Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Directive

DIR2003-01 revised

Organizing and Formatting a Complete Submission for Pest Control Products

In February 1998, the Pest Management Regulatory Agency (PMRA) produced Regulatory Proposal PRO98-02, *Organizing and Formatting a Complete Submission for Pest Control Products.* The information contained in the proposal was provided to assist applicants to prepare complete and properly formatted and organized submissions when applying to register new pest control products or to amend existing ones. Complete and well-organized submissions prepared according to this guidance are more likely to pass the screening stages within the PMRA and therefore contribute to the increased efficiency of the regulatory process. The PMRA received comments on the proposal and carefully considered comments from all respondents.

This directive, which is an amended version of PRO98-02, includes clarification and additional information related to definitions, index requirements, pre-submission consultations, letters of screening deficiencies, number of copies of information required, comprehensive data summaries and Organisation for Economic Co-operation and Development formats. Further amendments have been made to data requirements as a result of the publication of regulatory directives for product chemistry and residue chemistry.

This regulatory directive replaces PRO98-02 and regulatory directives DIR93-01, *Organization of Data for Technical Active Ingredients,* and DIR93-03, *Organization of Data for End-Use Products.*

NOTE: **In order to provide minor clarification in Appendix I and concerning the use of Appendix II, the February 14, 2003 version of this document has been revised.**

(publié aussi en français) **April 11, 2003**

This document is published by the Alternative Strategies and Regulatory Affairs Division, Pest Management Regulatory Agency. For further information, please contact:

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ISBN: 0-662-32856-6
Catalogue number: H113-3/2003-1E-IN

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Foreword

This document explains the process for organizing and formatting a complete submission. It describes procedural, organizational and formatting improvements aimed at:

- increasing the efficiency of submission processing; and
- preparing the Canadian pesticide industry and the Pest Management Regulatory Agency (PMRA) for international harmonization of registration standards and processes.

Canada is working with countries within the Organisation for Economic Co-operation and Development (OECD), including the United States, on harmonization activities aimed at developing international standards for common submission formats and data requirements (refer to Appendix IV). The PMRA accepts submissions formatted according to the *Guidelines and criteria for industry for the preparation and presentation of complete dossiers and of summary dossiers for plant protection products and their active substances in support of regulatory decisions in OECD countries* dated March 2001, found on the OECD web site http://www.oecd.org/ or at http://www.eddenet.ca, as well as through links via the PMRA web site http://www.hc-sc.gc.ca/pmra-arla. This OECD format contains a crosswalk of numbering systems (e.g., OECD, European Union, United States (U.S.), Canada, Japan, Australia) for organizing and indexing supporting data. The PMRA will also accept applications for microbials and pheromones submitted in OECD format as guidance is developed by the OECD.

There are major benefits, outlined below, to be gained in following the processes set out in this document.

- The numbering system for organizing and indexing supporting data explained here is important to the use of the new OECD format.
- The system for determining data requirements based on use–site categories (USCs) should help applicants put together a complete submission package containing all the required studies that will pass more efficiently through the registration process. This will reduce the cost to industry by allowing a regulatory decision to be made for products sooner.
- Today, the electronic environment is being utilized to a greater extent with the use of electronic indices, labels and comprehensive summaries. Downloading information onto a diskette requires little effort on the part of applicants, but is important to the PMRA, as the receipt of information in electronic format has been shown to reduce the time necessary to process and evaluate the information. Electronic submissions will also pave the way for new uses of information technology being developed by the PMRA and other international agencies.

The information contained in this document has been shared with industry, when requested, and most applicants have submitted applications that conform with these guidelines. From the date of publication of this revised document, the PMRA will require applicants to organize and format their submissions according to these standards or the OECD standards indicated above. Following initial verification, submissions that do not conform with the requirements for organizing and formatting will be found deficient. The applicant will be asked to address these deficiencies before the submission is screened further.

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1.0 Introduction

A number of efficiencies were implemented with the establishment of the Pest Management Regulatory Agency (PMRA) and the consolidation of various agencies responsible for pesticide regulation. One such efficiency was the comprehensive screening of submissions early in the registration application process. Submission screening contributes to a more efficient regulatory system by providing correctly formatted and complete submissions for efficient review. Complete and correctly formatted submissions also allow for improved handling, tracking, storage and retrieval. Screening also facilitates the identification of deficiencies to applicants early in the review process.

The PMRA Regulatory Proposal PRO96-01, *Management of Submissions Policy*, dated June 7, 1996, outlines submission categories and the submission management process, including submission screening. This regulatory directive describes the procedures and criteria for submission screening in more detail, and gives more complete direction on the organization of a submission and its supporting information package to companies that intend to apply to register new products, to amend existing registered products or to carry out research with new or currently registered pest control products. While this directive serves as a general guide for organizing and formatting most submissions, applicants should contact the PMRA for specific directives relating to biopesticides, specifically microbials and pheromones.

2.0 General definitions

Category A: includes submissions to register new technical grade of active ingredient (TGAI) or integrated system products (ISP) (not previously registered in Canada) and their related end-use product(s) (EPs), manufacturing-use products (MAs) or major new use (defined as the addition of a new use–site category to the use pattern for a specific registered TGAI), or to establish an import maximum residue limit(s) (MRL) 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 registrations) 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. Refer to Regulatory Note REG2003-01, *Guidance on Selecting the Correct Category for Pest Control Product Submissions*, for more details.

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 TGAIs. These submissions are supported by a partial database (not all data codes (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 (OEAS), for example. These submissions are less complex and take less time to review than Category A submissions. Refer to REG2003-01 for more details.

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 REG2003-01 for more details and Regulatory Note REG2002-04, *Category C submission Efficacy Reviews*.

Category D: includes submissions to register or to amend products within particular programs, for example, Import for Manufacture and Export Program (IMEP), own use import (OUI), master copy, private label, user requested minor use label expansion (URMULE), renewals. The current versions of regulatory documents concerning these special programs are listed in Appendix II. Refer to REG2003-01 for more details.

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 TGAIs and new use(s) of registered TGAIs, as well as research notifications carried out in Canada. Exemptions from data requirements are based on the size and location of treated areas. Refer to REG2003-01 for more details.

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

Data codes (DACOs): are numeric codes that are used to identify the individual scientific studies for each USC. Refer to Appendix IV for a complete list of DACOs.

DACO tables: list data requirements for registration of a product. These are available for the product types occurring in the 33 Use–site Categories for conventional chemical pesticides. DACO tables have been developed for other product types such as pheromones, establishing import MRLs, Category B submissions, and so on. DACO tables are to be posted on the PMRA web site; in the interim, tables are available upon request. Refer to Section 5.1 for more details.

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 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 require review and approval through an amendment; (b) changes that are acceptable when the PMRA has been notified in writing by submitting a notification letter; and (c) 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.

3.0 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 pre-submission 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 websites (http://www.hc-sc.gc.ca/pmra-arla or http://www.eddenet.ca), which contain all relevant guidance documents and information pertaining to such applications. An applicant may also contact the PMRA's Information Services for clarification of individual points before submitting any other type of application, to ensure that the submission meets standards for format, completeness and quality.

4.0 Submission verification

Within seven days of receipt, all submissions are verified to ensure that non-data elements such as covering letter, application form, fee form and fees (if required) (refer to detailed list in Appendix I) have been provided to support the application. Deficiencies result in a submission being returned to the applicant at the applicant's expense. An applicant whose submission is verified is provided with an acknowledgement card that includes the submission number. This number should appear on all correspondence dealing with that submission sent to the PMRA. Once verified, submissions are forwarded for screening.

5.0 Submission screening process

Submissions are screened in more depth for required elements, including data and non-data components, forms and various letters of documentation, as well as for completeness, proper formatting and organization according to the PMRA, DACO or OECD guidance

number. Scientific validity of data is not assessed by Submission Screening. If no deficiencies are identified, the submission is forwarded to the relevant section for scientific review.

5.1 Use–site categories and DACO tables

Data required to support an application to register a new product, amend an existing one or conduct research with a pest control product depend on the nature of the product (chemical or microbial, for example), the purpose of the product (IMEP, for example) and where the product will be used (use–site) (on food or in water, for example). All possible use–sites for pest control products have been grouped into a series of 33 use–site categories (USCs) based on similar data requirements. For each USC, a DACO table has been prepared that lists required (R) and conditionally required (CR) studies. Each study in the table is identified by a numeric data code or DACO. DACO tables for some USCs are posted on the PMRA web site; others are available from the PMRA upon request. These DACO tables were developed from existing guidelines and practices and do not establish new data requirements. Refer to Appendix III for a list of USCs for conventional chemical pesticides and their definitions. In addition to DACO tables based on use–sites, tables are also under development for certain product types (such as adjuvants and seed treatments) and submission categories (Category B) and, if completed, may be obtained from the PMRA upon request.

Certain Category A submissions (A1.1, A1.2, A3.2) would require that virtually all of the data outlined in the DACO table for the relevant use–site categories 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 relevant 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: if the applicant is not the owner of the TGAI used in the product, then a letter of confirmation of supply of TGAI is required and possibly a letter of authorization from the TGAI owner.

Data submitted should also include information that may indicate adverse or deleterious effects on human health and the environment. If foreign reviews, such as EPA Data Evaluation Reports, are available, it would be beneficial to submit them with the application.

5.2 Evaluation templates

Evaluation templates have been developed using the DACO tables that identify the R and CR studies for particular USCs. Evaluation templates are used to review the scientific studies that are submitted to support applications to register pest control products. These templates capture specific data components and record the reviewer’s conclusions and rationales that are based on each data set. Executive summaries from templates are used to

create an overall science monograph (a review document) on which the regulatory decision is based.

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

NOTE: The PMRA recognizes that the study and preparation period for a new pesticide submission can require a number of years. To facilitate the use of templates at the early stages of study development and report preparation, the PMRA will accept draft or older versions of approved templates even if newer versions are available at the time of the actual submission to the PMRA. The use and submission of draft or older templates will not exempt the submission from additional data requirements that are identified in the latest templates and regulations, for example. The PMRA strongly recommends that registrants check for and adopt new templates during the preparation of a submission.

To facilitate their use, identical versions of the evaluation templates are available in either WordPerfect or MS-Word format on the web at http://www.eddenet.ca. The templates are listed under their respective Divisions and represented in the lists by the heading ".wpd" (WordPerfect format) and ".doc" (Word format).

