

Pest
Management
Regulatory
Agency

Guidance for the Registration of Non-Conventional Pest Control Products

PMRA Guidance Document



*Protecting human health
and the environment*

*Protéger la santé humaine
et l'environnement*



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Updated	Update/Rationale:
March 2023	Revised to replace DIR2012-01 as part of PMRA document renewal program.
Feb 2012	Issuance of original.

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.



Note: This guidance update is not a result of the work performed for the PMRA's current transformation as communicated in April 2022.

This guidance is a reflection of the current process. If changes are required as a result of PMRA Transformation, updates to this document will take place at a later time.

Table of contents

1.0	Introduction	1
2.0	Information requirements	2
	Information required for product chemistry	3
	Information required for assessment of risk to human health	3
	Information required for assessment of risk to the environment	4
	Information required for assessment of value	4
3.0	Submission process	5
	Pre-submission consultation.....	5
	Submission of information for regulatory decision making.....	5
	Exemptions	5
	Performance timelines and fees.....	6
	Appendices	7
	Appendix A - Guidance on preparing waiver requests for information requirements	7
	Toxicology.....	7
	Environmental exposure/Environmental toxicology	8
	Appendix B - Directions for creating a draft label.....	9
	Principal display panel.....	9
	Secondary display panel.....	11
	Appendix C - Sample draft label.....	15
	PRINCIPAL DISPLAY PANEL	15
	SECONDARY DISPLAY PANEL.....	16
	Appendix D - Data codes (DACO) tables.....	17

1.0 Introduction

This guidance document outlines the regulatory approach for non-conventional pest control products (as defined below). Due to the varied nature of non-conventional pest control products, it can be challenging to define a specific mode of action, identify the active components of a mixture, or delineate a particular level of efficacy that allows innovation and flexibility in assessing that risks to human health and the environment and the value of a product are acceptable.

A wide range of non-conventional pest control products are reviewed under this guidance document. Certain biopesticide products (microbials, semiochemicals and pheromones) have unique information requirements which are outlined in separate publications available under [Policies and Guidelines](#) on the [Pesticides section](#) of Canada.ca. This guidance document does not replace these documents, and these documents should be used in conjunction with these guidelines when considering registration.

Products eligible for consideration under these guidelines should have one or more of the following characteristics:

- low toxicity to non-target organisms (products with low toxicity to humans and other non-target organisms are expected to have minimal environmental and health risks, even if exposure is extensive);

Note: Substances with chronic toxicity, genotoxicity, carcinogenicity, neurotoxicity or immunotoxicity, or that may cause reproductive or developmental effects, metabolize into compounds of toxicological concern, or are anticipated to bioaccumulate are not eligible for review under these guidelines.

- low potential for their use to result in significant human or environmental exposure (when exposure is negligible, risks may be minimal even if the product has some inherent toxicity);
- not persistent in the environment;
- already widely available to the public for other use(s) and with a history of safe use under conditions posing the equivalent potential for exposure to humans and the environment;
- pesticidal action that is not the result of toxicity to the target organism (for example, products that work by attracting, repelling, desiccating or smothering pests); or
- unlikely to select for pest resistance.

Substances eligible for review under these guidelines could include, but are not limited to:

- food items, extracts, preservatives, or additives (for example, crushed garlic, garlic powder, table salt, or citric acid);
- plant extracts and oils (for example, vegetable or mineral oils);

- commodity chemicals that have a range of non-pesticidal uses (for example, acetic acid); and
- other natural materials (for example, diatomaceous earth).

Note: The PMRA has published an addendum to address the unique risks posed by essential oil-based personal insect repellents (Regulatory Directive DIR2017-02, *Essential Oil-based Personal Insect Repellents (EOPIR)*). Refer to that publication for regulatory requirements.

2.0 Information requirements

The PMRA will assess the eligibility of products for review based on available evidence. Applicants should submit a detailed rationale explaining why they believe their product is eligible for consideration under these guidelines. The application should include details of the proposed use pattern and label claims and as much scientific evidence as possible on the characterization of the components, toxicity, exposure, and environmental fate. See Section 3 of this guidance document for the pre-submission consultation process.

The PMRA supports a tiered and flexible approach to information requirements and recognizes that the information needed to make a regulatory decision should be commensurate with the potential for risk. As for all pest control products, the PMRA will require applicants to provide sufficient information to assess that risks to human health and the environment and the value of a product are acceptable. Applicants are encouraged to make use of the pre-submission consultation process (described in Section 3 of this guidance document) to help determine what information is needed.

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

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

At any point during the PMRA assessment, the PMRA may, as per Section 8 of the Pest Control Products Regulations require the submission of additional information on potential risks if the available information is inadequate or if hazards are identified at the Tier I level.

Applicants are encouraged to consult the DACO Tables in Appendix D during the developmental phase of their product to gain an understanding of the scope of the data required to support their registration.

Information required for product chemistry

The applicant must provide enough information on both the technical grade active ingredient and the end-use product to characterize the product composition. The identity of any impurities of toxicological or environmental concern suspected to be present in a product must be disclosed, regardless of concentration.

For non-conventional products that contain a mixture of active components, the applicant may opt to register one technical product composed of all ingredients in the mixture instead of registering each active component separately.

For food-grade edible (FGE) products, the applicants are encouraged to use an “FGE Attestation Form” for simplified data requirements. The form is available during pre-submission consultation.

Information required for assessment of risk to human health

Toxicology information

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

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

Should identified toxicology data requirements require the generation of studies, please refer to Regulatory Directive DIR2005-01, *Guidelines for Developing a Toxicological Database for Chemical Pest Control Products*, as required.

Occupational and bystander exposure information

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

Information required includes:

- a description of typical practices for individuals applying the product, such as the amount of active ingredient handled and the site, timing, and method of mixing/loading and application, and required PPE;
- a description of the type, frequency and duration of any activities where postapplication exposure could occur; and

- a description of the potential for exposure to bystanders, particularly in nearby residential communities, schools or recreational areas.

Dietary exposure information

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

Information required for assessment of risk to the environment

The information required to assess potential risks to non-target aquatic and terrestrial organisms depends on the proposed use, which usually determines in which environmental media (soil, water, sediment, air) non-target organisms could be exposed. Applicants must provide a detailed description of the proposed use of the product(s), including where and how it is used, and how much is applied (also see Appendix A). This information, along with the draft product labels, will be considered when assessing the potential for environmental exposure. The applicant must provide information to show the product has low acute risk to non-target indicator species for aquatic or terrestrial organisms likely to be exposed. Products must not cause chronic or reproductive effects, metabolize into compounds of toxicological concern, or be anticipated to bioaccumulate. The amount of data or information that will be required is dependent on the use pattern, toxicity, and fate characteristics of the active ingredient. Summary information on environmental fate and toxicology must be provided if there is a potential for environmental exposure.

Information required for assessment of value

In the *Pest Control Products Act*, the value of a pest control product is defined as the product's actual or potential contribution to pest management, considering its conditions or proposed conditions of registration, and includes the product's:

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

The applicant must provide evidence that a product has acceptable value for the proposed uses claimed on the label. This could include information from experimental trials, published studies, scientific rationales, a product's use history in another jurisdiction and analysis of the product's potential benefits. In most cases, efficacy information requirements for non-conventional products will be less than for conventional pest control products. The PMRA recognizes that some non-conventional products may not be as efficacious as conventional products and, if a product is not effective enough to support a standard use claim, a lower-level claim such as "reduces damage, reduces

annoyance, reduces inoculum, reduces populations, suppresses symptoms or may inhibit" may be acceptable.

In addition to its efficacy, applicants are to submit any information describing the value of the product as a pest management tool.

