is contained only in a registered pest control product in respect of which a notice has been delivered under section 12 of the Act.

# RENEWAL OF REGISTRATION

Five-year periods

16. (1) Subject to subsections (2) and (3), the registration of a pest control product may be renewed, on application by the registrant to the Minister, for additional periods of not more than five years each.

conditional registrations

Renewal and delivery of new notice (2) A conditional registration may be renewed on application by the registrant to the Minister, and on the renewal a new notice is delivered to the registrant under section 12 of the Act and paragraph 14(1)(a) of these Regulations applies.

Exception

(3) Despite subsection (2), in the case of a conditional registration to which subsection 15(1) or (2) applies, no notice need be delivered.

Copies of labels

(4) An application to renew the registration of a pest control product must be accompanied by an electronic copy of the approved label and two hard copies of the marketplace label.

# **RE-EVALUATIONS AND SPECIAL REVIEWS**

Additional information — affidavit and contents

**17.** (1) When, in the context of a re-evaluation or special review, the Minister considers confidential information under paragraph 19(1)(c) of the Act, the registrant must be given access to that information by the Minister for the purpose of making representations under that paragraph with respect to the information, if the registrant submits to the Minister an affidavit made under oath or a statutory declaration under the Canada Evidence Act made before a commissioner for oaths or for taking affidavits that

- (a) identifies the information to which access is given;
- (b) acknowledges that the access is given only for the purpose of enabling the registrant to make representations to the Minister with respect to the information;
- (c) states that the registrant will not copy the information, make it available to any other person or use it for any other purpose; and
- (d) states that the information will be returned to the Minister when the stated purpose has been met.

No copying or other use

(2) The registrant to whom access is given to confidential information under subsection (1) may not use the information for any purpose other than to make representations under paragraph 19(1)(c) of the Act with respect to the information, and may not make the information available to any other person or use it for any other purpose.

Return of confidential information

(3) Confidential information to which access is given under subsection (1) must be returned to the Minister by the registrant as soon as they have made their representations with respect to the information.

## **EMERGENCY REGISTRATION**

Validity period and exemption

- **18.** Despite section 13, if a pest control product is registered for, or the registration of a pest control product is amended to permit its use in, the emergency control of a seriously detrimental infestation,
- (a) the validity period must not be longer than one year and may not be extended;
- (b) subsections 28(1) and 35(1) and paragraphs 42(2)(c) to (f) of the Act do not apply; and (c) the registration may not be renewed.

#### **STANDARDS**

Trifluralin

**19.** A pest control product that contains trifluralin (2,6-dinitro-*N*,*N*-dipropyl-4-(trifluoromethyl) benzenamine) as its active ingredient or that contains an active ingredient that is based on or derived from trifluralin must not contain N-nitrosodin-propylamine (NDPA) in excess of one part per million parts of trifluralin.

# **DENATURATION**

When required

**20.** If the physical properties of a pest control product are such that its presence may not be detected when it is used and it is likely to expose a person or domestic animal to a severe health risk, the pest control product must be denatured by means of colour, odour or any other means specified as a condition of registration by the Minister under paragraph 8(1)(a) of the Act to provide a signal or warning as to its presence.

# **ADVERTISING**

**Prohibition** 

21. A word or an expression that states or implies that the Government of Canada or any of its departments or agencies promotes, endorses or recommends the use of a pest control product must not appear on the package of, or in any advertisement for, a pest control product.

**LABELS** 

General

Official languages

(a) the day after December 31, 2002 on which the registration of the pest control product is granted, amended or renewed, and (b) January 1, 2008. (2) Until January 1, 2008, if the entirety of the Exception — emergency information on the label is not already in both English and French, the amended label, following the amendment of a registration under section 18, is exempt from the requirement of subsection (1). Exception — products destined (3) The information on the label of a registered pest abroad control product that is not authorized to be manufactured, imported, sold or used in Canada may be in either English or French, or in both. Label — presentation **23.** (1) All information that is required to be shown on a label must appear in a manner that is clearly legible and indelible. Marketplace label — batch number (2) The marketplace label must show the batch number of the pest control product's manufacture. Marketplace label — additional (3) Any graphic design or symbol that relates to the pest control product may be shown on the information marketplace label if it does not detract from or obscure the required information. Diseases of humans 24. (1) A label must not represent a pest control product as a treatment, preventive or cure for any disease, disorder or abnormal physical state listed in Schedule A to the Food and Drugs Act. Diseases of domestic animals (2) A label must not represent a pest control product as a treatment, preventive or cure for any disease, as defined in subsection 2(1) of the Health of Animals Act, that is required to be reported under that Act. Display Panel Principal and secondary display **25.** The display panel of a registered pest control panels product must consist of one principal display panel and one secondary display panel.

**22.** (1) Subject to subsections (2) and (3), all information on a label must be in both English and

French as of the earlier of

Principal display panel

- **26.** (1) Subject to subsection 8(2) of the Act, the principal display panel of a registered pest control product must show all of the following information:
- (a) the product name of the pest control product, which may include the common chemical name of its active ingredient, if established, and a distinctive brand or trade-mark;
- (b) the product type of the pest control product, which must be descriptive of its purpose;
- (c) the physical form of the pest control product;
- (d) the product class designation of the pest control product as set out in section 5:
- (e) information concerning the nature and degree of hazard inherent in the pest control product, which must identify the nature and degree of hazard by appropriate precautionary symbols and signal words selected from Schedule 3, together with a statement that indicates the nature of the primary hazard to which the symbol relates;
- (f) the statement "READ THE LABEL BEFORE USING.";
- (g) if the pest control product has the product class designation "DOMESTIC", the statement "KEEP OUT OF THE REACH OF CHILDREN.";
- (h) a guarantee statement, as follows:
  - (i) the word "GUARANTEE", followed by a colon,
  - (ii) the common chemical name of the active ingredient of the pest control product or, if it has no common chemical name, its chemical or other name,
  - (iii) the concentration of the active ingredient, expressed, if the pest control product is
    - (A) a liquid, as a percentage by mass, or as mass per unit volume, or both, as specified by the Minister in the conditions of registration under paragraph 8(1)(a) of the Act,
    - (B) a dust, wettable powder or other dry formulation, as a percentage by mass,
    - (C) neither a liquid nor a dry formulation, in terms specified by the Minister in the conditions of registration under paragraph 8(1)(a) of the Act, and
  - (iv) the viscosity, specific gravity, particle size or any other property or specification that the Minister may specify in the conditions of registration under paragraph 8(1)(a) of the Act;
- (i) the registration number of the pest control product, as follows: "REGISTRATION NO. (assigned registration number) PEST CONTROL PRODUCTS ACT" or, if space is limited on the

