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Pest
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Agency

Organizing and Formatting a Complete Submission for Pest Control Products

PMRA Guidance Document



*Protecting the health and
environment of Canadians*

*Protéger la santé des Canadiens
et l'environnement*



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2022	Changes were made to reflect current requirements
2009	Revisions made to web page based on document review
2003	Initial Issuance of Document

Disclaimer

This document does not constitute part of the *Pest Control Products Act* or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

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Preface

This guidance document assists applicants in the preparation of a complete, properly formatted and organized application to register a new pest control product or amend an existing registration with Health Canada's Pest Management Regulatory Agency (PMRA). Complete and well-organized submissions are more likely to pass the PMRA's verification, screening and scientific review processes and will contribute to the increased efficiency of the regulatory process.

This document replaces the 2003 edition of *Organizing and Formatting a Complete Submission for Pest Control Products* (updated 2009), as well as the regulatory note *Guidance on Selecting the Correct Category for Pest Control Product Submissions*.

The guidance document includes clarifications, updates and additional information related to submission requirements and processing. Further amendments have been made as a result of the updating of the following guidance documents:

- *Management of Submissions Policy*
- *Guidelines for the Registration of Non-Conventional Pest Control Products*
- *Notification/Non-notification*
- *Pest Control Products Fees and Charges Regulations*
- *Memorandum to Applicants and Registrants: Data Protection Submission Review Process*

1.0 Introduction

1.1 Background

In Canada, pest control products are carefully evaluated according to rigorous scientific standards by the PMRA, the branch of Health Canada that administers the *Pest Control Products Act* on behalf of the Minister of Health. The Organisation for Economic Co-operation and Development (OECD) has established protocols and internationally accepted test guidelines and principles of Good Laboratory Practices that are required by Health Canada to conduct the evaluations.

Companies that want to market a pest control product in Canada must submit a detailed information package to Health Canada for review. Health Canada uses this information to determine if the product meets current standards for protection of human health and the environment and if the product has value. The service standard for Health Canada's evaluations varies depending on the complexity of each submission. The PMRA conducts its own independent review of new active ingredients presented for registration.

Across this spectrum of needs, the PMRA strives to continuously improve its ability to manage and process submissions and ensure that the Canadian pesticide industry continues to adhere to international standards and practices.

This document will focus on:

- The registration process and how to organize a complete submission package;
- Procedural, organizational and formatting improvements;
- Electronic tools available to assist applicants in preparing for submission; and
- An overview of the Pest Control Products Fees and Charges Regulations.

The registration process is divided into the following stages: Pre-submission Consultation, Completeness Check, Review, and Public Consultation (though not all submission categories go through all four stages). The Pre-submission Consultation process is discussed in Section 3.1 Pre-submission Consultation service.

This guidance document also describes the comprehensive Completeness Check that is conducted early in the registration process and contributes to a more efficient regulatory system by providing evaluators with correctly formatted and complete submission packages for review. The Completeness Check also facilitates the identification of deficiencies early in the process. If a submission is found to be deficient, then the applicant will be asked to or will be given the opportunity to address those deficiencies before the submission can be processed any further.

The PMRA accepts submissions formatted according to the guidelines and criteria for industry for the preparation and presentation of complete dossiers and of summary dossiers for plant protection products and their active substances in support of regulatory decisions in OECD countries, found on the OECD website. Also refer to the Pesticides portion of the Canada.ca website.

The *Management of Submissions Policy (MOSP)* consolidates the performance standards and describes the process for managing submissions. The result is a submission management process that is more efficient, effective, and predictable for applicants/registrants and the PMRA. The expected result will be a closer alignment of the management of submissions with approaches used by regulatory authorities in other jurisdictions, which will facilitate work-share and joint review of applications with other jurisdictions.

Note: This guidance document serves as a general guide for organizing and formatting most submissions. Applicants should contact the PMRA to set up a pre-submission consultation and for specific guidance relating to non-conventional chemicals and biopesticides, specifically microbials, semiochemicals and pheromones, through the PMRA's presubmission guidance service at pmra.presubs-prealables.arla@hc-sc.gc.ca. Also refer to the Pesticides portion of the Canada.ca website.

1.2 Products that are subject to regulations

Pest Control Products Act section 2(1) provides the following definition for *pest control product*:

- a) a product, an organism or a substance, including a product, an organism or a substance derived through biotechnology, that consists of its active ingredient, formulants and contaminants, and that is manufactured, represented, distributed or used as a means for directly or indirectly controlling, destroying, attracting or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects;

- b) an active ingredient that is used to manufacture anything described in paragraph (a) (for example, a technical grade of the active ingredient is a pest control product used for manufacturing/formulating the end-use pest control product); and
- c) any other thing that is prescribed to be a pest control product.

The Pest Control Products Regulations further prescribes the following as pest control products:

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 not an ingredient of a pest control product described in paragraph (a) of that definition but is added to or used with such a product to enhance or modify its physical or chemical characteristics or to modify an effect on host organisms in connection with which the product is intended to be used, (for example, adjuvants/safeners).

1.3 Laws and regulations

Pursuant to section 6 of the *Pest Control Products Act*, it is prohibited to manufacture, possess, handle, store, transport, import, distribute or use a pest control product that is not registered under the *Pest Control Products Act*, except as otherwise authorized under the *Act* or Regulations.

Pest control products can only be registered in Canada if they meet current standards for protection of human health and the environment, and if they have value, as specified by the *Pest Control Products Act*. The PMRA determines whether products meet such requirements of the *Pest Control Products Act* and has policies that encourage the development and implementation of innovative and sustainable pest management strategies.

The PMRA has six science review streams that review the data provided by companies that wish to register a pest control product:

- Chemistry Evaluation
- Environmental Assessment
- Value Assessment
- Food Residue Exposure Assessment (part of Health Evaluation)
- Occupational Exposure (part of Health Evaluation)
- Toxicology (part of Health Evaluation)

1.4 Pest control products

Below are some common products and classes.

Manufacturing class product – The pest control product is to be used only in the manufacture of other pest control products (for example, manufacturing concentrate, commercial and domestic end-use products regulated under the Feeds Act or the Fertilizer Act). The most common manufacturing class products follow:

- Technical Grade Active Ingredients (TGAi) are registrations that are source/site specific, contain the active ingredient and normally contain impurities that are by-products of the manufacturing process. These registrations consist of the information that defines the chemical and toxicological profile and the behavioural impact of the chemical on the environment.
- Integrated System Products (ISP) are registrations with special chemistry considerations in which the ISP product may contain an active ingredient that is not isolated due to physical limitations or uncertainty as to the specific active component with the pesticidal mode of action or a mixture of components that are not separated and purified due to manufacturing and integrity considerations.
- Manufacturing Concentrates (MA) are intermediate products containing a registered technical grade active ingredient(s) and formulants intended for further reformulating and/or repackaging into end-use products.

End-use product – A product containing **active ingredient(s)** and usually **formulant(s)** that is labelled with instructions for direct pest control use or application. This registration consists of the information that defines the chemical and toxicological profile and the behavioural impact of the **formulation** on the environment. This is also where the information specific to the use pattern and where label claims are kept and food residues, human exposure and value data are found. Some types of end-use products are listed below:

- **Domestic Class** – Products meant for distribution primarily to the general public for personal use in or around their homes (for example, ready-to-use formulations).
- **Commercial Class** – Products meant for distribution primarily to professionals in an industry for use, often in large scale activities (for example, agricultural and industrial uses).
- **Restricted Class** – Products with additional requirements on the label concerning essential conditions respecting the display, distribution or limitations on use of, or qualifications of persons who may use the product to address special concerns regarding human health and/or the environment.

2.0 Submission categories

The PMRA categorizes submissions for pest control products according to:

- Product type
- Product purpose
- Registration type, and/or
- Program through which the application is being submitted.

This allows the PMRA to screen submissions and forward them to the appropriate divisions within the PMRA, and to apply appropriate performance standards (service standards) for their processing. Categorization is also a management tool that allows the PMRA to track numbers of different kinds of submission activities and allocate resources appropriately. A description of each category covered in this document is provided in this section.¹ This information is designed to assist applicants in identifying the proper category of their submission(s) for the purpose of entering this information into their application forms and cover letters.

To view a high-level depiction of how the PMRA triages and determines which review process a submission can take see Appendix B – Submission category triage.

Submission Category A – New to Canada

This category applies when there are no current similar precedents registered as a pest control product in Canada for the proposed active ingredient(s) or formulated end-use product(s) or the proposed label use pattern. The submissions are required to be accompanied by a significant amount of data to allow the PMRA to determine whether products meet current standards for protection of human health and the environment and if they have value as a pest control product. This category applies when the PMRA has little to no available information for comparison and for a regulatory decision on its acceptability.

The New to Canada category includes:

- New active ingredients or integrated system products, their related end-use products, and manufacturing concentrate products.
- Major new use of registered pest control products (defined as the addition of a new use-site category to the use pattern for a specific registered active ingredient).
- Specification of import maximum residue limits (MRLs) for an unregistered active ingredient.

Category submission review type	Comments/Examples
A.1.1: Registration of a new active ingredient as a pesticide for use in Canada. Submission package consists of TGAI products or integrated system products (ISP), their related end-use products, and if applicable, manufacturing concentrate products (MA).	Besides traditional agricultural chemical and biocidal active ingredients, this category also applies to any new adjuvants, biopesticides, microbial agents, pheromones and seed treatments for export only that have not been previously examined by Health Canada as an
A.1.2: International Work Sharing or Parallel review request	
A.1.3: Specification of Maximum Residue Limit(s) (MRLs) for an imported commodity for a previously unexamined active ingredient in Canada	
A.2.0: Defined as a major amendment to a registered active ingredient in Canada. When a new health or environmental	

¹ Other submission categories, such as H (Notices of Objection), N (Post-Market Review), S (Pesticide Sales), X (Incident Reports) and Y (Contact Management) are not within the scope of this guidance and are covered by their own specific documentation.

Category submission review type	Comments/Examples
assessment is necessary (For example, the addition of a new use that falls in a different use-site category than the currently registered use pattern for the active ingredient).	active ingredient for use as a pest control product.
A.3.1: User Requested Minor Use Registration (URMUR)	
A.3.2: Joint Reviews: See OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances.	
Applicable fees: can be as per Schedule 1 in the Pest Control Products Fees and Charges Regulations except for Semiochemical and Microbial Agent (Schedule 2) and for MRL applications (Schedule 3).	
Timelines: As published in Table 1 of the guidance document Management of Submissions Policy	

Submission Category B – Registrations and amendments

Registration and amendments covered in this category include:

- New pest control products containing registered active ingredients
- Amendment to existing pest control products (for example, product chemistry, labelling)
- Emergency registration
- MRLs for previously assessed active ingredients

This category applies when the PMRA has previously examined the active ingredient under certain conditions and uses. This review category is for new proposed product registration and/or amendments to currently registered products (for example, second-generation products that are similar but not identical to initial registrations). The introduction of new chemistry or new proposed label uses are not considered major changes when the PMRA does its comparative work to initial registrations. Therefore, the previous regulatory decision and its supporting data used in the initial assessment and registration still applies. There may be additional data gaps specific to the proposed product that the applicant must address. Hence, this is why a partial data package is often required to make a regulatory Category B review decision.

Note: Category L (data protection issue between applicants/registrants) and Category B (no data protection issues between applicants/registrants) are similar yet different registration processes based on whether or not applicants can access data that is already in house with the PMRA.

There cannot be data access issues or compensable status data implications in this submission type or it will be rejected. The onus is on applicants to fulfill additional data requirements to support their application, either by:

- Providing their own data, or
- Providing legal documentation (for example, a letter of access) that gives access to previously examined proprietary data from other registrants of the precedent product, to support the new application.

Note: Category B can be precedent setting for new proposed amendments. For example, the initial registration of a chemical is for food crops, specifically for wheat. Now, companies may propose the same chemical for use on berries. Most of the previously reviewed data can be used again, however,

partial data is needed to support and approve the specific use on berries. It is precedent setting in that the approved list of crop uses within an already approved use pattern (for example, Use Site Category No. 14-Terrestrial Food and Feed Crops) has been added/expanded to include berries.