Products like personal insect repellents, sanitizers, and pool bactericides, or a sub-set of pest claims on a product label (for example, bed bugs and cockroaches on structural products) where the pests controlled may pose a concern to public health, may not be eligible for reduced efficacy information requirements and/or reduced use claims.

For further information and guidance on value assessments, refer to PMRA Guidance Document, *Value Assessment of Pest Control Products*.

3.0 Submission process

Pre-submission consultation

Applicants are strongly encouraged to request pre-submission consultations for non-conventional products. A pre-submission consultation is a service offered at no cost by Health Canada's Pest Management Regulatory Agency that provides regulatory guidance to registrants or applicants prior to the submission of an application to register or amend a pest control product. The pre-submission process may also be utilized as a mechanism for obtaining guidance on a study protocol.

Applicants can request a consultation through the [Pre-submission Consultations](#) web page or by contacting the [Pest Management Information Service](#) on Canada.ca.

Submission of information for regulatory decision making

Details on how to prepare a submission package to register a product can be found under [Policies and Guidelines](#) on the Pesticides section of the Canada.ca web site. All information requirements identified during the pre-submission consultation must be addressed, using appropriate information from scientifically sound sources such as studies or requests for waivers based on scientific rationales. Only complete submissions will be considered for review by the PMRA. If the applicant did not make use of the pre-submission consultation process, the PMRA will assess eligibility for review under these guidelines early in the review process and will notify the applicant of any additional data requirements.

Exemptions

As with conventional pesticides, non-conventional products are eligible for exemption from registration: for research purposes, as described under sections 46 to 70 in the Pest Control Products Regulations; under Schedule II of the *Pest Control Products Act*; and for the Own-Use Import Program, subject to compliance with prescribed conditions.

Performance timelines and fees

The performance timeline for submission review of products under these guidelines follow the timelines presented in the PMRA Guidance Document, *Management of Submissions Policy*.

Some of the products reviewed under this guidance document will be eligible for a fee exemption or reduced fee status, as described in the PMRA's *Guidance Document: Pest Control Products Fees and Charges Regulations*. The applicant is responsible for providing a written rationale as to why their product should be considered for a fee exemption or reduced fee status.

Appendices

Appendix A - Guidance on preparing waiver requests for information requirements

A request can be made to waive information requirements based on a scientific rationale. The following guidance on preparing a waiver request is provided.

Toxicology

Requests to waive toxicology information requirements must be science-based and include supporting documentation. They can be based on one or more of several premises, as outlined in the example below. All relevant toxicity information should be submitted, including material safety data sheets and technical bulletins. Additional guidance on preparing waiver requests can be found in PMRA's *Guidance for Waiving or Bridging of Mammalian Acute Toxicity Tests for Pesticides*.

Sample waiver request for toxicity information requirements:

The waiver request is based on [one or more of] the following rationales:

Increased environmental exposure to the active ingredient due to the use of the product will be minimal: Describe levels of naturally occurring substance in the environment/use site.

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

Relying on surrogate compounds when no studies are available for the proposed active ingredient for a particular endpoint: Conduct an extensive literature search of key databases (for example, TOXLINE⁷, Biological Abstracts or CHEMTOX⁷ [Hazardous and Regulated Chemicals Database]), on the active ingredient and its metabolites, to ascertain whether there are any acute, short-term, and chronic toxicity animal studies available. If little or no published information is available on the toxicity of the active ingredient to be registered, information may be submitted on chemically equivalent or similar substances with an accompanying explanation, or bridging rationale, of why the surrogate data should be considered representative of the toxicological effects expected of the active ingredient. All required toxicological endpoints must be addressed.

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

Environmental exposure/Environmental toxicology

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

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

Appendix B - Directions for creating a draft label

Basic label requirements are outlined below. For more detailed information on the preparation of product labels, refer to the Memorandum on [Changes to Label Requirements](#) at Canada.ca:

Principal display panel

1. Product name

a) The product name:

- must match the name on the application form;
- must be specific to the product (unique);
- must not be misleading or contain unacceptable or scientifically unsupportable claims; and
- may include distinctive brand or trademark and common chemical name.

b) The product type of the product.

c) The physical form of the product.

2. Class designation

The class designation must:

- be based on the intended use, user groups (for example, public, commercial users) and potential hazards;
- match class indicated on the application form;
- appear on the principal display panel of the product only once (the product can have the class designation "commercial and restricted use", but this must not appear on the principal display panel)
- be one of the following:
 - DOMESTIC
 - COMMERCIAL (AGRICULTURAL, INDUSTRIAL, or INSTITUTIONAL have also been acceptable when targeting a sub-set of commercial uses)
 - RESTRICTED
 - MANUFACTURING (may appear for both manufacturing concentrates and technical grade actives—or a combination thereof. "TECHNICAL", "FORMULATING" or "REPACKAGING" have also been accepted on the principal display panel)

3. Precautionary symbols and words

If this information is required, poison, flammability, explosive and corrosive hazard symbols and signal words must appear on the label. (Refer to the *Checklist of Labeling Requirements for Pest Control Products* referenced in Schedule 3 of the Pest Control Products Regulations.)

4. **Read the label before using statement**

- If the product labelling does not include a brochure or leaflet, the following statement must appear on the label:

READ THE LABEL BEFORE USING

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

READ THE LABEL AND ATTACHED (OR ACCOMPANYING) BROCHURE (OR LEAFLET) BEFORE USING.

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

KEEP OUT OF REACH OF CHILDREN

5. **Active ingredient statement**

For the ACTIVE INGREDIENTS statement, the name and concentration of the active ingredient(s) must be stated. This information must match the information found on the product specification form.

6. **Registration number**

The registration number on the label must:

- match the one assigned; and
- appear as follows:

REGISTRATION NO. (*assigned registration number*) PEST CONTROL PRODUCTS ACT

or

REG. NO. (*assigned registration number*) P.C.P. ACT

7. **Net contents**

The net quantity of the product in the package must:

- be expressed in metric units (Imperial measure may appear in brackets after the metric measure);
- be expressed in millilitres (mL) or litres (L) for liquids and in grams (g) or kilograms (kg) for solids or pressurized products;
- define the maximum size for domestic products; and
- define the minimum size for bulk.

8. Registrant name

The registrant name:

- is defined as the company under which the name of the product is registered;
- must match the information in box 6 of the application form; and
- can consist of either:
 - the company name only;
 - the company name and a postal address;
 - the company name and URL or
 - the company name and an e-mail address

9. Name and full postal address and telephone number of a contact in Canada to which public inquiries may be directed

- The contact name, postal address and phone number can be the same or different from that of the Registrant.
- If the Registrant and the public inquirer's contact name are the same, one set of information can fulfill both provisions, but the information must include a phone number.
- Public inquirer's contact name and address:
 - For a Registrant in Canada: the address must be in Canada.
 - For a Registrant in the United States: the address must be in Canada.
 - For a Registrant NOT in Canada or the United States: the address must be in Canada.



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

Secondary display panel

1. Directions for use

For end-use products, the DIRECTIONS FOR USE statement must include complete information on site/crop, pest, application rates, how to apply the product, timing and frequency of application, and any use limitations. Additionally, restricted class products and uses must be located in a box that includes the header "RESTRICTED USES".

For technical/manufacturing class products, the standard DIRECTIONS FOR USE statement is as follows:

To be used only in the manufacture of a pest control product, which is registered under the Pest Control Products Act.



Note: Pest control product can be replaced with "insecticide," "herbicide" or "fungicide."

2. Precautions

The PRECAUTIONS statement:

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

KEEP OUT OF REACH OF CHILDREN

Note: Domestic class product may also include this statement under Precautions as well as on the Primary panel; and

- must include the following statement for manufacturing use products (for example, technical grade active ingredient (TGAI) or manufacturing concentrates).