Note to Word users: Once completed, the Word templates **must be converted** to (saved as) "portable document format (PDF) normal" to ensure that they can be accessed and used by PMRA evaluators; do not submit them as Word files.

Data that is not included with a study should not be added via the evaluation template. Additional data should be submitted as an attachment. Refer to Section 6.6 for information on organizing evaluation templates.

5.3 Elements of a complete submission package

Only complete submissions containing all of the required elements will be considered for review by the PMRA. A submission is normally composed of a covering letter, an application form, the fee and supporting information. The supporting information may comprise a product specification form, various letters of support or authorization, draft label, index of supporting scientific data or studies, and the scientific data. Please refer to Appendix I for a list of the elements of a complete submission package. These elements are either R or CR depending on the purpose of the submission and the site or location of use of the product. For all submissions, all data requirements identified as R, as well as *applicable* CR data for a particular USC, must be addressed with appropriate studies or information, references to previously submitted data, or requests for waivers.

Applicants are encouraged to include in their submission a letter allowing regulatory agencies to discuss submissions and share reviews (monographs) with regulatory authorities in other countries, to facilitate international harmonization and work sharing.

5.4 Electronic submission of information

The PMRA's electronic submission capability is named the EDDE (Electronic Dossier, Delivery, and Evaluation) system. EDDE provides electronic support for the registration process. It is the key to efficiency gains for both industry and the PMRA. EDDENet, PMRA's secure, online pilot registration site, supports the EDDE capability (http://www.eddenet.ca). The PMRA has also provided four guidance documents to assist registrants with an electronic submission capability: *Part I,* which provides an overview (Regulatory Note REG2001-06, *Guidance to applicants for preparing electronic submissions Part I: overview*), and *Parts II, III and IV (EDDE2001-01, -02, -03),* which provide more detailed information and describe how registrants may participate in joint PMRA–industry electronic pilot projects. Additional detail is available and registrants interested in joint PMRA–industry pilot projects are encouraged to request a pre-submission consultation meeting.

Certain elements of a submission, such as the data index, product labels and comprehensive data summaries (CDS), must be submitted electronically on a 3.5" diskette or CD in PDF normal format, unless specified otherwise. If the applicant wishes to make a fully electronic submission, with all previously mentioned elements and all forms, letters, data and other items, the requirements are the same. An applicant wishing to submit information in a different electronic environment is responsible for confirming that no text loss or format changes have occurred as a result of the PDF conversion. When submitting a diskette or CD, applicants must include a statement in the covering letter certifying that the diskette or CD, to the best of their ability, is virus-free and that the information contained in the diskette or CD is a true and accurate duplication of the submitted paper copies. Any diskette or CD found to contain a virus will be returned to the applicant. For more details on formatting, refer to the sections pertaining to the specific type of information to be submitted, for example, index or label. Only one (1) paper copy of the complete dossier is required when submitting a fully electronic version.

Full instructions on how to use this mechanism are provided on the PMRA web sites, http://www.hc-sc.gc.ca/pmra-arla and http://www.eddenet.ca.

The applicant will need:

- a computer (PC: 486 processor or more / Mac: G3 and up with OS 8.6 or more)
- an Internet browser such as Netscape or Microsoft Explorer
- Internet access through an Internet service provider
- Adobe Acrobat 4.0 or higher software. This is available from http://www.adobe.com.

5.5 New technical grade of active ingredient or integrated system product and related end-use product

The data required to support a new TGAI or ISP and related EPs are determined according to the DACO table for the appropriate USC. Since the data requirements for an ISP are the same as those for a TGAI, separate references to ISPs will not be made throughout this regulatory directive. Separate applications must be made for the TGAI and each EP, including separate indexes for the TGAI and each EP along with the required data for each. A submission to register a new TGAI (Category A submission) must be accompanied by a submission to register a related EP(s). When more than one company is involved, it is the responsibility of those companies to coordinate the concurrent submission of the TGAI and the EP application packages to ensure that they are received by the PMRA at the same time.

5.6 Manufacturing concentrate

Defined as a product containing a registered technical active ingredient(s) and formulant(s) intended for further reformulating or repackaging into EP(s).

In general, the data required to support an application to register an MA are as follows:

Part 0 Index
Part 1 Label
Part 3 Chemistry requirements set out in Regulatory Directive 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.*
Part 4 Toxicology as required for an EP

For more specific information on data organization refer to Section 6.1 below.

5.7 Major new use

A major new use is defined as the addition of a new use–site category to the use pattern for a specific registered TGAI. An application to amend the TGAI to register the major new use must be accompanied by an application to register or to amend a related end-use product. The data required to support a major new use for a currently registered TGAI and related EP(s) are determined according to the DACO table for the appropriate USC. For these Category A submissions, data previously submitted in support of the TGAI or related EPs that address data requirements for the major new use do not need to be resubmitted, but must be cited in the index (refer to Section 6.1, Part 0, Index). The applicant must indicate in writing, by means of a letter of access or letter of confirmation of supply of TGAI, whether or not the PMRA may access that data. Separate indices should be submitted for the EP (major new use) and TGAI.

5.8 Tailgate submissions

Defined as a submission for a new or existing product for which a current submission is open, past screening and awaiting a regulatory decision. A tailgate submission cannot be reviewed until the previously submitted application has been accepted or proposed for registration. For example:

(a) Category B submission for amendment to formulation when Category A decision for same formulation not finalized;
(b) application for a new similar product based on an EP not yet registered and containing a TGAI not yet registered, with no PCP numbers assigned and no certificate issued; or
(c) applications for new uses or tertiary amendments awaiting other decisions on current open submissions.

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

(a) changes in formulations or rates affect risk assessment because they require repetition of the review and risk assessment activities in numerous scientific disciplines, such as chemistry, occupational and food exposure, formulants issues;
(b) adding new uses or rates would require that parts of the review be redone: efficacy, exposure, environment and residue chemistry and all risk assessments.

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

(a) withdraw the tailgate submission and resubmit when the precedent submission is approved;
(b) maintain the tailgate submission but combine it with the precedent submission (adopt its category status) and reset the timelines for the precedent submission to start at the time of the tailgate submission; or
(c) screen and delay: that is, allow tailgate submission, perform preliminary screen and delay processing within the PMRA until the original submission is accepted for registration (proposed pilot project); during the delay status, any changes in scientific approach or new policies will apply to the submission in delay.

5.9 Responses to letters of screening deficiencies

A submission found to be deficient at the screening stage will result in a letter of screening deficiencies being sent to the applicant. All the deficiencies must be addressed in one response from the applicant, and any supporting information or data must be submitted together with the response in one consolidated package. It is not acceptable to address only some of the deficiencies in an initial response and then address the remainder at a later date. Where the submission for the TGAI is supported by a submission for an EP, as with new TGAIs, the deficiencies for both the TGAI and the EP must be addressed in the one response and any supporting information or data submitted with the response.

Each deficiency must be addressed in the response. Failure to address all the deficiencies adequately will result in the withdrawal of the submission. The submission number will no longer be valid. An applicant may resubmit the package, once the deficiencies have been addressed, as a new submission.

When deficiencies occur within more than one data part, the responses for each data part must be submitted in a separate binder, since each part is reviewed by a different division or section within the PMRA. Additional information can be added to the binders originally submitted, provided that there is adequate space. Alternatively, new binders can be submitted containing the responses. These binders should be given a new consecutive volume number, continuing from the numbers of the original package. Note that two copies of the information are always required, each in its own binder.

The index should be updated with an adequate number of copies included in the response. It is not necessary to replace the entire index: modifications and additions will suffice.

6.0 Organization of supporting data

Supporting data are organized into eleven general parts, as outlined below, and must be packaged individually.

Each major part is further divided into sub-parts. Some data parts apply to both the TGAI and the EP and should be submitted for each. Other parts apply specifically to the TGAI or the EP and should be submitted with either the TGAI or the EP application, as appropriate. Please refer to Appendix V for information on organizing and coding scientific data, studies, foreign reviews, comprehensive summaries, screening forms, and requests for waivers.

The DACO tables indicate the R and CR data for specific USCs. For CR data, the conditions under which the data would be required are provided in the DACO table. If the applicant realizes that a particular condition is applicable, it is essential that the CR data or a request for a waiver with a scientific rationale be supplied with the original submission. Where CR DACOs do not apply to a particular product, it is not necessary to reference these DACOs in the index or provide requests for waivers.

6.1 Data parts

Part 0, Index
The index must be submitted in both electronic format (PDF normal) and in hard copy with the appropriate number of copies (refer to Appendix V). The electronic version must be submitted on a diskette or CD. When submitting an index electronically, applicants must conform to the requirements outlined in Section 5.4. All submitted scientific data/studies, surrogate data/studies, requests for waivers and citations of previously submitted data that address a DACO must be properly indexed. Study protocols, comprehensive summaries, and requests for waivers accompanying or replacing studies

along with the scientific rationale or surrogate data must also be indexed under the relevant DACO and added under a subtitle *Comment* in the fourth column on the sample Index template (*Title, Source, Company.. etc*) after *Published or not* (Appendix II) . When previously submitted data are used in support of a new submission, the data must be fully referenced in the index, as a *Comment* in the same location to indicate when the data were submitted, and the associated submission registration number. Separate indexes must be submitted for each proposed product: the TGAI and each EP. Please refer to Appendix II for directions on preparing electronic and hard copy indexes. If the data are organized using the DACO numbering system, the first column of the index labelled *OECD data point number* (as well as the title in the table) should be relabelled as *PMRA Data Code.*

If a single report covers more than one DACO, but not more than one part, a single entry in the index is acceptable. For example, if a single report addresses most of the chemistry requirements, or a request for waiver addresses an entire part, then there would be one index entry for the report, or waiver request, with the applicable DACOs indicated in the *Comments* field. Evaluation templates do not have to be cited individually.

Part 1, Label

All submissions involving changes to the label must include a label in both electronic format (PDF normal) and hard copy. Please refer to LPS2003-01 *Labe1 Process Changes Part: Overview* and LPS2003-02 *Label Process Changes Part 2: Guidance for Industry* for guidance on the requirements for submission of the label.