B.1 New/Amendment to TGAI/ISP chemistry only	
Category submission review type	Comments/Examples
B.1.1: New alternate source/site of manufacture for TGAI/ISP by a current registrant.	Addition or substitution of a new source/site of manufacture. Company A has a TGAI product registered that is produced at a source/site of manufacture located in Canada. Company A wishes to now add an alternate source/site of manufacture located in the United Kingdom
B.1.2: New alternate source/site of manufacture for TGAI/ISP by a new applicant. The new applicant has their own data to support this application	Company A has a registered TGAI that is produced at a source/site of manufacture located in Canada. Company B wishes to register a similar TGAI product but at a different source/site, which is produced at site of manufacture in United Kingdom
B.1.3: Amendments to product Specifications or Manufacturing Process to a current TGAI/ISP registration. Change in the chemical composition of a technical product greater than 0.1% or impurities of toxicological significance to the limit of quantitation. Also includes amendments in manufacturing process.	Company A has a technical product that is registered with a guarantee of 80%. Company A wishes to change the guarantee of this product to 90%.
B.2 New/Amendment to End-use Product (EP) and MA chemistry only	
Category submission review type	Comments/Examples
B.2.1: Guarantee amendments: Change in the typical or nominal concentration of the active ingredient(s) in an EP or MA product.	Company A has an EP with a guarantee of 30%. Company A wishes to increase the guarantee to 40%.
B.2.2: Change in the Form of active ingredient(s) used in an EP or MA formulation. A proposed new CAS number for the TGAI. This excludes new active ingredients such as esters, amines and isomers which are considered Category A- new active ingredient.	Company A has an EP in which the active ingredient (an acid) is present in the form of salt A. Company A wishes to register a product in which the active ingredient is present in the form of salt B
B.2.3: Identity of Formulants: Change in identity of formulant(s) where amount of new formulant(s) is greater than 0.1%w/w (weight for weight) of the formulation. (Amendment does not qualify for Category C review as per criteria).	Company A wishes to replace solvent X in their registered product with solvent Y.
B.2.4: Proportion of Formulants: Change in the relative concentration of formulant(s). Where changes are greater than 0.1% w/w of the	Company A wishes to change the amounts of two formulants (for example, solvent A and surfactant B) in a registered EP.

formulation (Amendment does not qualify for Category C review as per criteria).	
B.2.5: Formulation type: Physical form of a product that is different from other registered products in the same use pattern (including water soluble packaging).	Company A has a product that is an emulsifiable concentrate formulation. Company A wishes to produce a product that is a water dispersable granule.
B.2.6: New combinations of active ingredients: The active ingredients in a proposed formulation are not currently registered in combination for the proposed uses. Proposed uses may or may not be common to the individual use-patterns of the active ingredients.	Active A is used on wheat to control pest 1. Active B is used on wheat to control pest 1. Company A wishes to produce a product containing active A and B for use on wheat to control pest 1. -OR- Active C is used in apples and pears to control pests 1, 2 and 3. Active D is used on peaches and plums to control pests 4, 5 and 6. Company G wishes to produce a product containing active C and D for use on pears and plums to control pests 1, 2, 3, 4, 5 and 6.
B.3 Label amendments for EP	
Category submission review type	Comments/Examples
B.3.1: Application Rate*: Change in the quantity of active ingredient (or acid equivalent) per unit area or volume, on individual crop or animal per application.	Product A is used on strawberries at a rate of 10 g of active ingredient per hectare to control pest 1. Company wishes to use the product at a rate of 20 g of active ingredient per hectare to control pest 1 in strawberries.
B.3.2: Application timing: Change in the schedule or frequency of application with respect to season, weather, pest or host development.	Product A is used in the spring to control pest 1 in wheat. Company A wishes to use Product A in the fall to control pest 1 in wheat.
B.3.3: Application number/frequency: Change in the total number of applications.	Product A is used 3 times throughout the season to control pest 1. Company A wishes to use the product 5 times throughout the season to control pest 1.
B.3.4: Application method: Change in method by which a pesticide is applied to a site, including contact time.	Product A is applied by ground boom equipment. Company A wishes to apply the product with a backpack sprayer.
B.3.5: Rotational crop or plant back intervals: Change in elapsed time between the last application and seeding of the same or alternate host.	Product A was registered with a rotational crop interval of two years for rotational crop A. Company A now wishes to reduce rotational crop interval to one year; or Company A wishes to add a rotational crop interval for crop B.
B.3.6: Preharvest interval (PHI), or withholding period, or preslaughter interval: Change in the minimum period of time that must elapse between the animal grazing on the treated feed/direct livestock treatment and slaughtering of the animal.	Product A was registered with a PHI of 80 days when the product was applied at the 4-leaf stage of the crop. Company A now wishes to have the PHI changed to 60 days when the product is applied at the 4-leaf stage of the crop.
B3.7: Pregrazing interval: Change in elapsed time between the last application and grazing or cutting of the crop used for animal feed.	The label for Product A has no pre-grazing interval: the label contains the statement: "do not cut or graze the crop". Company A now wishes to allow

	grazing of the treated crop 25 days after application.
B3.8 Restricted-entry interval: Change in the minimum period of time that workers, or anyone else, must not do hand labour in treated areas after a pesticide has been applied.	Product A was registered with a re-entry interval of 48 hours. Company A wishes to reduce the re-entry interval to 24 hours
B3.9 Level of control*: Change in pest control claim (for example, control, prohibit, suppress, prevent, destroy, mitigate, manage, eradicate, attract, disinfect, sanitize and inhibit).	Product A claims to "suppress" pest A. Company A requests to change this claim to "control".
B.3.10 Tank mixes*: Change in the labelled use of two or more registered pest control products mixed or applied together in a single application, including adjuvants and surfactants.	Product A and Product B are each registered for use on wheat. Company A requests to have the tank mix of Product A and Product B appear on the label of Product A.
B.3.11 New pests*: Addition of a pest(s) or different life stage of a pest, excluding a name synonymous with a pest name or stage on a registered label.	Company A wishes to add a pest(s) to the label of Product A.
B.3.12 New site/host: Addition of a site/host to the use-pattern that falls within the parameters of the currently registered USC for the active ingredient(s).	Product A is currently registered on wheat (USC 14, Terrestrial Food Crops). Company A wishes to add barley (USC 14, Terrestrial Food Crops) to the label of Product A.
B.3.13 Precautions: Changes including, but not limited to, Personal protective equipment, environmental warning statements or hazard symbols.	Company A requests the removal of the requirement for personal protection equipment.
B.3.14 Classification: Change in product classification (based on the intended use and associated hazards of a product).	Product A is currently classified as a commercial product. Company A wishes to have product A classified Domestic. This requires an application to register a new product.
Other registration/amendments	
Category submission review type	Comments/Examples
B.4 Addressing Conditions of registration for TGAI, ISP, EP or MA, the Section 12 notice requirements or other requirements issued under the Pest Control Products Act.	Product A was given registration on the condition that additional requirements outlined in the Section 12 notice or regulatory decision letter be addressed by a certain due date to remain in compliance.
B.5 Addition of MRL(s) for previously assessed active ingredients (TGAI and ISP) to Food and Drug Regulations Division 15. MRLs are specified under the Pest Control Products Act for the purposes of the adulteration provision of the Food and Drugs Act.	Product A contains TGAI B that is currently registered in Canada for use on apples only. Company A wishes to establish an MRL for the imported commodity grapes, for the purpose of importing grapes. In this case, grapes are registered on a foreign label importing this commodity. If it is an import MRL, it is on a foreign label. Or, if Company B wants to modify the established MRL on apples from 0.5 ppm to 1 ppm.
B.6 Emergency registration for EP only Submission requires provincial support. Refer to Guidance document Registration of Pesticides	Under section 18 of the Pest Control Products Regulations to permit the use of a pest control

for Emergency Use: Revised Procedures for list of requirements and criteria.	product in the emergency control of a seriously detrimental infestation.
B.7 Reinstatement of previously registered product TGA, ISP, EP or MA. Registration has lapsed for longer than 1 year.	Product was either cancelled or discontinued. Supporting data may be required to update database to new standards.
*Category B Streamline applications are restricted to B.3.1 (Rate decrease only), B.3.9 (Change in level of Control), B.3.10 (New PCP Tank Mix only), B.3.11 (New pests). These applications are restricted to a maximum of six changes and to these application types only. Other Category B types are beyond the scope of the streamline process.	
Applicable fees: can be as per Schedule 1 in the Pest Control Products Fees and Charges Regulations except for Semiochemical and Microbial Agent (Schedule 2) and for MRL applications (Schedule 3)	
Timelines: As published in Table 2 of the guidance document Management of Submissions Policy	

EP: end-use product; ISP: integrated system products; MA: manufacturing concentrate; TGA: technical grade active ingredient; USC: use-site category

Submission Category C – Submissions with No Data Requirements

This category is for product registrations and amendments with no data requirements. These types of submissions are for a product comparison review for registration or amendments.

There cannot be data access restrictions or compensable data implications in this submission type, therefore no data is reviewed in this type of submission. The onus is on applicants to provide the necessary legal documentation that gives authorization to rely on an existing precedent product whenever applicable, in support of the new application.

Criteria must be met to qualify for a Category C application review as per *Memorandum to Registrants, Applicants and Agents - Category C Guidance Document*:

- The source of active ingredient used to formulate an end-use product or manufacturing concentrate must be registered in Canada.
- The information on formulation changes (for example, formulant used in the manufacture of pest control products) must be acceptable to the PMRA. This means that complete information (in other words, 100% chemical composition information on a proposed substance) on new formulant CAS number or formulant proprietary mixtures must be provided to the PMRA.
- Requests to waive data review cannot be considered under a Category C application. If the applicant decides that a scientific waiver or data is needed to help support a regulatory decision then this is not the appropriate submission category to apply for.

Criteria for selecting a suitable precedent product:

Refer to the Category C review process for the criteria that is required for valid precedents.

- A maximum of two precedents may be cited to support an application. For situations where two precedent products are required to support the application, the applicant must explain in their cover letter how each of the precedent products supports the application.
- The precedent product must be substantially similar to the proposed product. Differences may be acceptable if they are deemed to have no adverse implications for product quality or biological activity such as safety, residues or efficacy.
- Products with conditions on the registration may be cited as a precedent for a new or amended registration.
- If the cited precedent product was registered as a similar or identical product (for example, repacks, relabels and master copies of other products), the PMRA will not consider it an appropriate precedent product for a Category C application review as the data access and ownership may not lie with these types of precedents.
- In addition to the above bullets, there may be regulatory issues that the PMRA will consider when validating the appropriateness of the cited precedent product.

C.1 New/Amendment to product specifications of TGAI or ISP	
Category submission review type	Comments/Examples
C.1.2 Alternate source of supply: Where no data is required and the alternate source of the TGAI is currently registered and chemically equivalent; requires LOC from the TGAI supplier and new Statement of Product Specification (SPSF).	Company B repacks a TGAI and wants to add another equivalent source.
C.1.3 Specifications: A minor calculation error or typo correction	Product A requires a new corrected SPSF form 6003
C.2 New/Amendment to product specifications of EP or MA	
Category submission review type	Comments/Examples
C.2.1 Guarantee C.2.2 Physical Form of TGAI or ISP used C.2.3 Identity of Formulants C.2.4 Proportion of Formulants C.2.5 Formulation type Amendments to the formulation require a new proposed SPSF and may also require label updates (if amendment affects information on the label). If the guarantee has been amended, the difference must be less than 10%, and the amount of active ingredient being applied is not affected. A precedent product must be cited	Company A wants to decrease the guarantee in Product A by 3% and the formulants in the formulation have all been adjusted to compensate for the change in guarantee. Amendments to the formulants, for example, change of carrier, change of propellant from fluorocarbons to hydrocarbons, changes in relative proportions of formulants (no qualitative changes), substitutions of dyes, buffers that are equivalent to the originals would only require a new SPSF otherwise a Category B review with data will be required.

C.3 New/Amendments to product labels of EP	
Category submission review type	Comments/Examples
C.3.1 Application rate change	<p>Amendments to the label (Category C3.1 to 3.15) that do not require data, are based on valid precedent. The product is equivalent to precedent and applicant has authorization to copy use pattern via Letter of Authorization or ownership. The submission will require new labels to update the register.</p> <p>Category C.3.1 C3.9, C3.10, C3.11: if based on precedent but product is not equivalent, data may be required to support amendment. Refer to REG2002-04 for criteria of acceptability to qualify for a Category B streamline value data only review (B.3.1, 3.9, 3.10, 3.11) to support the change.</p> <p>Company B wants to amend the label for Product B to match the label of Company A's Product A that contains the same active ingredient at the same guarantee and rate of application. The proposed amendment can not be under data protection (refer to notes above).</p>
C.3.2 Application timing	
C.3.3 Application number or frequency	
C.3.4 Application Method	
C.3.5 Rotational crops or plant-back intervals	
C.3.6 PHI or withholding period or pre-slaughter interval	
C.3.7 Pre-grazing interval	
C.3.8 Re-entry interval	
C.3.9 Level of control	
C.3.10 Tank mixes	
C.3.11 New pests	
C.3.12 New site/host	
C.3.13 Precautions	
C.3.14 Classifications	
C.3.15 Label improvements	
Administrative changes and special review	
Category submission review type	Comments/Examples
C.6.2 Addition or replacement of a registered source of TGA in a registered EP	The proposed new TGA source must be chemically equivalent to the currently registered source used in the EP. An LOC is required from the TGA supplier and a new SPSF.
C.6.3 Addition of supplemental label or minor use(s) to product label for EP. The supplemental label must have been previously approved with the minor use(s) under URMULE program. (Refer to Guidance document User Requested Minor Use Label Expansion).	Company B received a certificate for an approved URMULE and now wants to add this to the full product label. The submission number of the URMULE decision must be included in the covering letter.
C.7.0 Similar product and use(s) Registrations/Amendments for EP	<p>Company A wants to register a new product that has the same formulation and uses as Company B's product that is currently registered. Precedent product's registration number must be identified by applicant in covering letter and on application form. Requires SPSF, labels, and LOCs from the suppliers of the TGA/MA. Authorization is required to copy precedent via letter of authorization LOA may be required if under data protection (refer to notes above).</p> <p>Note: If Company A is referencing their own product, an LOA is not required.</p>

C.8.1 Master Product Status update for EP	Refer to Guidance document DIR93-20, Master Product/Master Copy Registration Process.
C.8.2 Initial Product Status update for EP	Refer to Guidance document DIR93-21, Initial Product/Private Label Registration Process.
C.9 Reinstatement of previously registered product TGAI, ISP, EP or MA Product registration has lapsed renewal for less than 1 year. Product was either cancelled or discontinued and no data is required to support the submission.	New updated copies of the label, SPSF and LOCs from the suppliers of the TGAI/MA are required for product register. If supporting data is required as per previous outstanding conditions on the registration, then a Category B.7 review is required instead.
Applicable fees: is the processing fee as per section 3 of the Pest Control Products Fees and Charges Regulations, except for Semiochemicals and Microbial Agents (Schedule 2).	
Timelines: As published in Table 3 of the guidance document Management of Submissions Policy.	

