



Regulatory Note

REG2003-01

Guidance on Selecting the Correct Category for Pest Control Product Submissions

The Pest Management Regulatory Agency (PMRA) categorizes submissions for pest control products according to their purpose and the amount of work involved with each submission. This allows the PMRA to screen submissions and forward them to the appropriate divisions within the Agency, and to apply appropriate performance standards (target time frames) for their processing; submissions with data require more time than those without data. It is also a management tool that allows the PMRA to track numbers of different kinds of submission activity and allocate resources appropriately.

Since 1998, the PMRA has fine-tuned the criteria for its submission category scheme. This document is designed to assist applicants in identifying the correct submission category and type when applying to register or amend pest control products. This document complements the Registration Handbook and Regulatory Directive DIR2003-01 *Organizing and Formatting a Complete Submission for Pest Control Products*.

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General definitions

Active ingredient (a.i.): The ingredient(s) of a control product to which the effects of the pest control product are attributed, including a synergist, but not including a solvent, diluent, emulsifier or component that by itself is not primarily responsible for the effects of the product.

End-use product (EP): A product containing active ingredient(s) and usually formulant(s) that is labelled with instructions for direct pest control use or application.

Integrated system product (ISP): May be used in manufacture of an EP or may itself be an EP; formed in a manufacturing process in which the ISP (a) contains an active ingredient that is not isolated due to physical limitations or uncertainty as to the specific active component(s); or (b) is purposely left as a mixture of components due to manufacturing or integrity considerations.

Manufacturing concentrate (MA): A product containing a registered technical active ingredient(s) and formulant(s) intended for further reformulating or repackaging into EPs.

Manufacturing-use product (MP) or intermediate product: Products for manufacturing use only that include TGAI and MAs. It may also include ISPs when they are used for reformulating or repackaging.

Technical active ingredient or technical grade of active ingredient (TGAI): The TGAI contains the active ingredient and normally contains impurities that are by-products of the manufacturing process.

Use-site category (USC): for chemical pesticides were developed to group use-sites with common data requirements into specific categories. For definitions of specific USCs, refer to Appendix I.

Introduction

The PMRA receives more than 3500 submissions each year to register new pest control products, to amend currently registered ones or to conduct research on new uses for currently registered or new pest control products. To better manage this workload, the PMRA first categorizes submissions according to purpose and complexity and then processes the submissions accordingly.

All submissions to the PMRA go through a screening, evaluation and regulatory decision-making process within specific time frames. The route a submission follows and the associated time frame depend on its category and type, which are derived from the purpose of the submission and its complexity (the review effort required to evaluate the supporting data and carry out the risk assessment).

This Regulatory Note is a guide to assist applicants to identify the proper category (A through E), subcategory and submission type for a submission. It also provides guidance on other PMRA sources of information regarding data requirements to support a submission. The submission categories, subcategories and types are defined for most new applications for new or amended technical grade active ingredients (TGAIs) and integrated system products (ISPs) as well as new or amended end-use products (EPs) or manufacturing concentrates (MAs).

The PMRA has also created use-site categories (USCs) (1–33) as an aid to describing data required to support registration of the uses of pest control products at different sites. All of the possible use-sites have been grouped into 33 USCs, each covering use-sites that require similar data. For each USC, data code tables (DACOs) have been developed to guide applicants on the complete set of data required to support an active ingredient and end-use product for use on a site included in a particular USC. (Details of data requirements and protocols are provided in guidelines.) The USC DACO tables are located on the PMRA web site www.hc-sc.gc.ca/pmra-arla. Certain Category A submissions (A1.1, A1.2, A3.2) would require that virtually all the data outlined in the USC be attached. For other submissions (the others within Category A, such as A4 major new use, and Category B submissions), the requirements for the data that must accompany the submission may be less than that in the DACO table, as the PMRA may already have some of the needed data on file from earlier registrations. Whether the PMRA can use data on file depends on which company has submitted it and what access subsequent applicants have to it.

Multiple amendments in one submission for a currently registered product

More than one amendment to a registered product can be requested with one application form. For example, an application to amend a currently registered EP may include changes to the formulation by adding a new surfactant (Category B2.3, Identity of Formulants, and B2.4, Proportion of Formulants), or the addition of a new use and a tank mix with another registered product (B3.12, Addition of Site/Host, and B3.10, Tank Mixes). The application would be processed as a Category B submission, combining B2.3, B2.4, B3.10 and B3.12. The data required to support the application would be indicated in a combined Category B DACO table, which can be obtained upon request from the PMRA.

If an amendment does not require supporting data, then it is a Category C submission. As with a Category B amendment, one application form can cover several changes for a Category C submission. For example, the application might include updating the disposal statements according to Regulatory Directive DIR99-04, *Disposal statements for control product labels* (Category C3.15), upgrading to Master Product status (Category C8.1) and substituting an equivalent solvent for one that is no longer marketed (Category C2.3).

Submissions based on currently registered products

If the application is to register a pest control product, or to amend a currently registered product (precedent product), for example, a new EP with similar or identical formulation and uses to the precedent product, then the precedent product's trade name and registration number must be stated in the covering letter and application form.

