



Notice of Intent

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revised

Proposed Revisions to the Pest Control Products Regulations

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Introduction

The *Pest Control Products Act* (PCPA) and Pest Control Products Regulations provide the legislative mandate to regulate pest control products in Canada. Pest control products must be registered by the Minister of Health before they can be used in Canada. The Pest Control Products Regulations contain provisions describing the types of products requiring registration, registration process procedures (including labelling requirements for pest control products), storage, display, packaging, sampling, import and detention, distribution, prohibitions respecting use, the types of pest control products that are exempt from registration under the *Pest Control Products Act* as well as definitions of terms used throughout the regulations.

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 pesticides. Canadians will have access to more information and new opportunities for input into major pesticide registration decisions.

A multi-phase approach will be used in implementing the new PCPA, with phase I providing for the new Act to come into force. Phase I of the approach includes revisions to the existing Pest Control Products Regulations and key new regulations to support the new PCPA. These key new regulations, in various stages of development, are noted below.

Regulatory proposals that have already been prepublished in Part I of the *Canada Gazette* include:

Pest Control Product Safety Information Regulations	Specifies the content and format of material safety data sheets (MSDS) and their distribution to workplaces.
Pest Control Products Sales Information Reporting Regulations	Details information registrants must report on the sale of each of their pest control products.
Pest Control Products Adverse Effects Reporting Regulations	Detail types of information to be reported and timelines for reporting.

The following will be prepublished in *Canada Gazette*:

List of Formulants and Contaminants of Health or Environmental Concern	Presents the identity and concentration of formulants and contaminants of health or environmental concern in a pest control product.
Review Panel Regulations	Detail the process for establishing a review panel tasked with reconsidering major decisions.

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1.0 Proposed Content of the Revised Pest Control Products Regulations

The proposed revisions to the Pest Control Products Regulations will be structured in a very similar manner to the existing Pest Control Products Regulations, although the language will be simplified, where possible, using plain language. The Regulations will continue to provide provisions describing definitions of terms used in the regulations, types of pest control products that may be exempt (from the Act or registration), procedures detailing the registration process including provisions relating to labelling requirements for products, packaging, storage and display, distribution, import, sampling and detention.

It is proposed to revise the Pest Control Products Regulations by:

- ensuring coherence of the regulations with the new PCPA;
- clarifying and modernizing provisions in the regulations, where appropriate; and
- codifying current policies and practices in the regulations.

1.1 Ensuring Coherence of the Pest Control Products Regulations with the New PCPA

The new PCPA contains several new provisions. Many of the proposed revisions to the Pest Control Products Regulations are necessary to establish coherence with the new PCPA. These revisions can be categorized as follows:

- removing provisions from the Regulations that are now in the new Act to avoid duplication;
- removing provisions from the Regulations that are now obsolete;
- removing provisions not within the mandate of the PCPA and Regulations; and
- adding provisions based on new authorities in the new PCPA.

1.1.1 Provisions to be Removed from the Pest Control Products Regulations

Certain provisions that are now in the new PCPA will be removed from the Pest Control Products Regulations, so as to avoid duplication.

- Section 2.1, Certificate of designation of Inspector—The new Act contains a number of provisions describing the new powers of an inspector, including the designation of an inspector (new PCPA, section 45). These new authorities will allow greater control of pest control products after they are registered.
- Sections 53 and 54, Detention—New, stronger authorities for inspectors are now contained in the new PCPA and are no longer required in the Regulations.

Obsolete provisions will also be removed from the Pest Control Products Regulations.

- Definitions that are no longer used, such as “Plant Industry Branch” and “Director General” as well as any use of these terms.

- All references that no longer apply, such as references in sections 47 and 48 to active ingredients that are no longer contained in any registered pest control products.

In proposing revisions to the Pest Control Products Regulations and ensuring coherence with the new Act, provisions that do not meet the mandate of the *Pest Control Products Act* will be removed, for example, section 37 of the existing Pest Control Products Regulations.