EP: end-use product; ISP: integrated system products; MA: manufacturing concentrate; TGAI: technical grade active ingredient

Submission Category D – Special program reviews

This category is for special registration activities. It includes submissions to register or to amend products within these particular programs:

Category submission review type	Comments/Examples
D.1 IMEP: Import for Manufacture and Export Program	Refer to DIR95-05, Importation for Manufacturing and Export Program
D.2 OUI: Own Use Import	Refer to Grower Requested Own Use Program
D.3 URMULE: User Requested Minor Use Label Expansion	Refer to User Requested Minor Use Label Expansion
D.4 Master Copy	Refer to Guidance document DIR93-20, Master Product/Master Copy Registration Process.
D.5 Private Labels	Refer to Guidance document DIR93-21, Initial Product/Private Label Registration Process.
D.6 Renewal	Renewals and discontinuations are described in Pesticide registration cost recovery on Canada.ca
D.7 Discontinuation	Refer to our website for details
Applicable fees: are the processing fees as per section 3 of the Pest Control Products Fees and Charges Regulations except for Renewal applications which is outlined in section 5. Schedule 3 applicable fees apply to IMEP application	
Timeline: As published in Table 4 of the guidance document Management of Submissions Policy.	

Submission Category E – Submissions for research and amended products

Formerly called Research Permits, Category E refers to research authorization or research notifications depending on the criteria that need to be met. Also see Health Canada's

Overview of Requirements for Research Involving a Chemical Active Ingredient on Canada.ca. For instructions and details on submitting a request for research authorization/notification see Research Authorizations and Notifications on the Pesticides portion of the Canada.ca website.

Submissions for research include:

- Research authorizations for new active ingredients and new use(s) of registered active ingredients.
- Research notifications for research carried out in Canada.

Submission category	Submission type	Comments
E.1	Research Authorization for New TGAI for Food Use	Refer to Health Canada Guidance documents on Research.
E.2	Research Authorization for New TGAI for Non-Food Use	
E.3	Research Authorization for new use(s) of registered active ingredient, food and non-food	
E.4	Research Notification	
Applicable fees: as per Schedule 3 of the Pest Control Products Fees and Charges Regulations		
Timeline: As published in Table 5 of the guidance document Management of Submissions Policy		

Submission Category F – Submissions (Notifications)

Notifiable changes are minor changes to registered products that do not require a standard amendment application. Types of amendments that can be made to registered products are as follows:

- Minor changes to the label or the product specification form that are considered administrative. There are criteria that need to be met to qualify for this review.
- Changes where the PMRA does not need to be informed (non-notification).

Refer to document **Notification/Non-notification** for more details and guidance on notifiable and non-notifiable changes to currently registered products acceptable to the PMRA.

Applicable fees: are the other fees as per section 4 of the Pest Control Products Fees and Charges Regulations.
Timeline: As published in Table 6 of the guidance document Management of Submissions Policy.

Submission Category L – Data protection applications

This category is for the registration or amendment of a pest control product where an applicant intends to rely upon data supporting a precedent product to support their application. These applications require both a product equivalency and a data compensation assessment.

Applicants who wish to make an application to register a new pest control product or amend a registration with reliance on a different registrant's data may refer to the following in preparation of their submission package:

- Provisions in the Pest Control Products Regulations (s. 17.1-17.94) related to the protection of test data.
- Guidance document *Guidelines for Reliance on Proprietary Data Under the Pest Control Products Regulations* provides detailed guidelines to applicants on how the PMRA is administering Pest Control Products Regulations (s. 17.1-17.94).
- Memorandum to Registrants, Applicants and their Representatives: *Data Protection Submission Review Process* (15 December 2014).
- *Ministerial Agreement for Data Protection Under the Pest Control Products Act* outlines the agreement that is entered into when an applicant wishes to rely on a registrant's compensable data in support of an application to register a generic product (5 April 2019).

This guidance **does not apply** to the following cases:

- Applicants are relying on their own data.
- A letter of access (LOA) to all relevant data has been provided.
- The applicant has previously secured access to the data through a previous policy.
- The applicant is relying on test data from the registrant who is providing the pest control product used in the manufacture of the applicant's product (Section 17.4 Pest Control Products Regulations). A letter of confirmation of source (LOC) would be required in this case; however, an amendment to replace or add a source from another registrant could trigger the need for compensation.

As outlined in Health Canada's *Data Protection Submission Review Process*, data protection applications have three phases:

Phase I: Equivalency assessment and data compensation analysis

The PMRA conducts the equivalency assessment and determines the protection status of the precedent product's database.

Phase II: Negotiation/Arbitration

The applicant and registrant enter into negotiations for access to the compensable data. The outcome could be a negotiated agreement and a letter of access (LOA) request to go to binding arbitration. The applicant may also decide to withdraw from the process.

Phase III: Regulatory Decision

The PMRA issues the regulatory decision for the data protection application.

Submission category	Submission type	Comments
L.1.1	Technical grade active ingredient or ISP: A complete Chemistry package is required to confirm chemical equivalency. End-use products or MA: Specification Form comparison only with precedent (no data required to establish chemical equivalency)	A technical grade active ingredient can be registered by a new applicant without a related end-use product. Major new use(s) cannot be combined with a Category L sub (in other words, the use pattern available is restricted to the use-site categories already registered for the cited

Submission category	Submission type	Comments
L.1.2	Technical grade active ingredient or ISP or end-use product or MA: An additional partial data package for health, chemistry data, environmental or value supporting the use pattern by the new Applicant	precedent or a subset of the use-site categories). Historical products or uses may be valid precedents if not cancelled due to health or environmental concerns.
L.4.1	Regulatory Decision	-
L.5.1	Requests to Extend the Exclusive Use Protection Period	The minor use incentive provisions of the Pest Control Products Regulations outline how and when registrants may ask for an extension to the exclusive protection status of their proprietary databases. The exclusive use protection period provided to the original data set will be extended by one year for each three eligible minor use crops added to a label, up to a maximum of five additional years of exclusive use data protection.
Applicable fees: as per Schedule 1 of the Pest Control Products Fees and Charges Regulations.		
Timeline: as published in Table 7 of the guidance document Management of Submissions Policy.		

Submission Category P – Pre-submission Consultations

For more information see Section 3.1 Pre-submission Consultation service.

Administrative requirements for submissions Category type A, B, C, D, E, F, L

This section refers to the e-index builder. For more information see Section 4.2.1 Electronic Index Builder.

Components of a submission package	Product class			Prescribed device
	TGAI/ISP	MA	EP	
Part 0-Index, Forms and Correspondences Using the e-Index Builder (EIB), create a prz index file that includes the following documents:	Yes	Yes	Yes	Yes
DACO 0.1.6005 Application for New or New/Amended Registration (form 6005) Note: Does not apply to Cat 6.0, Cat D 7.0 or Category E	Yes	Yes	Yes	Yes
DACO 0.1.6011 - Fee Estimate Form	Yes	Yes	Yes	Yes
DACO 0.8 - Cover letter	Yes	Yes	Yes	Yes
and when applicable:				

Components of a submission package	Product class			Prescribed device
	TGAI/ISP	MA	EP	
DACO 0.8.6 - Letter of Authorization of Access to Data (LOA) ¹	Yes	Yes	Yes	Yes
DACO 0.8.7 - Letter of Authorization of Representation (LOA)	Yes	Yes	Yes	Yes
DACO 0.8.8 - Letter of Confirmation of Source of Supply (LOC)	No	Yes	Yes	No
DACO 0.8.13 - Letter of Confirmation of Source of Supply of registered preservative	No	Yes	Yes	No
DACO 0.9.1 - Formulant Material Safety Data Sheet or Confidential Statement of Ingredients	No	Yes	Yes	No
DACO 0.1.6003- Statement of Product Specification Form (SPSF) * Applicable for new chemistry and chemistry amendment submissions	Yes	Yes	Yes	No
Part 1- Label(s)				
DACO 1.1.1 - Proposed English Label	Yes	Yes	Yes	Yes
DACO 1.1.2 - Proposed French Label	Yes	Yes	Yes	Yes
DACO 1.5 - Approved Foreign labels (if applicable)	Yes	Yes	Yes	Yes

EP: end-use product; DACO: data code; ISP: integrated system products; MA: manufacturing concentrate; TGAI: technical grade active ingredient

¹ This requirement will be determined on a case-by-case basis.

Data package component for Category A or B or L review in support of registrations and amendments

Manufacturing use product submission		End-use product submission
Technical grade active ingredient (TGAI)/ ISP Note: Requirements for a technical grade active ingredient products or ISP review are source specific and based on Use-site Category (use-site category number)	Manufacturing Concentrate (MA) Note: Requirements for an MA review are a subset of what is required for an End-use-product review and is formulation specific	End-use product (EP) Note: Requirements for an end-use product is formulation specific and based on Use-site Category (use-site category number)
Data package may include: Part 2 Chemistry Part 4 Toxicology Part 6 Metabolism/ Toxicokinetics Studies	Data package may include: Part 3 Chemistry Part 4 Toxicology (acute studies only)	Data package may include: Part 3 Chemistry Part 4 Toxicology (acute studies only) Part 5 Occupational Exposure Part 6 & 7 Metabolism/ Toxicokinetics Studies &

Manufacturing use product submission		End-use product submission
Part 8 & 9 Environmental Fate and Ecotoxicology		Food Residues Part 8 & 9 Environmental Fate and Ecotoxicology Part 10 Value
<p>Note: If the use pattern includes food contact surfaces or treatment of food/feed crops or their seeds or animals destined for human consumption or animal husbandry, then part 6 and part 7 data components are required and Maximum Residue limits (MRL) may be established for products with uses that fall within the use-site category number:</p> <p>1 - Aquaculture and Aquatic Food sites</p> <p>5 - Greenhouse Food Crops – proposed name change: Food Crops Grown Indoors in Greenhouses or other Enclosed Structures</p> <p>8 - Animals for Food Production – proposed name change: Terrestrial Animals for Food Production</p> <p>10 - Seed and Plant Propagation Materials Food and Feed</p> <p>12 - Stored Food and Feed – proposed name change: Food and Feed Processing and Storage</p> <p>13 - Terrestrial Feed Crops</p> <p>14 - Terrestrial Food Crops</p> <p>15 - Indoor Hard Surfaces – proposed name change: Indoor Hard Surfaces: Antimicrobials (Note: Only for products used in areas where food may be in contact)</p> <p>20 - Structures (Food Handling Establishments)</p>		
<p>Note: If the use pattern is expected to result in minimal environmental exposure, such as strictly indoor use or direct application to humans and companion animals, parts 8 and 9 data components are not required for uses that fall within use-site category number:</p> <p>3 - Empty Food and Feed Storage Structures and Areas</p> <p>12 - Stored Food and Feed – proposed name change: Food and Feed Processing and Storage</p> <p>15 - Indoor Hard Surfaces – proposed name change: Indoor Hard Surfaces: Antimicrobials</p> <p>19 - Other Indoor Surfaces, Water and Air – proposed name change: Other Indoor Surfaces, Water and Air: Antimicrobials</p> <p>24 - Companion Animals</p> <p>26 - Human Skin, Clothing and Proximal Sites</p> <p>28 - Indoor Plants and Landscapes</p> <p>29 - Swimming Pools – proposed name change: Swimming Pools: Algicides and Bactericides</p>		
<p>Note: Certain prescribed pest control products such as Adjuvants, Safeners and Devices require data specific to their use scenario. Please consult with our Pre-submission Consultation section for specific data requirements.</p>		

3.0 The registration process

Is your product subject to regulation?

Whether a product falls under the *Pest Control Products Act* and requires regulation depends on the product's label claims, how the product will be used and its mode of action.