Please contact the Information Service at 1-800-267-6315 (in Canada) or 1-613-736-3799 (outside Canada) to obtain a Registration Kit and further guidance.

Reduced-risk pesticides

In May 2002, the PMRA introduced an initiative whereby the North American Free Trade Agreement (NAFTA) Joint Review Programs for Reduced-Risk Pesticides will be extended by the PMRA to include submissions made to the PMRA only. The program is designed to encourage pesticide manufacturers to apply for Canadian registration of reduced-risk products including those that are currently available in the United States (U.S.); Canada will use the same criteria as the U.S. Environmental Protection Agency (EPA) to determine eligibility of chemicals for the reduced-risk program and recognize the U.S. EPA's biopesticide designation, thus further harmonizing the respective approaches of the two countries. Through this program, the PMRA will also commit to shorter review timelines for products that have been shown to qualify as reduced-risk chemicals or biopesticides. Refer to Regulatory Directive DIR2002-02, *The PMRA initiative for Reduced-Risk Pesticides*, for more details and guidance on preparation of submissions to the PMRA.

Notification/non-notification

There are three ways to make amendments to currently registered products: (a) changes that are acceptable when the PMRA has been notified in writing; (b) changes where the PMRA does not need to be informed (non-notification) (refer to Regulatory Directive DIR2001-04, *Notification/non-notification*, for more details and guidance on notifiable and non-notifiable changes to currently registered products acceptable to the PMRA); and (c) changes that require review and approval through an amendment that requires an application, applicable fees and possibly data. This document will help qualify this third method of making amendments to currently registered products.

Presubmission consultations

It is recommended that applicants for a Reduced-Risk Pesticide, Joint Review or URMUR, and those making a Category A submission or an electronic submission, contact the PMRA and arrange for a presubmission consultation. Please refer to Regulatory Proposal PRO2000-03, *“Single window” for inquiries to the Pest Management Regulatory Agency*, or to *Updated procedures for joint review of microbials and semiochemicals* or *Updated procedures for joint review of chemical pesticides* for guidance. Before contacting the PMRA, please visit the PMRA web sites (www.hc-sc.gc.ca/pmra-arla or www.eddenet.ca), which contain all relevant guidance and information pertaining to such applications. An applicant may also contact the PMRA's Information Service for clarification of individual points before submitting any other type of application, to ensure that the submission meets standards for format, completeness and quality.

Definitions for submission categories

Category A: Includes submissions to register a new technical grade of active ingredient (TGAI) or integrated system product (ISP) (not previously registered in Canada) and their related end-use product(s) (EPs), manufacturing-use products (MPs) or major new use (defined as the addition of a new USC to the use pattern for a specific registered TGAI), or to establish an import maximum residue limit(s) (MRLs) for a new active ingredient. These submissions are usually accompanied by a significant amount of data supporting safety and value and include URMURs (user requested minor use registration) and joint reviews. Besides traditional agricultural chemical and biocidal active ingredients, this category also applies to adjuvants, biopesticides including microbial pesticides, pheromones and seed treatments for export only.

- Category B: Includes submissions to register new pest control products (must contain an active ingredient that is currently registered for use in Canada) or to amend existing products. These include changes in product chemistry for the TGAI or ISP, changes in product chemistry for the EP or Manufacturing Concentrate (MA), changes in product labelling, the conversion or extension of temporary registration and the addition of import MRLs for previously assessed TGAI. These submissions are supported by a partial database (not all DACOs), as the PMRA has some of the data on file from previous registrations, or may require scientific assessment by the Occupational Exposure Assessment Section, for example. These submissions are less complex and take less time to review than Category A submissions.
- Category C: Includes submissions with no or reduced data requirements for new or amended registrations requiring minor label or formulation reviews, such as product registrations based on precedent. Refer to Regulatory Note REG2002-04, *Category C submission efficacy reviews*, for guidance on “fast track” Category C submissions that only require Part 1 value data.
- Category D: Includes submissions to register or to amend products within particular programs, such as the Import for Manufacture and Export Program (IMEP), Own Use Import (OUI), Master Copy, Private Label, User Requested Minor Use Label Expansion (URMULE) and renewals. The current versions of regulatory documents concerning these special programs are listed in Appendix II.
- Category E: Includes submissions for Research Permits (refer to Regulatory Directives DIR98-05, *Chemical pesticides research permit guidelines*, and DIR97-02, *Guidelines for the research and registration of pest control products containing pheromones and other semiochemicals*, and Regulatory Proposal PRO93-05, *Research permit guidelines for microbial pest control products*), for new TGAI, new use(s) of registered TGAI, as well as research notifications carried out in Canada. Exemptions from data requirements are based on the size and location of treated areas.