Secondary display panel

- label, as follows: "REG. NO. (assigned registration number) P.C.P. Act";
- (j) a declaration of net quantity of the product in the package, expressed
  - (i) by volume, if the product is a liquid or gas or is viscous,
  - (ii) by mass, if the product is a solid or pressure-packed, and
  - (iii) in terms specified by the Minister in the conditions of registration under paragraph 8(1)(a) of the Act, in any other case;
- (k) the registrant's name; and
- (*I*) the name, postal address and telephone number of a contact person in Canada to which public inquiries may be directed.
- (2) Subject to subsection 8(2) of the Act, the secondary display panel of a registered pest control product must show all of the following information:
- (a) under the heading "DIRECTIONS FOR USE", the directions for the use of the pest control product, including application rates, timing and frequency of application, and any limitations on its use:
- (b) information that identifies any significant risk associated with the handling, storage, display, distribution and disposal of the pest control product, and instructions on procedures to reduce those risks and, if specified by the Minister in the conditions of registration under paragraph 8(1)(a) of the Act, instructions on decontamination procedures and disposal of the pest control product and its empty packages;
- (c) under the heading "PRECAUTIONS", information that identifies any significant risk to health, the environment or anything in connection with which the pest control product is to be used, and instructions on procedures to reduce that risk; (d) under the heading "PRECAUTIONS", the following warning:
  - (i) if the pest control product does not have the product class designation "DOMESTIC": "KEEP OUT OF THE REACH OF CHILDREN.", or
  - (ii) if the pest control product is to be used only in the manufacture of another pest control product: "PREVENT ACCESS BY UNAUTHORIZED PERSONNEL.";
- (e) under the heading "FIRST AID", instructions that
  - (i) set out the practical measures to be taken in the event of poisoning, intoxication or injury caused by the pest control product, and (ii) include the statement "Take the container label or product name and Pest Control

Product Registration Number with you when seeking medical attention.";

(f) under the heading "TOXICOLOGICAL INFORMATION", information that is essential to the treatment of persons who are poisoned, intoxicated or injured by the pest control product that includes all of the following:

- (i) antidotes and remedial measures or, if no specific antidote or remedial measure exists, the statement "Treat symptomatically.",
- (ii) a description of the symptoms of poisoning or intoxication, and
- (iii) a list of the components of the product, not including the active ingredient, that may affect the treatment; and
- (g) the following notice to users: "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."
- **27.** (1) The principal display panel of a registered pest control product may also show the registrant's Internet address or the e-mail address to which public inquiries may be directed.
- (2) The secondary display panel of a registered pest control product may also show the name and address or telephone number of persons other than the registrant, if the function of each other person with respect to the product is identified.
- **28.** (1) Despite section 26, any of the information that is required to be shown on the principal and secondary display panels may, if specified by the Minister in the conditions of registration relating to the label under subsection 8(2) of the Act, be shown instead in a brochure or leaflet that accompanies the pest control product.
- (2) If the information referred to in subsection (1) is shown elsewhere than on the display panel, (a) the principal display panel must have prominently shown on it the statement "READ ATTACHED BROCHURE (or LEAFLET) BEFORE USING."; and
- (b) the brochure or leaflet must contain all of the information that is to be shown on the principal and secondary display panels in addition to the information described in subsection (1).

Optional contact information

Optional contact information

Brochures or leaflets

When subsection (1) applies

Product class designation
"RESTRICTED"

**29.** (1) If the principal display panel shows the product class designation "RESTRICTED", the notice that is required by paragraph 26(2)(*g*) must appear prominently at the top of the secondary display panel, followed by the heading "RESTRICTED USES", followed by the directions for use, the application rates, the timing and frequency of application and the limitations on the use of the pest control product to which the restriction relates. All of the foregoing must be circumscribed by a line to set the information apart from all other information that is required to be shown on the secondary display panel.

## Brochure or leaflet alternative

(2) Despite subsection (1), if the principal display panel shows the product class designation "RESTRICTED", the directions for use, the application rates, the timing and frequency of application and the limitations on the use of the pest control product to which the restriction relates, together with the information required by paragraphs 26(1)(a) to (I) and (2)(a) and (c) may, if specified by the Minister in the conditions of registration relating to the label under subsection 8(2) of the Act, be shown instead in a brochure or leaflet that accompanies the pest control product.

## Prescribed Devices

## Requirements

**30.** The label for a pest control product that is a device of a type described in Schedule 1 must contain the information set out in paragraphs 26(1)(i), (k) and (l) and (2)(a) to (c).

## **Bulk Containers**

# Required information

- **31.** (1) If a pest control product is distributed in a bulk container, the information required by paragraphs 26(1)(a) to (d) and (h) to (l) and (2)(e) and (f) must be shown
- (a) on the bulk container; and
- (b) on the documents that accompany the shipment.

#### Additional information

(2) If a pest control product is distributed in a bulk container directly to a user of the product, the information required by paragraph 26(1)(e) must also be shown in accordance with paragraphs (1)(a) and (b).