PREVENT ACCESS BY UNAUTHORIZED PERSONNEL

3. First aid

A clear and concise statement of practical first-aid measures will be required in cases where the product could pose a hazard as the result of accidental contact with skin or eyes, ingestion, or inhalation. PMRA Guidance Document, *First Aid Labelling Statements*, contains guidance on labelling statements. On all product labels, it must include the statement: "Take the container label or product name and Pest Control Product Registration Number with you when seeking medical attention."

4. Toxicological information

The TOXICOLOGICAL INFORMATION portion of the label contains information to assist medical caregivers in treating symptoms associated with exposure to the product; this will include antidotes and remedial measures, description of the symptoms and a list of any components that may affect the treatment.

If there is no antidote or corrective measures, the default statement is:

TREAT SYMPTOMATICALLY

5. **Storage statement**

Must include information on appropriate storage conditions (for example, temperature range and light restrictions) and any other relevant information aimed at ensuring product stability, performance, and safety. Instructions for storage are listed under the heading STORAGE, near the DISPOSAL section. The following may be presented on the label for agriculture products and as required for products with other uses (for example, industrial and domestic products):

STORE THIS PRODUCT AWAY FROM FOOD OR FEED

6. **Disposal**

Domestic class

(a) Products of DOMESTIC class designation must present the appropriate disposal conditions on the label.

Commercial class

Liquid products

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

1. Rinse the emptied container thoroughly and add the rinsings to the spray mixture in the tank. For Antimicrobial products, triple or pressure-rinse the empty container. Add the rinsings to the treatment site.
2. Follow provincial instructions for any required additional cleaning of the container prior to its disposal.
3. Make the empty container unsuitable for further use.
4. Dispose of the container in accordance with provincial requirements.
5. For information on disposal of the unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of a spill.

Solid products

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

1. Thoroughly empty the contents of the container into the application device.

2. Make the empty container unsuitable for further use.
3. Dispose of the container in accordance with provincial requirements.
4. For information on disposal of the unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of a spill.

Manufacturing class

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

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

7. Notice to user

The NOTICE TO USER statement presented below is required on all COMMERCIAL, RESTRICTED and MANUFACTURING class products.

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

Appendix C - Sample draft label

NOTE: This is an example label only for non-conventional pest control products. Registrants should always consult the most up-to-date guidance as this guidance may change over time.

PRINCIPAL DISPLAY PANEL

PEST AWAY

Flowable Pesticide [indicate type of pesticide]

DOMESTIC

READ THE LABEL BEFORE USING

KEEP OUT OF REACH OF CHILDREN

ACTIVE INGREDIENT: active ingredient X g/L

REGISTRATION NO: XXXXX PEST CONTROL PRODUCTS ACT

or

REG. NO. XXXXX PCPA

[Precautionary symbols and signal words (if appropriate)]

Net Contents: 1 L

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

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

SECONDARY DISPLAY PANEL

NOTICE TO USER: (Note: not required on domestic products)	This pest control product is to be used only in accordance with the directions on the label. It is an offence under the <i>Pest Control Products Act</i> to use this product in a way that is inconsistent with the directions on the label.
DOMESTIC USE:	For use against dandelions in lawns.
DIRECTIONS FOR USE:	Treat when plants are growing. Do not mix with any other materials. Spray foliage at a rate of 100 mL/m ² . Spray uniformly over all plant surfaces to be treated.
PRECAUTIONS:	KEEP OUT OF REACH OF CHILDREN. Avoid contact with skin, eyes, and clothing. Wash with soap and water after use.
FIRST AID:	
If swallowed (assumes no petroleum distillates in the product):	Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control centre or doctor. Do not give anything by mouth to an unconscious person.
If on skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15–20 minutes. Call a poison control centre or doctor for treatment advice.
If inhaled:	Move person to fresh air. If a person is not breathing, call 911 or an ambulance then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control centre or doctor for further treatment advice.
If in eyes:	Hold eye open and rinse slowly and gently with water for 15–20 minutes. Remove contact lenses, if present, after the first 5 minutes then continue rinsing eye. Call a poison control centre or doctor for treatment advice.
NOTE: Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.	
TOXICOLOGICAL INFORMATION:	Treat symptomatically.
STORAGE	Store this product away from food or feed.
DISPOSAL:	Do not reuse empty container. Dispose of empty container in household garbage. Unused or partially used products should be disposed of at provincially or municipally designated hazardous waste disposal sites.

Appendix D - Data codes (DACO) tables

Table 1: Chemistry information requirements for non-conventional technical grade active ingredients

Data code (DACO)	Title	Data required	Test notes
2	Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient (TGA)		
2.1	Applicant's Name and Office Address	R	1
2.2	Manufacturer's Name and Office Address and Manufacturing Plant's Name and Address	R	1
2.3	Product Trade Name	R	1
2.3.1	Other Names	R	1
2.4	Common Name	R	1
2.5	Chemical Name	R	1
2.6	Chemical Abstracts Registry Number	R	1
2.7	Structural Formula	R	1
2.8	Molecular Formula	R	1
2.9	Molecular Weight	R	1
2.11	Manufacturing Methods for the TGA		2
2.11.1	Manufacturing Summary	R	1
2.11.2	Description of Starting Materials	R	1
2.11.3	Detailed Production Process Description	R	1
2.11.4	Discussion of Formation of Impurities	CR	1
2.12	Specifications		
2.12.1	Establishing Certified Limits	R	1
2.12.2	Control Product Specification Form	R	1
2.13	Preliminary Analysis		
2.13.1	Methodology/Validation	CR	1, 2
2.13.2	Confirmation of Identity	R	1, 2, 3
2.13.3	Batch Data	CR	1, 2, 4
2.13.4	Impurities of Human Health or Environmental Concern	CR	1
2.14	Chemical and Physical Properties		5
2.14.1	Colour	R	1

Data code (DACO)	Title	Data required	Test notes
2.14.2	Physical State	R	1
2.14.3	Odour	R	1
2.14.4	Melting Point / Melting Range	R	1
2.14.5	Boiling Point / Boiling Range	R	1
2.14.6	Density or Specific Gravity	R	1
2.14.7	Water Solubility (mg/L)	R	1
2.14.8	Solvent Solubility (mg/L)	R	1
2.14.9	Vapour Pressure	R	1
2.14.10	Dissociation Constant	CR	1
2.14.11	Octanol/Water Partition Coefficient	R	1
2.14.12	UV/Visible Absorption Spectra	R	1
2.14.13	Stability (Temperature, Metals)	R	1
2.14.14	Storage Stability Data	CR	1
2.14.15	pH	R	
2.14.16	Nanomaterial Characteristics	CR	
2.15	Sample(s) of Analytical Standards and Residue of Concern	NR	
2.16	Other Studies/Data/Reports	CR	1

1. Information must be provided in accordance with the *PMRA Guidance for Developing Datasets for Conventional Pest Control Product Applications – February 2021*.
2. Not required if the Technical Grade Active Ingredient is a food-grade edible product.
3. For food-grade products, the Technical Grade Active Ingredient must be identified using the methods outlined in the Food Chemicals Codex (FCC).
4. For food-grade products, results of the tests as required by the FCC in order to demonstrate that the product conforms to the FCC specifications.
5. For food-grade edible and food-grade products, these studies are not required to be GLP-compliant and information from public domain is acceptable.