Category A submissions

Submission subcategory	Submission type	Product type ¹	Comments ^{2, 3}
A1 New active ingredient to Canada	A1.1 Canadian registration	TGAI, ISP, MA, or EP	
	A1.2 Parallel review	TGAI, ISP, MA, or EP	International work sharing
	A1.3 Import MRL(s) only	TGAI	For new active ingredients to Canada (not previously or currently registered for sale or use in Canada). Also refer to Regulatory Directive DIR98-02, <i>Residue chemistry guidelines</i> , Section 11 for further guidance.
A2 Major new use		TGAI or ISP	Addition of new USC to a currently registered active ingredient. All data may not need to accompany submission as some may be on file with the PMRA. Please contact the PMRA before making application to determine specific data requirement.
		EP	If the applicant is not the owner of the TGAI, the data currently on file with the PMRA can only be used if applicant has legitimate access by providing a letter of confirmation (LOC) or letter of authorization from registrant of TGAI.
A3 New active ingredient to Canada	A 3.1 URMUR	TGAI, ISP, MA, EP	For details on the information and data required refer to Regulatory Directive DIR99-05, <i>User Requested Minor Use Registration (URMUR)</i> .
	A 3.2 NAFTA Joint Review	TGAI, ISP, MA, EP	Refer to process outlined on the PMRA Web page.
A4 Major new use priority		TGAI, ISP	Addition of new USC identified as a critical need . This would be identified as a priority and processed in a shorter time.
		MA, EP	

¹ TGAI, technical grade of active ingredient; ISP, integrated system product; MA, manufacturing concentrate or intermediate product; EP, end-use product.

² Data requirements for Category A submissions are determined according to the DACO table for the appropriate USC unless otherwise noted in the Comments. Please refer to DIR2003-01 for further guidance.

³ See Appendix I, USC definitions.

Category B submissions

Submission subcategory	Submission type	Product type ¹	Definitions	Examples	Comments ²
B1 New or changes to product chemistry of TGAI or ISP	B1.1 New source (site of manufacture) by current registrant	TGAI or ISP	Addition or substitution of a new source (site of manufacture) of a registered TGAI or ISP (no change in registrant and no product specific registration (PSR) implications).	Company A has a technical product registered that is produced at a source (site of manufacture) located in Canada. Company A wishes to add a second source (site of manufacture) located in the U.K.	Refer to Regulatory Directive DIR98-04, <i>Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product</i> , for further guidance.
	B1.2 New source (site of manufacture) by different registrant		Registration of a new source (site of manufacture or toll manufacturer) of a registered TGAI or ISP by a different registrant/ applicant from the currently registered source(s) (PSR implications).	Company A has a registered TGAI that is produced at a source (site of manufacture) X. Company B wishes to register a different source of the same TGAI, which is produced at site of manufacture Y.	Data ownership issues (PSR) may arise (Trade Memorandum T-1-232)
	B1.3 Specifications or manufacturing process		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 changes 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%.	Refer to Regulatory Directive DIR98-04 for further guidance.

Submission subcategory	Submission type	Product type ¹	Definitions	Examples	Comments ²
B2 New or changes to product chemistry of EP or MA	B2.1 Guarantee	EP or MA	Change in the typical or nominal concentration of the active ingredient(s) in an EP.	Company A has an EP with a guarantee of 30%. Company A wishes to increase the guarantee to 40%.	Refer to Regulatory Directive DIR98-03, <i>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</i> , for further guidance
	B2.2 Form of TGAI or ISP	EP or MA	Change in the form of active ingredient(s) in an EP, or a new CAS number for the TGAI (excluding new active ingredient(s) esters, amines and isomers, classed as Category As).	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.	
	B2.3 Identity of formulants	EP or MA	Change in identity of formulant(s) where amount of new formulant(s) is greater than 0.1%.	Company A wishes to replace solvent X in their registered product with solvent Y.	
	B2.4 Proportion of formulants	EP or MA	Change in the relative concentration of formulant(s).	Company A wishes to change the amounts of two formulants (e.g., solvent A and surfactant B) in a registered EP.	
	B2.5 Formulation type	EP or MA	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 dispersible granule.	

Submission subcategory	Submission type	Product type ¹	Definitions	Examples	Comments ²
	B2.6 New Combination of TGAIs	EP or MA	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.	<p>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.</p> <p>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.</p>	
B3 New, or changes to, labels	B3.1 Application rate increase	EP	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.	Category B3.1, B3.9, B3.10 and B3.11: if only Part 10 efficacy data are required to support these types of amendments, they may qualify as Category C submission efficacy reviews (refer to REG2002-04 for the most recent updated document)
	B3.2 Application timing	EP	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.	

Submission subcategory	Submission type	Product type ¹	Definitions	Examples	Comments ²
	B3.3 Application number or frequency	EP	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.	
	B3.4 Application method	EP	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.	
	B3.5 Rotational crops or plant-back intervals	EP	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.	
	B3.6 Preharvest interval (PHI), or withholding period, or pre-slaughter interval	EP	Change in elapsed time between the last application and harvest of the food commodity.	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.	

Submission subcategory	Submission type	Product type ¹	Definitions	Examples	Comments ²
	B3.7 Pre-grazing interval	EP	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 Re-entry interval	EP	Change in elapsed time between application and safe re-entry.	Product A was registered with a re-entry interval of 48 hours. Company A wishes to reduce the re-entry interval to 24 h.	
	B3.9 Level of control	EP	Change in pest control claim, (e.g., 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”.	Please refer to comments under B3.1.
	B3.10 Tank mixes	EP	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.	Please refer to comments under B3.1.