Labels that have been converted to a PDF normal format can be submitted electronically to the PMRA along with the appropriate application forms. These forms are also available electronically on the web.

The electronic version of the label should be saved in a PDF normal format and submitted on a 3.5" diskette or CD. When submitting a label electronically, the requirements outlined in Section 5.4 and in LPS2003-02 *Label Process Changes Part 2: Guidance for Industry,* must be followed.

More information on the labelling can be obtained from the *Pest Control Products Regulations*, the Registration Handbook, model labels (where available), and labels of registered products on the PMRA web site.

As outlined in the *Regulations Amending the Pest Control Products Regulations*, published in the *Canada Gazette* Part II on December 19, 2001, all registrations granted, amended or renewed must be based on bilingual label information (English and French) from January 1, 2003. The regulations prescribe a date of January 1, 2008 as the date by which all registered products must have bilingual labels, thereby allowing a five-year phase-in period. Please refer to LPS2003-01 *Labe1 Process Changes Part: Overview* and LPS2003-02 *Label Process Changes Part 2: Guidance for Industry*) for detailed guidance on the implementation of the bilingual labelling requirement as it impacts on the submission process.

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

Data must be organized according to the DACOs outlined in Appendix IV (DACO Part 2). Please refer to Regulatory Directive, DIR98-04 *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, for more detailed information on chemistry requirements for a TGAI or an ISP.

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

Data must be organized according to the DACOs outlined in Appendix IV (DACO Part 3). Please refer to Regulatory Directive 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* for more detailed information on chemistry requirements for an EP or a MA.

Part 4, Toxicology: TGAI or EP

Data for the TGAI and the EP must be organized according to the DACOs outlined in Appendix IV (DACO Part 4). Refer to Memorandum T-1-245, *Guidelines for Developing a Pesticide Toxicology Data Base*, for information on toxicological studies. To help expedite the review of submissions, historical data for blood chemistry, hematology, tumour incidences, skeletal variation and other malformations should be submitted, if available, for the appropriate studies.

Part 5, Exposure (Occupational and/or Bystander): EP

Data must be organized according to the DACOs outlined in Appendix IV (DACO Part 5) and submitted with the EP package. Refer to Appendix VI for details on the DACOs for this part.

Part 6, Metabolism or Toxicokinetics Studies: TGAI or EP

Data must be organized according to the DACOs outlined in Appendix IV (DACO Part 6) and submitted with either the TGAI or the EP, as appropriate.

Part 7, Food, Feed and Tobacco Residue Studies: EP

Data must be organized according to the DACOs outlined in Appendix IV (DACO Part 7) and submitted with the EP package. Refer to Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*, for details.

Part 8, Environmental Chemistry and Fate: TGAI or EP

Data must be organized according to the DACOs outlined in Appendix IV (DACO Part 8). Refer to Memorandum T-1-255, *Guidelines for Determining Environmental Chemistry and Fate of Pesticides*, for information on environmental chemistry and fate studies.

Part 9, Environmental Toxicology: TGAI and EP

Data must be organized according to the DACOs outlined in Appendix IV (DACO Part 9). In general, studies conducted according to scientifically supportable protocols and

using relevant, established guidelines such as the U.S. EPA or the OECD guidelines will be acceptable. Applicants may submit study protocols for review prior to conducting a study.

Part 10, Value: EP
Data must be organized according to the DACOs outlined in Appendix IV (DACO Part 10) and submitted with the EP package. The following guidelines may also be useful in preparing a value package:

DIR93-17	*Assessment of the Economic Benefits of Pesticides*
T-1-215	*Efficacy Data for Antimicrobial Products*
DIR93-07a	*Guidelines for Efficacy Assessment of Chemical Pesticides*
DIR93-07b	*Guidelines for Efficacy Assessment of Herbicides and Plant Growth Regulators*
DIR96-01	*Guidelines for Efficacy Assessment of Fungicides, Bactericides and Nematicides*

6.2 Comprehensive data summaries (DACO 12.7)

Applications for registration of a major new use or new TGAI with related EP(s), that is, Category A submissions, must include a CDS prepared according to the Tier II and III models in the OECD *Guidelines and criteria for industry for the preparation and presentation of complete dossiers and of summary dossiers for plant protection products and their active substances in support of regulatory decisions in OECD countries*. This document is available on the Internet at the OECD web site http://www.oecd.org.

For information on the requirement for submission of a CDS, refer to Regulatory Directives DIR96-05 and DIR97-01, *Comprehensive data summaries*. Summaries will provide reviewers with a clear comprehensive summary of the characteristics, risks and values associated with the proposed product. The summary should be in such detail that it is apparent that the applicant has performed a thorough evaluation of each study and reported the full detail of this evaluation. For major new uses, the CDS should incorporate only those studies submitted in support of the application.

Comprehensive Data Summaries should be submitted in a separate binder under DACO 12.7. This binder should be labelled as outlined in Section 7.1. Part summaries, e.g., DACO 4.1 and 5.1, are not required if a CDS has been submitted.

One electronic copy of the CDS (refer to Section 5.4) must be submitted in addition to the required number of paper copies. The applicant must describe the contents and file structure of the electronic version through a “Read Me” file or other means.

6.3 Requests for waivers of data requirements

When required data or studies are not submitted, the applicant must submit a request for a waiver of the requirement. Requests for waivers must be recorded in the index and supported by surrogate data: studies performed with a product other than the one indicated in the application for TGAI, raw material or EP as indicated in the DACO table, or a scientific rationale (with references), in place of the data or studies. The *Comments* field which should be used to indicate the nature of the information: request for waiver, surrogate study, and so on. The request for waivers with supporting rationale or surrogate data must be placed in the data binders under the appropriate DACO. Refer to Appendix VII for details on requests for waivers.

6.4 Using the same study or information to support more than one DACO

When a study or information is used to address more than one DACO within a specific data part, the information need only be included under one DACO and referenced for the other DACO(s). However, when information is used to support a DACO requirement in more than one data part, the information in its entirety must be submitted for both data parts, that is, data cannot be referenced between different data parts. The exceptions are Parts 6 and 7, which are reviewed by the same section of the Health Evaluation Division.

Data submitted for one submission can be cited to address the data requirements for another submission provided that the data is appropriate for, and applies to, the second submission. These submission(s) must be submitted at the same time and hence follow the same timelines (refer to Section 5.8 on tailgate submissions).

6.5 Using literature to address data requirements

When literature such as a published journal article is used as supporting data, it must be fully referenced in the index. The *Comments* field should be used for the citation, which should state the name of the journal, volume number and page numbers. A copy of the article should be submitted and placed in the binder of the related data part binder. Any references noted in the article may be requested.

6.6 Multiple or additional studies or information and evaluation templates

When more than one study is submitted for a particular DACO, all studies should be submitted under that DACO and separated by divider pages with side tabs. Refer to Section 7.0 below for instructions on labelling side tabs for divider pages. Evaluation templates, protocols or other information, excluding foreign reviews, submitted for a particular DACO should be included under that DACO and separated with divider pages. Evaluation templates should be included under the DACO corresponding to the study and placed before the study. Evaluation templates should be separated from the study using a divider page with a side tab. The *Comments* field should be used to indicate the nature of the information. When a study submitted does not correspond to a specific DACO, it

should be submitted under the appropriate other study DACO within the pertinent data part, for example, Part 5, Exposure, DACO 5.14, Other Studies/Data/Reports.

Foreign reviews should be coded under DACO 12.5 as outlined in Appendix IV and included at the end of the last binder for its related data part. For example, a foreign review of toxicology data would be coded as DACO 12.5.4, but would be included at the end of the last binder for Part 4, Toxicology.

6.7 Published literature search

A search of published literature on the active ingredient(s) may be requested by the PMRA. Legible photocopies of both the printout and relevant papers should be submitted to the PMRA. These published papers should be organized as set out in Appendix V: each report should be submitted under the appropriate DACO. The *Comments* field of the index should be used for the citation, which should state the name of the journal, volume number and page numbers. The index should be updated to include these submitted published studies.

7.0 Organization of submission package

The components of a submission should be organized as outlined below. Separate packages and envelopes should be submitted for each proposed product, that is, the TGAI or ISP, the MA (if applicable), and each EP, and each should include a covering letter, application form, product specification form, fee form, fee, supporting documentation, label, index, and relevant data. Certain submission components should be submitted in an envelope while data components should be compiled in binders and boxed, as outlined below.

Envelope
The following elements for each TGAI or ISP, the MA (if applicable) and each EP should be submitted in an envelope. All envelopes should be placed in Box 1 of the shipment:

- Covering letter, forms as required, fee and supporting documentation;
- Label in hard copy.
- One copy of the Material Safety Data Sheet (MSDS) for the proposed product and each formulant. The applicant should ensure that the MSDS includes the CAS number.
- Labelled 3.5" diskettes or CDs.

Binders
Data parts and other information submitted under DACOs, such as waiver requests, foreign reviews and evaluation templates, should be organized in three-ring binders (8.5×11", and varying widths as necessary to a maximum of 3").

Other data, i.e., Parts 2–10, should be placed in binders, with each data part in a separate binder. Where necessary, data parts may be organized into volumes and may consist of a

number of volumes. Each binder should be clearly labelled on both the cover and spine as outlined below. Divider pages with labelled side tabs indicating the DACO number should be used to separate studies and DACOs. When more than one study is submitted for a particular DACO, the divider tab should also include a reference number that is used in the Table of Contents to indicate the location of a particular study in the binder: DACO 7.3.1-1, for example, to indicate that this is the first study submitted under DACO 7.3.1. This referencing method should only be used in the data binders and not in the index.

Individual studies or DACOs and attachments should be paginated logically, with consecutive page numbers beginning at page 1. All data and information submitted must be legible. There should be only one set of page numbers on the studies.

7.1 Labelling of binders

The following information should be on the cover and spine of each binder:

- Name of the registrant
- Product name
- Common name of the TGAI(s)
- Part number and title
- Volume number (of total number of volumes) for that particular part
- DACOs included in volume
- Date of submission

Examples:

XYZ Chemicals Inc.
EXCELL Flea Control for Dogs
Active Ingredient: Pyrethrin
Part 3, Product Chemistry: EP
Volume 1 of 2
DACOs 3.1–3.3
May 19, 1996

XYZ Chemicals Inc.
EXCELL Flea Control for Dogs
Active Ingredient: Pyrethrin
Part 3, Product Chemistry: EP
Volume 2 of 2
DACOs 3.4–3.5
May 19, 1996

7.2 Table of contents

If a binder contains more than one DACO, a brief table of contents for each binder should be included at the beginning of each binder. The table of contents should include the DACO, which also serves as the tab number for locating the study or information within the binder, DACO title, and abbreviated study citation (author, year, title). Foreign reviews should be noted in the table of contents.