- This section refers to the “Notice to Buyer” statement. As this matter falls under provincial jurisdiction, it should not be addressed in a federal regulation. A portion of this statement will be retained (“the buyer assumes the risk to persons or property arising from the use or handling of this product”) and added to the “Notice to User” statement, which is currently a labelling provision under paragraph 27(2)(n) of the Pest Control Products Regulations.

1.1.2 Provisions to be Added to the Pest Control Products Regulations

Under the new PCPA, the Minister may consider information from a source other than the applicant or registrant during the evaluation process or during re-evaluation or special reviews. Should the Minister do so, provisions will be necessary in the Pest Control Products Regulations to allow the applicant or registrant access to this additional information.

2.0 Clarifying and Modernizing Provisions in the Pest Control Products Regulations

The Pest Control Products Regulations will be updated, where appropriate, to reflect a modern regulatory approach. To achieve this, plain language has been used throughout the Regulations. The following new provision is also proposed:

- Product Classes

Under the existing Pest Control Product Regulations, the product classes “domestic” and “restricted” are named, although two other classes are used in the registration system—commercial and manufacturing. The proposed Pest Control Product Regulations will describe the four classes of pest control products, making the system more transparent and clarifying other provisions within the Regulations.

3.0 Codifying Current Policies and Practices into the Pest Control Products Regulations

Revision to the Pest Control Product Regulations will also codify current policies and practices in the Regulations. Specifically, this involves three areas:

- Temporary/conditional registration
- Own Use Import (OUI)
- Research

3.1 Temporary/Conditional Registration

A pest control product becomes a registered product if the Minister determines the health and environmental risks and the value of the product are acceptable. There are situations, however, where a product receives a registration that is conditional upon the submission of additional, confirmatory data. This information does not impact on the risk assessments conducted to grant registration. In these situations, the registration is termed a “temporary registration”.

Section 17 of the existing Pest Control Products Regulations allows a temporary registration to be granted in one of two situations:

- when the applicant agrees to provide additional scientific or technical information related to the pest control product; or
- for the sale of the product for emergency control of infestations considered seriously detrimental to health or the environment.

A temporary registration is valid for up to one year and may be renewed. Typically, temporary registrations are renewed as one year is insufficient time for the registrant to collect and provide the information required to convert a temporary registration into a full registration.

A number of authorities under the new PCPA impact upon temporary registrations, namely sections 28, 35 and 42. These sections pertain to public consultation prior to the Minister making a registration decision, the ability of anyone to object to a registration decision and the placement of information in a public Register.

In light of these new authorities and the current practice of granting temporary registrations, revisions to the Pest Control Products Regulations are proposed to achieve the following:

- update terminology to reflect current language—the term “temporary registration” will change to “conditional registration”;
- provide for a validity period that is more in line with the time required to submit required data; and

- provide a balance between transparency and meeting the needs of bringing a pest control product onto the market.

The option of being able to obtain an emergency registration, in warranted situations, will remain in the revised Regulations. A separate provision will detail such a registration, but this type of registration remains unchanged.

As with a current temporary registration, a conditional registration will be granted for a pest control product when there are outstanding confirmatory data requirements, but the risks and value of the pest control product have been determined to be acceptable given the limited duration of the registration. An example of an outstanding confirmatory data requirement resulting in a conditional registration could be the requirement to submit data regarding the large scale production of the pest control product. Such data would only be available after the product receives registration and becomes available on a larger scale. Prior to that, data submitted with regards to product production would be in relation to small scale production, such as in a laboratory.

Under the proposed revisions to the Pest Control Products Regulations, when a notice is delivered to a registrant of a pest control product under section 12 of the new PCPA, a product will receive a conditional registration. As a conditional registration, the following are proposed:

- the validity period of the registration could be up to three years; and
- the registration is not subject to public consultation [subsection 28(1)], reconsideration of decisions [subsection 35(1)] and placing of information in the Register [paragraphs 42(2)c) to (e)] until the registrant complies with the notice or applies to renew the registration.