Submission subcategory	Submission type	Product type ¹	Definitions	Examples	Comments ²
	B3.11 New Pests	EP	Addition of a pest(s) or different life stage of a pest, excluding a name considered 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.	Please refer to comments under B3.1.
	B3.12 New site/host	EP	Addition of a site 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.	
	B3.13 Precautions	EP	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.	
	B3.14 Classification	EP	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.	
B4 Conversion or extension of temporary registrations	B4.1 Conversion	TGAI, ISP, MA, or EP	A product or use has been granted temporary registration under Section 17 of the <i>Pest Control Products Act</i> and Regulations.		Case-by-case evaluation. Data requirements depend on the conditions of the specific temporary registration.
	B4.2 Extension				

Submission subcategory	Submission type	Product type ¹	Definitions	Examples	Comments ²
B5 New import MRL for previously assessed TGAI		TGAI or EP	Addition of MRL for previously assessed active ingredients to Food and Drug Regulations Division 15, for imported food commodities.	Product A contains TGAI B that is currently registered in Canada for use on apples. Company A wishes to add an import MRL for grapes on Product A.	Refer to DIR98-02 section 11 for further guidance.
B6 Emergency registration requests		EP			Requires provincial support. Refer to Regulatory Directive DIR2001-05, <i>Registration of pesticides for emergency use</i>
B7 Reinstatement of registered product		TGAI, ISP, MA, or EP	Registered product has lapsed renewal for 1 year or more.		If supporting data are required, please contact the PMRA for guidance.

¹ TGAI, technical grade of active ingredient; ISP, integrated system product; MA, manufacturing concentrate or intermediate product; EP, end-use product.

² Data requirements for Category B submissions are determined according to the specific DACO table modified using the appropriate USC table, unless otherwise noted in the Comments. For example, a B3.12 will have different data requirements if the product's registered uses are USC 4 versus USC 14. Please refer to DIR2003-01 for further guidance.

Category C submissions

Submission subcategory	Submission type	Product type ¹	Examples	Comments ²
C1 New, or changes to, product chemistry of a TGAI or ISP	C1.2 Alternate source of supply	TGAI or ISP	Company B repacks a TGAI and wants to add another equivalent source.	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).
	C1.3 Specifications		The SPSF of Product A has a minor calculation error or typo.	Requires new SPSF.
C2 New, or changes to, product chemistry of an EP or MA	C2.1 Guarantee	EP or MA	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 formulation require a new SPSF and may also require new labels (if amendment affects information on the label). If the guarantee has been amended, the difference is less than 10%, and the rate of application is not affected or a precedent product can be cited, only a Statement of Product Specification (SPSF) need be submitted (with a label, if applicable). Amendments to the formulants, e.g., change of carrier, change of propellant from fluorocarbons to hydrocarbons, changes in relative proportions of formulants (no qualitative changes), substitutions of dyes, perfumes, buffers that are equivalent to the originals would only require a new SPSF
	C2.2 Form of TGAI or ISP			
	C2.3 Identity of Formulants			
	C2.4 Proportion of Formulants			
	C2.5 Formulation Type			
C3 New, or changes to, product labels	C3.1 Application rate decrease or rate increase.	EP	Company A wants to decrease the rate of application on corn for Product A.	Application rate decrease: No data if based on precedent, or Data Part 10 only, required to support rate change (refer to REG2002-04) Application rate increase: no data if based on precedent

Submission subcategory	Submission type	Product type ¹	Examples	Comments ²		
	C3.2 Application timing		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.	Amendments to the label (Category C3.1 to 3.15) that do not require data or are based on precedent (and the precedent product has a similar formulation) will require new labels.		
	C3.3 Application number or frequency					
	C3.4 Application method					
	C3.5 Rotational crops or plant-back intervals					
	C3.6 PHI, or withholding period, or pre-slaughter interval					
	C3.7 Pre-grazing interval					
	C3.8 Re-entry interval					
	C3.9 Level of control				Company C wants to add a tank mix between its Product C and Company B's Product B where neither label currently has this tank mix.	Category C3.9, C3.10, C3.11: No data if based on precedent, or Data Part 10 only, are required to support amendment (refer to REG2002-04)
	C3.10 Tank Mixes					
	C3.11 New Pests					
	C3.12 New site/host			Amendments to the label (Category C3.1 to 3.15) that do not require data or are based on precedent (and the precedent product has a similar formulation) will require new labels.		
	C3.13 Precautions					
	C3.14 Classification					
	C3.15 Label Improvement					
C6 Administrative changes	C6.1 Transfer of ownership	TGAI, ISP, MA or EP		If no major changes to the formulation or label (refer to C2 and C3). New labels and SPSF are required, also refer to the Regulatory Directive DIR2001-04 and the Registration Handbook for more details.		