#### Units of Measurement

Metric units

**32.** (1) Quantities shown on a label must be expressed in metric units.

Decimal system

100 mL, 100 cm<sup>3</sup>, 100 cm<sup>2</sup> or 100 cm, it may be shown truncated to two decimal figures, and, in either case, any final zero that appears to the right of the decimal point need not be shown. Net quantity less than one (3) A net quantity that is less than one must be shown in the decimal system, with a zero before the decimal point, or in words. Metric units (4) The metric units in the declaration of net quantity must be shown (a) in millilitres, if the net volume of the pest control product is less than 1 000 mL, except that 500 mL may be shown as 0.5 L; (b) in litres, if the net volume is 1 000 mL or more; (c) in grams, if the net mass is less than 1 000 g, except that 500 g may be shown as 0.5 kg; and (d) in kilograms, if the net mass is 1 000 g or more. **Optional Canadian** (5) In addition to being expressed in accordance with subsection (1), quantities shown on a label units of measurement may also be expressed in the Canadian units of measurement set out in Schedule II to the Weights and Measures Act. **PACKAGING Packages** 33. (1) The package of a pest control product must be constructed to contain the product safely under normal conditions of storage, display and distribution. Safe access to contents (2) Every package must be constructed to permit (a) the withdrawal of any or all of the contents in a manner that is safe to the user; and (b) the closing of the package in a manner that will contain the pest control product safely under normal storage conditions. (3) Every package must be constructed to minimize Minimize degradation the degradation or change of its contents. When package essential to safety (4) If the package is essential to the safe and effective use of the pest control product, it must be constructed to meet any specifications that the Minister may specify in the conditions of registration under paragraph 8(1)(a) of the Act. STORAGE AND DISPLAY Conditions 34. (1) Pest control products must be stored and displayed in accordance with any conditions set out on the label.

(2) The declaration of net quantity must be shown

except that, if the net quantity is less than 100 g,

in the decimal system to three figures,

Procedure to avoid contamination

(2) Pest control products that bear the signal word POISON superimposed on the precautionary symbol for danger set out in item 2 of Schedule 3 must not be stored or displayed with human food or animal feed, but must be stored or displayed in a separate room or be separated in such a way as to avoid any possible contamination of the food or feed.

## **DISTRIBUTION**

Conditions on documents

**35.** When conditions of registration that relate to the distribution of a pest control product are specified by the Minister under paragraph 8(1)(*a*) of the Act, those conditions must be shown on the documents that accompany the shipment.

## **IMPORT**

## General

Declaration and contents

- **36.** A pest control product may be imported into Canada if it is accompanied by a declaration, in English or in French, signed by the importer, that sets out all of the following information:
- (a) the name and postal address of the shipper;
- (b) the product name of the pest control product;
- (c) the chemical, common chemical or other name of the active ingredient of the pest control product and the amount of it contained in the product;
- (*d*) the total amount of the pest control product being imported;
- (e) the name and address of the importer; and (f) the purpose of the importation, as follows:
  - (i) "For Resale", together with the registration number of the pest control product, if it is registered and is being imported for resale,
  - (ii) "For Manufacturing Purposes", if the pest control product is being imported for use in the manufacture of a registered pest control product,
  - (iii) "For Research Purposes", if the pest control product is being imported for research purposes, or
  - (iv) "For Own Use", if the pest control product is being imported under an own-use import certificate.

# Own-use Import

Specified purposes

**37.** For the purpose of subsection 41(1) of the Act, the use of an imported foreign product for a person's own use and the importation of that product are specified purposes.

Conditions of import

- **38.** A pest control product may be imported by or on behalf of a person for that person's own use if the following conditions are met:
- (a) it is a foreign product for which an equivalency certificate is in effect; and
- (b) it is imported under an own-use import certificate.

# Equivalence

- **39.** (1) A person or an organization may apply to the Minister to determine whether a foreign product that meets the requirements of paragraphs 43(*a*) to (*d*) is equivalent to a registered pest control product that does not have the product class designation "RESTRICTED".
- (2) The application must include information that indicates that the requirements of paragraphs 43(a) to (d) are met, a copy of the proposed own-use import label that shows the information referred to in section 40, and all of the following information:
  (a) in respect of both the foreign product and the registered pest control product,
  - (i) all of the following information:
    - (A) the composition of the product and of the active ingredient that is used to manufacture it which, in the case of the registered pest control product and its active ingredient, must be the composition specified by the Minister in the conditions of registration under paragraph 8(1)(a) of the Act, (B) the name, manufacturer and manufacturing process of the active ingredient that is used to manufacture each of the products, and (C) the guarantee statement described
  - (ii) a detailed and comprehensive analysis, with an accompanying explanation of methodology that, on its own merits, permits validation of procedures, results and conclusions, to determine the composition of the foreign product and of the registered pest control product, including the identity and concentration of the active ingredient, formulants and contaminants of the two products; and

in paragraph 26(1)(h), or

(b) the comparable retail price in Canadian dollars of the same quantity of both the registered pest control product and the foreign product.

Application

Contents

Written consent equivalent

(3) Instead of providing the information required by subsection (2) with respect to the registered pest control product, the applicant may provide the written consent of the registrant of that product for the Minister to use or rely on any information that the registrant had previously provided to the Minister.

When processing of application will be refused

(4) The Minister must refuse to process an application to determine equivalence if the information provided under paragraph (2)(b) fails to establish that the price of the registered pest control product is at least 10% higher than the comparable price of the foreign product.

When processing of application will be suspended

(5) If subsection (4) does not apply, the Minister must suspend, for the duration of the relevant growing season, the processing of an application to determine equivalence if he or she is advised that the price difference between the two products has been less than 10% for the last two months.

Information in Register

- (6) The Minister must place all of the following information in the Register with respect to an application to determine equivalence made under subsection (1):
- (a) the name of the applicant;
- (b) the date of the application;
- (c) the identity of the registered pest control product and of the foreign product;
- (*d*) the identity of the registrant of the foreign product;
- (e) the country of registration of the foreign product; and
- (f) the comparable retail price in Canadian dollars of the same quantity of both the registered pest control product and the foreign product.

Issuance of equivalency certificate

(7) If the Minister determines that a foreign product is equivalent to a registered pest control product, the Minister must issue an equivalency certificate.

Equivalency certificate

- (8) An equivalency certificate
- (a) applies only to the foreign products for which the Minister has determined equivalency under subsection (7);
- (b) expires on the date specified in the certificate, which must be no later than one year after it is issued;
- (c) is no longer valid if the composition of either the foreign product or the registered pest control product changes; and
- (d) is no longer valid if any of the circumstances described in paragraphs 43(b) to (d) occurs.