Under the Pest Control Products Regulations, certain products are exempt from registration. If you are unsure whether a product should be regulated under the *Pest Control Products Act*, complete *Form 6301 - Subject to Regulation* and include specific

information about the product such as its full composition, proposed use(s) and mode of action. To request a copy of *Form 6301 – Subject to Registration* contact PMRA Publications. Send product details to: pmra.subject.to.regulation-sujet.a.la.reglementation.arla@hc-sc.gc.ca.

The PMRA will review the information and provide the proper regulatory advice.

3.1 Pre-submission consultation service

A pre-submission consultation is a no-cost service offered by the PMRA. The purpose of this service is to provide prospective applicants with written guidance to help them generate and submit a complete, high-quality application package to register a new pesticide, or to amend the registration of an approved pest control product.

The main objectives of a pre-submission consultation are to determine:

- The appropriate test substances, study protocols and data that may be required.
- Whether the proposed product and technical grade active ingredient(s) are eligible for review under this guidance document or programs; and
- What information is required to support the health, environment and value evaluations.

Pre-submission consultations are mandatory for some submission categories or product types (that is, joint review requests and microbial applications) and recommended for others (such as, Biopesticides). For submission categories in which a pre-submission consultation is neither required nor recommended, applicants may request one if they:

- Are not familiar with the Canadian regulatory system, or
- Need assistance in determining specific information requirements.

See the information page for pre-submission consultations under Registrants and Applicants on the Pesticides portion of the Canada.ca website for the purpose of this free service and the requirements to start. Also see the FAQ page: Pre-submission Consultation - Frequently Asked Questions

3.2 PMRA review process

The PMRA will assess each submission as follows:

1. Completeness Check
2. Science and Data Review
3. Decision
4. Registration

4.0 Assembling and submitting your application

4.1 Completeness Check (Submission verification and screening)

The PMRA performs a completeness check on all submissions to ensure a complete submission has been received before the review stage of the registration process is started.

The Completeness Check generally consists of an initial **submission verification** step and a more detailed **screening** step. The same general process applies to most categories of submissions, although some steps, such as the review stage or the Public Consultation stage are not required for certain categories.

Table 1: Completeness Check process

Action/sub-step	Reason/Response/Outcome	Timeline
Submission verification stage		
Application acknowledgement	<ul style="list-style-type: none"> Applicants are provided a submission number acknowledging receipt of the submission. This number should appear on all subsequent correspondence to the PMRA relating to that submission. 	Automatic receipt email sent by the PMRA as soon as the application is received and verified.
Application verification	<ul style="list-style-type: none"> Performed by the PMRA to ensure non-data elements (covering letter, appropriate application form, Statement of Product Specification Form, Fee Form, fee and the electronic Index Builder) have been provided. 	7-calendar day verification
On-hold email notice (if necessary)	<ul style="list-style-type: none"> If a submission is deficient at the verification step, an email outlining the deficiencies is sent to the applicant notifying them that the submission has been placed "on-hold". 	Applicant is given 14 calendar days to respond.
Second Verification Period (if necessary)	<ul style="list-style-type: none"> If the applicant's response is not adequate then the submission will be rejected. 	Maximum of 7 calendar days will begin and the Completeness Check clock will be reset to day 0.
Submission screening stage		
In-depth review for required elements	<ul style="list-style-type: none"> Review includes data and non-data components, forms and various letters of documentation, as well as for completeness, proper formatting and organization of the electronic Index Builder according to the PMRA DACOs or OECD guidance number. Screen to ensure that submissions meet the PMRA format, quality of data and fee requirements. Officers will communicate minor clarifications and issues with applicants, usually by email for documentation purposes. <p>NOTE: Scientific validity of data and waivers are not assessed at this step.</p>	30-calendar day screening (for most categories).
Clarification Request sent by the PMRA (if necessary)	<ul style="list-style-type: none"> Problem observed during screening. Missing components of the application package. Screening continues while applicant responds. 	Applicant has 10 calendar days to respond.
Notice of Deficiencies sent	<ul style="list-style-type: none"> Adequate response to clarification is not provided within the specified timeframe. 	Applicant must respond within timeframe specified in the Notice

Action/sub-step	Reason/Response/Outcome	Timeline
by the PMRA (if necessary)	<ul style="list-style-type: none"> Notice may also be sent if significant issues are identified during screening. Completeness Check (Submission screening) is halted. 	(usually 45 calendar days).
Applicant responds to Notice of Deficiencies (if necessary)	<ul style="list-style-type: none"> Applicant must provide all the requested information as directed. The Completeness Check clock is reset. The PMRA to confirm acceptability of the applicant's response (and the overall submission package ready for review). 	PMRA has 15 calendar days to respond.
Submission Review stage		
Review by relevant section	<ul style="list-style-type: none"> If the application is deemed acceptable at the Screening stage, the submission is sent to review. <p>The review stage includes the following activities:</p> <ul style="list-style-type: none"> Science evaluation of the pest control product to determine if it meets Pest Control Products Act requirements related to protection of human health, the environment and value. The review of the bilingual product label, and The decision-making process. 	The timeline is variable depending on the Category sub type (Cat A, B, C, D, E, F, L) and is specified in, Management of Submissions Policy.
Notice of Deficiencies sent by the PMRA (if necessary)	<ul style="list-style-type: none"> During the review step, applicants can receive a Notice of Deficiencies. Applicants may also receive a Clarification request via email at this stage. 	Applicant must respond within timeframe specified in the Notice (usually 90 calendar days)"

Non-response or incomplete responses from the applicant

If there is no response to the Notice of Deficiencies or if the response is incomplete or inadequate, the application will be denied in accordance with subsection 7(5) of the *Pest Control Products Act*, unless the applicant withdraws the application. Any submission that has been previously withdrawn by the applicant, or denied by the PMRA during a previous examination, may be re-submitted at a future date. It will be considered a new submission and assigned a new submission number, however, making reference to the previous application in the cover letter is useful and creates efficiencies.

No reminders will be issued to applicants.

4.2 Electronic requirements of a complete submission package

Only complete submissions containing all of the required elements will be considered for review by the PMRA. A submission is generally composed of administrative components and a data package (when applicable). The administrative components and data package are listed as follows:

- Electronic Index (e-Index) Builder (EIB) (see Section 4.2.1)
- Letters (see Section 4.2.2):

- Cover letter stating the purpose of the application
 - Letter of representation - regulatory mail designate
- Forms (see Section 4.2.3):
 - Application for New or Amended Registration (form 6005)
 - Fee estimate form (form 6011)
 - Statement of product specification form (form 6003)
 - Addition or deletion of uses (Proposed New Uses and/or Uses to be Withdrawn from the Label - form 6023)
- Proposed Product Label (see Section 4.2.4)
- Supporting scientific data/information or a letter of access to support the application (see Section 4.2.5)
 - Scientific data
 - Types of data
 - Use-site Categories and DACO tables

For access to the forms, see the Pesticides portion of the Canada.ca website. For more information on the other required elements see Appendix C – Other Elements of Submission.

4.2.1 Electronic Index Builder

Applicants and Registrants must create an e-Index in XML format using the EIB. Applicants need to download the PMRA's **e-Index Builder (EIB)**, a stand-alone Java-based software application which facilitates the creation of an electronic index (in Extensible Mark-up Language XML format) into a PRZ file that contains all the components in the data package.

The EIB fully describes each document submitted in support of applications to register or amend a pest control product registration, re-evaluation, special review, or in response to requests for information. XML is a format that allows for the sharing of information between different computers and different applications with different interfaces and data structures.

The EIB application contains a drop-down list of DACOs. The drop-down list contains DACOs not only for confidential test data but also for other documents that may be required (for example, cover letter, letter of confirmation of source of supply). The application also ensures that there is a confidential business information (CBI) indicator for each document described in the e-Index.

The EIB also provides the ability to submit information in any of the approved data numbering systems. **While PMRA's DACO numbering system is preferred, OECD (IIA) and USEPA (OPPTS) are also accepted.**

After the PRZ file is created, name the file according to the application type or according to the documents being submitted. If a submission number has been assigned to the application, include the number in the PRZ file name.

Examples:

- Application for new product - "Pest-Cure Category A Application.prz"
- Application for product amendment - "PCP.99999 Category B Application.prz"
- Response to PMRA deficiency letter - "1995-0001 Deficiency Response.prz"

Please refer to the *e-Index Builder Documentation* Section for the *e-Index Builder User Guide* and for additional information on the requirements for submitting data index, documents, and forms. To obtain electronic copies of the *e-Index Builder User Guide* or the *e-Index Builder Tutorial*, please contact PMRA. For further questions on using the e-Index Builder refer to the Pest Management Information Service (InfoServ). The central email is pmra.info-arla.sc@hc-sc.gc.ca.

4.2.2 Letters

Requirements for letters are the company letterhead, current date, signature and person with authority to sign for the company.

The package of letters should include:

- A **Cover letter** stating the purpose of the application; and
- A **Letter of representation** that lists the Submission Contact designate. The Submission Contact indicates to where and to whom the PMRA will direct inquiries specific to the application. This role only lasts for the life of the submission and is provided at the time of the submission.
- Letter of Authorization of Access to Data (LOA)
- Letter of Confirmation of Source of Supply (LOC) for a technical grade active ingredient or for a registered preservative.

4.2.3 Forms

The following forms are used in applications:

- Application for New or Amended Registration (form 6005)
- Fee estimate Form (form 6011) – also see Section 8.3 Applicable fees as per the Fees and Charges Regulations of this document.
- Statement of Product Specification Form (form 6003)
- Addition or deletion of uses (Proposed New Uses and /or Uses to be Withdrawn from the Label – form 6023) (for End-use Products only)

Forms are available on the Pesticides portion of the Canada.ca website, Instructions to download or request copies via email are found at the top of the web page.

Statement of Product Specification (form 6003)

- Along with the registration certificate, the product specification form and the labels are part of the product register, whether it is a technical grade active ingredient or the end-use product. The information provided in form 6003 are supported by chemistry batch data analysis as required in the chemistry data package (part 2 and part 3 of the DACO table list of requirements). Please visit the Pesticides portion of the Canada.ca website to review the *Policies, Guidelines and Codes of Practice*.

- Prescribed devices which are regulated (chemical generators, UV devices, Ultrasonics) do not need to have this form in the register.
- Full chemical composition is required for all pest control products including new formulants used in the formulation of a product. For more details refer to *Formulants Policy and Implementation Guidance Document*.
- The form 6003 has the A/F/I feature on the left side of the form page that will highlight the required boxes on the form to be filled out depending on its active ingredient, formulant or impurity information. For a video of the *Pest Management Regulatory Agency Statement of Product Specification Form* see the Government of Canada's Health-related video gallery.

4.2.4 Proposed product label

Separate English and French labels must be submitted with the application. The PMRA will only accept labels in MS Word format (.doc or .docx) within the context of any submission for which a label is required. This includes proposed and corrected labels for new or amended registration applications. This does not apply to any special PMRA requests for Marketplace labels.

The proposed label should clearly identify the uses and claims for the product. The properties of the product (for example sanitizer, herbicide, fungicide, insect repellent, plant growth regulator) must be identified on the label, in addition to the specific use pattern (site/host+pest+rate of application). The label should include appropriate directions for use, including the duration of effectiveness and the methods of application.

Note: Human and animal disease control claims on the label are not permitted as per section 24 of the Pest Control Products Regulations, however, certain public health claims may be allowed. For more details see applicable guidance with respect to the advertising of pest control products available on the Pesticides portion of the Canada.ca website.

It is important to note that label claims and rates must be supported by data. New label claim assessments are based on sound science, and a weight of evidence approach is used in regulatory decisions. Various types of benefit information may be provided, as appropriate, to provide context about the proposed uses. This can include social and economic impacts, survey of alternatives, health, safety or environmental benefits. The objective of the information is to ensure that there is a benefit to the proposed uses, and that the product works as claimed at rates which are effective but not excessive.

A generic Sample Draft Label template is found in Appendix D of this document.

The label review process is directed at applications to register a new product or amend the label of a currently registered product. The following conditions are required by applicants.

1. All label components must be consolidated into one English file and one French file that will make up the bilingual label.
2. A combined SPS and label declaration is included in section 14 of the Application for New or Amended Registration (form 6005).

Labeling references

Principal and Secondary Display Panel requirements for the labels are found in Pest Control Products Regulations (section 22-32): SOR-2006-124.

For information on label requirements, please refer to our Policies and Guidelines page.

Searching existing labels

To see a fully searchable database of registered labels, go to Health Canada's *Consumer Product Safety: Label Search Engine* Search and review examples for creating a product label similar to your own.

Changes to labels

Note: If the label is new, the entire label is reviewed. If the label is amended then it is the responsibility of the registrant to describe any changes made to the label.

All label changes made by either the registrant or the PMRA, to both the English and French label must be annotated in accordance with the standards published in Health Canada's *Label Review – Appendix A: Preparing Amended Labels Using Word*. For further instructions on how to use the Track Changes feature in MS Word to demonstrate amendments to the text label see Health Canada *Memo for Changes to Label Requirements*.²

Label posting

After the review and decision process, if the submission is successful the full label will be posted to the Pesticides portion of the Canada.ca website and will become the current label text of record. The applicant will also receive a MS Word version of the approved label from the PMRA.