Example of a single entry:

4.3.5	Short-term Dermal	Hartley, M. and Murray, W. (1994) S-1234 (Technical Grade) Twenty-one Day Dermal Study in Rabbit.

7.3 Required number of copies of data

Refer to Appendix V for guidance on the number of copies required for data parts and other information supporting submissions.

8.0 Data submission

A complete application package, including forms, fees, data and supporting information and documentation, should be submitted directly to:

Submission Coordination and Documentation Division
Pest Management Regulatory Agency
Health Canada
A.L. 6605E1
2720 Riverside Drive
Ottawa, ON K1A 0K9

With the centralization of Submission Screening in the Submission Coordination and Documentation Division (SCDD) and co-location of the Science Division, direct delivery of data is no longer acceptable to the Science Division. Envelopes with forms, fees, labels, and other information should be included in Box 1 of a shipment for both the TGAI and EP(s).

When sending data in boxes, the weight of individual boxes must not exceed 15 kg (30 lbs).

NOTE: All required submission components must be submitted together. It is unacceptable to submit only some components, with an indication that more are to follow.

9.0 Maximum residue limits solely for imported commodities

Applications to establish MRLs for imported foods under the *Food and Drugs Act* (FDA) are to be directed to the PMRA. Applications for import MRLs for TGAIs not previously assessed and not currently registered in Canada will be treated as Category A submissions. Applications for additional import MRLs for previously assessed TGAIs will be treated as Category B submissions. Applicants should contact the PMRA for DACO tables for Category A or B submissions for establishing import MRLs.

List of Abbreviations

CDS	comprehensive data summary
CPSF	Control Product Specification Form
CR	conditionally required
DACO	data code
EAD	Environmental Assessment Division
EP	end-use product
EPA	Environmental Protection Agency (United States)
ESAD	Efficacy and Sustainability Assessment Division
FDA	*Food and Drugs Act*
FREAS	Food Residues Exposure Assessment Section
HDWP	heavy duty wood preservation
HED	Health Evaluation Division
IGR	insect growth regulator
IMEP	Import for Manufacture and Export Program
ISP	integrated system product
LSS	Laboratory Services Sub-division
MA	manufacturing concentrate
MRID	master record identifier
MRL	maximum residue limit
MSDS	Material Safety Data Sheet
OEAS	Occupational Exposure Assessment Section
OECD	Organisation for Economic Co-operation and Development
OPP	Office of Pesticide Programs (EPA)
OPPTS	Office of Prevention, Pesticides and Toxic Substances (EPA)
OUI	own use import
PDF	portable document format
PGR	plant growth regulator
PMRA	Pest Management Regulatory Agency
R	required
SCDD	Submission Coordination and Documentation Division
TGAI	technical grade of active ingredient
TOX	Toxicology Evaluation Section
URMULE	user requested minor use label expansion
URMUR	user requested minor use registration
USC	use–site category

Appendix I Elements of a complete submission to register, to amend or to conduct research with a pest control product

Some of the elements listed below are CR, depending on the purpose of the submission. For more information, refer to the *Registration Handbook for Pest Control Products Under the Pest Control Products Act and Regulations* (Registration Handbook).

Required elements include:

- Covering letter outlining the purpose of the submission and a brief description of the submitted package. It should include the product name, relevant use–site categories, related submissions, and relevant history, if applicable. Data should not be included as part of the covering letter. A distinct letter should be included with each submission. If the application for a new product is based on a currently registered product, the product's name and Registration Number should be stated in the covering letter.

  For Category A submissions, the covering letter must be submitted with the envelope (refer to Section 7.0).

- Application form: completed, signed and dated.
- Complete fee form. Requests for reduced fees must be signed and dated.
- Fee as indicated on the application form in a micro-encoded cheque payable to the Receiver General for Canada, or provide MasterCard or Visa number and expiry date.

Conditionally required elements include:

- Statement of Product Specification form: completed, signed and dated.
- Letter(s) of confirmation: of source of TGAI(s)/ISP(s).
- Letter(s) of authorization: to cite data previously submitted by another company.
- Letter(s) of authorization: designating agent, formulator, consultant, etc.
- Letter(s) of authorization: to share data reviews with other countries.
- Draft label: in the proper electronic and paper formats.
- Index: of supporting data in the proper electronic and paper format.
- Scientific data or studies: supporting the safety and effectiveness of the proposed product or amendment.

- Foreign reviews of the submitted scientific data or studies, if available.

- Comprehensive data summary for Category A submissions only, in accordance with the OECD guidelines. Refer to DIR96-05 and DIR97-01. This should be submitted in the proper electronic and paper formats.

- Requests for waivers of the requirement to submit specific scientific data or studies. Such requests must be recorded in the index and supported by surrogate data or a scientific rationale in place of the DACO or study. See Appendix VII.

Appendix II Directions for creating a data index

Electronic format

All data and supporting information submitted to address required DACOs should be listed in an index following the spreadsheet format of the OECD dossier reference lists. This would include requests for waivers, surrogate studies, protocols, evaluation templates and published literature being submitted to address the data requirements for the current submission only. Data submitted previously which is cited in the current data package need not be re-submitted. Applicants are required to supply both electronic (PDF normal format) and paper versions of the index. The diskette or CD should be labelled with the following information:

- name of the registrant
- product name
- common name of the TGAI(s)
- part number and title
- date of submission

Reference for this is found in *Guidelines and criteria for industry for the preparation and presentation of complete dossiers and of summary dossiers for plant protection products and their active substances in support of regulatory decisions in OECD countries* at http://www.oecd.org/ or can be accessed through PMRA web sites.

If the data are organized using the DACO numbering system, the first column of the index labelled *OECD data point number* (as well as the title in the table) should be relabelled as *PMRA Data Code.*

Viruses

NOTE: Applicants are required to include in the covering letter a statement which indicates that, to the best of their ability, the diskettes or CD are virus free. Any diskette or CD found to contain a virus will be returned to the applicant.

The following is an example of an index format taken from the OECD Dossier:

Reference List, by OECD Data Point | **Active Substance - XXX 1111** | **Company Name** | **Month & Year List Compiled**

Section 3, Toxicological and Metabolism Studies on the Active Substance

OECD data point number / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
Active Substance Data and Information					
IIA 5.1.1 / 01	Casida JE Gaughan LC Ruzo LO	1979	Comparative metabolism of pyrethroids derived from 3-phenoxybenzyl and α-cyano-3-phenoxybenzyl alcohols. Advances in pesticide science, Fourth International Congress of Pesticide Chemistry, Zürich, Switzerland, July 24-38, 1978, part 2, 182-189 Not GLP, Published	N	-
IIA 5.1.1 / 02	Chopade HM McCann SA Gentile CC	1983	The distribution and metabolism of XXX 1111 in laying hens. Organics Inc Report No: MR86044 Not GLP, Unpublished	N	ORG
IIA 5.1.1 / 03	Eben A Thyssen J	1981	Thiocyanate excretion in rats' urine after intraperitoneal administration of XXX 1111 and decamethrin in comparable doses and after exposure to defined XXX 1111 concentrations in the inhalation air. Organics Inc Report No: 10130 Not GLP, Unpublished	N	ORG
IIA 5.1.1 / 04	Eben A Heimann KG Machemer L	1982a	Comparative study of rats on absorption of XXX 1111 after single oral administration in polyethylene glycol 400 or cremophor El/water as formulation vehicle. Organics Inc Report No: 10715 Not GLP, Unpublished	N	ORG
IIA 5.1.1 / 05	Eben A Machemer L Thyssen J	1982b	Comparative study of inhibition of the Na^+, K^+ and Mg^{++}-dependent ATPase from rats and chickens' brains in vitro by XXX 1722, some of its metabolites and further substances DDT, ouabain, some pyrethroids and phosphoric acid esters. Organics Inc Report No: 11116 Not GLP, Unpublished	N	ORG

Appendix III Use–site category definitions for conventional chemical pesticides

USC	Definition	Exclusions
Agriculture/forestry		
1. Aquaculture - 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.	• for hydroponics, see Greenhouse Food Crops (USC no. 5) and Greenhouse Non-Food Crops (USC no. 6)
2. Aquatic Non-Food Sites - Insecticides - Herbicides - Piscicides - Molluscides - Algicides - Lampricides	Outdoor natural and man-made environments (marine or fresh water), including, but not limited to: • 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	• Industrial Process Fluids (USC no. 17) • Underwater Structures and Materials (USC no. 22) • Swimming Pools (USC no. 29) • Other Indoor Surfaces, Water and Air (USC no. 19) • treatments of drinking water in municipal systems and private wells
3. Empty Food Storage Areas - 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: • disinfection of potato storage bins on farms and cooperatives • empty food storage or packaging areas • empty greenhouses and mushroom houses devoid of growth media	• disinfection or sanitization of all other commercial food storage areas subject to the FDA
4. Forests and Woodlots - Insecticides - Herbicides - Fungicides - PGRs - IGRs	Forested areas, including, but not limited to: • plantations • forest nurseries • Christmas tree plantations and nurseries • site preparation • seed production (seed orchard) • conifer release	• Ornamentals Outdoors (USC no. 27) • Greenhouse Non-Food (USC no. 6)