In keeping with the requirement to place reports regarding the health and environmental risks and the value of registered pest control products in the Register [paragraph 42(2)(f)] and the overall objective of transparency in the new PCPA, a Regulatory Note will be published to describe the risk and value assessments conducted, the outstanding data requirements and the rationale for the decision. This is inline with the current practices for temporary registrations.

When the registrant submits the required information, the following is proposed:

- the validity period will automatically be extended for up to two years, allowing for the data to be evaluated;
- the validity period could further be extended to allow the Minister to conduct public consultation in accordance with section 28 of the new PCPA; and
- the information will be made available in the Register [paragraphs 42(2)c) to (e)] when a final registration decision is made.

The registrant will still have the option to renew a conditional registration in a similar way to renewing a temporary registration. The proposed differences will be that on renewal of a conditional registration before complying with the requirements of the notice delivered under section 12 of the new Act:

- the validity period will be up to three years; and
- the registration will be subject to public consultation, notice of objection and placement of information in the Register [subsections 28(1) and 35(1), and paragraphs 42(2)c) to (e)].

The provisions proposed for conditional registration balance addressing the needs of bringing new pest control products onto the market in accordance with the registration system and providing for greater transparency throughout the registration procedure. Although a conditional registration initially delays the public consultation provision of the new Act, this procedure provides a timeline for submission of required confirmatory data and subsequent consultation as well as provides an opportunity for the public to participate in the decision making process with access to the complete data package.

3.2 Own Use Import Program

The OUI Program allows users to import into Canada a foreign product that is determined to be equivalent to a Canadian registered product. This program is intended to allow access to competitively priced pest control products.

Under the existing Pest Control Products Regulations, paragraph 5(1)(d) and subsection 5(3) contain provisions for exempting from registration a foreign-registered control product, criteria for the product as well as criteria for determining equivalency.

A number of provisions in the new PCPA have a direct impact on the OUI Program. Subsection 6(1) of the new PCPA prohibits the use of an unregistered pest control product unless the use is authorized under subsection 41(1) of the Act or its Regulations. Subsection 41(1) of the new Act allows the Minister to authorize the use of any unregistered pest control product for a specified purpose.

The proposed revision to the Pest Control Products Regulations pertaining to OUI will incorporate the new authorities under the new PCPA and further detail and modernize the existing Pest Control Products Regulations provisions. Provisions pertaining to the OUI Program will describe the process for determining equivalency and detail how to obtain an OUI Certificate.

Proposed Equivalency Provisions

- Initial screening criteria that specify that a foreign control product cannot
 - be an organism
 - be under official re-evaluation or special review in the country where it is registered
 - contain an active ingredient that is under re-evaluation or special review in Canada
 - contain a formulant that is on the List of Formulants and Contaminants of Health or Environmental Concern and that has not been accepted for use in Canada
- Description of the application requirements for determining equivalency for both the foreign and registered product including
 - composition details
 - manufacturing process information
 - retail price comparison (in Canadian dollars)
- Requirements for a continued price differential of 10% while determining equivalency
- Particulars for the equivalency certificate including expiry and process for renewal of the certificate
- Information regarding the approval of an OUI label

Proposed OUI Certificate Provisions

- Description of the application process for requesting an OUI Certificate
- Provision allowing for the submission of an application for an OUI Certificate to be made by a representative of an individual
- Details on the criteria for using an unregistered product under this program, including stipulations that
 - the product must be the subject of a foreign equivalency certificate
 - that it can only be used for an intended use
 - that the imported quantity cannot exceed the amount needed for one growing season
 - that it must have an approved OUI label attached
- Description of the OUI Certificate, including conditions of use

3.3 Research Programs

Research plays a fundamental role in developing the scientific and technical information required in a submission to register a pest control product or to register a new use of a registered pest control product.

Under paragraph 5(1)(b) of the existing Pest Control Products Regulations, a pest control product used for research purposes is exempted from registration. Policy directives contain additional information on how such products can be used in a research setting and still comply with the PCPA. These documents are noted below.