Submission subcategory	Submission type	Product type ¹	Examples	Comments ²
	C6.2 Source of registered TGAI in a registered EP	MA or EP	Company A has two (2) sources of active ingredient currently but wants to add a third source that is currently registered in Canada.	This additional or replacement source of TGAI must be registered and be chemically equivalent to the other sources; requires LOC from the TGAI supplier and new SPSF.
	C6.3 Addition of supplemental label or minor use(s) to product label	EP	Company B received a certificate for an approved URMULE and now wants to add this to the full product label.	The supplemental label must have been previously approved and the submission number should be included in the covering letter. The Minor Use(s) must have been approved under URMULE program. (Refer to Regulatory Directive DIR93-23, <i>User Requested Minor Use Label Expansion</i>), include the submission number in the covering letter.
C7 Similar product or use(s)		EP	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 and labels.
C8 Upgrade to Master Product Status	C8.1 Master Product	EP		Refer to Regulatory Directive DIR93-20, <i>Master Product/Master Copy Registration Process</i>
	C8.2 Initial Product	EP		Refer to Regulatory Directive DIR93-21, <i>Initial Product/ Private Label Registration Process</i>
C9 Reinstatement of registered product		TGAI, ISP, MA or EP		If no data are required to support submission. New labels and SPSF required.

¹ TGAI, technical grade of active ingredient; ISP, integrated system product; MA, manufacturing concentrate or intermediate product; EP, end-use product.

² Amendments that require no or reduced data to support the change and are not precedent setting, qualify as a Category C submission.

Category D submissions

Submission subcategory	Submission type	Product type ¹	Comments
D1 IMEP		TGAI, ISP, MA, EP	Refer to Regulatory Directive DIR95-05, <i>Importation for Manufacturing and Export Program</i> .
D2 OUI		EP	Refer to section 16.2 of the Registration Handbook and the PMRA web site for details and forms. OUI information kit can also be obtained by contacting the PMRA.
D3 URMULE		EP	Refer to Regulatory Directive DIR93-23.
D4 Master Copy		EP	Refer to Regulatory Directive DIR93-20.
D5 Private Labels		EP	Refer to Regulatory Directive DIR93-21.
D6 Renewal		TGAI, ISP, MA or EP	A renewal package is published annually, this can be obtained by contacting the PMRA or checking the PMRA web site for details.
D7 Discontinuation		TGAI, ISP, MA or EP	Refer to Part 13 of the Registration Handbook.
D8 Printed labels (pilot)		TGAI, ISP, MA or EP	Refer to Regulatory Note R98-01, <i>Implementation of the Label Review Working Group Recommendations</i> .
D9 Label Improvement Programme		TGAI, ISP, MA or EP	Based on Regulatory Directives or Notes.

¹ TGAI, technical grade of active ingredient; ISP, integrated system product; MA, manufacturing concentrate or intermediate product; EP, end-use product.

Category E submissions**Research permits and research notifications**

Submission subcategory	Product type¹	Comments
E1 Research Permit for New TGAI, Food use	TGAI, ISP, MA or EP	Refer to Regulatory Directives DIR98-05 and DIR97-02 and Regulatory Proposal PRO93-05.
E2 Research Permit for New TGAI, Non-food use		
E3 Research Permit for New use		
E4 Research Notification		

¹ TGAI, technical grade of active ingredient; ISP, integrated system product; MA, manufacturing concentrate or intermediate product; EP, end-use product.

List of abbreviations

DACO	data code
EP	end-use product
EPA	Environmental Protection Agency (United States)
IGR	insect growth regulator
IMEP	Import for Manufacture and Export Program
ISP	integrated system product
LOC	letter of confirmation of supply of active ingredient
MA	manufacturing concentrate
MP	manufacturing-use product
MRL	maximum residue limit
NAFTA	North American Free Trade Agreement
OECD	Organisation for Economic Co-operation and Development
OUI	own use import
PGR	plant growth regulator
PHI	preharvest interval
PMRA	Pest Management Regulatory Agency
PSR	product specific registration
SCDD	Submission Coordination and Documentation Division
SPSF	Statement of Product Specification
TGAI	technical grade of active ingredient
URMULE	user requested minor use label expansion
URMUR	user requested minor use registration
USC	use-site category

Appendix I USC definitions for conventional chemical pesticides

USC	Definition	Exclusions
Agriculture or forestry		
1. Aquaculture <ul style="list-style-type: none"> - Insecticides - Herbicides - Insect Growth Regulators (IGRs) - Antifouling products 	Plants or animals produced in an aquatic (marine or fresh water) environment for human consumption, including antifouling products for nets and pens.	<ul style="list-style-type: none"> • for hydroponics, see Greenhouse Food Crops (USC 5) and Greenhouse Non-Food Crops (USC 6)
2. Aquatic Non-Food Sites <ul style="list-style-type: none"> - Insecticides - Herbicides - Piscicides - Molluscides - Algicides - Lampricides 	Outdoor natural and man-made environments (marine or fresh water), including, but not limited to: <ul style="list-style-type: none"> • non-food algae • weeds • lamprey eels • fish • aquatic life stages of insects • zebra mussels and other mollusks • includes once-through treatment of industrial water systems for zebra mussel control 	<ul style="list-style-type: none"> • Industrial Process Fluids (USC 17) • Underwater Structures and Materials (USC 22) • Swimming Pools (USC 29) • Other Indoor Surfaces, Water and Air (USC 19) • treatments of drinking water in municipal systems and private wells
3. Empty Food Storage Areas <ul style="list-style-type: none"> - Insecticides - Herbicides - Rodenticides - Disinfectants - Plant Growth Regulators (PGRs) - Insect Growth Regulatory (IGRs) 	Empty commercial premises where food is to be stored or grown, including, but not limited to: <ul style="list-style-type: none"> • disinfection of potato storage bins on farms and cooperatives • empty food storage or packaging areas • empty greenhouses and mushroom houses devoid of growth media 	<ul style="list-style-type: none"> • disinfection or sanitization of all other commercial food storage areas subject to the <i>Food and Drugs Act</i>
4. Forests and Woodlots <ul style="list-style-type: none"> - Insecticides - Herbicides - Fungicides - PGRs - IGRs 	Forested areas, including, but not limited to: <ul style="list-style-type: none"> • plantations • forest nurseries • Christmas tree plantations and nurseries • site preparation • seed production (seed orchard) • conifer release 	<ul style="list-style-type: none"> • Ornamentals Outdoors (USC 27) • Greenhouse Non-Food (USC 6)