Renewal

(9) On the expiry of an equivalency certificate in accordance with paragraph (8)(b), the Minister may renew it, on application, if he or she is satisfied of all of the following:

(a) that the circumstances described in paragraphs 43(b) to (d) continue to be true;

- (b) that the composition of neither the registered pest control product nor the foreign product has changed; and
- (c) that the retail price in Canadian dollars of the registered pest control product has been at least 10% higher than the comparable price of the foreign product for the same quantity of product for the last two months.
- **40.** When the Minister issues an equivalency certificate, the Minister must also approve the proposed own-use import label if it shows the information that is relevant to the intended use and disposal of the foreign product in Canada that is shown on the approved label of the equivalent registered pest control product.

# Authorization and Certificate

- **41.** (1) A person who wishes to import for their own use and use a foreign product for which an equivalency certificate is in effect must apply to the Minister for authorization to do so.
- (2) The application must include all of the following information:
- (a) the applicant's name, address and signature;
- (b) a copy of the applicable equivalency certificate;
- (c) a copy of the approved own-use import label;
- (d) a description of the intended use of the foreign product, including the location where it will be used; and
- (e) the quantity of the foreign product required for that intended use for one growing season.
- (3) If the proposed use meets the conditions described in section 43, the Minister must authorize the use by issuing an own-use import certificate that sets out the conditions specified under subsection 41(1) of the Act and that includes all of the following:
- (a) the identity of the certificate holder;
- (b) the amount of the foreign product that may be imported under the certificate; and
- (c) the location where the foreign product is to be used by the certificate holder.

Own-use import label

Authorization required

Application and contents

Issuance of own-use import certificate

Own-use import certificate

Not transferable

No

distribution

Disposal of unused

product

Conditions of authorization

No inconsistent use

Notice

- (4) An own-use import certificate
- (a) is valid for one growing season only;
- (b) expires on the date specified in it, which must be no later than one year after it is issued; and (c) is no longer valid if the relevant equivalency

certificate is no longer valid.

- (5) An own-use import certificate is not transferable.
- (6) The holder of an own-use import certificate may not distribute any of the foreign product that was imported under the certificate.
- **42.** The holder of an own-use import certificate must dispose of any unused foreign product in accordance with the disposal information set out on the approved own-use import label.
- **43.** The Minister must authorize a person to use an unregistered pest control product that is imported under an own-use import certificate if the product
- (a) is a foreign product that is not an organism;
- (b) is not under official re-evaluation or special review in the foreign country where it is registered;
- (c) does not contain an active ingredient that is under re-evaluation or special review in Canada;
- (d) does not contain a formulant that is on the List of Pest Control Product Formulants and

Contaminants of Health or Environmental Concern and that has not been accepted for use in Canada; (e) is the subject of a valid equivalency certificate;

- (f) is intended for a use that is specified in the conditions of registration of the equivalent registered pest control product and will be imported in a quantity of not more than the amount that is required for that use for one growing season; and
- (g) bears, in addition to any other label, an approved own-use import label.
- **44.** A foreign product that is exempt from the application of subsection 6(1) of the Act under paragraph 4(1)(d) must not be used in a manner

that is inconsistent with the conditions set out on the own-use import certificate.

Notice of Import

**45.** A person or an organization that imports a pest control product under an own-use import certificate must notify the Minister of the importation without delay in accordance with the conditions set out on the certificate.

RESEARCH

Manufacture for Research

Non-application of subsection 6(1) of the Act

**46.** Subsection 6(1) of the Act does not apply to the manufacture of a pest control product that is for use only in conducting research under these Regulations.

## Research Authorization

Specified purpose

**47.** For the purpose of subsection 41(1) of the Act,

research is a specified purpose.

Application

**48.** A person who seeks permission for a research establishment to conduct research must apply to the Minister to obtain a research authorization.

Contents

49. An application for a research authorization must include the information specified in subsections 6(1) and (3) in addition to all of the following:

(a) an electronic copy of the proposed experimental

label:

(b) a copy of the research plan; and

(c) any other information described in section 8 that the Minister may require to evaluate the health and environmental risks posed by the proposed

research.

Authorization

50. (1) If the Minister considers that the health and environmental risks are acceptable and that the proposed experimental label meets the requirements of section 60, the Minister must authorize the use of the pest control product to

conduct the research.

Issuance of research authorization certificate

(2) When the Minister authorizes the use of a pest control product to conduct research, the Minister must issue a research authorization certificate to the research establishment that sets out the conditions specified under subsection 41(1) of the Act, including those that relate to the experimental label.

#### Research Notification

Exemption

**51.** A research establishment is exempt from the application of subsection 6(1) of the Act and section 48 if the Minister confirms under section 54 that the proposed research meets all of the criteria set out in section 53.

Notice and contents

**52.** A research establishment that wishes to obtain confirmation under section 54 must notify the Minister by providing the information specified in subsections 6(1) and (3) in addition to both of the following:

(a) an electronic copy of the proposed experimental

label; and

(b) a copy of the research plan.

Criteria

- **53.** The following are the criteria referred to in section 51:
- (a) the research does not involve the use of a semiochemical:
- (b) in the case of research that involves the use of a chemical pest control product,
  - (i) it does not involve the use of an antimicrobial agent,
  - (ii) it does not involve aerial application,
  - (iii) it does not involve the application of a pest control product to water or to a place where runoff water may remove residues from the research site,
  - (iv) it does not involve the use of a pest control product in any of the following areas:
    - (A) greenhouses,
    - (B) residential areas, including lawns, gardens and parks,
    - (C) industrial premises, and
    - (D) food-handling areas,
  - (v) it does not involve the use of a pest control product for either
    - (A) structural pest control, or
    - (B) fumigation,
  - (vi) it does not involve the use of a pest control product that contains a formulant that is on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern or that contains a formulant that is not a component of any registered pest control product,
  - (vii) in the case of a pest control product that contains an unregistered active ingredient, the application of the pest control product is carried out by the researcher alone
    - (A) on 5 to 50 ha of land owned or operated by a research establishment, or
    - (B) on 1 to 5 ha of land owned or operated by a cooperator, and