4.2.5 Supporting scientific data/information

The supporting information may comprise:

- Scientific data
- Various letters of support or authorization

Please refer to Appendix C – Other Elements of Submission for a list of the elements of a complete submission package.

² Memo for Changes to Label Requirements.

4.2.5.1 Scientific data

Applicants submitting scientific data to support an application to register, amend or conduct research with a pest control product, must consider several factors:

- The type of product (for example, conventional or non-conventional chemical, IMEPs, pheromones, semiochemicals, or microbials);
- Where it will be used (for example, on food crops or on structural sites); and
- The purpose of the submission (for example, research, to register a major new use, or the addition of a new pest to a crop already registered on a product for which the PMRA has previously assessed information on file).

4.2.5.2 Types of data

As a guide for determining data requirements and the submission category, the most common uses have been grouped into a series of use-site categories. For definitions of each Use-site category, refer to Product Application on the Pesticides portion of the Canada.ca website.

4.2.5.3 Use-site categories and DACO tables

Each use-site category has a list of required (R) and conditionally required (CR) studies organized and assigned a numeric data code (DACO) and organized in a table format (DACO Table). Applicants must organize their information (documents) submitted to the PMRA in this order. The DACO table we have in the Pesticides portion of the Canada.ca website is a visual checklist of what the index builder creates electronically. The DACO numbering system allows the organization of submitted documents by review stream (chemistry study, toxicology, exposure, etc.). These DACO tables were developed from existing guidelines and practices and do not establish new data requirements.

DACO tables for conventional technical grade active ingredient and end-use product requirements are posted on the Pesticides portion of the Canada.ca website and divided up by its use-site category.

For other types of products, like microbial agents and non-conventional products, these specialised DACO tables are available from the PMRA upon request via pre-submission.

Category A submissions (New to Canada) require more supporting data and information as outlined in the DACO table to support a regulatory decision. Category B submissions, when precedents exist, the data gaps can be less and therefore less supporting information is needed for the regulatory decision. Non-conventionals will follow a tiered approach to the health and environmental data requirements. Microbial agents have their own unique DACO set of requirements.

For all pest control products, the PMRA will require applicants to provide sufficient information to assess that a product has value and meets standards for protection of human health and the environment. Products that contain ingredients and impurities of concern like mycotoxins, heavy metals, methyl eugenol, etc., can trigger additional data requirements beyond the established standards for each type of product.

The PMRA will use data that is already on file only when there is no data protection and ownership issues. For example, if the applicant is not the owner of the technical grade active ingredient source used in the end-use product formulation product, then a letter of confirmation of source of supply (LOC) from the technical grade active ingredient owner is required and possibly a letter of authorization of Access to Data (LOA) from the associated end-use product owner(s) to obtain data access in support of an application when based on precedent. The e-index builder has a feature that allows applicants to address a required DACO by cross referencing previously reviewed studies.

4.3 Submitting your application

Applicants and registrants must submit PRZ files to the PMRA using one of the following three (3) submission methods:

- e-PRS Secure Web Portal
- Postal mail
- Email

For information on how we manage the different types of submissions refer to the *Management of Submissions Policy (MOSP)*.

4.3.1 Using the e-PRS Secure Web Portal for electronic submissions

The Electronic Pesticide Regulatory System (e-PRS) Secure Web Portal is an Internet portal available through the Pesticides section of the Canada.ca website where applicants and registrants can send a compiled PRZ file quickly and securely to the PMRA. Files must be in an electronic format to be sent as PRZ files via the Secure Web. If any files/documents are not available in electronic format, they must be scanned before submitting them to the PMRA.

The e-PRS Secure Web Portal is the most secure channel. It accepts files up to 250 MB in size, and Applicants / Registrants can specify clearly what is being sent to the PMRA.

If the documents being submitted already have a submission number or are related to a document that has already been assigned a submission number then that number should be included in the online form's Subject Line field.

For more information on submitting an electronic package for registration see Electronic Pesticide Regulatory System (e-PRS) on the Pesticide section of Canada.ca.

4.3.2 Submitting via email

Applicants and registrants can send compiled PRZ files by email to the Submission and Information Management Division.

The Submission and Information Management Division's Central email is designed to accept files in PRZ format from Applicants and Registrants for PMRA applications. The Central email has the advantages of accepting electronic files, allowing fast transmission of documents, however, the following caveats/restrictions must be taken into account:

- The **Central email is not secure**. As such, the PMRA is not responsible for any files lost or intercepted during transmission from the Applicant or Registrant.

- **The total size** of the documents sent via the Central email cannot exceed 5MB. If the sent email is too large, then the PMRA may not receive the documents and an error message will be emailed back to the sender. No further notification of the rejected transmission will be sent from the PMRA.
- **Do not forward** a hard copy or other electronic versions of the document.

4.3.2.1 Composing your email Submission

Subject line – Keywords

Make sure to insert appropriate **keywords** into the subject line as the system uses keyword criteria when accepting emails. If an applicable keyword is not included in the subject line, the system will automatically return the email to the sender. A list of these keywords and when to use them is detailed in this subsection.

Submission numbers

If a submission number has been assigned, list it within the email subject line and the PRZ file. The email can reference only one submission number – multiple submissions **bundled** into a single email will be rejected.

The PMRA sends an automatic email acknowledgement to the applicant upon receipt of any email.

Table 2: Populating the subject line in your email

Purpose of email	Applicable keywords in email subject line
Any	Submission number (if one has been assigned)
New application	[Pest product name] [Application Type].PRZ
Submit corrected labels	Label, labels, étiquette, étiquettes,
Submit corrected SPSF (form 6003)	specification, specifications, sps, spsf, spécification, spécifications, fdsp, dsp
Submit a notification	Notify, notification
Submit a Discontinuation	Discontinuation
Submit an Incident Report	Incident, IR
Submit a new Index or information	PRZ

Body of email



IMPORTANT

Do not include any information in the body of the email as it will not be uploaded into the system. Any information related to the submission or documents should be captured within another document, which should then be indexed and attached to the PRZ. This ensures that the document and its information is automatically loaded into our database, and, as such, will be viewed by the requisite PMRA officers.

In all three methods, if a submission number has already been assigned that is related to the documents being submitted, that number must be included on the CD/DVD if sending by mail, or in the subject line if submitting by email. The Secure Web Portal has a specific field where the number must be entered.

Information submitted by third parties

If information is submitted by a third party, the third party must submit a cover letter indicating the information they submitted. The applicant must list the third-party cover letter in the EIB under Data Numbering Code 0.8.1.

4.4 Decision tree

The PMRA Online Decision Tree is a tool that uses a Q&A triage exercise to help applicants determine which submission category is appropriate for their application. It also provides a basic summary of reference documents for the applicant and a list of forms they need to include in their submission package.

The Registrants and Applicants Online Decision Tree is currently being updated to reflect changes to various interpretive guidance, including *Management of Submissions Policy* and *Notification/Non-notification*. Please visit our Policies and Guidelines page for updated directives and policies.

If the Online Decision Tree is not available online, it can be requested by email: pmra-arla.docs@hc-sc.gc.ca. Included in the email response are two additional tables to complement the Online Decision Tree:

- The PMRA **Submission Categories table**: A comprehensive listing of submission types that provides the minimum set of documents required for each submission.
- The PMRA **Similar Type Products table**: Submission types that are to register "similar products", providing a quick comparison of their differences, their associated costs, timelines, as well as pros/cons.

5.0 Designating confidential business information (CBI)



IMPORTANT

Applicants who wish to designate information submitted in support of their application as confidential business information must ensure the information meets all the criteria as per the content in this section.

The *Pest Control Products Act* ensures that the PMRA is dedicated to a transparent regulatory system. However, certain types of information cannot be released to the public because they contain valuable marketing information and trade secrets. This information is known as confidential business information (CBI). This information which includes descriptions of each document, document title, author(s), and number of pages is inputted using the EIB.

Note: Applicants may designate which information in their submission package is considered CBI, however, the Minister is required to ensure that appropriate information be sent to the register, or be available for public inspection.

For more information on Designation and Segregation of CBI, refer to *Guidance and Requirements for Confidential Business Information* at the Policies and Guidelines page.

5.1 Criteria that CBI must meet

According to s. 43(4) of the *Pest Control Products Act*, information must meet all the following criteria in order to qualify as CBI:

- **Part 1:** Qualify as one of the categories of CBI listed in the *Pest Control Products Act* ss. 43(4) or (5).
- **Part 2:** Be designated as CBI by the person who provided it under the *Pest Control Products Act*.
- **Part 3:** Qualify for an exemption under the *Access to Information Act (ATIA)*.

Part 1: Qualify as one of the categories of CBI as per ss. 43(4) or (5) of the *Pest Control Products Act* as to the:

- Manufacturing or quality control processes relating to a pest control product; or
- Methods for determining the composition of a pest control product; or
- Monetary value of sales of pest control products and other financial or commercial information provided pursuant to the *Pest Control Products Act* or the *Pest Control Products Regulations*; or
- Identity and concentration of the formulants and contaminants in a pest control product, other than those considered to be of health or environmental concern that are identified on a list to be made available to the public.

Part 2: Be designated as CBI by the person who provided it under the *Pest Control Products Act*.

Information has to be designated as CBI by the data owner in order to be considered by the PMRA. This includes information submitted under the new act or referenced under the former *Pest Control Products Act* and applies to information supporting pre-market submissions and post-market reviews.

Clients can designate CBI to their documents using the EIB. For more information see the *e-Index Builder User Guide* and the *e-Index Builder Quick Tutorial*.

Part 3: Qualify for an exemption under the *Access to Information Act (ATIA)*.

The ATIA exemption that covers third party information (s. 20) is the most likely exemption that would apply in the context of the definition of CBI in the *Pest Control Products Act*.

The disclosure of the following information types may be refused under the ATIA s. 20 (1):

- a) **Trade secrets** of a third party;
- b) **Financial, commercial, scientific or technical information** that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the third party;
- c) Information of which the disclosure could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, a third party; or

- d) Information of which the disclosure could reasonably be expected to interfere with contractual or other negotiations of a third party.

Information that serves the public interest as it relates to public health, public safety or protection of the environment may be disclosed. For example, **some** information on the identity and concentration of the formulants and contaminants in a pest control product are identified as health or environmental concern and are made available to the public.

Review process

PMRA CBI officers review CBI claims made by data owners prior to the registration decision. CBI processes have been developed to support *Pest Control Products Act* transparency requirements. CBI designation has to be completed before the final registration decision to allow for the release of information into to reading room.

5.2 Protection of CBI

If the PMRA determines that information designated as CBI does not meet the definition of CBI as defined in the *Pest Control Products Act*, **then it is not CBI**. The PMRA is required by the *Pest Control Products Act* to give written notice to the information provider stating the reasons why the information is not CBI.

6.0 Additional information about submission management

6.1 Pre-market submissions and post market reviews

The PMRA sometimes receives submissions to expand, or change use patterns, or to make substantial amendments to the conditions of registration while a post-market review is underway. Thus, in order to reach consistent and timely regulatory decisions, the PMRA coordinates the review of these pre-market submissions and the science review component of the post-market review. Consequently, the PMRA applies any updated science findings to any subsequent (pre-market and post-market) decisions.

6.2 Concurrent submissions

Separate applications must be made for the technical grade active ingredient and each end-use product, including separate indexes for the technical grade active ingredient and each end-use product along with the required data for each. A submission to register a new technical grade active ingredient (Category A submission) must be accompanied by a submission to register at least one related end-use product.

When more than one applicant is involved in a submission, it is the responsibility of those companies to coordinate the concurrent submission of the technical grade active ingredient and the end-use product application packages to ensure that they are received by the PMRA at the same time.

If submission for the end-use product is supported by a submission for a technical grade active ingredient, the deficiencies for both the technical grade active ingredient and the end-use product must be addressed before either submission can move to the next step in the registration process. All the deficiencies must be addressed in one response from the applicant(s), and any supporting information or data must be submitted together with the response in one consolidated package. It is not acceptable to address

some of the deficiencies in an initial response and then address the remainder at a later date.

Failure to address all the deficiencies adequately will result in the denial of all submissions. The submission number will no longer be valid. After the deficiencies have been addressed, an applicant may resubmit the package, as a new submission.

It is not necessary to resubmit the entire original index when submitting a new index in response to clarifications and Notices of Deficiencies; the modifications and additions will suffice. This ensures that we do not receive duplicate documents.

6.3 Tailgate submissions

A tailgate submission is defined as a submission for a new or existing product for which a current submission is open, past the screening stage and is awaiting a regulatory decision. It is at the discretion of the PMRA to assess each separate tailgate submission.

A tailgate submission cannot be reviewed until the previously submitted application has been accepted or proposed for registration. For example:

- Category B submission for amendment to formulation when Category A decision for same formulation not finalized;
- Application for a new similar product based on an end-use product not yet registered and containing a technical grade active ingredient not yet registered, with no PCP numbers assigned and no certificate issued; or
- Applications for new uses or tertiary amendments awaiting other decisions on current open submissions.