USC	Definition	Exclusions
5. Greenhouse Food Crops <ul style="list-style-type: none"> - Insecticide - Herbicides - Fungicides - PGRs - IGRs 	Edible crops growing in greenhouses, including, but not limited to: <ul style="list-style-type: none"> • mushrooms growing in mushroom houses • indoor hydroponically-grown food plants • greenhouses cleared of edible crops, but containing soil and growth media 	<ul style="list-style-type: none"> • for treatment of empty greenhouses and empty mushroom houses devoid of growth media, see Empty Food Storage Areas (USC 3) • disinfection or sanitization of greenhouses or mushroom houses where a food crop is growing is subject to the <i>Food and Drugs Act</i>
6. Greenhouse Non-Food Crops <ul style="list-style-type: none"> - Insecticide - Herbicides - Fungicide - Disinfectants - PGRs - IGRs 	Non-food crops growing in greenhouses, including, but not limited to: <ul style="list-style-type: none"> • non-food crops growing hydroponically indoors 	<ul style="list-style-type: none"> • for treatment of empty greenhouses devoid of growth media, see Empty Food Storage Areas (USC 3)
7. Industrial Oil Seed Crops and Fibre Crops <ul style="list-style-type: none"> - Insecticides - Herbicides - Fungicides - PGRs - IGRs 	Terrestrial plants being commercially grown only for seed production, including, but not limited to: <ul style="list-style-type: none"> • seed crops 	
8. Livestock for Food <ul style="list-style-type: none"> - Insecticide - Insecticide feed-through - Insect Repellents - IGRs 	Terrestrial animals and bees raised as a source of food for human consumption, including, but not limited to: <ul style="list-style-type: none"> • milk • meat • meat by-products • honey Also including: <ul style="list-style-type: none"> • topical application for ectoparasite control 	<ul style="list-style-type: none"> • all methods other than topical application for the control of ectoparasites. All disease control agents, no matter how they are applied, are subject to the <i>Food and Drugs Act</i> • for other treatments of animals, see Aquaculture (USC 1) and Companion Animals (USC 24)
9. Livestock Non-Food <ul style="list-style-type: none"> - Insecticides 	Terrestrial animals raised for uses other than as food for human consumption, including, but not limited to: <ul style="list-style-type: none"> • fur-bearing animals 	<ul style="list-style-type: none"> • Companion Animals (USC 24) • Livestock for Food (USC 8) • all methods, other than topical application, for the control of ectoparasites • All disease control agents, no matter how they are applied, are subject to the <i>Food and Drugs Act</i>

USC	Definition	Exclusions
10. Seed Treatments Food and Feed <ul style="list-style-type: none"> - Insecticides - Fungicides - Bactericides 	Seed for food or feed in a commercial application facility or on a farm to prevent insect infestation or infectious diseases. Includes the planting of treated seed either indoors or outdoors. Including, but not limited to: <ul style="list-style-type: none"> • seed potatoes • rootstock • bulbs • cuttings • true seed 	
11. Seed Treatments Non-Food <ul style="list-style-type: none"> - Insecticides - Fungicides - Bactericides 	Seed for a non-food crop in a commercial application facility or on a farm to prevent insect infestation or infectious diseases. Included are the planting of treated seeds either indoors or outdoors. Including, but not limited to: <ul style="list-style-type: none"> • rootstock • corms • bulbs • cuttings • true seeds 	
12. Stored Food and Feed <ul style="list-style-type: none"> - Insecticides - Fungicides - Rodenticides - PGRs - IGRs 	Stored bulk food, including, but not limited to: <ul style="list-style-type: none"> • grains in elevators, ships' holds, etc. • post-harvest treatment of crops, e.g., fruits, potatoes, etc. • stored packaged food and feed • stored bulk feed • food processing areas, food processing plants, restaurants and other areas where food is present during treatment 	
13. Terrestrial Feed Crops <ul style="list-style-type: none"> - Insecticides - Herbicides - Fungicides - PGRs - IGRs 	Crops grown outdoors as a source of feed for livestock, including direct treatment of crops or the soil during one or more of the various growth stages, including pre-plant and pre-emergence.	<ul style="list-style-type: none"> • for crops treated after harvest, see Stored Food and Feed (USC 12)
14. Terrestrial Food Crops <ul style="list-style-type: none"> - Insecticides - Herbicides - Fungicides - PGRs - IGRs 	Crops grown outdoors as a source of food for human consumption, including direct treatment of crops or soil during one or more of the various growth stages, including pre-plant and pre-emergence. Including, but not limited to: <ul style="list-style-type: none"> • non-bearing stages of plants, e.g., pre- and post-bloom fruit trees, non-bearing strawberries, etc. • crops grown for seeds for subsequent planting • cranberries • tobacco • land to be used for future crop growth, e.g., fallow land 	