(viii) in the case of a pest control product that contains a registered active ingredient,

(A) the application of the pest control product is carried out by a researcher or cooperator on 10 to 50 ha of land owned or operated by a research establishment or a cooperator, and (B) there is a reasonable expectation that the research will not increase occupational exposure above the level that is expected when the pest control product is used in accordance with its conditions of registration; and

(c) in the case of research that involves the use of a microbial agent,

- (i) it does not involve aerial application,
- (ii) it does not involve the use of a pest control product that contains a formulant that is on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern or that contains a formulant that is not a component of any registered pest control product,
- (iii) the micro-organism is indigenous to the area where it is intended to be used, and (iv) the application of the pest control product is carried out on a maximum of 10 ha of land owned or operated by a research establishment or, in the case of an aquatic application, on a body of water that has a maximum of 1 ha of surface area and that is wholly contained on land owned or operated by a research establishment.

Issuance of research notification certificate

**54.** If the Minister confirms that the proposed research meets the criteria set out in section 53 and the proposed experimental label meets the requirements of sections 60 and 61, the Minister must issue a research notification certificate to the research establishment.

# **Exemptions and Conditions**

Exemption — research solely in laboratory

**55.** (1) A research establishment is exempt from the application of subsection 6(1) of the Act and sections 48, 52 and 59 to 65 if the research is conducted solely in a laboratory.

Exemption and criteria — research not solely in laboratory

- (2) A research establishment is exempt from the application of subsection 6(1) of the Act and sections 48 and 52 if all or part of the research is conducted outside a laboratory and meets all of the following criteria:
- (a) it does not involve the use of a microbial agent;(b) in the case of research that involves the use of a chemical pest control product,
  - (i) it does not involve the use of an antimicrobial agent,
  - (ii) it does not involve aerial application,
  - (iii) it does not involve the application of a pest control product to water or to a place where runoff water may remove residues from the research site.
  - (iv) it does not involve the use of a pest control product in any of the following areas:
    - (A) greenhouses,
    - (B) residential areas, including lawns, gardens and parks,
    - (C) industrial premises, and
    - (D) food-handling areas,
  - (v) it does not involve the use of a pest control product for either
    - (A) structural pest control, or
    - (B) fumigation,
  - (vi) it does not involve the use of a pest control product that contains a formulant that is on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern or that contains a formulant that is not a component of any registered pest control product,
  - (vii) in the case of a pest control product that contains an unregistered active ingredient, the application of the product is carried out by the researcher alone
    - (A) on a maximum of 5 ha of land owned or operated by a research establishment, or
    - (B) in the case of land owned or operated by a cooperator, on a maximum of 1 ha or 5% of the total area of the crop under research, whichever is less, and
  - (viii) in the case of a pest control product that contains a registered active ingredient,
    - (A) the application of the product is carried out by a researcher or cooperator on a maximum of 10 ha of land owned or operated by a research establishment or a cooperator, or on a maximum of 20% of the total area of the crop under research, whichever is

less, and

- (B) there is a reasonable expectation that the research will not increase occupational exposure above the level that is expected when the pest control product is used in accordance with its conditions of registration; and
- (c) in the case of research that involves the use of a semiochemical.
  - (i) it does not involve aerial application,
  - (ii) it does not involve the application of a pest control product to water,
  - (iii) it does not involve the use of a pest control product in any of the following areas:
    - (A) greenhouses,
    - (B) residential areas, including lawns, gardens and parks,
    - (C) industrial premises, and
    - (D) food-handling areas,
  - (iv) it does not involve the use of a pest control product for either
    - (A) structural pest control, or
    - (B) fumigation,
  - (v) it does not involve the use of a pest control product that contains a formulant that is on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern or that contains a formulant that is not a component of any registered pest control product,
  - (vi) in the case of a pest control product that contains an unregistered active ingredient, other than an arthropod pheromone, the application of the product is carried out by the researcher alone on a maximum of 5 ha of land owned or operated by a research establishment.
  - (vii) in the case of a pest control product that contains a registered active ingredient, other than an arthropod pheromone, the application of the product is carried out by a researcher or cooperator on a maximum of 10 ha of land owned or operated by a research establishment or cooperator, and (viii) in the case of a pest control product that contains an active ingredient that is an arthropod pheromone,
    - (A) the application of the product is carried out on a maximum of 100 ha of land owned or operated by a research establishment or cooperator and the maximum use rate does not exceed 375 g of active ingredient per hectare per year, and

(B) if used in a food or feed crop, the pheromone is contained in an affixed solid matrix dispenser or in a retrievable-sized polymeric matrix dispenser, and the dispenser is not in direct contact with the crop.

# General Requirements for Certificates

- **56.** A research authorization certificate and a research notification certificate expire on December 31 of the year in which they are issued, unless another expiry date is specified in the certificate.
- **57.** Neither a research authorization certificate nor a research notification certificate is renewable.
- **58.** Neither a research authorization certificate nor a research notification certificate is transferable.

# Signage at Research Sites

- **59.** Unless otherwise specified as a condition by the Minister under subsection 41(1) of the Act, a research establishment must post signs at every research site that
- (a) show all of the following information:
  - (i) the following primary message, in both English and French:
    "PEST CONTROL EXPERIMENTAL SITE / SITE D'EXPÉRIMENTATION DE LUTTE ANTIPARASITAIRE
    DO NOT ENTER WITHOUT AUTHORIZATION. / ACCÈS INTERDIT SANS AUTORISATION
    CONTACT (contact name) AT (phone number). / S'ADRESSER À (nom du responsable) AU (no de téléphone)", and (ii) the research authorization certificate number, when there is one:
- (b) are visible, legible, indelible and posted at every entrance to the research site on each side of the entrance:
- (c) are posted before treatment begins and remain posted until any treated food or feed crop is harvested or as long as data are being collected; and
- (*d*) may include the name of the pest control product that is the subject of the research and the name and logo of its manufacturer, if they are printed smaller than the primary message.