Tailgate submissions delay the processing of the original submission by causing the review to cease and refocus to encompass the amendment. For example:

- Changes in formulations or rates may require review and risk assessment activities in numerous scientific disciplines, such as chemistry, occupational and food exposure, formulants issues;
- Adding new uses or rates would require that parts of the review be redone: efficacy, exposure, environment and residue chemistry and all risk assessments.

Currently, tailgate submissions are identified at the screening stage. After a tailgate submission is identified, the following options are given to the applicant:

- (a) **Withdraw** the tailgate submission and resubmit after the previous submission is approved;
- (b) **Maintain** the tailgate submission but combine it with the previous submission (adopt its category status) and reset the service standards for the precedent submission to start at the time of the tailgate submission; or
- (c) **Screen and delay** by allowing the tailgate submission to receive preliminary screening and delay processing within the PMRA until the original submission is accepted for registration. During the delay status, any changes in scientific approach or new policies will apply to the submission in delay.

6.4 Major new use submissions

A major new use submission is defined as the addition of a new use-site category to the use pattern for a registered active ingredient. An application to amend the technical grade active ingredient source product to add the major new use must be accompanied by an application to register or to amend a related end-use product. The data required to support a major new use for a currently registered technical grade active ingredient and related end-use product(s) are determined according to the DACO table for the appropriate use-site category. For these Category A type submissions, if data previously submitted and reviewed in support of a technical grade active ingredient or end-use product registration can address data requirements for the new addition of a major use, this data must be cross-referenced and cited in the index using appropriate corresponding DACO. Separate indices must always be submitted for the end-use product and technical grade active ingredient product submission.

It is the applicant's responsibility to address all data gaps in the submission review and ensure there is no data protection issues which can be done by including in their index supporting documentation, such as a letter of authorization and access to data (LOA) and or a letter of confirmation of source of supply (LOC) from data owners (other registrants), giving the PMRA permission to access proprietary data to support third party application.

Multiple amendments in one submission for a registered product

More than one amendment to a registered product can be requested in one application within a submission category. For example, an application to amend a product may include changes to the formulation (Category B.2.3 - Identity of formulants and B.2.4 - Proportion of Formulants) and/or changes to the label, such as the addition of a new tank mix with another registered product on a new crop (Category B.3.10 - Tank Mixes and B.3.12 - Addition of Site/Host). The data required to support the application would be indicated in a combined DACO table for a Category B.2.3, 2.4, 3.10, 3.12 submission type, which can be obtained upon request from the PMRA. The data required for a combined DACO table can be requested through the Pest Management Information Service (InfoServ) or the Pre-Submission Consultation services.

7.0 Organizing supporting data

Data requirements vary by submission type. Datasets must be submitted in accordance with the guidance in the: *Guidance for Developing Datasets for Conventional Pest Control Product Applications: Data Codes for Parts 1, 2, 3, 4, 5, 6, 7 and 10*. This document is hereafter referred to as the **Datasets Guidance**.

Supporting data are organized into eight science review parts, as outlined in the following sub-sections, and **must be addressed separately**.

Certain DACO requirements are product chemistry specific (technical grade active ingredient vs. end-use product) information and require testing results be obtained specifically using the product's formulation. Other DACOs are specific to address concerns regarding the use pattern and are label use specific. It can be possible that data supporting a technical grade active ingredient application be used to support the end-use product application. Applicants must always ensure that they provide appropriate bridging rationales when referencing other product data.

7.1 Addressing DACO requirements

A DACO is either required (R) or conditionally required (CR) in the table depending on the purpose of the submission and the site or location of use of the product. For all submissions, all data requirements identified as R in the DACO table, for a particular use-site category and product type, must be addressed with appropriate studies or information.

Each data requirement (DACO) can be met via:

- **Good Laboratory Practice studies**
- **Cross references to previously submitted data** (Applicant-owned)
 - Cross references must be done through the e-Index Builder and you must reference specific PMRA document ID numbers in order for the studies to be identified in the existing database
- **Bridging data and rationales**
- **Published literature**
 - Referenced literature must be submitted and organized according to the appropriate DACO.
- **Scientifically valid request for data waiver**
 - When required data or studies are not submitted, the applicant must submit a request for a waiver of the requirement. Requests for waivers must be recorded in the index and supported by surrogate data: studies performed with a product other than the one indicated in the application for technical grade active ingredient, raw material or end-use product as indicated in the DACO table, or a scientific rationale (with references), in place of the data or studies. Each request for waiver must be submitted under the applicable DACO. The request should include the elements indicated below. A statement should also be included in the Comments field of the index to indicate that the item is a request for waiver.
 - The following elements should be included in a data waiver request:
 - DACO number
 - Author(s)
 - Date of the waiver request
 - Brief description of the product
 - Explanation detailing why the study is not necessary
 - Description of relevant scientific literature which supports the explanation
 - Conclusions
 - References

If foreign reviews, such as USEPA Data Evaluation Reports (DER), are available, they should be submitted with the application.

Cross-referencing practices in support of multiple DACOs

When a study or information is used to address more than one DACO within a specific data part, the information need only be submitted once and reference all relevant DACOs that the information addresses (for example: one lab study could address all DACOs for **Toxicology Acutes** DACO 4.6.1–4.6.6). That said, when information is used to support a DACO requirement in more than one data part, the information for each data part must be submitted in its entirety. This is because more than one evaluation directorate will need to do a separate review. (For example, if one study addresses DACOs in part 2 - **Product Chemistry** but also addresses certain DACOs in part 8 -

Environmental Chemistry and Fate, then the study should be submitted twice; once with the Part 2 DACOs identified and then again with the Part 8 DACOs identified.

Data submitted for one submission can be cited and cross-referenced to address the data requirements for another submission provided that the data is appropriate for, and applies to, the second submission. Refer to Section 4.2.1 Electronic Index Builder for further details on using EIB to cross-reference documents. Cross-referencing data in a tailgate submission scenario would not be accepted. See Section 6.3 Tailgate submissions for details on what is considered a tailgate submission.

Referencing literature to address data requirements

When literature such as a **published journal article** is used as supporting data, it must be **fully referenced** in the index. The Comments field in the EIB should be used for a citation that states the name of the journal, volume number and page numbers.

7.2 Presenting data in a template format

Templates should be used to present the scientific studies that are submitted to support applications to register pest control products. These evaluation templates capture specific data components and record the reviewers' conclusions and rationales that are based on each data set. Evaluation templates have been developed using the DACO tables that identify the required (R) and conditionally required (CR) studies for particular use-site categories.

The PMRA encourages study directors to use templates during the preparation of the studies and the creation of their study reports. The level of detail, however, should be the same as would normally be included in a study report. Their early use provides significant benefits to PMRA evaluators and industry, and results in consistency of content and format that facilitates the evaluation process.

Templates should be organized into two major categories covering chemical and microbial pesticides. To obtain an electronic copy of the ZIP file for Chemical Evaluation Templates or Microbial Evaluation Templates, please contact pmra.publications-arla@hc-sc.gc.ca.

Please refer to the Evaluation Templates on the Pesticides portion of the Canada.ca website, under Product Application.

7.3 Data parts

Part 0 (Index) and Part 1 (Label) are not covered in this section. For more information on labels refer to Section 4.2.3 Proposed product label. Data Parts 8 and 9 are not included in the *Datasets Guidance*. Parts 8 and 9 are found in the proposal document PRO2016-01.

Chemistry evaluation

Part 2, Product Chemistry: Technical Grade of Active Ingredient or Integrated System Product

and/or

Part 3, Product Chemistry: End-use Product or Manufacturing Concentrate

Product chemistry information is developed and submitted for review in order to meet two objectives:

- (i) to identify and quantify the active ingredient(s) for purposes of the pest control product's certified limits; and
- (ii) to fully characterize the product composition, including active ingredient(s), formulants and impurities, in order to:
 - a) determine the uniqueness of each source of product with respect to purity and potency; and
 - b) assess the safety to humans and the environment in relation to the proposed use of the product.

The chemistry requirements have been harmonized with those of the United States Environmental Protection Agency (USEPA) as described in the Code of Federal Regulations (CFR), 40 CFR § 158, and the Product Properties Test Guidelines 830 Series.

Data must be organized according to the DACOs outlined in the *Datasets Guidance*.

Health Canada's Guidance document, *Good Laboratory Practice*, should also be consulted for the PMRA's regulatory position on implementing good laboratory practice requirements.

Storage stability data requirements

Please refer to the appropriate memo at the following address to determine PMRA's data requirements for end-use products and manufacturing concentrates as they pertain to DACO 3.5.10 *Storage Stability Data*. Refer to Memoranda to Registrants, Applicants and their Representatives on the Pesticides section of the Canada.ca website.

Full Chemical composition is required for pest control products in Canada which includes the chemistry of all formulants used in a formulated product. For more information see the *Formulants Policy and Implementation Guidance Document*. This document outlines PMRA's policy on the regulation of formulants found in pest control products and ensures that only acceptable formulants which meet certain standards will be approved for use.

Health evaluation

Part 4, Toxicology: Technical grade active ingredient or End-use product

The PMRA is responsible for the assessment of potential health risks from pesticide residues in food as well as from occupational and residential exposure to pest control products. This activity is carried out under the authority of both the *Pest Control Products Act* and

Food and Drugs Act and their respective Regulations. The PMRA requires applicants and registrants to be responsible for demonstrating the safety of any pest control product and produce data for the evaluation of hazards and risks. The Canadian toxicology data requirements are similar to those in other countries within the OECD and are harmonized with USEPA requirements to a high degree.

Data must be organized according to the *Datasets Guidance* Part 4. Also refer to the guidance document *Guidelines for Developing a Toxicological Database for Chemical Pest Control Products*.

For information on toxicological studies refer to memorandum T-1-245, *Guidelines for Developing a Pesticide Toxicology Data Base*.

For preparing a toxicological database for microbials or pheromones and other semiochemical pest control products, please refer to the applicable guidance on research found in Policies and Guidelines on the Pesticides section of the Canada.ca website.

Part 5, Exposure (occupational and/or bystander): End-use product

Data must be organized according to the DACOs outlined in Part 5 and submitted with the end-use product package only. Part 5 is only required for end-use products.

Use description/scenario (application and postapplication)

Part 5 stores information that fully describes the use of the product and human activity associated with its use. Qualitative information that will help characterize exposure should be included here and can be divided into mixer/loader/applicator and postapplication categories. The sources of the information should be cited (for example, label, surveys, custom applicators, industry experts, and associations). Where relevant, specific information should be provided for different product users (such as, commercial/professional users vs. domestic users). All numerical values should be reported as fully as possible (for example, min, max, mean). The applicant is also expected to address the potential for exposure to bystanders, particularly those in nearby residential areas. This information relates to the anticipated human exposure during an application and postapplication scenario. The information will help determine appropriate mitigation measures and precautionary statements for the product label including appropriate Personal Protective Equipment or re-entry times for the safe use of a pest control product.

More details for applicants to confirm their product use description / scenario can be found in Appendix III of the *Datasets Guidance*. For specific study requirements see Part 5 of the *Datasets Guidance*.

Part 6, Metabolism or toxicokinetics studies: Technical grade active ingredient or end-use product and Part 7 Food, feed residue studies: End-use product

Food/Feed contact and Crop Uses include use-site categories 1, 5, 8, 10, 12, 13, 14, 15, and 20 where establishing Maximum Residue Levels (MRL) may be needed (including imported commodities). Data studies in DACO Part 6 can be performed either using the technical grade active ingredient source or the end-use product formulation, as

appropriate. Requirements may include metabolism information on livestock and or plants treated by a pesticide and produced for human consumption.

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

Data must be organized according to the DACOs outlined in Part 7 and submitted with the end-use product package. This may include Analytical Methodology data for plant and/or Animal Commodities as well as Crop Residues data for food and feed commodities.

Refer to the PMRA's Guidance document, *Residue Chemistry Guidelines*, for details. To obtain a copy, contact our publication office.

For the latest updates on our Revisions to the residue chemistry crop groups refer to the Policies and Guidelines on the Pesticides section of the Canada.ca website.

- Revisions to the *Residue Chemistry Crop Field Trial Requirements* (section 9 of is revised).
- Revision to *Residue Chemistry Crop Groups* (section 15 of DIR98-02 is revised).
- Update on the *Status of the Revisions to the Residue Chemistry Crop Groups* from 2010 and 2011.

For Residue Chemistry Crop Group Information and the software spreadsheet see the Residue Chemistry Crop Groups on the Pesticides section of the Canada.ca website.