USC	Definition	Exclusions
5. Greenhouse Food Crops - Insecticide - Herbicides - Fungicides - PGRs - IGRs	Edible crops growing in greenhouses, including, but not limited to: • mushrooms growing in mushroom houses • indoor hydroponically-grown food plants • greenhouses cleared of edible crops, but containing soil and growth media	• for treatment of empty greenhouses and empty mushroom houses devoid of growth media, see Empty Food Storage Areas (USC no. 3) • disinfection or sanitization of greenhouses or mushroom houses where a food crop is growing is subject to the FDA
6. Greenhouse Non-Food Crops - Insecticide - Herbicides - Fungicide - Disinfectants - PGRs - IGRs	Non-food crops growing in greenhouses, including, but not limited to: • non-food crops growing hydroponically indoors	• for treatment of empty greenhouses devoid of growth media, see Empty Food Storage Areas (USC no. 3)
7. Industrial Oil Seed Crops and Fibre Crops - Insecticides - Herbicides - Fungicides - PGRs - IGRs	Terrestrial plants being commercially grown only for seed production, including, but not limited to: • seed crops	
8. Livestock for Food - 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: • milk • meat • meat by-products • honey Also including: • topical application for ectoparasite control	• all methods other than topical application for the control of ectoparasites. All disease control agents, no matter how they are applied, subject to the FDA • for other treatments of animals, see Aquaculture (USC no. 1) and Companion Animals (USC no. 24)

USC	Definition	Exclusions
9. Livestock Non-Food - Insecticides	Terrestrial animals raised for uses other than as food for human consumption, including, but not limited to: • fur-bearing animals	• Companion Animals (USC no. 24) • Livestock for Food (USC no. 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 FDA
10. Seed Treatments Food and Feed - 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: • seed potatoes • rootstock • bulbs • cuttings • true seed	
11. Seed Treatments Non-Food - 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: • rootstock • corms • bulbs • cuttings • true seeds	
12. Stored Food and Feed - Insecticides - Fungicides - Rodenticides - PGRs - IGRs	Stored bulk food, including, but not limited to: • 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 - 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.	• for crops treated after harvest, see Stored Food and Feed (USC no. 12)

USC	Definition	Exclusions
14. Terrestrial Food Crops - 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: • 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	
Industry		
15. Indoor Hard Surfaces - 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 FDA: • 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 - Herbicides - PGRs	Terrestrial vegetation sites on non-agricultural lands, including, but not limited to: • industrial sites • parking lots • tennis courts • rights-of-way • driveways and patios	• for agricultural land to be used for a Terrestrial Food or Feed Crop in subsequent years, see Terrestrial Food Crops (USC no. 14) and Terrestrial Feed Crops (USC no. 13)
17. Industrial Process Fluids - Slimicides	Industrial process fluids, including, but not limited to: • water cooling towers (open, once-through and closed systems) • pulp and paper • drilling muds	• for slime control in other sites see Swimming Pools (USC no. 29) and Aquaculture (USC no. 1) • for ornamental ponds, see Aquatic Non-Food Sites (USC no. 2) • Material (USC no. 18)

USC	Definition	Exclusions
18. Material - Material Preservatives	Products used or added to manufacture or processing to preserve the material or its function, including, but not limited to: • metal cutting fluid • leather • textiles • fuel • paint • canvas • caulking	• Underwater Structures and Materials (USC no. 22) • Wood (USC no. 23)
19. Other Indoor Surfaces, Water and Air - Slimicides - Disinfectants - Sanitizers	Including, but not limited to: • laundry • air ducts • air • water beds • humidifiers • building-related illness treatment Food contamination must be avoided by appropriate label precautions.	
20. Structural - 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.	• Indoor Hard Surfaces (USC no. 15) • for termite control, see Structures and Surrounding Soil (USC no. 21) • products for disinfectant treatments of food storage and processing areas subject to the FDA
21. Structures and Surrounding Soil - Termiticides	Structures and surrounding soil for preventive treatment or control of termite infestations.	• Structural (USC no. 20)
22. Underwater Structures and Materials - Antifouling coatings	Structures intended for underwater use, including, but not limited to: • lobster traps • boat hulls • fishing nets • intake pipes	• for wood preservation of underwater structures, piers and docks, see Wood (USC no. 23) • aquaculture pens and nets
23. Wood - 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.	• Underwater Structures and Materials (USC no. 22) • Structural (USC no. 20) • Structures and Surrounding Soil (USC no. 21)

USC	Definition	Exclusions
Society		
24. Companion Animals - 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.	• Livestock for Food (USC no. 8) and Non-Food (USC no. 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 FDA • for products to be used on pet sleeping areas, see Structural (USC no. 20)
25. Human Habitat and Recreational Areas - Insecticides	Commercial treatment of urban or rural habitation and recreational areas, including, but not limited to control of: • adult biting flies • black flies • mosquitoes • other insects	• for aquatic larval stages, see Aquatic Non-Food (USC no. 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.	• products intended to repel or control ectoparasites, e.g., lice, subject to FDA
27. Ornamentals Outdoor - Insecticides - Herbicides - Fungicides - PGRs - IGRs	Non-food plants growing outdoors, including, but not limited to: • flowers • trees • shrubs • seed crops on non-agricultural land	• for grass, lawns, turf soil, sod farms, see Turf (USC no. 30)
28. Indoor Plants and Plantscapes - Insecticides - Herbicides - Fungicides - PGRs - IGRs	Plants grown indoors, including, but not limited to: • shopping malls • commercial buildings • residences	• see also Terrestrial Food Crops (USC no. 14)
29. Swimming Pools - Algicides - Bactericides	Water in public or private swimming pools, hot tubs and spas.	• for ornamental ponds, see Aquatic Non-Food (USC no. 2)

USC	Definition	Exclusions
30. Turf - Insecticides - Herbicides - Fungicides - PGRs - IGRs	Grass sites, including, but not limited to: • lawns • golf courses • parks • recreational areas • sod farms • turf soil	• for natural grassland and pastures, see Terrestrial Feed Crops (USC no. 13) • Residential Outdoors (USC no. 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.	• Terrestrial Food Crops (USC no. 14) • Terrestrial Feed Crops (USC no. 3)
32. Various Outdoor Sites - Vertebrate Pest Control Products - Rodenticides - Avicides	Commercial products used outdoors to control animal pests, including, but not limited to: • gophers • coyotes • wolves • birds	• Terrestrial Food Crops (USC no. 14) • Terrestrial Feed Crops (USC no. 13)
33. Residential Outdoors - Insecticides - IGRs	Control of domestic home and yard nuisance insects and ticks, including, but not limited to: • wasps • hornets • ticks • fleas • mosquitoes and black flies	• any food use • for termite control, see Structures and Surrounding Soil (USC no. 21) • for insect repellents, see Human Skin, Clothing and Proximal Sites (USC no. 26) • Turf (USCs no. 30) • Ornamental Outdoors (USC no. 27)

Appendix IV Organization of supporting data and studies for TGAIs

DACOs for information supporting TGAIs of conventional chemical pest control products

Specific data requirements for product types and use–site categories should be obtained from the PMRA or from the PMRA web site. To facilitate the organization of a data package, the overall data requirements for conventional chemical pest control products are presented here. The comparative EPA and OECD numbering has been provided from the crosswalk in the OECD dossier guidance document found at http://www.oecd.org/. For the EPA numbering, information has been provided for both the Office of Prevention, Pesticides and Toxic Substances (OPPTS) and the Office of Pesticide Programs (OPP).

Any studies listed here should be performed **using the technical active, or pure active,** as indicated in the table. If this is not the case please provide a rationale for using surrogate data, either with the DACO or study or in the *Comments* field of the index. If metabolism (Part 6) studies are performed using the TGAI, they should be submitted as part of the technical active database. If metabolism studies are performed using the EP, they should be submitted with the corresponding EP database.

NOTE: Items in **bold** are titles only. —, data are not required.

Canadian DACO Number	Title	EPA		OECD
		OPPTS	OPP	
0	Index	—	—	—
1	Label	Forms, 8570-1(1) 8570-4(5), 860.1200 875.1700 875.2700 40CFR 156.10 (a)(4)(ii)(a) 40CFR 156.10 (h)(1) 40CFR 156.10 (h)(1)(i) 40CFR 156.10 (i) 40CFR 156.10 (1)(2)(x)(b) 40CFR 156.10 (1)(2)(x) 40CFR 156.212 (d) 40CFR 165.8(a)-(c) 40CFR 165.9(a)-(d) 40CFR 165.10(a)-(h) 40CFR 165.10(g)	Forms, 8570-1(1) 8570-4(5) 171-2 171-3	IIA 1.1 IIA 1.5.2 IIA 3.4.1
2	**Chemistry requirements for the Registration of a Technical Grade of Active Ingredient (TGAI) or an Integrated System Product (ISP)**			
2.1	Applicant's Name and Office Address	Forms, 8570-1(1) 8570-4(5)	Forms, 8570-1(1) 8570-4(5)	IIA 1.1
2.2	Manufacturer's Name and Office Address and Manufacturing Plant's Name and Address	Forms, 8570-1(1) 8570-4(2) 8570-4(11)	Forms, 8570-1(1) 8570-4(2) 8570-4(11)	IIA 1.2
2.3	Product Trade Name	Form, 8570-1(1)	Form, 8570-1(1)	IIA 1.5.2
2.3.1	Other Names	Form, 8750-1(1)	Form, 8750-1(1)	IIA 1.5.1
2.4	Common Name	Form, 8570-4(10) 830.1550	Form, 8570-4(10) 61-1	IIA 1.3
2.5	Chemical Name	Form, 8570-4(10) 830.1550	Form, 8570-4(10) 61-1	IIA 1.4
2.6	Chemical Abstracts Registry Number	Form, 8570-4(10) 830.1550	Form, 8570-4(10) 61-1	IIA 1.6
2.7	Structural Formula	830.1550	61-1	IIA 1.7
2.8	Molecular Formula	830.1550	61-1	IIA 1.7
2.9	Molecular Weight	830.1550	61-1	IIA 1.7