Regulatory Directive DIR98-05	<i>Chemical Pesticides Research Permit Guidelines</i>
Regulatory Directive DIR97-02	<i>Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals</i>
Regulatory Proposal PRO93-05	<i>Research Permit Guidelines for Microbial Pest Control Agents</i>

There are a number of provisions in the new PCPA that impact directly on research. The new PCPA states that the use of an unregistered pest control product is prohibited [subsection 6(1)]. However, the Minister may authorize the use of an unregistered pest control product for a specified purpose such as research [subsection 41(1)]. Provisions are also in place to provide regulation making authority for the exemption of pest control products specific to research [paragraph 67(1) (z.4)]. The proposed revisions to the Regulations pertaining to research will make use of these authorities under the new PCPA and bring provisions, clarifying where necessary, to regulate research projects under one document. The revised Pest Control Products Regulations will:

- maintain the current categories into which research projects can fall (i.e., authorization [permit], notification and exemption);
- clearly stipulate the criteria for the notification and exemption categories;
- provide definitions used in research; and
- detail the requirements for labels, signs, material safety data sheets, record keeping, importation, disposal and aspects of distribution.

3.3.1 Research Project Categories

Under the existing PMRA policies for research using chemical pesticides, semiochemicals and microbials, research projects fall into one of three categories:

- authorization (currently referred to as “permits”)
- notification
- exemption

The three categories are based on the level of risk, with the exemption category representing research projects posing the least risk and authorizations representing the highest risk. The designation of a research project depends largely on the proposed product that is the subject of the research, who is conducting the research and where the research is being conducted. Research projects not meeting criteria for exemption or notification fall into the authorization category.

The proposed revisions to the Pest Control Products Regulations will detail how to apply for a research authorization, formerly referred to as a “permit”. This procedure will be similar to that used to apply for a research permit, as outlined in PMRA policy directives. Using the authority in section 41 of the new PCPA, the Minister will issue a research authorization certificate setting out the conditions for research if the associated health and environmental risks are deemed acceptable.

Depending on the scope of the proposed research project, the project might not require an authorization, but rather fall into the notification category or the exemption category. Under the notification category, the research needs to be exempted from subsection 6(1) and section 41 of the Act, if the Minister confirms that the proposed research meets certain criteria. Upon confirmation, a research notification certificate will be issued. Under the exemption category, the research also requires an exemption from subsections 6(1) and 41(1) of the new PCPA as well as an exemption from the requirement to hold a research notification certificate.

Currently, the designation criteria for determining if a research project is eligible for the notification or exemption categories are presented in PMRA regulatory documents. These criteria will be brought under the proposed Pest Control Products Regulations, allowing an applicant to determine the proper category for the proposed research (see Appendix I and II).

3.3.2 Definitions Used in Research

Definitions used in research will be included in the interpretation section of the Pest Control Products Regulations. These definitions have been drawn from various PMRA policies and the current Pest Control Product Regulations. They have been updated to reflect the objectives of the new PCPA and the intent of research. The following will be defined:

- Cooperator
- Experimental label
- Research
- Researcher
- Research establishment
- Research site

3.3.3 Research Requirements

In addition to specifying criteria for notification and exemption in the proposed Pest Control Products Regulations, other areas with ties to research are proposed to be included in the Regulations, including:

- Signage at research sites
- Experimental labels
- Material safety data sheets
- Records
- Importation
- Disposal
- Distribution

3.3.3.1 Signage at Research Sites

Research policies require that signs be posted at research sites and specify the information they must contain, the general appearance of signs and how and when they are to be posted. The following will be codified under the revisions to the Pest Control Products Regulations.

- Information on signs must be in both French and English and contain the following message:

Pest Control Experimental Site / Site d'expérimentation de lutte antiparasitaire
Do not enter without authorization/ Accès interdit sans autorisation
Contact (name) at (Phone number) / S'adresser à (nom) au (téléphone)
Authorization / Notification certificate number (not required for exempted research).