Environmental assessment

Part 8, Environmental chemistry and fate: Technical grade active ingredient or end-use product and Part 9, Environmental toxicology: Technical grade active ingredient and end-use product

Environmental data submitted to the PMRA provides essential insight into the potential impact of a pesticide on the environment and are the foundation of the environmental risk assessment. The information required to assess potential risks to non-target aquatic and terrestrial organisms (vertebrates, invertebrates and plants) will primarily depend on the proposed use, which usually determines in which environmental media (soil, water, sediment, air) non-target organisms could be exposed. The applicant must provide information to show the product does not negatively impact non-target aquatic or terrestrial organisms. For concerns pertaining to the fate, the applicant must submit information indicating the level of persistence in the environment and the potential for mobility (if applicable, based on the proposed use pattern). The applicant may also need to characterize the chronic/subchronic toxicity to non-target organisms. The information provided allows the PMRA to determine any appropriate precautionary statements or risk mitigation measures for the product label necessary to support a favourable regulatory decision.

For non-conventional submissions, the PMRA reviews the environmental risk in a tiered approach with a subset DACO list of requirements. The need for higher-tier information will be determined based on the results from lower-tier information and the proposed use pattern. Higher-tiered information will be required if the potential for adverse effects is observed in the lower-tier information. Microbial agents will have their own specific environmental DACO list of requirements to be addressed.

For more information see Health Canada's *Revised Environmental Data Requirements*.

Data must be organized according to the DACO's outlined in Part 8. For information on environmental chemistry and fate studies refer to Memorandum T-1-255, *Guidelines for Determining Environmental Chemistry and Fate of Pesticides*.

Data must be organized according to the DACOs outlined in Part 9. In general, acceptable studies are conducted according to scientifically supportable protocols and using relevant, established guidelines such as the USEPA or the OECD guidelines. Applicants may submit new study protocols for review and comment prior to conducting a study via our Pre-submission Consultation service.

Value assessment

Part 10, Value: End-use product

Data must be organized according to the DACOs outlined in Part 10 of the *Datasets Guidance* and submitted with the end-use product package. As per the *Datasets Guidance*, the applicant is expected to submit "A report that summarizes the value information provided to support an application. The report should follow the PMRA value review template."

As the data requirements for a value review are based on the proposed label claims. The directions for use should be clear and relevant, and the claims scientifically supported. The directions for use should contain all the necessary information for the proper use of the pesticide, including the site, method, rate and frequency of application relating to each proposed use. A pesticide use is generally defined by site/pest/rate combination. The objective of the value information is to ensure that there is a benefit to the proposed uses, and that the product works as claimed, at rates that are effective but not excessive. Different types of information may be used to address product efficacy and value. These include use history information, published papers, scientific rationales, and/or trial data. Applicants need to demonstrate the level of performance and that the proposed product has value as a pest management tool. Products that are not effective enough to support a standard use claim, may have a lower acceptable level claim such as "reduces damage, reduces annoyance, reduces inoculum, reduces populations, suppresses symptoms or may inhibit".

The following guidance documents may be useful in preparing a value package:

- Guidance Document Value Assessment of Pest Control Products
- Guidance Document Efficacy Guidelines for Plant Protection Products

Refer to Policies and Guidelines on the Pesticides section of the Canada.ca website for product specific label and value data requirements pertaining to specific types of pest control products such as antimicrobials and treated articles, spot-on pesticides used on companion animals and personal insect repellents. These are as examples of PCPs that

may have special regulatory requirements beyond the standard agricultural products. The label information is what defines the use pattern (which use-site category) it falls under. Value assessment determines if the use pattern (site/pest/rate scenario) is efficacious and is considered an important factor in regulatory decisions pertaining to label claims.

Part 12, Comprehensive data summaries (CDS): DACO 12.7

Applications for registration of Category A submissions, normally could upon recommendation include a CDS prepared according to the Tier II and III models in the *OECD Guidelines and criteria for industry for the preparation and presentation of complete dossiers and of summary dossiers for plant protection products and their active substances in support of regulatory decisions in OECD countries*. This document is available at the OECD website.

Summaries will provide reviewers with a comprehensive summary of the characteristics, potential risks and value associated with the proposed product. The summary should be in such detail that it is apparent that the applicant has performed a thorough evaluation of each study and reported the evaluation in full detail. For major new uses, the CDS should only incorporate studies submitted in support of the application.

Comprehensive Data Summaries should be submitted in the e-index under DACO 12.7.

The DACO 12.7 - Comprehensive Data Summaries (Applicant Generated Study Reviews) can be submitted in Canada either as one comprehensive document or divided into multiple document parts as per OECD guidance. For Canada-only applications, the CUSMA study profile templates are requested, however, OECD format is also accepted.

The list of CUSMA/USEPA study profile templates used for Products can also be found and uploaded directly from the USEPA website for *Pesticide Registration Study Profile Templates*. CUSMA/USEPA study profile templates can be ordered through publications on the Pesticides portion of the Canada.ca website via zip file for either conventional chemical or microbial agents. See the Evaluation Templates on the Pesticides section of the Canada.ca website.

Foreign reviews

Foreign regulatory reviews and decision are considered supplemental information. Publications from other jurisdictions such as USEPA or agencies in the EU can be submitted for review and consideration under DACO 12.5 in the index.

8.0 Cost recovery information

8.1 Overview of cost recovery

Fees are updated with the publication of the Pest Control Products Fees and Charges Regulations.

Frequently asked questions regarding fees are discussed in the Pesticide Cost Recovery (FAQs) on the Pesticides portion of the Canada.ca website.

In our Cost Recovery web page, you will find additional information including a Guidance Document for understanding and calculating your applicable fees.

The purpose of these Regulations is to prescribe user fees for the right and privilege to manufacture or sell pest control products in Canada. Fees cover the services provided by the PMRA for the examination of applications for registration of pest control products submitted by applicants, and for establishing pesticide maximum residue limits.

8.2 Pest Control Products Fees and Charges Regulations

The Fees and Charges Regulations provides important information in regards to the fees payable for the examination of applications for pest control products. The section headers point to the important information found in this guidance document:

- 1.0 – Purpose and General Information Contacts
- 2.0 – Fee Exemptions
- 3.0 – Types of Application Fees
- 4.0 – Fee Estimate Form
- 5.0 – Application for Reduced Application Fees
- 6.0 – Payment of Application Fees
- 7.0 – Annual Charge for all Registered Pest Control Products
- 8.0 – Interest and Administrative Charges
- 9.0 – Methods of Payment
- 10.0 – Refunds
- 11.0 – Complaint Mechanism and Appeals Procedure

For more details see Healthy Canada's New Process for Fee Payments - Canada.ca.

8.3 Applicable fees as per the Fees and Charges Regulations

Applicants must assess their potential fees for the review services they are requesting from the PMRA based on Category type of review A, B, C, D, E, F or L (described in Section 2 of this document) and also by the product type described in the Schedules 1, 2 or 3 of the Fees and Charges Regulations and summarized in this section of this document. Other submissions to register or amend a PCP that are excluded from the schedules may fall instead within the description for applicable fees outlined in section 3, 4 or 5 of the Fees and Charges Regulations described below.

The **Fee Estimate Form (form 6011)** is divided into Tables (Part A, B, C, D) to reflect the applicable fees outlined in the Schedules 1,2,3 and in the Sections 3,4,5 found in the Fees and Charges Regulations. Copies of the form can be ordered via email from our publication services on the Pesticides portion of the Canada.ca website. Simply follow instructions at the top of the webpage.

8.3.1 Schedule 1 Applicable fees

This section refers to **Part A** of the *Fee Estimate form*.

Box A	PART A SCHEDULE 1 FEES FOR APPLICATIONS TO REGISTER, OR TO AMEND THE REGISTRATION OF, A PEST CONTROL PRODUCT OTHER THAN A SEMIOCHEMICAL OR MICROBIAL AGENT
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Schedule 1 fees are for the applications to register or amend the registration of a PCP that is conventional or meets the criteria for a non-conventional (including prescribed devices) and requires a Category A, B or L science component review. However, Schedule 1 fees do not include semiochemicals and microbial agents:

- Table Part A shows the fee value for each science data component review.
- Based on the data requirements to register or amend, listed in the DACO tables, applicants may need to add the sum total of a chemistry, toxicology, exposure, metabolism, residue, environmental fate, environmental toxicology, value and effectiveness review.
- The identification of compensable data applicable fee is only required for Category L submission reviews.
- The **processing fee** as per subsection 3 of the Fees and Charges Regulations is required for all Category A, B, C and L submission types. However, for Category C non data component reviews, use Table D on the fee estimate form 6011 instead.
- Applicants submitting a Category A or B submission to register a **new PCP** as per Schedule 1 applicable fees, and that meet the criteria for **Fee Reduction** as outlined in the *Guidance Document: Pest Control Products Fees and Charges Regulations (Section 5.0)* can choose to complete Box Part E Application for Reduction of Fees, on the fee estimate form. They must then provide the necessary supporting information to the PMRA for consideration. Fee reductions are only considered for **new pest control products**.

Applicants submitting a Category A or B submission to **register or amend** a PCP as per Schedule 1 applicable fees, and that meet the criteria for **Fee Exemptions** as outlined in the Section 2.0 of the *Guidance Document: Pest Control Products Fees and Charges Regulations*, are only required to pay the **processing fee** as found in Part A of the fee estimate form 6011, after the fee exemption is approved

The amount of effort required to review an average science package of supporting information is also factored in. Therefore, the same applicable fee is charged for a data component (for example, chemistry, toxicology, value) regardless of the amount of information submitted by the applicant (for example, number of studies or pages or waivers) in that package. A waiver or scientific rationale will also be subject to applicable fees as the PMRA must still determine its acceptability for substituting actual studies. A waiver can consist of a scientific rationale with supporting documentation (for example, literature search, surrogate data), all of which requires an assessment.

The applicable fees to review data parts will be less in a category B application review when previous assessments can be used in support of a new registration or amendment.

If the total assessed fees are less than \$2500, payment for the full amount must be payable on receipt of the invoice. If the total assessed exceeds \$2500, a payment installment schedule of 35% is required at the Completeness Check and 65% at the

review period in the process. Late payments may accrue interest charges or result in applications not being processed.

Refer to the PMRA Guidance Document, *Pest Control Products Fees and Charges Regulations* for additional fee information on the following:

- **Applying for Fee Exemption** (Section 5.0)
- **Annual Charges** (Section 7.0)
- **Interest and Administrative Charges** (Section 8.0)
- **Method of Payment** (Section 9.0)
- **Refunds** (Section 10.0)
- **Complaint and Appeals** (Section 11.0)

Invoices are sent to applicants via email. After invoice is sent to the applicant, the submission coordinator will move the submission in the queue for review. For payment information, questions regarding your invoice and your account balance, please contact the PMRA account receivables unit at: 613-736-3530, toll free 1-800-267-6315 or email pmra.receivable-receivable.arla@hc-sc.gc.ca.

PMRA Data Codes (DACO) exempted from applicable fees:

DACO **5.2** – Use Description/Scenario (Application and Post Application)

DACO **8.2.1** – Summary of Physicochemical Properties

DACO **8.2.3.2** – Hydrolysis

DACO **8.4** – Storage, Disposal and Decontamination

DACO **8.4.1** – Summary

For example, if DACO 5.2 is the only document submitted for part 5, then fees will not be charged for exposure data review.

Withdrawn and denied applications

Application fees may be subject to refund if the application is withdrawn or denied before it is accepted for evaluation. The amount of the fee refunded will be based on the fees payable at the stage of the application process where the submission has reached when it is withdrawn or denied.

8.3.2 Schedule 2 Applicable fees in Fees and Charges Regulations

This section refers to Part **B** of the *Fee Estimate form*.

Box A	PART B*
SCHEDULE 2 FEES FOR APPLICATIONS IN RESPECT OF A PEST CONTROL PRODUCT THAT IS A SEMIOCHEMICAL OR MICROBIAL AGENT	
(do not complete Part B if you have already completed Part A, C or D)	

Schedule 2 Fees are for the applications to register or amend the registration of a Pest Control Product that is a **semiochemical or a microbial agent** and are found in Table Part B of the fee estimate form 6011. The fees can vary depending on:

- Straight-chain lepidopteran pheromones are separate from other semiochemical types and microbial agents

- New active ingredient registration on food use versus non-food use (Category A.1.1 review)
- Amendment of a registration where new risk assessment is needed for Human Exposure and Environment (Category A.2.0 review)
- Amendment of registration where data and or label changes are needed (Category B review)

8.3.3 Schedule 3 Applicable Fees in Fees and Charges Regulations

This section refers to Part **C** of the *Fee Estimate form*.

Box A	Part C* SCHEDULE 3 FEES FOR OTHER APPLICATIONS IN RESPECT OF A PEST CONTROL PRODUCT (do not complete Part C if you have already completed Part A, B or D)
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Schedule 3 are Fees for Other Applications in Respect of a Pest Control Product such as:

- Research authorization,
- Research notification,
- Registration or Amendments of active ingredients manufactured only for export (IMEP),
- Specification of maximum residue limit for a previously unexamined PCP or an unregistered use of a previously examined pest control product (MRL).

8.3.4 Other types of application fees

This refers to Applicable Fees for the Examination of a Pest Control Product Application that is **not** mentioned in the Schedules of the Fees and Charges Regulations and does not require a scientific data component review. These are additional fees found in sections within the Fees and Charges Regulations.