# Experimental Labels

**60.** (1) A research establishment must ensure that every pest control product that is used in research is accompanied by an experimental label.

Expiry

Not renewable

Not transferable

Requirements

Requirement

Contents

(2) An experimental label must

(a) show all of the information specified in section 26:

(b) show

(i) the following information on the principal display panel:

(A) the statement "EXPERIMENTAL USE ONLY",

(B) the research authorization certificate number or the research notification certificate number, when there is one, and

(C) the statement "NOT FOR SALE. NOT FOR DISTRIBUTION TO ANY PERSON OTHER THAN A RESEARCHER OR COOPERATOR.", and

(ii) on the secondary display panel, when the research involves the use of an unregistered pest control product, in the instructions on decontamination procedures and disposal referred to in paragraph 26(2)(*b*), the statement "Any unused product must be returned to the manufacturer."; and

(c) represent the intended research as described in the research plan.

(3) Despite paragraph (2)(a),

paragraph 26(2)(g).

- (a) paragraphs 26(1)(d), (i), (k) and (l) apply only when the research involves the use of a registered pest control product; and
- (b) when the research involves the use of a registered pest control product, the following information need not be shown on the experimental label if that label is used in conjunction with the approved label:
  - (i) the net quantity referred to in paragraph 26(1)(j),
  - (ii) instructions on decontamination procedures and disposal referred to in paragraph 26(2)(*b*),
  - (iii) information that identifies any significant risk to the environment, and instructions on procedures to reduce those risks, referred to in paragraph 26(2)(c), and (iv) the notice to users referred to in

Exception

Additional requirements
—occupational safety

- **61.** In the case of research that meets the criteria set out in section 53 or subsection 55(2), the experimental label must also include
- (a) in the information required by paragraph 26(2)(b), a recommendation to wear the following personal protective equipment during mixing, loading, application, clean-up and repair:
  - (i) coveralls over a long-sleeved shirt and pants,
  - (ii) goggles,
  - (iii) a respirator,
  - (iv) chemical-resistant gloves, and
  - (v) socks and boots; and
- (b) the following requirements in the information required by paragraph 26(2)(c):
  - (i) that no person may enter a treated area within 4 hours after application of the pest control product, and
  - (ii) that no person may enter a treated area within 48 hours after application of the pest control product, unless they wear the personal protective equipment specified in paragraph (a).
- 62. A research establishment must
- (a) supply to every researcher and cooperator involved in the research a copy of the experimental label, which must be the approved experimental label if a research authorization certificate or research notification certificate has been issued; and
- (b) produce a copy of the experimental label to an inspector, on request.
- **63.** A researcher or cooperator must not handle, store, transport, use or dispose of a pest control product in a way that is inconsistent with
- (a) the research plan, if a research authorization certificate or research notification certificate has been issued; or
- (b) the directions on the experimental label.

Material Safety Data Sheets

**64.** (1) A research establishment must supply to every researcher and cooperator involved in the research a material safety data sheet for every pest control product that is used in the research in the format specified in the *Pest Control Products Safety Information Regulations*.

Copies

Inconsistent use

Requirement and format

Δ	Itarı	つつけいん	format

(2) Despite subsection (1), when the research involves the use of an unregistered pest control product or a class of pest control products to which the *Pest Control Products Safety Information Regulations* do not apply, the material safety data sheet may be in the format that is in accordance with Part I of the *Controlled Products Regulations*.

#### Records

#### Contents

- **65.** A research establishment must keep records that contain all of the following information for each research project:
- (a) the name and quantity of every pest control product used;
- (b) the names of the researchers and cooperators;
- (c) the locations of the research sites;
- (d) a description of the application methods; and
- (e) the test data generated.

# Import for Research Purposes

# Conditions for import

- **66.** A research establishment may import an unregistered pest control product for the purpose of conducting research if
- (a) the product is imported in accordance with section 36; and
- (b) the quantity being imported is not more than that specified in a research authorization certificate or research notification certificate, or, if the quantity is not so specified, the amount that is necessary to conduct the research.

#### **Unused Pest Control Products**

## Unregistered products

**67.** A research establishment must return to the manufacturer any unused unregistered pest control products.

# Registered products

**68.** A research establishment must return to the manufacturer any unused registered pest control product unless it is kept by the research establishment to be used by a researcher or cooperator involved in the research in a way that is consistent with the directions on the approved label.

#### Distribution

## Researchers and cooperators only

**69.** A research establishment may not distribute a pest control product that is used in the conduct of research to any person that is not a researcher or cooperator involved in the research, except in accordance with section 67 or 68.

Treated food and feed crops

- **70.** When a research authorization certificate is issued, treated food and feed crops from research sites and meat (including meat by-products and fat), milk and eggs that may contain residues as a result of the research must not be sold unless (a) written authorization to do so is set out on the certificate; and
- (b) in the case of research that involves the use of a chemical pest control product, residues do not exceed an amount that would result in the sale of the food being prohibited under section 4 of the Food and Drugs Act.

Research —section 53 criteria

- **71.** In the case of research that meets the criteria set out in section 53 and for which a research notification certificate is issued,
- (a) in the case of research that involves the use of a chemical pest control product, treated food and feed crops from research sites and meat (including meat by-products and fat), milk and eggs that may contain residues as a result of research must not be sold unless the residues do not exceed an amount that would result in the sale of the food being prohibited under section 4 of the *Food and Drugs Act*; and
- (b) in the case of research that involves the use of a microbial agent, other than one that contains Bacillus thuringiensis registered for use on agricultural crops, treated food and feed crops from research sites and meat (including meat byproducts and fat), milk and eggs that may contain residues as a result of research must not be sold.

Research — subsection 55(2) criteria

- **72.** In the case of research that meets the criteria set out in subsection 55(2), treated food and feed crops from research sites and meat (including meat by-products and fat), milk and eggs that contain residues as a result of research must not be sold unless
- (a) in the case of research that involves the use of a chemical pest control product, residues do not exceed an amount that would result in the sale of the food being prohibited under section 4 of the Food and Drugs Act, and
- (b) in the case of research that involves the use of a semiochemical, the research meets the criteria set out in subparagraph 55(2)(c)(viii).