Table 2: Chemistry information requirements for non-conventional end-use products

Data code (DACO)	Title	Data required	Test notes
3	Chemistry Requirements for the Registration of Manufacturing Concentrates and End-Use Products Formulated from Registered Technical Grade of Active Ingredients		
3.1	Product Identification		
3.1.1	Applicant's Name and Office Address	R	1
3.1.2	Formulating Plant's Name and Address	R	1
3.1.3	Trade Name	R	1
3.1.4	Other Names	R	1
3.2	Formulation Process		
3.2.1	Description of Starting Materials	R	1
3.2.2	Description of the Formulation Process	R	1
3.2.3	Discussion of the Formation of Impurities of Toxicological Concern	CR	1
3.3	Specifications		
3.3.1	Establishing Certified Limits	R	1
3.3.2	Control Product Specification Form	R	1
3.4	Product Analysis		
3.4.1	Enforcement Analytical Method	CR	1
3.4.2	Impurities of Human Health or Environmental Concern	CR	1
3.5	Chemical and Physical Properties		
3.5.1	Colour	CR	1
3.5.2	Physical State	R	1
3.5.3	Odour	CR	1
3.5.4	Formulation Type	R	
3.5.5	Container Material and Description	R	
3.5.6	Density or Specific Gravity	R	1
3.5.7	pH	R	1
3.5.8	Oxidizing or Reducing Action (Chemical Incompatibility)	R	1
3.5.9	Viscosity	R	1
3.5.10	Storage Stability Data	CR	1
3.5.11	Flammability	R	1

Data code (DACO)	Title	Data required	Test notes
3.5.12	Explosibility	R	1
3.5.13	Miscibility	R	1
3.5.14	Corrosion Characteristics	R	1
3.5.15	Dielectric Breakdown Voltage	R	1
3.5.16	Nanomaterial Characteristics	CR	
3.6	Sample(s)	NR	
3.7	Other Studies/Data/Reports	CR	1

1. Information must be provided in accordance with the *PMRA Guidance for Developing Datasets for Conventional Pest Control Product Applications – February 2021*.

Table 3: Toxicology information requirements

Data code (DACO)		USEPA guideline number	Information requirement	Use patterns		Test substance	Test notes	
TGAI/ISP	EP			Food	Non-food			
<p>Use patterns. (1) Food use patterns, in general, include products classified under the following general uses: terrestrial food crop use; terrestrial feed crop use; aquatic food crop use; greenhouse food crop use. (2) Non-food use patterns include products classified under the general use patterns of terrestrial non-food crop use; aquatic non-food domestic use; aquatic non-food outdoor use; aquatic non-food industrial use; greenhouse non-food crop use; forestry use; domestic outdoor use; domestic indoor use; indoor food use; indoor non-food use; indoor medical use.</p> <p>Key. R = Required; CR = Conditionally required; NR = Not required; TGAI = Technical grade of active ingredient; ISP = Integrated system product; EP = End-use product</p>								
Tier I								
Acute studies								
4.2.1	4.6.1	870.1100	Acute oral	R	R	TGAI/ISP	EP	1, 5
4.2.2	4.6.2	870.1200	Acute dermal	CR	CR	TGAI/ISP	EP	2, 5, 6
4.2.3	4.6.3	870.1300	Acute inhalation	R	R	TGAI/ISP	EP	1, 7
4.2.4	4.6.4	870.2400	Primary eye irritation	R	R	TGAI/ISP	EP	3, 6
4.2.5	4.6.5	870.2500	Primary dermal irritation		R	TGAI/ISP	EP	3, 5, 6
4.2.6	4.6.6	870.2600	Dermal sensitization	R	R	TGAI/ISP	EP	4, 6, 8
4.2.9	4.6.8	None	Other acute studies	CR	CR	TGAI/ISP	EP	9

Data code (DACO)		USEPA guideline number	Information requirement	Use patterns		Test substance		Test notes
TGAI/ISP	EP			Food	Non-food			
Short-term studies								
4.3.1	4.7.1	870.3100	Short-term oral (90 day rodent)	R	CR	TGAI/ISP	EP	1, 11, 10, 12
4.3.2	4.7.2	870.3150	Short-term oral (90 day and/or 12 month dog)	CR	CR	TGAI/ISP	EP	10, 12, 13, 14
4.3.4	4.7.3	870.3250	Short-term dermal (90 day rodent)	CR	CR	TGAI/ISP	EP	1, 12, 16
4.3.6	4.7.6	870.3465	Short-term inhalation (90 day rodent)	CR	CR	TGAI/ISP	EP	1, 12, 17
4.3.8	4.7.7	None	Other short-term studies	CR	CR	TGAI/ISP	EP	9, 12
Special studies								
4.5.2	NR	870.3700	Prenatal developmental toxicity (rodent)	R	CR	TGAI/ISP	NR	1, 22, 25, 26
4.5.4	NR	870.5100	Genotoxicity: Bacterial Reverse mutation assay	R	CR	TGAI/ISP	NR	28
4.5.5	NR	870.5300	Genotoxicity: In vitro mammalian cell assay	R	CR	TGAI/ISP	NR	27, 28
4.8	4.8	None	Other studies/Data/ Reports	CR	CR	TGAI/ISP	EP	9
Tier II								
Mutagenicity testing (In vivo cytogenetics)								
4.5.7	NR	870.5385	Mammalian bone marrow chromosomal aberration	CR	CR	TGAI/ISP	NR	29
		870.5395	Mammalian erythrocyte micronucleus	CR	CR	TGAI/ISP	NR	29
Developmental toxicity								
4.5.3	NR	870.3700	Prenatal developmental	CR	CR	TGAI/ISP	NR	3, 22, 25, 26

Data code (DACO)		USEPA guideline number	Information requirement	Use patterns		Test substance		Test notes
TGAI/ISP	EP			Food	Non-food			
			toxicity (non-rodent)					
Special studies								
4.3.8	NR	880.3550	Immunotoxicity	CR	CR	TGAI/ISP	NR	29, 30
Tier III								
Long-term studies/Special studies								
4.4.1	NR	870.4100	Chronic oral (rodent and non-rodent)	CR	CR	TGAI/ISP	NR	1, 18, 19, 32
4.4.2	NR	870.4200	Carcinogenicity (rodent species 1)	CR	CR	TGAI/ISP	NR	1, 18, 19, 33
4.4.3	NR	870.4200	Carcinogenicity (rodent species 2)	CR	CR	TGAI/ISP	NR	18, 20, 21, 33
4.4.5	NR	880.3800	Immune response	CR	CR	TGAI/ISP	NR	31
Special Studies								
4.5.1	NR	870.3800	Reproduction and fertility effects	CR	CR	TGAI/ISP	NR	1, 18, 23, 24
4.5.7	NR	870.5380	Mammalian spermatogonial chromosome aberration test	CR	CR	TGAI/ISP	NR	34
NR	4.9	870.7200	Safety to treated animals	CR	CR	NR	EP	35

1. The preferred species is the rat.
2. The preferred species is the rat or the rabbit.
3. The preferred species is the rabbit.
4. The preferred species is the guinea pig.
5. Not required if the test substance is a gas or highly volatile liquid.
6. Not required if the test substance is corrosive to the skin or has a pH lower than 2 or greater than 11.5.
7. Required if the test substance consists of, or under conditions of use will result in, a respirable material, for example, gas, vapour, aerosol or particulate.
8. Required if repeated contact with human skin is likely to occur under conditions of use. Diluted end-use product testing may be required if the end-use product is diluted under conditions of use.