Canadian DACO Number	Title	EPA		OECD
		OPPTS	OPP	
2.11	**Manufacturing Methods for the TGAI**			
2.11.1	Manufacturing Summary	830.1620 830.1670	61-3	IIA 1.8.1
2.11.2	Description of Starting Materials	830.1600	61-2	IIA 1.8.2 IIA 3.7
2.11.3	Detailed Production Process Description	830.1620 830.1670	61-3	IIA 1.8.1
2.11.4	Discussion of Formation of Impurities	830.1620 830.1670	61-3	IIA 1.8.1
2.12	**Specifications**			
2.12.1	Establishing Certified Limits	Form, 8570-4(13) 8570-4(10) 830.1550 830.1750	Form, 8570-4(13) 8570-4(10) 61-1 62-2	IIA 1.9.1 IIA 1.9.2 IIA 2.5.1.6
2.12.2	Control Product Specification Form (Statement of Product Specification Form)	Form, 8570-4(13) 8570-4(10) 830.1550 830.1750	Form, 8570-4(13) 8570-4(10) 158.155 61-1 62-2	IIA 1.9.1 IIA 1.9.2 IIA 1.9.3 IIA 1.10.1 IIA 1.10.2 IIA 2.5.1.6
2.13	**Preliminary Analysis**			
2.13.1	Methodology/Validation	830.1000	62-3	IIA 4.2.1
2.13.2	Confirmation of Identity	830.7050	—	IIA 2.5.1 IIA 2.5.1.2 IIA 2.5.1.3 IIA 2.5.1.4 IIA 2.5.1.5 IIA 2.5.2
2.13.3	Batch Data	830.1700	—	IIA 1.11.1 IIA 1.11.2
2.13.4	Impurities of Toxicological Concern	Form, 8570-4(10) 830.1000 830.1550	Form, 8570-4(10) 158.155 62-3	IIA 1.10.2 IIA 4.2.3
2.14	**Chemical and Physical Properties**			
2.14.1	Colour	830.6302 830.6303	63-2 63-3	IIA 2.4.1
2.14.2	Physical State	830.6302 830.6303	63-20 63-3	IIA 2.4.1
2.14.3	Odour	830.6304	63-4	IIA 2.4.2 IIA 2.5.1

Canadian DACO Number	Title	EPA		OECD
		OPPTS	OPP	
2.14.4	Melting Point/Melting Range	830-7200	63-5	IIA 2.1.1
2.14.5	Boiling Point/Boiling Range	830.7220	63-6	IIA 2.1.2
2.14.6	Density or Specific Gravity	Form, 8570-4(7) 830.7300	Form, 8570-4(7) 63-7	IIA 2.2
2.14.7	Water Solubility (mg/L)	830.7840 830.7860	63-8	IIA 2.6
2.14.8	Solvent Solubility (mg/L)	830.1000 830.7840 830.7860	63-8	IIA 2.7
2.14.9	Vapour Pressure	830.7950	63-9	IIA 2.3.1
2.14.10	Dissociaton Constant	830.7370	63-10	IIA 2.9.4
2.14.11	Octanol–Water Partition Coefficient	830.7550 830.7560 830.7570	63-11	IIA 2.8.1 IIA 2.8.2
2.14.12	UV–Visible Absorption Spectra	830.7050	—	IIA 2.5.1.1 IIA 2.5.1.5
2.14.13	Stability (Temperature, Metals)	830.6313	63-13	IIA 2.5.1.1 IIA 2.5.1.5 IIA 2.17.2
2.14.14	Storage Stability Data	830.6317	63-17	IIA 2.17.1 IIA 2.17.2
2.15	Sample(s) of Analytical Standards and Residue of Concern	830.1900 860.1650	64-1 171-13	IIA 4.1.1 IIA 4.1.2 IIA 4.1.3 IIA 4.1.4
2.16	Other Studies/Data/Reports	—	—	IIA 1.12 IIA 2.18 IIA 3.10 IIA 4.9
4	**Toxicology**			
4.1	Summary: Toxicology Profile	—	—	—
4.2	**Acute Studies**			
4.2.1	Acute Oral	870.1100	81-1	IIA 5.2.1
4.2.2	Acute Dermal	870.1200	81-2	IIA 5.2.2
4.2.3	Acute Inhalation	870.1300	81-3	IIA 5.2.3
4.2.4	Primary Eye Irritation	870.2400	81-4	IIA 5.2.5
4.2.5	Primary Dermal Irritation	870.2500	81-5	IIA 5.2.4
4.2.6	Dermal Sensitization	870.2600	81-6	IIA 5.2.6
4.2.7	Potentiation: Interaction	—	—	IIA 5.2.7

Canadian DACO Number	Title	EPA		OECD
		OPPTS	OPP	
4.2.8	Antidote	—	—	IIA 5.9.5 IIA 5.9.6
4.2.9	Other Acute Studies	—	—	IIA 5.10
4.3	**Short-Term Studies**			
4.3.1	Short-Term Oral (90 day) (rodent)	870.3100	82-1	IIA 5.3.2
4.3.2	Short-Term Oral (6-12 month) (non-rodent, e.g., dog)	870.3150	82-1	IIA 5.3.4
4.3.3	Short-Term Oral (21 day, 30 day)	—	—	IIA 5.3.1
4.3.4	Short-Term Dermal (90 day rodent)	870.3250	82-3	IIA 5.3.8
4.3.5	Short-Term Dermal (21 day, rodent)	870.3200	82-2	IIA 5.3.7
4.3.6	Short-Term Inhalation (90 day)	870.3465	82-4	IIA 5.3.6
4.3.7	Short-Term Inhalation (21 day, 30 day)	—	—	IIA 5.3.5
4.3.8	Other Short-Term Studies	—	—	IIA 5.10
4.4	**Long-Term Studies**			
4.4.1	Chronic (rodent)	870.4100	83-1	IIA 5.5.1
4.4.2	Oncogenicity (rodent species 1)	870.4200	83-2	IIA 5.5.2
4.4.3	Oncogenicity (rodent species 2)	870.4200	83-2	IIA 5.5.3
4.4.4	Combined Chronic/Oncogenicity (rodent)	870.4100 870.4200	83-1 83-2	IIA 5.5.1 IIA 5.5.2
4.4.5	Other Long-Term Studies	—	—	IIA 5.10
4.5	**Special Studies**			
4.5.1	Multigeneration-Reproduction (rodent)	870.3800 870.5450	83-4 84-2	IIA 5.6.1 IIA 5.6.2 IIA 5.6.3 IIA 5.6.4 IIA 5.6.5 IIA 5.6.6 IIA 5.6.7 IIA 5.6.8 IIA 5.6.9
4.5.2	Teratogenicity (rodent)	870.3700	83-3	IIA 5.6.10
4.5.3	Teratogenicity (non-rodent)	870.3700	83-3	IIA 5.6.11

Canadian DACO Number	Title	EPA		OECD
		OPPTS	OPP	
4.5.4	Genotoxicity: Microbial Point Mutation	870.5100 870.5140 870.5250	84-2	IIA 5.4.1
4.5.5	Genotoxicity: Mammalian (cell) Point Mutation	870.5195 870.5200 870.5300	84-2	IIA 5.4.2
4.5.6	Genotoxicity: *in vitro* Chromosomal Aberrations	870.5375 870.5900	84-2	IIA 5.4.3
4.5.7	Genotoxicity: *in vivo* Chromosomal Aberrations	870.5380 870.5385 870.5395 870.5915	84-2	IIA 5.4.4
4.5.8	Other Genotoxicity Studies	870.5275 870.5450 870.5460 870.5500 870.5550 870.5575	84-2	IIA 5.4.5 IIA 5.4.6 IIA 5.10
4.5.9	Metabolism/Toxicokinetics in Mammals (laboratory animal)	870.7485	85-1	IIA 5.1.1 IIA 5.1.2 IIA 5.1.3
4.5.10	Delayed Neurotoxicity Following Acute Exposure (28 day hen)	870.6100	81-7	IIA 5.7.2
4.5.11	Delayed Neurotoxicity (28 day hen)	870.6100	82-6	IIA 5.7.3
4.5.12	Acute Neurotoxicity (rat)	870.6200	81-8	IIA 5.7.1
4.5.13	Subchronic Neurotoxicity (90 day rat)	870.6200	82-7	IIA 5.7.4
4.5.14	Developmental Neurotoxicity	870.6300	83-6	IIA 5.7.5
4.8	Other Studies/Data/Reports Including Formulants Data	—	—	IIA 5.10
6	**Metabolism/ Toxicokinetic Studies**			
6.1	Summary	860.1550	171-6	—
6.2	Livestock	860.1300 860.1480	171-4 171-4(b)	IIA 6.2.2 IIA 6.2.3 IIA 6.2.4
6.3	Plants	860.1300 860.1480	171-4 171-4(a)	IIA 6.2.1

Canadian DACO Number	Title	EPA		OECD
		OPPTS	OPP	
6.4	Other Studies/Data/Reports	860.1300 860.1400 860.1480	171-4 171-4(c)	IIA 6.10
8	**Environmental Chemistry and Fate**			
8.1	Summary	—	—	—
8.2	**Laboratory Studies**			
8.2.1	Summary of Physicochemical Properties to Include Solubility in Water, Vapour Pressure, Octanol:Water Partition Coefficient, Dissociation Constant, UV-Visible Absorption, Density or Specific Gravity (see Part 2)	—	—	—
8.2.2	**Analytical Methodology (parent compound and transformation products)**			
8.2.2.1	Soil	—	—	IIA 4.4
8.2.2.2	Sediment	835.1220 835.1230	163-1	IIA 4.6
8.2.2.3	Water	840.1400	171-4f	IIA 4.5
8.2.2.4	Biota (biomass: living or dead)	875.2600	235	IIA 4.8
8.2.3	**Laboratory Studies of Transformation**			
8.2.3.1	Summary	—	—	—
8.2.3.2	Hydrolysis	835.2120 830.7370	161-1 63-10	IIA 2.9.1 IIA 2.9.5 IIA 7.5
8.2.3.3	**Phototransformation**			
8.2.3.3.1	Soil	835.2410	161-3	IIA 7.1.3
8.2.3.3.2	Water	835.2240	161-2	IIA 2.9.2 IIA 7.6
8.2.3.3.3	Air	835.2370	161-4	IIA 2.10 IIA 7.10
8.2.3.4	**Biotransformation in Soil**			