SAMPLING

Representative samples

**73.** A sample of a pest control product that is taken by an inspector under paragraph 48(1)(b) of the Act must be representative of the lot from which it is

taken and may consist of

(a) the entire package, in the case of a liquid packaged in containers of less than 5 L;

(b) the entire package, in the case of a dry material packaged in containers of less than 5 kg; and (c) the entire device, in the case of a device.

#### **DETENTION**

Detention tag

**74.** If a pest control product is seized under subsection 52(1) of the Act, the inspector must attach a detention tag to at least one package of the pest control product in the lot that is seized.

#### **TRANSITIONAL**

Meaning

of "old Regulations"

75. (1) In subsections (2) and (3), "old Regulations" means the Pest Control Products

Regulations, C.R.C., c. 1253, as they read immediately before the coming into force of

these Regulations.

Completed applications

(2) When information that is required under section 17 of the old Regulations was provided

before the coming into force of these

Regulations but a final registration decision has not been made when these Regulations come into force, the information requirement is deemed to have been imposed for the purpose of these Regulations by delivery of a notice under section 12 of the Act, and section 14 of these Regulations applies to the registration.

Incomplete applications

(3) When the holder of a temporary registration has not provided the information required under section 17 of the old Regulations before these Regulations come into force, they may make a new application for registration in

accordance with the Act.

#### REPEAL

Pest Control Products Regulations

76. The Pest Control Products Regulations (see

footnote 1) are repealed.

## **COMING INTO FORCE**

Coming into force

77. These Regulations come into force on the day on which they are registered.

SCHEDULE 1 (Paragraph 3(1)(a) and section 30)

#### PRESCRIBED DEVICES

1. Garment bags, cabinets or chests that are manufactured, represented or sold as a

means to protect clothing or fabrics from pests.

- **2.** Devices that are manufactured, represented or sold as a means to attract or destroy flying insects, or to attract and destroy them.
- **3.** Devices that are manufactured, represented or sold as a means to repel pests by causing them physical discomfort by means of sound, touch or electromagnetic radiation.
- **4.** Devices for attachment to garden watering hoses that are manufactured, represented or sold as a means to dispense or apply a pest control product.
- **5.** Devices that are manufactured, represented or sold as a means to provide the automatic or unattended application of a pest control product.
- **6.** Devices that are sold for use with chemical products that contain cyanide as a means to control animal pests.

# SCHEDULE 2 (Subparagraph 4(1)(b)(i) and subsection 4(2))

#### PEST CONTROL PRODUCTS EXEMPT FROM REGISTRATION

- **1.** Feed for animals, if the pest control product contained in the feed is registered under the Act for the purpose of mixing with feed.
- **2.** A fertilizer that is subject to the *Fertilizers Act*, if the pest control product contained in it is registered under these Regulations.
- **3.** Seed that has been treated with a pest control product that is registered for the purpose of treating such seed, if
- (a) the seed is sold and shipped in bulk and the documents that accompany the shipment include the common chemical name of the active ingredient of the pest control product used to treat the seed or, if it has no common chemical name, its chemical or other name; or
- (b) in the case of seed that is packaged for distribution, the label shows the statement "This seed is treated with", followed by the name of the pest control product, including the chemical name or common chemical name of its active ingredient, together with the appropriate precautionary symbols and signal words set out in Schedule 3 and any other applicable statements that are required by these Regulations.
- 4. A water conditioner that
- (a) is represented to control algae and is for use in or around homes in humidifiers, aquariums, waterbeds or any appliance that has a water reservoir;
- (b) contains as its only active ingredient at most 60% copper sulphate registered under

the Act; and

- (c) is in a package whose label shows all of the following information:
  - (i) on the principal display panel,
    - (A) the identity of the water conditioner in terms of its function referred to in paragraph (a),
    - (B) the information set out in items 1 to 3 of the table to section 6 of this Schedule,
    - (C) in the case of a water conditioner whose concentration of copper sulphate is set out in column 1 of item 2 or 3 of the table to this section, the precautionary symbol set out in column 2 of item 7 of Schedule 3, and
    - (D) the appropriate signal words set out in column 2 of the table to this section, and
  - (ii) on the secondary display panel, the information set out in items 4 to 7 of the table to section 6 of this Schedule.

#### **TABLE TO SECTION 4**

	Column 1	Column 2
Item	Concentration of Copper Sulphate in Water Conditioner	Signal Words
1.	Less than 12 %	None
2.	12% or more but less than 30 %	"Caution — Poison"
3.	30% or more but not more than 60%	"Warning — Poison"

- **5.** A device that is manufactured, represented or sold as a means to attract and destroy flying insects indoors, by means other than the use of an active ingredient that is a chemical, if
- (a) the device is certified by the Canadian Standards Association as meeting the requirements of Standard CAN/CSA-C22.2 No. 189-M89, entitled *High-Voltage Insect Killers*, as amended from time to time; and
- (b) all of the following information appears on the label of the device:
  - (i) the logo of the Canadian Standards Association,
  - (ii) the identity of the device in terms of its function,

- (iii) the information set out in items 3 to 6 of the table to section 6 of this Schedule,
- (iv) the precaution statement "This device should not be installed directly on or over surfaces where food is exposed, processed or prepared.", and
- (v) the statement "To aid in the reduction of housefly population, use this device in conjunction with sanitary practices.".
- **6.** A device that is manufactured, represented or sold as a means to attract and destroy flying insects outdoors, by means other than the use of an active ingredient that is a chemical, if
- (a) the device is certified by the Canadian Standards Association as meeting the requirements of Standard CAN/CSA-C22.2 No. 189-M89, entitled *High-Voltage Insect Killers*, as amended from time to time; and
- (b) all of the following information appears on the label of the device:
  - (i) the logo of the Canadian Standards Association,
  - (ii) the identity of the device in terms of its function,
  - (iii) the information set out in items 3 to 6 of the table to this section,
  - (iv) the statement "For Outdoor Use Only.", and
  - (v) the statement "This device does not control blackflies, mosquitoes or other biting flies.".