9. Other available studies that elaborate on the toxicity profile of a test substance.
10. Required for non-food uses that are likely to result in repeated oral exposure to humans.
11. The incorporation of a post-treatment recovery phase should be considered.
12. Depending on the use pattern, this may be required if any component of the end-use product may increase absorption of the active ingredient(s) or increase the toxic or pharmacological effects.
13. May be required when the product is to be used on food or likely come in contact with food.
14. Consideration of a 90-day study in lieu of a 12-month study will be given if this species has demonstrated to be the least sensitive laboratory animal in the 90-day study and there is no evidence for the potential of cumulative or delayed toxicity. Consideration will also be given if the results of the 90-day study and structure-activity relationships of the test substance elicits no specific effects on target organ toxicity when fed at dietary levels of 1–5 % of the total diet composition.
15. Other available studies of shorter duration including range-finding studies that elaborate on the toxicity profile of the test substance.
16. Required to support uses involving purposeful application to the human skin or which would result in comparable prolonged exposure to the product (for example, insect repellents) and if any of the following criteria are met:
 - (i) Data from a 90-day oral study are not required.
 - (ii) The active ingredient is known or expected to be metabolized differently by the dermal route of exposure than by the oral route and the metabolite is of toxicological concern.
 - (iii) The use pattern is such that the dermal route would be the primary route of exposure.
17. Required if there is a likelihood of significant levels of repeated inhalation exposure to the pesticide as a gas, vapour, or aerosol.
18. The oral route is recommended when the product is to be used on food or likely to come in contact with food.
19. The minimum study duration for the rat should be 24 months.
20. The preferred species is the mouse.
21. The minimum study duration for the mouse should be 18 months.
22. Required if the use of the product under widespread and commonly recognized practice may reasonably be expected to result in significant exposure to female humans (for example, occupational exposure or repeated application of insect repellents directly to the skin). Tier II data are required on a different test species from Tier I data when developmental effects are observed in the first study and information on species-to-species extrapolation is needed.
23. Required if there is evidence of: (a) endocrinological effects from the short-term toxicity studies, (b) developmental effects in the prenatal developmental toxicity study(ies), or (c) genotoxicity to mammals based on the results from the

mutagenicity tests. A second litter per generation should be considered if any effect on routinely evaluated reproductive parameters required elucidation, especially at dose levels below those causing minimal adverse effects in repeated exposure studies in the same species; the observed effects in the first litters were induced post-implantation; or the test substance is known or likely to be bioaccumulative, and when blood and tissue levels had not stabilized or attained plateau levels prior to mating.

24. A combined study which uses the two-generation reproduction study in rodents as a basic protocol for the addition of other endpoints or functional assessments in the immature animal is encouraged.
25. Unless the chemical or physical characteristics of the test substance or the likely pattern of human exposure suggests a more appropriate route of exposure, administration by oral intubation is preferred.
26. Additional routes for testing may be requested if prenatal developmental toxicity is observed after oral dosing.
27. Choice of assay using the mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing assay conditions for small colony expression and detection; Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (HGPRT) gene locus; or CHO cell strain AS52, xanthine-guanine phosphoribosyl transferase (XPRT) gene locus.
28. It is required to support non-food uses if either (i) the use is likely to result in significant human exposure; or (ii) if the active ingredient (or its metabolites) is structurally related to a known mutagen or belongs to any chemical class of compounds containing a known mutagen. Additional mutagenicity tests that may have been performed plus a complete reference list (and a copy of each reference) must also be submitted. Subsequent testing may be required based on the available evidence.
29. Required if results from the Tier I mutagenicity tests are positive. Assays using rodent bone marrow, using either metaphase analysis (aberrations) or a micronucleus assay, are preferred.
30. Required if there are effects on hematology, clinical chemistry, lymphoid organ weights and histopathology are observed in the 90-day studies.
31. Required if adverse effects are observed in the Tier II immunotoxicity study. The protocol for evaluating adverse effects to the immune response should be developed after evaluating the effects noted in the immunotoxicity study.
32. Required if the potential for adverse long-term effects is indicated based on any of the following criteria:
 - (i) The short-term effect level established in the following Tier I studies: 90-day (or 12-month) feeding toxicity study, the 90-day dermal toxicity study, or the 90-day inhalation toxicity study.
 - (ii) The pesticide use pattern (for example, rate, frequency, and site of application).
 - (iii) The frequency and level of repeated human exposure that is expected.

33. Required if the product meets either of the following criteria:
- (i) The active ingredient (or any of its metabolites, degradation products, or impurities) produce(s) in Tier I short-term studies a morphologic effect (for example, hyperplasia or metaplasia) in any organ that potentially could lead to neoplastic change.
 - (ii) Adverse cellular effects suggesting carcinogenic potential are observed in Tier II immunotoxicity and Tier III immune response study or in Tier II mammalian mutagenicity assays.
- In addition, a 90-day range-finding study in both rats and mice is required to determine the dose levels if carcinogenicity studies are required. If the mouse carcinogenicity study is not required, the 90-day mouse short-term study is likewise not required.
34. Required if results from lower tiered mutation or reproductive studies indicate there is potential for chromosomal aberration to occur.
35. May be required if the product's use will result in domestic animals being exposed through, but not limited to, direct application or consumption of treated feed.

Table 4: DACO Part 5 - Occupational exposure information requirements

Data code (DACO)		USEPA guideline number	Information requirement	Use patterns		Test substance	Test notes
TGAI/ISP	EP			Food	Non-food		
<p>Use patterns. (1) Food use patterns, in general, include products classified under the following general uses: terrestrial food crop use; terrestrial feed crop use; aquatic food crop use; greenhouse food crop use. (2) Non-food use patterns include products classified under the general use patterns of terrestrial non-food crop use; aquatic non-food domestic use; aquatic non-food outdoor use; aquatic non-food industrial use; greenhouse non-food crop use; forestry use; domestic outdoor use; domestic indoor use; indoor food use; indoor non-food use; indoor medical use.</p> <p>Key. R = Required; CR = Conditionally required; NR = Not required; TGAI = Technical grade of active ingredient; ISP = Integrated system product; EP = End-use product</p>							
Tier I							
NR	5.2	875.1700	Use description scenario (Application and postapplication)	R	R	EP	1
Tier II							
NR	5.3	None	Pesticide handlers exposure database (PHED) assessment	CR	CR	EP	2, 3
NR	5.4	875.1100 875.1200 875.1300 875.1400	Mixer/Loader/Applicator - Passive dosimetry	CR	CR	EP	2, 4

Data code (DACO)		USEPA guideline number	Information requirement	Use patterns		Test substance	Test notes
TGAI/ISP	EP			Food	Non-food		
		875.1500					
NR	5.5	875.1100 875.1200 875.1300 875.1400 875.1500 875.2600	Mixer/Loader/Applicator - Biological monitoring	CR	CR	P	2, 5
NR	5.6	860.1200 875.2400 875.2500 875.2600	Postapplication - Passive dosimetry	CR	CR	EP	2, 4
NR	5.7	860.1200 875.2400 875.2500 875.2600	Postapplication - Biological monitoring	CR	CR	EP	2, 5
NR	5.8	870.7600	Dermal absorption study	CR	CR	EP	2, 6, 7
NR	5.9	860.1200 875.2100 875.2200 875.2400 875.2500 875.2600	Dislodgeable residues (Foliar, soil and surface)	CR	CR	P	2, 8
NR	5.10	875.2400 875.2500 875.2600	Ambient air samples	R	CR	EP	2, 9
NR	5.11	875.1100 875.1200 875.1300 875.1400 875.1500	Gloves/Clothing penetration data	CR	CR	EP	2
NR	5.12	None	Epidemiology	CR	CR	EP	2
NR	5.13	None	Package integrity study	CR	CR	EP	2