Canadian DACO Number	Title	EPA		OECD
		OPPTS	OPP	
8.2.3.4.2	Aerobic Soil 20°–30°C	835.4100	162-1	IIA 7.1.1 IIA 7.2.1 IIA 7.2.2 IIA 7.2.3
8.2.3.4.4	Anaerobic Soil 20°–30°C	835.4200	162-2	IIA 7.1.2 IIA 7.2.4 IIA 7.2.5
8.2.3.5	**Biotransformation in Aquatic Systems**			
8.2.3.5.2	Aerobic Water 20°–30°C	835.4300	162-4	IIA 7.8.1
8.2.3.5.4	Aerobic Water/Sediment 20°–30°C	835.4300	162-4	IIA 7.8.1
8.2.3.5.6	Anaerobic Sediment/Water 20°–30°C	835.4400	162-3	IIA 7.8.2
8.2.4	**Laboratory Studies of Mobility**			
8.2.4.1	Summary	—	—	—
8.2.4.2	Adsorption/Desorption	835.1230	163-1	IIA 7.4.1 IIA 7.4.2
8.2.4.3	**Soil Column Leaching**			
8.2.4.3.1	Unaged Soil	835.1240	163-1	IIA 7.4.3 IIA 7.4.4
8.2.4.3.2	Aged Soil	835-1240	163-1	IIA 7.4.3 IIA 7.4.4 IIA 7.4.5
8.2.4.4	Soil TLC Leaching	—	—	IIA 7.4.6
8.2.4.5	Volatilization	835.1410	163-2	IIA 7.4.9
8.4	**Storage, Disposal and Decontamination**			
8.4.1	Summary	860.1520 860.1540 40CFR 165.8 (a)-(c) 40CFR 165.9 (a)-(d)	171-3 171-4 171-5 40CFR 165.9 (a)-(d)	IIA 3.8.2 IIA 3.9
8.5	**Other Environmental Fate Studies**			
8.5.1	Summary	—	—	IIA 7.13
8.5.2	Incineration-thermal Decomposition at High and Low Temperatures	—	—	—

Canadian DACO Number	Title	EPA		OECD
		OPPTS	OPP	
8.6	Other Studies/Data/Reports	—	—	IIA 3.10 IIA 4.9 IIA 7.13
9	**Environmental Toxicology**			
9.1	Summary	—	—	—
9.2	**Non-Target Terrestrial Invertebrates**			
9.2.1	Summary	—	—	—
9.2.3	**Earthworms**			
9.2.3.1	Acute Toxicity	—	—	IIA 8.9.1
9.2.4	**Bees/Pollinators**			
9.2.4.1	Acute Contact	850.3020	141-1	IIA 8.7.2
9.2.4.2	Acute Oral	—	—	IIA 8.7.1
9.2.4.3	Hive Study (including brood)	—	—	IIA 8.7.4
9.2.5	Predators	—	—	IIA 8.8.1.2 IIA 8.8.1.3 IIA 8.8.1.4 IIA 8.8.2.2 IIA 8.8.2.3 IIA 8.8.2.4
9.2.6	Parasites	—	—	IIA 8.8.1.1 IIA 8.8.2.1
9.2.7	Other Terrestrial Invertebrates	—	—	IIA 8.8.2.5
9.3	**Non-Target Freshwater Invertebrates**			
9.3.1	Summary	—	—	—
9.3.2	Daphnia sp. Acute	850.1010	72-2	IIA 8.3.1 IIA 8.3.1.1
9.3.3	Daphnia sp. Chronic (Life-Cycle)	850.1300	72-4	IIA 8.3.2.1
9.3.4	Laboratory Studies with Other Species	850.1010	72-2	IIA 8.3.1 IIA 8.3.1.2 IIA 8.3.1.3 IIA 8.3.2.2 IIA 8.16.1
9.4	**Non-Target Marine Invertebrates**			
9.4.1	Summary	—	—	—

Canadian DACO Number	Title	EPA		OECD
		OPPTS	OPP	
9.4.2	Acute (Crustacean)	850.1025 850.1035 850.1045 810.1055 810.1075	72-3	IIA 8.11.1
9.4.3	Mollusk Embryo Larvae	850.1025 850.1035 850.1045 810.1055 810.1075	72-3	IIA 8.11.1
9.4.4	Mollusk Shell Deposition	850.1025 850.1035 850.1045 810.1055 810.1075	72-3	IIA 8.11.1
9.4.5	Chronic (Mollusk or Crustacean)	850.1350	72-4	IIA 8.3.2 IIA 8.3.2.3
9.4.8	Bioconcentration/ Depuration (Bivalve or Crustacean)	850.1710 850.1850	72-6	IIA 8.2.7
9.5	**Fish**			
9.5.1	Summary	—	—	—
9.5.2	**Acute Studies**			
9.5.2.1	Cold Water Fish (rainbow trout)	850.1075	72-1	IIA 8.2.1 IIA 8.2.1.1
9.5.2.2	Warm Water Fish (bluegill sunfish)	850.1075	72-1	IIA 8.2.1 IIA 8.2.1.2
9.5.2.3	Other Freshwater Fish Species	850.1075	72-1	IIA 8.2.1 IIA 8.2.1.1 IIA 8.2.1.2
9.5.2.4	Marine/Estuarine Fish	—	—	—
9.5.2.4.1	Salinity Challenge	—	—	IIA 8.11.2
9.5.3	**Sublethal and Chronic Studies**			
9.5.3.1	Fish Early Life Cycle Toxicity Test	850.1400	72-4	IIA 8.2.4
9.5.3.2	Fish Life Cycle Toxicity Test	850.1500	72-5	IIA 8.2.5
9.5.6	Bioaccumulation	850.1730	165-4	IIA 8.2.6.1 IIA 8.2.6.2
9.6	**Wild Birds**			
9.6.1	Summary	—	—	—
9.6.2	**Acute Studies**			
9.6.2.1	Oral (LD_{50}) Bobwhite Quail	850.2100	71-1	IIA 8.1.1

Canadian DACO Number	Title	EPA		OECD
		OPPTS	OPP	
9.6.2.2	Oral (LD_{50}) Mallard Duck	850.2100	71-1	IIA 8.1.1
9.6.2.3	Oral (LD_{50}) Other Species	850.2100	71-1	IIA 8.1.1
9.6.2.4	Dietary (LC_{50}) Bobwhite Quail	850.2200	71-2	IIA 8.1.2
9.6.2.5	Dietary (LC_{50}) Mallard Duck	850.2200	71-2	IIA 8.1.2
9.6.2.6	Dietary (LC_{50}) Other Species	—	—	IIA 8.1.3
9.6.3	**Chronic Studies**			
9.6.3.1	Avian Reproduction Bobwhite Quail	850.2300	71-4	IIA 8.1.4
9.6.3.2	Avian Reproduction Mallard Duck	850.2300	71-4	IIA 8.1.4
9.6.3.3	Avian Reproduction Other Species	850.2300	71-4	IIA 8.1.4
9.6.6	Special Studies Related to the Intended Use-Pattern (TGAI and EP)	—	—	IIA 8.16.1 IIA 8.16.2
9.7	**Wild Mammals**			
9.7.1	Summary	850.2400	71-3	IIA 8.13
9.8	**Non-Target Plants**			
9.8.1	Summary	—	—	—
9.8.2	Fresh Water Algae	850.5400	123-2	IIA 8.4
9.8.3	Marine Algae	850.5400	123-2	IIA 8.4
9.8.4	Terrestrial Vascular Plants	—	—	IIA 8.12
9.8.5	Aquatic Vascular Plants	850.4400	123-2	IIA 8.6
9.9	Other Studies/Data/Reports	—	—	IIA 8.16.1 IIA 8.16.2
12.5	**Foreign Reviews**			
12.5.2	Foreign Reviews of Chemistry Requirements for TGAIs or ISPs	—	—	—
12.5.4	Foreign Reviews of Toxicology	—	—	—
12.5.6	Foreign Reviews of Metabolism/ Toxicokinetics Studies	—	—	—
12.5.8	Foreign Reviews of Environmental Chemistry and Fate	—	—	—

Canadian DACO Number	Title	EPA		OECD
		OPPTS	OPP	
12.5.9	Foreign Reviews of Environmental Toxicology	—	—	—
12.7	Comprehensive Data Summaries	—	—	—

DACOs for Information Supporting EPs of Conventional Chemical Pest Control Products

Specific data requirements for product types and use–site categories can be obtained from the PMRA.

Any studies listed here should be performed using the appropriate EP. If this is not the case, please provide a rationale for using surrogate data either with the DACO or study or in the *Comments* field of the index. If metabolism (Part 6) studies are performed using the TGAI, they should be submitted as part of the technical active database. If metabolism studies are performed using the EP, they should be submitted with the corresponding EP database.

NOTE: Items in **bold** are titles only. —, data are not required.

Canadian DACO Number	**TITLE**	**EPA**		**OECD**
		OPPTS	**OPP**	
0	Index	—	—	—
1	Label	Forms, 8570-1(1) 8570-4(5) 860.1200 875.1700 875.2700 40CFR 156.10 (a)(4)(ii)(a) 40CFR 156.10 (h)(1) 40CFR 156.10 (h)(1)(i) 40CFR 156.10 (i) 40CFR 156.10 (1)(2)(x)(b) 40CFR 156.10 (1)(2)(x) 40CFR 156.212 (d) 40CFR 165.8 (a)-(c) 40CFR 165.9 (a)-(d) 40CFR 165.10 (a)-(h) 40CFR 165.10 (g)	Forms, 8570-1(1) 8570-4(5) 171-2 171-3	IIIA 3.3.3 IIIA 3.4 IIIA 3.5 IIIA 3.6 IIIA 3.7.1 IIIA 3.7.2 IIIA 3.7.4 IIIA 3.7.5 IIIA 3.9 IIIA 4.3.5 IIIA 4.3.6 IIIA 4.3.7 IIIA 4.4 IIIA 4.4.1 IIIA 4.4.2 IIIA 4.4.3 IIIA 4.4.4 IIIA 4.4.5 IIIA 4.4.6 IIIA 4.4.7 IIIA 4.5.1 IIIA 4.5.2 IIIA 4.5.3 IIIA 4.5.4 IIIA 4.5.5 IIIA 4.6.3