- Signs must be visible, legible, indelible and posted at every entrance to a site, on each side.
- Signs must be posted before treatments begin and remain in place until any treated food or feed crop is harvested or for as long as data is being collected.

Signs may include the name of the pest control product under research as well as the name and logo of the manufacturer, provided this information is smaller than the message noted above.

3.3.3.2 Experimental Labels

The label of a pest control product used in research is called an “experimental label”. Requirements concerning experimental labels are outlined in PMRA research policies. These requirements will be incorporated into the Pest Control Products Regulations, as follows.

- Electronic copies of proposed experimental labels must be included with applications for authorizations and notifications.
- The labels must contain the same information required in making application to register a pest control product.
- The labels must also include the following text:
 - EXPERIMENTAL USE ONLY
 - NOT FOR SALE. NOT FOR DISTRIBUTION TO ANY PERSON OTHER THAN A RESEARCHER OR COOPERATOR.
 - Any unused product must be returned to the manufacturer. (This applies to unregistered pest control products).
- The labels must include the authorization or notification certificate number.
- For research conducted under notification or exemption, experimental labels must also contain information on personal protective equipment that should be worn while using the product as well as re-entry information.
- The experimental label must present the intended research project.
- Research establishments will be required to supply copies of the experimental label to researchers and cooperators.
- Researchers and cooperators will be required to produce the experimental label for inspection, if requested.

3.3.3.3 Material Safety Data Sheets

In keeping with the current requirement of providing material safety data sheets when applying for a research permit (authorization) and the proposed Pest Control Product Safety Information Regulations, research establishments will also be required, under the Pest Control Products Regulations, to supply material safety data sheets (MSDSs) to all researchers and cooperators involved in a particular research project. This will apply to research under any of the three categories.

3.3.3.4 Records

A provision will be added to the Pest Control Products Regulations detailing the information that must be maintained when conducting research.

- Name and quantity of each product used in the research
- Names of researchers and cooperators
- Location of research sites
- Description of application methods
- Test data generated

3.3.3.5 Importation

A provision will be added to the Pest Control Products Regulations detailing how a product may be imported to be used for research.

3.3.3.6 Disposal

The Pest Control Products Regulations will contain provisions detailing how to dispose of pest control products used in research. A provision will be included requiring that unregistered pest control products must be returned to the manufacturer for disposal. For registered pest control products used in research, any unused product must be returned to the manufacturer unless the research establishment can use the product according to approved label directions.

3.3.3.7 Distribution

Provisions will be added to the Pest Control Products Regulations to regulate the distribution of any product used in research and any crop from a research site. Under the new PCPA, distribution includes the sale of any pest control product. A provision will be added to the Regulations such that a product used in research cannot be distributed to any person that is not a researcher or cooperator involved in the research.

For treated food or feed crops from research sites (including meat, milk and eggs that may contain residues as a result of the research), provisions for each category of research (authorization, notification or exemption) will specify when such crops could be distributed for sale.

4.0 Next Steps

These revisions will migrate the existing Pest Control Products Regulations under the PCPA. The revisions proposed in this document will be prepared for prepublication in the *Canada Gazette*, Part I, for a 30-day consultation period. Comments received during this period will be considered before publishing the revised Pest Control Products Regulations in the *Canada Gazette*, Part II. Any substantive policy change necessary will be addressed in phase III of the multi-phase project to implement the new PCPA.