1. Information should be submitted which fully describes the proposed use of the product(s) and the human activity associated with its use, if applicable.
Mixer/Loader/Applicator - site of application, size of crop and area of crop that can be treated in a work day, description of typical application rates, number of applications per season, frequency of applications, when the product is to be applied relative to standard cultivation practices, crop height at application, method of application, individuals involved, mixing/loading method, clean-up and repair activities, and personal protective equipment and clothing.
Postapplication - method of crop cultivation, re-entry intervals, re-entry activities, timing, frequency, and duration of the re-entry activities, description of the re-entry workers, principal sources of exposure, and personal protective equipment and clothing.
2. These data are required when any toxicology data in Part 4 indicate that the biochemical pesticide may pose a potential hazard to the applicator/user. It is recommended that the Agency be consulted prior to study initiation to determine what studies are appropriate based on the nature of the adverse effects seen in the toxicology studies and the available exposure data. Studies performed to support registration of insect repellents may require modifications to these guidelines.
3. The current version of PHED should be used for assessing the exposure.
4. Passive dosimetry studies conducted with surrogate compounds may be acceptable if an acceptable rationale is submitted with the study.
5. Surrogate data may be acceptable if the toxicokinetics are well understood for the purposes of converting internal to external dose.
6. In vivo studies are usually conducted on rodents.
7. In vitro studies should be performed using viable skin and a flow-through apparatus.
8. Media of interest include foliage, indoor surfaces such as carpets, fur or companion animals, soil, etc.
9. Breathing zone samples are preferred.

Table 5: DACO Part 6 and 7: Metabolism and food residue information requirements

Data code (DACO)		USEPA Guideline Number	Information requirement	Use patterns		Test substance		Test notes
TGAI/ISP	EP			Food	Feed			
Required only when there is a TIER I toxicological concern								
Use patterns. (1) Food use patterns, in general, include products classified under the following general uses: terrestrial food crop use; terrestrial feed crop use; aquatic food crop use; greenhouse food crop use.								
Key. R = Required; CR = Conditionally required; NR = Not required; TGAI = Technical grade of active ingredient; ISP = Integrated system product; EP = End-use product								
Metabolism/Toxicokinetic studies (Nature of residue)								
6.2	6.2	860.1300 860.1480	Livestock	CR	CR	TGAI/ISP	EP	1, 6, 7, 9
6.3	6.3	860.1300 860.1480	Plants	CR	CR	TGAI/ISP	EP	1, 4, 5
6.4	6.4	860.1300 860.1400 860.1480	Other studies/Data/ Reports	CR	CR	TGAI/ISP	EP	1, 4, 5, 6, 7, 9
Analytical methodology								
NR	7.2.1	860.1300 860.1340 860.1360	Supervised residue trial analytical methodology	CR	CR	NR	EP	1, 4, 5, 6, 7, 8, 9, 10
NR	7.2.2	830.1800 860.1300 860.1340 860.1360	Enforcement analytical methodology	CR	CR	NR	EP	8
NR	7.2.3	860.1300 860.1340 860.1360	Inter-laboratory analytical methodology	CR	CR	NR	EP	9, 10
NR	7.2.4	860.1300 860.1340 860.1360	Multi-residue analytical methodology evaluation	CR	CR	NR	EP	9, 10
NR	7.2.5	860.1300 860.1340 860.1360	Storage stability of working solutions in analytical methodology	CR	CR	NR	EP	–

Data code (DACO)		USEPA Guideline Number	Information requirement	Use patterns		Test substance		Test notes
TGAI/ISP	EP			Food	Feed			
NR	7.3	860.1380 860.1850	Freezer storage stability tests	CR	CR	NR	EP	2
Crop Residue Data								
NR	7.4.1	860.15	Supervised residue trial study	CR	CR	NR	EP	1, 3, 4
NR	7.4.2	860.15	Residue decline study	CR	CR	NR	EP	1, 3, 4
NR	7.4.3	860.15	Confined crop rotation	CR	CR	NR	EP	1, 3, 4
NR	7.4.4	860.1200 860.1900	Field crop rotation trial study	CR	CR	NR	EP	1, 3, 4
NR	7.4.5	860.1520 860.1540	Processed food/Feed	CR	CR	NR	EP	1, 9, 15, 16
NR	7.4.6	860.15	Residue data for crops used as livestock feed (if needed for forage crops)	CR	CR	NR	EP	1, 3, 4
NR	7.5	860.1300 860.1480	Livestock, poultry, egg and milk residue data (from feeding of treated crops)	CR	CR	NR	EP	1, 6, 7, 9
NR	7.6	860.1300 860.1480	Livestock, poultry, egg and milk residue data (external application)	CR	CR	NR	EP	1, 6, 7, 9
NR	7.7	860.15	Tobacco residue data	CR	CR	NR	EP	–
NR	7.8	860.1100 860.1300 860.1400 860.1480 860.1550 860.1560 860.1650 860.1850	Other studies/Data/Reports	CR	CR	NR	EP	1, 4, 5, 6, 7, 9, 11, 12, 13, 14, 17

1. Residue chemistry data requirements apply to biochemical pesticide products when Tier II or Tier III toxicology data are required, as specified for biochemical pesticides in Part 4.

2. Storage stability data will be required in conjunction with most magnitude of residue studies, for example, crop field trials, processing studies, livestock feeding studies, and for primary standards, stock solutions and working solutions of standards. The Agency will make the following exception: unless a pesticide or residue of concern is otherwise known to be volatile or labile, storage stability data will not be needed for samples stored frozen for less than 30 days.
3. Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.
4. Residue data for outdoor residential uses are required if home gardens are to be treated and the home garden use pattern is different from use patterns where tolerances/maximum residue limits have been established.
5. Required for indoor uses where the pesticide is applied directly to food, in order to determine metabolites and/or degradation products.
6. Data on metabolism in livestock are required when residues occur on a livestock feed or if the pesticide is to be applied directly to livestock. If results from the plant metabolism study show differing metabolites in plants from those found in animals, an additional livestock metabolism study involving dosing with the plant metabolite(s) may also be required.
7. Livestock feeding studies are required whenever a pesticide residue is present in livestock feed or when direct application to livestock uses occurs.
8. A residue method suitable for enforcement of tolerances/maximum residue limits is required whenever a numeric tolerance/maximum residue is proposed.
9. Required for indoor uses if the indoor use could result in pesticide residues in or on food or feed.
10. Data are required to determine whether multiresidue methodology would detect and identify the pesticides and any metabolites.
11. Data on residues in potable water are required whenever a pesticide is to be applied directly to water, unless it can be determined that the treated water would not be used (eventually) for drinking purposes, by humans or animals.
12. Data on residues in fish are required whenever a pesticide is to be applied directly to water inhabited, or that will be inhabited, by fish that may be caught or harvested for human consumption.
13. Data on residues in irrigated crops are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.
14. Data on residues in food/feed in food handling establishments are required whenever a pesticide is to be used in food/feed handling establishments.
15. Data on the nature and level of residue in processed food/feed are required when detectable residues could concentrate on processing.
16. Anticipated residue data are required when the assumption of tolerance level/maximum residue limit residues would result in predicted exposure at an unsafe level of exposure. Data on the level or residue in food as consumed would be used to obtain a more precise estimate of potential dietary exposure.

17. The proposed tolerance/maximum residue limit must reflect the maximum residue likely to occur in crops in meat, milk, poultry, or eggs.