USC	Definition	Exclusions
Industry		
15. Indoor Hard Surfaces <ul style="list-style-type: none"> - Hard Surface Disinfectants - Sanitizers 	Indoor hard surfaces, e.g., counters, sinks, toilets and floors, in non-food areas and also in areas such as kitchens where there may be food contact. Food contamination must be avoided by appropriate label precautions.	The following antimicrobial controls are still subject to the <i>Food and Drugs Act</i> : <ul style="list-style-type: none"> • food processing and meat packaging • medical instruments • medical care facilities, e.g., hospitals and veterinary clinics • drinking water devices
16. Industrial and Domestic Vegetation Control for Non-Food Sites <ul style="list-style-type: none"> - Herbicides - PGRs 	Terrestrial vegetation sites on non-agricultural lands, including, but not limited to: <ul style="list-style-type: none"> • industrial sites • parking lots • tennis courts • rights-of-way • driveways and patios 	<ul style="list-style-type: none"> • for agricultural land to be used for a Terrestrial Food or Feed Crop in subsequent years, see Terrestrial Food Crops (USC 14) and Terrestrial Feed Crops (USC 13)
17. Industrial Process Fluids <ul style="list-style-type: none"> - Slimicides 	Industrial process fluids, including, but not limited to: <ul style="list-style-type: none"> • water cooling towers (open, once-through and closed systems) • pulp and paper • drilling muds 	<ul style="list-style-type: none"> • for slime control in other sites see Swimming Pools (USC 29) and Aquaculture (USC 1) • for ornamental ponds, see Aquatic Non-Food Sites (USC 2) • Material (USC 18)
18. Material <ul style="list-style-type: none"> - Material Preservatives 	Products used or added to manufacture or processing to preserve the material or its function, including, but not limited to: <ul style="list-style-type: none"> • metal cutting fluid • leather • textiles • fuel • paint • canvas • caulking 	<ul style="list-style-type: none"> • Underwater Structures and Materials (USC 22) • Wood (USC 23)
19. Other Indoor Surfaces, Water and Air <ul style="list-style-type: none"> - Slimicides - Disinfectants - Sanitizers 	Including, but not limited to: <ul style="list-style-type: none"> • laundry • air ducts • air • water beds • humidifiers • building-related illness treatment Food contamination must be avoided by appropriate label precautions.	

USC	Definition	Exclusions
20. Structural <ul style="list-style-type: none"> - Insecticides - Fungicides - Rodenticides - IGRs 	Residential, farm and office buildings, air, land and sea transport vehicles, ships and other commercial structures not associated with commercial food production or storage. Food contamination must be avoided by appropriate label precautions.	<ul style="list-style-type: none"> • Indoor Hard Surfaces (USC 15) • for termite control, see Structures and Surrounding Soil (USC 21) • products for disinfectant treatments of food storage and processing areas subject to the <i>Food and Drugs Act</i>
21. Structures and Surrounding Soil <ul style="list-style-type: none"> - Termiticides 	Structures and surrounding soil for preventive treatment or control of termite infestations.	<ul style="list-style-type: none"> • Structural (USC 20)
22. Underwater Structures and Materials <ul style="list-style-type: none"> - Antifouling coatings 	Structures intended for underwater use, including, but not limited to: <ul style="list-style-type: none"> • lobster traps • boat hulls • fishing nets • intake pipes 	<ul style="list-style-type: none"> • for wood preservation of underwater structures, piers and docks, see Wood (USC 23) • aquaculture pens and nets
23. Wood <ul style="list-style-type: none"> - Heavy duty wood preservatives (HDWPs) - Anti-sapstains - Millwork and joinery products - Remedial treatment products - Wood stains and coatings 	Preservation and protection of wood and wood products, including, but not limited to, HDWPs for wood used in underwater structures.	<ul style="list-style-type: none"> • Underwater Structures and Materials (USC 22) • Structural (USC 20) • Structures and Surrounding Soil (USC 21)
Society		
24. Companion Animals <ul style="list-style-type: none"> - Insecticides - Fungicides - Molluscides - Algicides - IGRs 	Indoor and outdoor companion animals and aquatic life forms. Control of pests is solely by topical application or directly to aquarium water.	<ul style="list-style-type: none"> • Livestock for Food (USC 8) and Non-Food (USC 9) • all other prescribed veterinary drugs • all methods other than topical application for the control of ectoparasites. All disease control agents, no matter how they are applied, are subject to the <i>Food and Drugs Act</i> • for products to be used on pet sleeping areas, see Structural (USC 20)