This section refers to **Part D** of the *Fee Estimate form*.

Box A	Part D* OTHER FEES
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Part D of the Fee Estimate form includes:

- Fee as per section 3 of the Fees and Charges Regulations applies to Category C, Master Copy and Private Label reviews
- Fee as per section 4 of the Fees and Charges Regulations applies to Category F notifications
- Fee as per section 5 of the Fees and Charges Regulations applies to Category D renewals

9.0 Register of Pest Control Products

The *Pest Control Products Act* requires that a register of Pest Control Products be established. The Register of Pest Control Products (Register) is:

- A body of pest control product information to which the rules of access of the *Pest Control Products Act* apply. The information that the Register must contain is prescribed in accordance with subsection 42 of the *Pest Control Products Act*

and the Pest Control Products Regulations. *The Pest Control Products Act* specifies:

- i) what information about pest control products is to be placed in the Register,
 - ii) at what time the information is to be placed in the Register, and
 - iii) how access to the information is to be granted to the public. (See subsection 42(2) of the *Pest Control Products Act*).
- The test data supporting the registration decision are placed in the Register following the registration decision. After test data are placed in the Register, they are to be made accessible for public inspection under controlled conditions.

Appendix A – Glossary of acronyms and terms

A1 – Acronyms

ATIA	Access to Information Act
CBI	Confidential Business Information
CDS	Comprehensive Data Summary
CR	conditionally required / conditionally required data
DACO	data code
DER	Data Evaluation Record
EIB	E-index Builder
IGR	insect growth regulator
IMEP	Import for Manufacturing and Export Program
ISP	integrated system product
LOA	Letter of Access to Data or Letter of Authorization for representation
LOC	Letter of Confirmation of Source of Supply of Active Ingredient
MA	manufacturing concentrate
MOSP	Management of a Submissions Policy
MSDS	Material Safety Data Sheet
OECD	Organisation for Economic Co-operation and Development
OPPTS	Office of Prevention, Pesticides and Toxic Substances (USEPA)
OUI	Own use import
PCP	Pest Control Product
PDF	portable document format
PHED	Pesticide Handlers Exposure Database
PHI	Preharvest Interval
PMRA	Pest Management Regulatory Agency
PIIP	Protection of Proprietary Interests in Pesticide Data in Canada
R	required / required data
SPSF	Statement of Product Specification Form
URMULE	user requested minor use label expansion
URMUR	user requested minor use registration
USEPA	United States Environmental Protection Agency

A2 – Terms

The following terms are all derived from the *Pest Control Products Act*.

Confidential business information (CBI) is information that:

- Is designated as CBI by the information provider; and
- Concerns information related to the following:
 - Manufacturing or quality control processes relating to a pest control

- product; or
- Methods for determining the composition of a pest control product; or
- The monetary value of sales of pest control products and other financial or
- Commercial information provided pursuant to the *Pest Control Products Act 2002* or the *Pest Control Products Regulations*; or
- The identity and concentration of the formulants and contaminants in a pest
- Control product, other than those considered to be of health; or
- Environmental concern that are identified on a list to be made available to the public.
- Access to may be refused under *the Access to Information Act* and that meets the requirements of subsection 43(4) or (5).
- Means a component of a pest control product to which the intended effects of the product are attributed and includes a synergist but does not include a solvent, diluent, emulsifier or other component that is not primarily.

Label includes any written, printed or graphic matter

(a) that is or is to be applied or attached to or included in, or that accompanies or is to accompany, a pest control product or a package; or

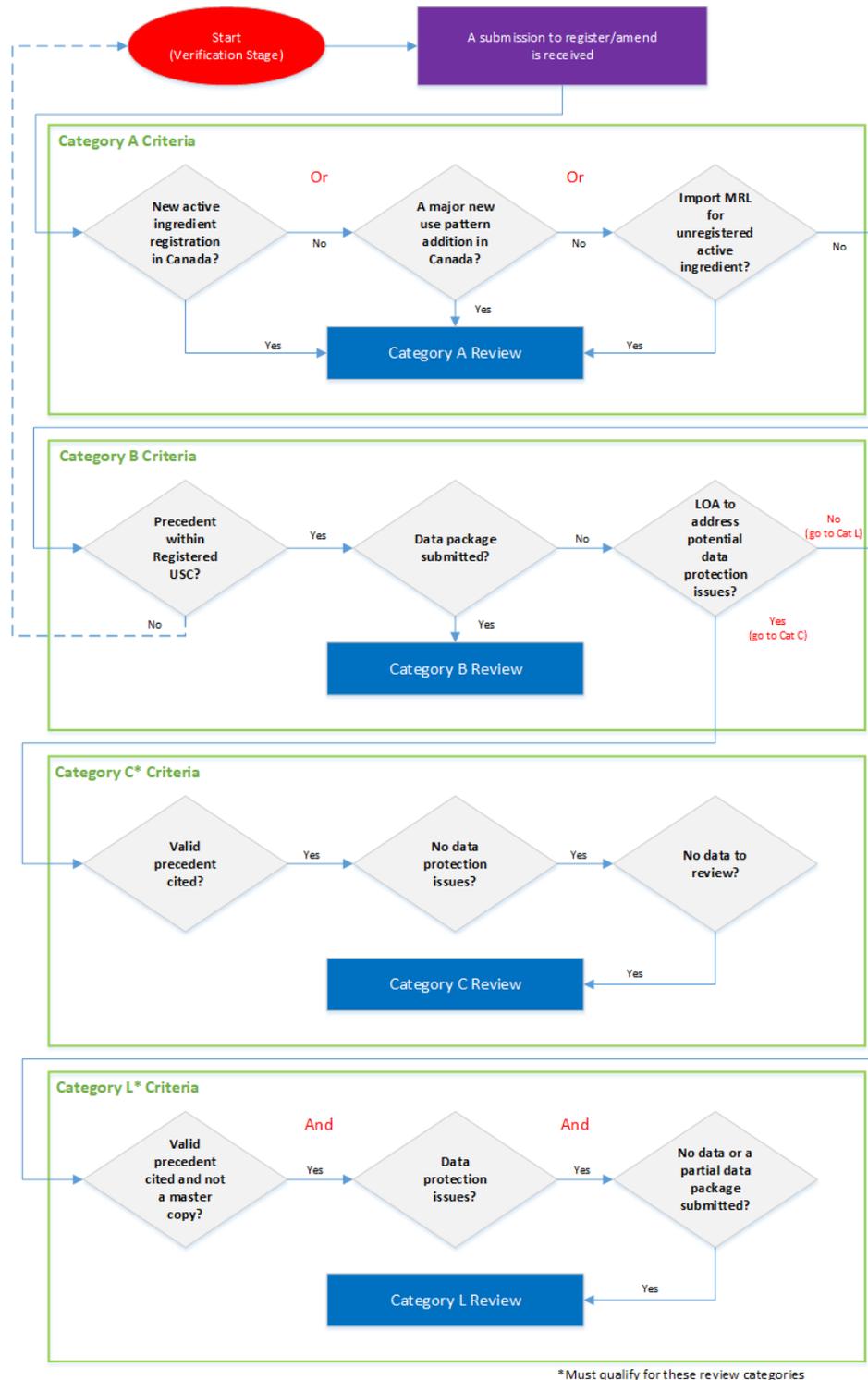
(b) that belongs to a pest control product and is transmitted electronically, in accordance with the regulations.

Test data, as defined by the *Pest Control Products Act*, are:

- Scientific or technical information respecting the health or environmental risks, or
- The value of a pest control product.

Value, in respect of a pest control product, means the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact.

Appendix B – Submission category triage



Appendix C – Other Elements of Submission

Formulant Confidential Statement of Ingredients (CSI): Only required if using a new formulant not currently used in any Canadian pest control product. The information is kept confidential and is only used to update our Formulant database. Full chemical disclosure is now required for all pest control products registered in Canada. A Material Safety Data Sheet (MSDS) and a Confidential Statement of Ingredients (CSI), which includes the chemical names, Chemical Abstract Services (CAS) number and percentage composition for each formulant and their components listed is required. Each formulant, whether food grade or mixtures, should describe 100% composition on the MSDS otherwise a CSI is required from the supplier to confirm its composition as per Guidance document Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products. See Sections 5.1 and 5.2 of the Formulant Policy Guidance document in the Policies and Guidelines on the Pesticides section of the Canada.ca website.

Note: It is understood that a pesticide formulator or registrant is not necessarily privy to this proprietary information. This information may be submitted directly by the supplier or manufacture to the PMRA. The information will be held in confidence by the PMRA and will be used by the screening and reviewing sections when assessing pesticide submissions. If the formulant information is submitted by the supplier they must reference the submission number on their response and send it to the attention of the administrative coordinator for the open submission.

Table 3. Example of CSI Required Information

Chemical Name/Trade Name ¹	Chemical Abstract Service (CAS) number	%w/w (totaling 100%)	Purpose (component or impurity)

¹ Please note that if there are trade names within the formulant mixture that are not currently on the PMRA List of Formulants, an MSDS and CSI may be required for those mixtures as well.

Letter(s) of Confirmation of Source of Supply (LOC):

The purpose of an LOC is to substantiate that registered pest control products are being used to provide the active ingredient(s) in the manufacture of formulated products. This also pertains to instances where a registered product is used as a preservative in the formulation of another pest control product. Required if making an application to register a new end-use product or MA formulated product.

Exceptions: An LOC is not required for submissions in which the registrant for the source of active ingredient and the applicant for the subject product are the same.

The PMRA can request new updated copies of LOC in situations where the information in the letter on file is considered outdated or the letter is older than five years as well as when regulatory changes require new updates.

TEMPLATES

[COMPANY LETTERHEAD]

[Date]

[Chief Registrar/PMRA Officer]

Pest Management Regulatory Agency
2720 Riverside Drive
Ottawa, ON K1A 0K9

Subject: Letter of Confirmation of Source of Supply (*PMRA submission number*)

This is to certify that **[supplier name, address and contact information]** supplies **[receiver, address and contact information]** with the following for the manufacture of products registered under the *Pest Control Products Act*.

Product Name	Active Ingredient	Registration Number
ABCD Manufacturing Concentrate	Pyrethrins	87645

Yours truly,

[Registrant signature]

[Printed signatory name and contact information]

Letter(s) of access to data (LOA):

Required if applicant needs to rely on data previously submitted by another registrant to support their submission for registration or amendment.

TEMPLATE

[COMPANY LETTERHEAD]

Date

Chief Registrar
Pest Management Regulatory Agency
2720 Riverside Drive
Ottawa, ON K1A 0K9

Subject: Letter of access to [NAME OF APPLICANT]

This is to inform you that [NAME OF REGISTRANT] is granting to [NAME OF APPLICANT] the right to rely on [NAME OF REGISTRANT]'s protected data in (specify the access to: DACO, Data parts, Submission No., Product Reg. No.)

Yours truly,

[Registrant's signature]

[Printed signatory name and contact information]

Letter(s) of authorization of representation:

Letter authorizing the PMRA to discuss information in a submission with third parties (designated agent, formulator, distributor, consultant, etc.)

TEMPLATE

[COMPANY LETTERHEAD]

Date

Chief Registrar
Pest Management Regulatory Agency
2720 Riverside Drive
Ottawa, ON K1A 0K9

Subject: Letter of authorization of representation to [NAME OF APPLICANT]

This is to inform you that [NAME OF REGISTRANT] is granting authorization to [NAME OF REPRESENTATIVE] for submission number, product number or product name to communicate with the PMRA for clarifications and deficiencies on our behalf.

Yours truly,

[Registrant's signature]

[Printed signatory name and contact information]

Appendix D – Generic Label Templates

TEMPLATE LABEL

PRINCIPAL PANEL

NAME: PEST AWAY

PRODUCT FORMULATION TYPE: Liquid Herbicide

CLASS DESIGNATION: (E.G., DOMESTIC, COMMERCIAL, RESTRICTED, MANUFACTURING)

READ THE LABEL BEFORE USING

{KEEP OUT OF REACH OF CHILDREN and
PREVENT ACCESS BY UNAUTHORIZED PERSONNEL}

ACTIVE INGREDIENT: *active ingredient* X% or g/L

REGISTRATION NO: XXXXX PEST CONTROL PRODUCTS ACT

Precautionary symbols and signal words (if appropriate)

NET CONTENTS: (e.g. 1-1000 L)

[REGISTRANT COMPANY NAME]

and

Canadian contact information for public enquiry

Postal Address and Telephone Number

SECONDARY PANEL

NOTICE TO USER: This pest control product is to be used only in accordance with the directions on the label. It is an offence under the *Pest Control Products Act* to use this product in a way that is inconsistent with the directions on the label.

FIRST AID: standard wording is found in Regulatory Directive: First Aid Labelling Statements DIR2007-01

TOXICOLOGICAL INFORMATION

PRECAUTIONS

ENVIRONMENTAL PRECAUTIONS

DIRECTIONS FOR USE (e.g., host/site+ pest+ rate+ method of application+ timing and frequency etc.)

STORAGE

DISPOSAL