# **TABLE TO SECTION 6**

- 1. The following guarantee statement:
- (a) the word "GUARANTEE", followed by a colon;
- (b) the common chemical name of the active ingredient of the pest control product or, if it has no common chemical name, its chemical or other name; and
- (c) the concentration of the active ingredient, expressed, if the pest control product is
  - (i) a liquid, as a percentage by mass, or as mass per unit volume, or both, or
  - (ii) a dust, wettable powder or other dry formulation, as a percentage by mass.
- 2. A declaration of net quantity of the package, expressed
- (a) by volume, if the pest control product is a liquid or gas or is viscous; or

- (b) by mass, if the pest control product is a solid or pressure-packed.
- 3. The name and postal address of the distributor.
- 4. The directions for the use of the pest control product, including application rates, timing of application and any limitations on its use.
- 5. Information that identifies any risks associated with the handling, storage, display, distribution and disposal of the pest control product, and instructions on procedures to reduce those risks.
- 6. Information that identifies any risks to health, the environment or anything in connection with which the pest control product is to be used, and instructions on procedures to reduce those risks.
- 7. Instructions in first aid, under the heading "FIRST AID INSTRUCTIONS", that set out the practical measures to be taken in the event of poisoning, intoxication or injury caused by the pest control product.

# 7. A swimming pool product that

- (a) is represented or sold as a product the function of which is to control bacteria or algae, or both;
- (b) contains as its only active ingredient a registered active ingredient of the type, concentration and percentage of available chlorine set out in the table to this section; and
- (c) is in a package and whose label shows all of the following information:
  - (i) on the principal display panel,
    - (A) the identity of the product in terms of its function referred to in paragraph (a),
    - (B) the information set out in items 1 to 3 of the table to section 6 of this Schedule,
    - (C) the appropriate signal words set out in column 4 of the table to this section,
    - (D) in the case of an active ingredient set out in column 1 of the table to this section, the precautionary symbol set out in column 5 of item 1 or of paragraph 2(b), 3(b), 4(b), 5(b) or 6(b) of that table, as applicable, and
    - (E) in the case of an active ingredient set out in column 1 of any of items 2 to 6 of the table to this section, the precautionary symbol set out in column 5 of paragraph 2(a), 3(a), 4(a), 5(a) or 6(a) of that table, as applicable, and

(ii) on the secondary display panel, the information set out in items 4 to 7 of the table to section 6 of this Schedule.

# TABLE TO SECTION 7

	Column 1	Column 2	Column 3	Column 4	Column 5
Item	Active Ingredient	Concentration (%)	Available Chlorine (%)	Signal Words	Precau- tionary Symbol
1.	Sodium Hypochlorite	10.8	10.3	"Warning — Corrosive"	
2.	Calcium Hypochlorite	65 or 70	65 or 70	(a) "Warning — Poison"	(a)
				(b) "Caution — Corrosive"	(b)
3.	Lithium Hypochlorite	29	35	(a) "Warning — Poison"	(a)
				(b) "Caution — Corrosive"	(b)
4.	Trichloro-s- triazinetrione	100	90	(a) "Caution — Poison"	(a)
				(b) "Caution — Corrosive"	(b)

5.	Sodium Dichloro-s- triazinetrione	100	62	(a) "Caution — Poison"	(a)
				(b) "Caution — Corrosive"	(b)
6.	Sodium Dichloro-s- triazinetrione dihydrate	100	56	(a) "Caution — Poison"	(a)
				(b) "Caution — Corrosive"	(b)

# 8. A spa product that

- (a) is represented or sold as a product the function of which is to control bacteria or algae, or both;
- (b) contains as its only active ingredient a registered active ingredient of the type, concentration and percentage of available chlorine set out in the table to this section; and
- (c) is in a package and whose label shows all of the following information:
  - (i) on the principal display panel,
    - (A) the identity of the product in terms of its function referred to in paragraph (a),
    - (B) the information set out in items 1 to 3 of the table to section 6 of this Schedule,
    - (C) the appropriate signal words set out in column 4 of the table to this section,
    - (D) in the case of an active ingredient set out in column 1 of any of items 1 to 3 and 5 of the table to this section, the precautionary symbol set out in column 5 of paragraph 1(b), 2(b) or 3(b) or item 5 of that table, as applicable, and

- (E) in the case of an active ingredient set out in column 1 of any of items 1 to 3 of the table to this section, the precautionary symbol set out in column 5 of paragraph 1(a), 2(a) or 3(a) of that table, as applicable, and
- (ii) on the secondary display panel, the information set out in items 4 to 7 of the table to section 6 of this Schedule.

# **TABLE TO SECTION 8**

	Column 1	Column 2	Column 3	Column 4	Column 5
Item	Active Ingredient	Concentration (%)	Available Chlorine (%)	Signal Words	Precau- tionary Symbol
					<b>A</b>
1.	Lithium Hypochlorite	29	35	(a) "Warning — Poison"	(a)
				(b) "Caution — Corrosive"	(b)
2.	Sodium Dichloro-s- triazinetrione	100	62	(a) "Caution — Poison"	(a)
				(b) "Caution — Corrosive"	(b)
3.	Sodium Dichloro-s- triazinetrione dihydrate	100	56	(a) "Caution — Poison"	(a)
				(b) "Caution — Corrosive"	(b)
4.	Sodium Bromide	35	N/A	None	None

5.	Potassium Monopersulfate	32	N/A	"Caution — Corrosive"	
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# SCHEDULE 3 (Paragraph 26(1)(e), subsection 34(2) and Schedule 2)

# SIGNAL WORDS AND PRECAUTIONARY SYMBOLS

	Column 1	Column 2
Item	Signal Word	Precautionary Symbol
1.	Caution	
2.	Danger	Ŏ
3.	Warning	$\Diamond$
4.	Corrosive	
5.	Explosive	
6.	Flammable	
7.	Poison	

[46-1-0]

Footnote a

S.C. 2002, c. 28

# Footnote 1

C.R.C., c. 1253

## **NOTICE:**

The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.



**Important notices** 

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