USC	Definition	Exclusions
25. Human Habitat and Recreational Areas - Insecticides	Commercial treatment of urban or rural habitation and recreational areas, including, but not limited to control of: <ul style="list-style-type: none"> • adult biting flies • black flies • mosquitoes • other insects 	<ul style="list-style-type: none"> • for aquatic larval stages, see Aquatic Non-Food (USC 2)
26. Human Skin, Clothing and Proximal Sites - Insecticides - Insect Repellents	Direct application, placement in close proximity to humans, e.g., coils and candles; impregnation into, or a spraying onto materials, e.g., clothing, tablecloths and canvas.	<ul style="list-style-type: none"> • products intended to repel or control ectoparasites, e.g., lice, subject to <i>Food and Drugs Act</i>
27. Ornaments Outdoor - Insecticides - Herbicides - Fungicides - PGRs - IGRs	Non-food plants growing outdoors, including, but not limited to: <ul style="list-style-type: none"> • flowers • trees • shrubs • seed crops on non-agricultural land 	<ul style="list-style-type: none"> • for grass, lawns, turf soil, sod farms, see Turf (USC 30)
28. Indoor Plants and Plantscapes - Insecticides - Herbicides - Fungicides - PGRs - IGRs	Plants grown indoors, including, but not limited to: <ul style="list-style-type: none"> • shopping malls • commercial buildings • residences 	<ul style="list-style-type: none"> • see also Terrestrial Food Crops (USC 14)
29. Swimming Pools - Algicides - Bactericides	Water in public or private swimming pools, hot tubs and spas.	<ul style="list-style-type: none"> • for ornamental ponds, see Aquatic Non-Food (USC 2)
30. Turf - Insecticides - Herbicides - Fungicides - PGRs - IGRs	Grass sites, including, but not limited to: <ul style="list-style-type: none"> • lawns • golf courses • parks • recreational areas • sod farms • turf soil 	<ul style="list-style-type: none"> • for natural grassland and pastures, see Terrestrial Feed Crops (USC 13) • Residential Outdoors (USC 33)
31. Various Indoor and Outdoor Sites - Animal Repellents	Products used indoors or outdoors in small quantities to repel dogs, cats, birds, bears and other vertebrate pests.	<ul style="list-style-type: none"> • Terrestrial Food Crops (USC 14) • Terrestrial Feed Crops (USC 3)
32. Various Outdoor Sites - Vertebrate Pest Control Products - Rodenticides - Avicides	Commercial products used outdoors to control animal pests, including, but not limited to: <ul style="list-style-type: none"> • gophers • coyotes • wolves • birds 	<ul style="list-style-type: none"> • Terrestrial Food Crops (USC 14) • Terrestrial Feed Crops (USC 13)

USC	Definition	Exclusions
33. Residential Outdoors <ul style="list-style-type: none">- Insecticides- IGRs	Control of domestic home and yard nuisance insects and ticks, including, but not limited to: <ul style="list-style-type: none">• wasps• hornets• ticks• fleas• mosquitoes and black flies	<ul style="list-style-type: none">• any food use• for termite control, see Structures and Surrounding Soil (USC 21)• for insect repellents, see Human Skin, Clothing and Proximal Sites (USC 26)• Turf (USC 30)• Ornamental Outdoors (USC 27)

Appendix II Documents referenced in this note

Regulatory Proposals

- PRO93-05 *Research Permit Guidelines for microbial Pest Control Products*
PRO96-01 *Management of Submissions Policy*
PRO2000-03 *“Single Window” for Inquires to the Pest Management Regulatory Agency*

Regulatory Directives

- DIR93-20 *Master Product/Master Copy Registration Process*
DIR93-21 *Initial Product/ Private Label Registration Process*
DIR93-23 *User Requested Minor Use Label Expansion*
DIR95-05 *Importation for Manufacturing and Export Program*
DIR97-02 *Guidelines for Research and Registration of Pest Control Products Containing Pheromones and other Semiochemicals*
DIR98-02 *Residue Chemistry Guidelines*
DIR98-03 *Chemistry Requirements for the Registration of a Manufacturing Concentrate or an End-Use Product Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products*
DIR98-04 *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*
DIR98-05 *Chemical Pesticides Research Permit Guidelines*
DIR99-05 *User Requested Minor Use Registration (URMUR)*
DIR2001-04 *Notification/non-notification*
DIR2001-05 *Registration of Pesticides for Emergency Use*
DIR2002-02 *The PMRA Initiative for Reduced Risk Pesticides*
DIR2003-01 *Organizing and Formatting a Submission for Pest Control Products*

Memorandum

- T-1-232 *Product Specific Registration (PSR) Policy: Pesticides*

Regulatory Notes

- R98-01 *Implementation of the Label Review Working Group Recommendations*
REG2002-04 *Category C Submission Efficacy Reviews*

Registration Handbook for Pest Control Products Under the Pest Control Products Act and Regulations

Pest Control Products Act and Regulations

Food and Drugs Act and Regulations

NAFTA Technical Working Group on Pesticides

- Updated Procedures for Joint Reviews of Microbials and Semiochemicals*
Updated Procedures for Joint Reviews of Chemical Pesticides