Table 6: DACO Part 8 and 9 – TGAI and EP

Data code	Study type	Data required	Comments
Environmental data requirements – PARTS 8 and 9			
TIER I Data/Information requirements: The requirement to address each Tier I data code will depend on the proposed uses and the potential for exposure to the environment.			
Key. R = Required; CR = Conditionally required			
8.1	Environmental chemistry and fate summary	R	The applicant is required to provide a summary of environmental chemistry and fate. It is recommended that available environmental chemistry and fate studies and any other relevant information also be submitted. This would include, if available: degradation rates in days/weeks/months and formation of metabolites; levels of the naturally occurring substance in the environment and geographical distribution or sources (for example, plant extract), if relevant.
8.4	Storage, disposal and decontamination	R	Special instructions, label directions.
9.1	Environmental toxicology summary	R	Complete study reports are required to be submitted for applicant-generated studies. The applicant is encouraged to conduct a thorough search of the scientific literature and provide a summary of relevant information, including any applicant-generated data, to support the assessment of the ecotoxicity of the TGAI.
9.2	Non-Target terrestrial invertebrates		
9.2.4.1	Bee adult acute contact toxicity	R	
9.2.4.2	Bee adult acute oral toxicity	CR	
9.2.4.3	Bee larvae toxicity	CR	
9.2.5	Predators	CR	
9.2.6	Parasites		

Data code	Study type	Data required	Comments
9.2.7	Other terrestrial invertebrates	CR	The applicant is required to address acute toxicity to bees. If concerns are raised, or the active ingredient is systemic and may be translocated to pollen or nectar within the plant, further information may be required (for example, with bee larvae or predators and parasites). Other pollinator studies may also be considered (DACO 9.2.4.9).
9.2.8	Laboratory studies with EP	CR	
9.3/9.4	Non-target invertebrates (Freshwater and marine)		
9.3.2	<i>Daphnia</i> sp. Acute	R	The applicant is required to address acute toxicity to aquatic invertebrates by providing one of the studies indicated. Acute toxicity to daphnids is preferred. Information on marine species may be submitted if there is a potential for exposure to estuarine or marine areas, and/or if marine species are more sensitive than freshwater invertebrates.
9.4.2	Marine: Acute (Crustacean)		
9.3.4 / 9.3.5 / 9.4.6	Other species, or laboratory studies with EP		
9.5	Fish (Freshwater and Marine)		
9.5.2.1	Acute cold water fish (rainbow trout)	R	The applicant is required to address acute toxicity to fish. Toxicity to fish can be addressed by one of the study types indicated. Information on marine species may be submitted, if available, if there is a potential for exposure to estuarine or marine areas and/or if marine fish are more sensitive than freshwater fish.
9.5.2.2	Acute warm water fish (bluegill sunfish)		
9.5.2.4	Acute marine/Estuarine fish		
9.5.2.3 / 9.5.4	Other species, Or laboratory studies with EP		
9.6	Birds		
9.6.2.1	Oral (LD ₅₀) bobwhite quail	R	The applicant is required to address toxicity to birds. Toxicity to birds can be addressed by one of the study types indicated: either an acute oral or dietary study type.
9.6.2.2	Oral (LD ₅₀) mallard		
9.6.2.3	Oral (LD ₅₀) other species		
9.6.2.4	Dietary (LC ₅₀) bobwhite quail		

Data code	Study type	Data required	Comments
9.6.2.5	Dietary (LC ₅₀) mallard		
9.6.2.6	Dietary (LC ₅₀) other species		
9.6.4	Laboratory studies with EP		
9.8	Non-target plants		
9.8.2	Fresh water algae	R	The applicant is required to address toxicity to algae. Either a toxicity study with freshwater algae or marine algae may be submitted. Laboratory studies with an EP may also be considered (DACO 9.8.6 – plants).
9.8.3	Marine algae		
9.8.4	Terrestrial vascular plants	R	The applicant is required to address toxicity to terrestrial vascular plants.
9.8.5	Aquatic vascular plants	R	The applicant is required to address toxicity to aquatic vascular plants, for example, <i>Lemna</i> sp. Laboratory studies with an EP may also be considered (DACO 9.8.6 – plants).
Other – Summary and review documents			
12.5.8	Foreign reviews – Environmental chemistry and fate	CR	If available.
12.5.9	Foreign reviews – Environmental toxicology	CR	If available.
EP = end-use product; TGAI = technical grade active ingredient			
If toxicity is evident, or concerns are raised, other Tier I data, as well as higher tiered data, may be required. The information/data requirements would be adjusted depending on the proposed use and potential for environmental exposure. See Table 2 for further details.			
Table 2. Tier II and III Information requirements (not required at this time)			
TIER II Data/Information requirements			
8.2.3.2	Hydrolysis	CR	
8.2.3.3.1	Phototransformation on soil	CR	
8.2.3.3.2	Phototransformation in water	CR	

Data code	Study type	Data required	Comments
8.2.3.3.3	Phototransformation in air	CR	If active ingredient(s) are volatile and persistence in air is a concern.
8.2.3.4.2	Biotransformation in aerobic soil: 20–30°C	CR	May include transformation products.
8.2.3.4.4	Biotransformation in anaerobic soil: 20–30°C	CR	May include transformation products.
8.2.3.5.4	Biotransformation in aerobic water/Sediment: 20–30°C	CR	May include transformation products.
8.2.3.5.6	Biotransformation in anaerobic aquatic sediment: 20–30°C	CR	May include transformation products.
8.2.3.6	Special studies related to use-pattern or formulation (TGAI or EP)	CR	For example, phototransformation on wood (USC 23).
8.2.4.2	Sediment and soil adsorption/desorption	CR	One of 8.2.4.2 or 8.2.4.3 may be submitted, if required.
8.2.4.3	Soil column leaching	CR	
8.2.4.5	Volatilization (from soil)	CR	
8.2.4.6	Special studies related to use-pattern or formulation (EP)	CR	For example, leaching from wood (USC 23)
8.3.2	Terrestrial field study of dissipation/accumulation	CR	
8.3.4	Aquatic field study of dissipation/accumulation	CR	
TIER III Data/Information requirements			
9.2.3.2	Earthworm chronic toxicity	CR	If toxicity to terrestrial arthropods is indicated.
9.2.4.4	Bee adult chronic toxicity	CR	
9.2.4.5	Bee toxicity of residues on foliage (EP)	CR	
9.2.4.6	Semi-field studies for pollinators (EP)	CR	
9.2.4.7	Field studies for pollinators (EP)	CR	
9.2.4.8	Residue studies for pollinators (EP)	CR	

Data code	Study type	Data required	Comments
9.2.9	Field studies with EP (Other than pollinators)	CR	
9.3.3	<i>Daphnia</i> species chronic (life cycle)	CR	
9.3.6	Freshwater invertebrates - Field studies with EP	CR	
9.4.3	Mollusk embryo larvae	CR	
9.4.4	Mollusk shell deposition	CR	
9.4.5	Chronic (mollusk or crustacean)	CR	Most sensitive (in other words, one of) daphnid (9.3.3); marine crustacean or estuarine/marine mollusk (9.4.5); or fish (9.5.3.1), where there is concern based on acute effects, persistence, potential for exposure or frequency of application
9.4.7	Marine invertebrates - Field studies with EP	CR	
9.4.8	Bioconcentration / Depuration (bivalve or crustacean)	CR	
9.5.2.4.1	Salinity challenge - fish	CR	
9.5.3.1	Fish, early life cycle toxicity	CR	
9.5.3.2	Fish life cycle toxicity	CR	
9.5.5	Fish – Field study	CR	
9.5.6	Bioaccumulation - fish	CR	
9.6.3.1	Avian reproduction – bobwhite	CR	If reproductive effects are observed in mammals, the applicant should provide information to address the potential for reproductive effects in non-target bird species. [One study (9.6.3.1, 9.6.3.2, or 9.6.3.3) may be submitted to satisfy this data requirement.]
9.6.3.2	Avian reproduction – mallard	CR	
9.6.3.3	Avian reproduction – other species	CR	
9.6.5	Avian - field studies	CR	
9.7.2	Wild mammals – field studies	CR	
9.8.7	Non-target plants – field studies	CR	
EP = end-use product; TGAI = technical grade active ingredient			