Appendix I Notification Category Criteria

Chemical Pest Control Products	Semiochemicals	Microbial Agents
<ul style="list-style-type: none"> • No antimicrobial agents • No aerial application • No application to water or to areas where runoff water will remove residues from the research site • Cannot be used in: <ul style="list-style-type: none"> – greenhouses – residential areas – industrial premises – food handling areas • Cannot be used for: <ul style="list-style-type: none"> – structural pest control – fumigation • Cannot contain a formulant or a contaminant on the List of Formulants and Contaminants of Health or Environmental Concern or a formulant or contaminant that is not a component of any registered product • If using an unregistered product: <ul style="list-style-type: none"> – may only be used by a researcher – may only be used on 5–50 ha if land owned by research establishment or on 1–5 ha if land owned by cooperator • If using a registered product: <ul style="list-style-type: none"> – used by either researcher or cooperator – may only be used on 10–50 ha of land – no expected increase in occupational exposure 	<ul style="list-style-type: none"> • Cannot be used under notification 	<ul style="list-style-type: none"> • No aerial application • Cannot contain a formulant or a contaminant on the List of Formulants and Contaminants of Health or Environmental Concern or a formulant or contaminant that is not a component of any registered product • The micro-organism is indigenous to the area where it will be used • Application area is owned by the research establishment and measures: <ul style="list-style-type: none"> – max. 10 ha for land – max. 1 ha for aquatics

Appendix II Exemption Category Criteria

Chemical Pest Control Products	Semiachemicals	Microbial Agents
<ul style="list-style-type: none"> • No antimicrobial agents • No aerial application • No application to water or to areas where runoff water will remove residues from the research site • Cannot be used in: <ul style="list-style-type: none"> – greenhouses – residential areas – industrial premises – food handling areas • Cannot be used for: <ul style="list-style-type: none"> – structural pest control – fumigation • Cannot contain a formulant or a contaminant on the List of Formulants and Contaminants of Health or Environmental Concern or a formulant or contaminant that is not a component of any registered product • If using an unregistered product: <ul style="list-style-type: none"> – may only be used by a researcher – max. 5 ha land owned by research establishment; 1 ha or 5% crop under research if land owned by cooperator • If using a registered product: <ul style="list-style-type: none"> – used by either researcher or cooperator; 10 ha or 20% crop under research – No expected increase in occupational exposure 	<ul style="list-style-type: none"> • No aerial application • No application to water • Cannot be used in: <ul style="list-style-type: none"> – greenhouses – residential areas – industrial premises – food handling areas • Cannot be used for: <ul style="list-style-type: none"> – structural pest control – fumigation • Cannot contain a formulant or a contaminant on the List of Formulants and Contaminants of Health or Environmental Concern or a formulant or contaminant that is not a component of any registered product. • If using an unregistered active ingredient, other than an arthropod pheromone: <ul style="list-style-type: none"> – used by researcher only – max. 5 ha of land, owned by research establishment • If using a registered active ingredient, other than an arthropod pheromone: <ul style="list-style-type: none"> – used by researcher or cooperator – 10 ha of land • If using an arthropod pheromone: <ul style="list-style-type: none"> – max. 100 ha – max. use rate of 375 g of active ingredient per hectare per year 	<ul style="list-style-type: none"> • Cannot be used under exemption

References

Full Legal Text

Pest Control Products Act [in force]
<http://laws.justice.gc.ca/en/P-9/93378.html>

Pest Control Products Regulations [in force]
<http://laws.justice.gc.ca/en/P-9/C.R.C.-c.1253/index.html>

Pest Control Products Act [new]
<http://laws.justice.gc.ca/en/P-9.01/92455.html>

Regulatory Initiatives

Pest Control Product Safety Information Regulations
Canada Gazette, Part 1, July 17, 2004, pages 2044–2060

Pest Control Products Sales Information Reporting Regulations
Canada Gazette, Part 1, March 27, 2004, pages 839–851

Pest Control Products Adverse Effects Reporting Regulations
Canada Gazette, Part 1, October 23, 2004, page 2952–2977

List of Formulants and Contaminants of Health or Environmental Concern
[Not yet published]

Proposed Review Panel Regulations
[Not yet published]

PMRA Regulatory Documents

Regulatory Directive [DIR98-05](#), *Chemical Pesticides Research Permit Guidelines*

Regulatory Directive [DIR97-02](#), *Guidelines for the Research and Registration of Pest Control Products Containing Pheromones and Other Semiochemicals*

Regulatory Proposal [PRO93-05](#), *Research Permit Guidelines for Microbial Pest Control Agents*