Table 7: DACO Part 10 – End-use product (EP)

Data Code	Title	Data Required	Conditions/ Guidance	Use-Site Category (USC 1-33)
10	Value (applicable to each pest / site or host combination)			
10.1	Value summary	R	A report that summarizes the value information provided to support an application. The report should follow the PMRA value review template (available in Appendix I of PMRA Guidance Document, Value Assessment of Pest Control Products).	All
10.2	Efficacy			
10.2.1	Mode of action (TGA) and description of the product	R	A description of the formulated product, including its name, active ingredient, mode of action, guarantee, and formulation type. Information on the active ingredient's chemical class, site of action classification, mechanism of selectivity, absorption or translocation in the host should be included if available.	All
10.2.2	Description of pest problem	R	For plant protection uses: A description of the pest problem, including importance of the pest (major/minor), and why pest management is required (affects yield, increases chance of secondary infections/infestations, part of complex, decay, etc.). Information regarding the economic or pest threshold for Canadian users should be provided. For non-plant protection uses: A description of the pest problem for the use-site(s), including importance of the pest (major/minor), and where the proposed product will be used must be provided. For antimicrobial products, the information should include the description of organisms causing the contamination/decay/fouling and their possible sources and the consequences of non-treatment. Information regarding the economic or pest threshold for Canadian users should be provided.	All
10.2.3	Efficacy trials		Required if use history is not available or scientific rationales are not appropriate to support proposed use. This is a section of the value summary report that specifically addresses the efficacy of the product in relation to a pest claim and use.	
10.2.3.1	Efficacy summary table	CR	Required if efficacy trials are being provided and there is a large number of trials.	All

Data Code	Title	Data Required	Conditions/ Guidance	Use-Site Category (USC 1-33)
			This is a summary of the efficacy trials being submitted in an Excel format following the template provided in the website/efficacy guidelines. Results of statistical analyses should be included, as appropriate. Required if submitting trial data.	
10.2.3.2	Efficacy: Laboratory, growth chamber trials	CR	<p>Required if small plot trials are not appropriate or available to support label claims and scientific rationales are not sufficient to support the proposed use. Laboratory are generally considered supplemental information. Rationales should be provided to support extrapolation from the laboratory to an operational scenario.</p> <p>These are individual study reports of laboratory trials to support the application for registration.</p>	All
10.2.3.3	Efficacy: Small-scale Trials (Field, greenhouse)	CR	<p>Required if applicable and use history information is not available and scientific rationales are not sufficient to support the proposed use for registration.</p> <p>These are individual trial reports of small plot studies or published papers used to support the application for registration.</p>	All
10.2.3.4	Efficacy: Operational trials	CR	<p>Required if applicable and there is a need to demonstrate value of proposed use under typical commercial/operational conditions or to show the performance of the product when used in an IPM system or under commercial operations.</p> <p>These are individual trial reports of studies conducted on a field scale (for example, use of commercial scale farming equipment, incorporation of IPM strategies, materials such as wood tested outdoor). Appropriate experimental design is key in order to obtain meaningful results.</p>	All
10.2.4	Use history	CR	Information regarding the use of a pesticide product registered in a foreign country. Required if little or no efficacy or crop tolerance/use site damage data is available or if a scientific rationale is not appropriate since there is no basis to form a scientific argument.	All

Data Code	Title	Data Required	Conditions/ Guidance	Use-Site Category (USC 1-33)
			If the product is registered in a foreign jurisdiction with a comparable pesticide regulatory system, use history information may be submitted to supplement or replace the required efficacy information to support a label claim. This consists of (1) comparison of use patterns, (2) description of the product's effectiveness against the pest and its potential for adverse effects on the crop or use site and (3) a validation statement from a resource person with direct experience with the product. Templates for compiling this information are available upon request.	
10.3	Adverse effects on use site		This requirement may be addressed through trials, use history or scientific rationales.	
10.3.1	Summary table	CR	Required if specific trials on non-safety adverse effects are being provided. A summary of the trials in an Excel format (following the template provided upon request) is required if dedicated non-safety adverse effects trials were conducted. Otherwise, a statement referring to absence of non-safety adverse effects may be made under the comments column of the efficacy trials.	All
10.3.2	Non-safety adverse effects [for example, to crop, site of application (discoloration, corrosion)]	R	These are individual trial reports, rationales or use history information giving details of the adverse effects of the treatment on the crop or use site.	All
10.3.3	Damage to rotational crops	CR	Required for all soil applied herbicides and herbicides that are persistent in soil. Effects of fungicides or insecticides on rotational crops may be addressed within the section on efficacy. Information demonstrating the effect of a herbicide application on subsequent crops grown in rotation, conducted under climatic and edaphic conditions representative of the area of use.	Conditionally required for USC 7, 10, 11, 13, 14, 16, 27, and 30

Data Code	Title	Data Required	Conditions/ Guidance	Use-Site Category (USC 1-33)
10.4	Social and economic impact	R	Provide information explaining why the product is needed as well as how and to what extent product registration would benefit Canadian users.	All
10.5	Sustainability and consideration of benefits		This section consists of information relating to the benefits of the proposed pesticide use, including its social and economic impact, compatibility with current management practices, its role in resistance management and any potential health, safety or environmental benefits.	
10.5.1	Survey of alternatives (conventional and non-conventional)	R	An overview of conventional and non-conventional products that are currently registered for the proposed use. The date when the search for alternatives was conducted should be reported.	All
10.5.2	Compatibility with current management practices, including IPM	R	Discuss how use of the product contributes to sustainability and how it can be integrated into current pest management practices.	All
10.5.3	Resistance management	R	Where appropriate, an analysis of the proposed use pattern's impact on resistance management is required. Describe how the proposed use contributes to resistance management and indicate how the proposed use pattern supports current resistance management recommendations. Information on baseline pest sensitivity and reports of laboratory-induced or field resistance should also be provided, when they are available.	All
10.5.4	Contribution to risk reduction	R*	*Required if applicable Information explaining the contribution of the product to risk reduction such as if the product is considered a replacement for a product being phased out following re-evaluation.	
10.5.5	Health, safety and environmental benefits	R*	*Required if applicable Information regarding the benefits of the proposed use could be described. This is not a summary of the supporting information for the human health or environmental risk assessment. An explanation of specific benefit/s such as arising from the management of a poisonous or allergenic weed or an invasive alien species or	All

Data Code	Title	Data Required	Conditions/ Guidance	Use-Site Category (USC 1-33)
			the control of pests that have human health impact could be included, where appropriate.	
10.6	Other studies/ Data/Reports	CR	Required if information other than those identified above are needed to assess the value of the proposed use. Other documents that are vital to the value review, such as a certificate of electrical safety.	All
12.5	Foreign Reviews		Reviews relating to the value of the proposed use from the pesticide regulatory organization in foreign countries.	
12-5-10	Foreign reviews pertaining to value		If available. Reviews relating to the value of the proposed use from the pesticide regulatory organization in foreign countries should be submitted, or if unavailable for submission, please indicate if another regulatory authority has completed a value review.	All
12.7.10	Applicant generated study reviews	R*	Study reviews prepared by applicants using standard review templates. *Required if results of research trial results provided to support an application are not included under DACO 10.2.2, 10.2.3, 10.2.4, 10.3.2, or 10.3.3. a) For Canada-only applications (in other words, not Joint Review applications), NAFTA study profile templates are requested [although use of OECD format is also acceptable (see link to OECD format below)]. NAFTA study profile templates are available upon request at the Evaluation Templates page on Canada.ca. b) For Joint Review applications of conventional (traditional) chemicals - OECD format is required.	All *Required for Joint Reviews; strongly recommended for other submission types