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
3	**Chemistry Requirements for the Registration of Manufacturing Concentrate(s) or End-Use Product(s) Formulated from Registered Technical Grade of Active Ingredients or Integrated System Products**			
3.1	**Product Identification**			
3.1.1	Applicant's Name and Office Address	Forms, 8570-1(5) 8570-4(1)	Forms, 8570-1(5) 8570-4(1)	IIIA 1.1
3.1.2	Formulating Plant's Name and Address	Forms, 8570-1(1) 8570-4(2)	Forms, 8570-1(1) 8570-4(2)	IIIA 1.2.1
3.1.3	Trade Name	Forms, 8570-1(1) 8570-1(4) 8570-4(3) 8570-4(10)	Forms, 8570-1(1) 8570-1(4) 8570-4(3) 8570-4(10)	IIIA 1.3
3.1.4	Other Names	Forms, 8570-1(1) 8570-1(4) 8570-4(3) 8570-4(10)	Forms, 8570-1(1) 8570-1(4) 8570-4(3) 8570-4(10)	IIIA 1.3
3.2	**Formulation Process**			
3.2.1	Description of Starting Materials	Forms, 8570-4(10) 8570-4(13) 8570-4(15) 830.1550	Forms, 8570-4(10) 8570-4(13) 8570-4(15) 61-1	IIIA 1.2.3 IIIA 1.4.4
3.2.2	Description of the Formulation Process	830.1650	61-2	IIIA 1.4.5.1
3.2.3	Discussion of the Formation of Impurities of Toxicological Concern	830.1670	61-3	IIIA 1.4.5.2
3.3	**Specifications**			
3.3.1	Establishing Certified Limits	Form, 8570-4(10) 8570-4(14) 8570-4(15) 830.1550 830.1750	Form, 8570-4(10) 8570-4(14) 8570-4(15) 61-1 62-2	IIIA 1.4.2 IIIA 1.4.3.3 IIIA 1.4.4

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
3.3.2	Control Product Specification Form (Statement of Product Specification Form)	Form, 8570-4(10) 8570-4(13) 8570-4(14) 8570-4(15) 830.1550 830.1750	Form, 8570-4(10) 8570-4(13) 8570-4(14) 8570-4(15) 61-1 62-2	IIIA 1.4.1 IIIA 1.4.2 IIIA 1.4.3.1 IIIA 1.4.4
3.4	**Product Analysis**			
3.4.1	Enforcement Analytical Method	830.1800	62-3	IIIA 5.2.1 IIIA 5.2.2
3.4.2	Impurities of Toxicological Concern	830.1800	62-3	IIIA 5.2.4
3.5	**Chemical and Physical Properties**			
3.5.1	Colour	830.6302	63-3	IIIA 2.1
3.5.2	Physical State	830.6303	63-3	IIIA 2.1
3.5.3	Odour	830.6304	63-3	IIIA 2.1
3.5.4	Formulation Type	—	—	IIIA 1.5
3.5.5	Container Material and Description	Form 8570-1(1) 8570-1(2)	Form 8570-1(1) 8570-1(2)	IIIA 2.14 IIIA 4.1.1
3.5.6	Density or Specific Gravity	Form 8570-4(7) 830.7300	Form 8570-4(7) 63-7	IIIA 2.6.2
3.5.7	pH	830.7000	63-12	IIIA 2.4.1 IIIA 2.4.2
3.5.8	Oxidizing or Reducing Action (Chemical Incompatibility)	830.6314	63-14	IIIA 2.2.2
3.5.9	Viscosity	830.7100	63-18	IIIA 2.5.1 IIIA 2.5.2
3.5.10	Storage Stability Data	830.6313 830.6317	63-13 63-17	IIIA 2.7.1 IIIA 2.7.2 IIIA 2.7.3 IIIA 2.7.4 IIIA 2.7.5 IIIA 2.7.6
3.5.11	Flammability	830.6315	63-15	IIIA 2.3.1 IIIA 2.3.2 IIIA 2.3.3
3.5.12	Explodability	830.6316	63-16	IIIA 2.2.1
3.5.13	Miscibility	830.6319	63-19	IIIA 2.11
3.5.14	Corrosion Characteristics	830.6320	63-20	IIIA 2.13 IIIA 4.1.3
3.5.15	Dielectric Breakdown Voltage	830.6321	63-21	IIIA 2.12

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
3.6	Sample(s)	830.1900 860.1650	64-1 171-13	IIIA 5.1.1 IIIA 5.1.2 IIIA 5.1.3 IIIA 5.1.4 IIIA 5.1.5
3.7	Other Studies/Data/Reports	—	—	IIIA 1.7 IIIA 2.15 IIIA 4.9 IIIA 5.9
4	**Toxicology**			
4.1	Summary: Toxicology Profile	—	—	—
4.6	**Acute Studies**			
4.6.1	Acute Oral	870.1100	81-1	IIIA 7.1.1
4.6.2	Acute Dermal	870.1200	81-2	IIIA 7.1.2
4.6.3	Acute Inhalation	870.1300	81-3	IIIA 7.1.3
4.6.4	Primary Eye Irritation	870.2400	81-4	IIIA 7.1.5
4.6.5	Primary Dermal Irritation	870.2500	81-5	IIIA 7.1.4
4.6.6	Dermal Sensitization	870.2600	81-6	IIIA 7.1.6
4.6.7	Potentiation: Interaction	—	—	IIIA 7.1.7
4.6.8	Other Acute Studies	—	—	IIIA 7.11
4.7	Short-Term Studies			
4.7.1	90 day Rodent	870.3200 870.3250	82-2 82-3	IIIA 7.2
4.7.2	90 day Dog	870.3200 870.3250	82-2 82-3	IIIA 7.2
4.7.3	90 day Dermal	870.3200 870.3250	82-2 82-3	IIIA 7.2
4.7.4	21/28 day Dermal	870.3200 870.3250	82-2 82-3	IIIA 7.2
4.7.5	28 day Inhalation	870.3200 870.3250	82-2 82-3	IIIA 7.2
4.7.6	90 day Inhalation	870.3200 870.3250	82-2 82-3	IIIA 7.2
4.7.7	Other Special Studies - EP	—	—	IIIA 7.11
4.8	Other Studies/Data/Reports Including Formulants Data	—	—	IIIA 7.9.2 IIIA 7.11
4.9	Animal Safety Studies	870.7200	85-2	IIIA 7.10
5	**Exposure (Occupational and/or Bystander)**			
5.1	Summary	—	—	—

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
5.2	Use Description/Scenario (Application and Post Application)	Form 8570-1(1) 860.1200 875.1700 875.2700 40CFR 156.10 (i)(c)(2)(iii) 40CFR 156.10 (i)(c)(2)(viii) 40CFR 156.212 (d)	Form 8570-1(1) 40CFR 156.10 (i)(c)(2)(iii) 171-2 171-3	IIIA 3.3.1 IIIA 3.3.2 IIIA 3.3.3 IIIA 3.4 IIIA 3.5 IIIA 3.6 IIIA 3.7.1 IIIA 3.7.2 IIIA 3.7.3 IIIA 3.7.4 IIIA 3.7.5 IIIA 4.1.1 IIIA 4.2.1 IIIA 4.2.2 IIIA 4.3.3 IIIA 4.3.5 IIIA 4.4.5 IIIA 4.4.6 IIIA 4.4.7
5.3	Pesticides Handlers' Exposure Database Assessment (or other database)	—	—	IIIA 7.3.1 IIIA 7.3.2
5.4	Mixer/Loader/Applicator: Passive Dosimetry Data	875.1100 875.1200 875.1300 875.1400 875.1500	231 232 233 234 235	IIIA 7.3.3
5.5	Mixer/Loader/Applicator: Biological Monitoring Data	875.1100 875.1200 875.1300 875.1400 875.1500 875.2600	231 232 233 234 235	IIIA 5.8 IIIA 7.3.3
5.6	Post Application: Passive Dosimetry Data	860.1200 875.2400 875.2500 875.2600 40CFR 156.10 (i)(c)(2)(viii)	133-3 133-4 171-3 235	IIIA 4.3.3 IIIA 4.3.5 IIIA 7.4.1 IIIA 7.4.2 IIIA 7.5.1 IIIA 7.5.2 IIIA 7.5.3 IIIA 7.5.4

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
5.7	Post Application: Biological Monitoring Data	860.1200 875.2400 875.2500 875.2600 40CFR 156.10 (i)(c)(2)(viii)	133-3 133-4 171-3 235	IIIA 4.3.3 IIIA 4.3.5 IIIA 5.8 IIIA 7.4.1 IIIA 7.4.2 IIIA 7.5.1 IIIA 7.5.2 IIIA 7.5.3 IIIA 7.5.4
5.8	Dermal Absorption (*in vivo*)	870.7600	85-3	IIIA 7.6.1 IIIA 7.6.2
5.9	Dislodgeable Residues (Foliar, Soil and Surface)	860.1200 875.2100 875.2200 875.2400 875.2500 875.2600 40CFR 156.10 (i)(c)(2)(viii)	132-1 133-3 133-4 171-3 235	IIIA 4.3.3 IIIA 4.3.5 IIIA 7.4.1 IIIA 7.4.2 IIIA 7.5.1 IIIA 7.5.2 IIIA 7.5.3 IIIA 7.5.4 IIIA 7.7.1 IIIA 7.7.2 IIIA 7.7.3
5.10	Ambient Air Samples (Indoor – Outdoor)	875.2400 875.2500 875.2600	133-3 133-4 235	IIIA 7.4.1 IIIA 7.4.2 IIIA 7.5.1 IIIA 7.5.2 IIIA 7.5.3 IIIA 7.5.4
5.11	Glove/Clothing Penetration Data	875.1100 875.1200 875.1300 875.1400 875.1500 40CFR 156.212 (d)	171-3 231 232 233 234 235	IIIA 4.4.5 IIIA 4.4.6 IIIA 4.4.7 IIIA 7.3.3
5.12	Epidemiology	—	—	IIIA 7.8
5.13	Package Integrity Study	—	—	IIIA 4.1.2
5.14	Other Studies/Data/Reports	—	—	IIIA 3.10 IIIA 4.9 IIIA 5.9 IIIA 7.11
6	**Metabolism/Toxicokinetic Studies**			
6.1	Summary	860.1550	171-6	IIIA 8.7.1 IIIA 8.7.2

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
6.2	Livestock	860.1300 860.1480	171-4 171-4(b)	IIIA 8.2 IIIA 8.4.1 IIIA 8.4.2 IIIA 8.4.3
6.3	Plants	860.1300 860.1480	171-4 171-4(a)	IIIA 8.2
6.4	Other Studies/Data/Reports	860.1300 860.1400 860.1480	171-4 171-4(c)	IIIA 8.2 IIIA 8.4.4 IIIA 8.9
7	**Food, Feed and Tobacco Residue Studies**			
7.1	Summary	860.1550	171-6	IIIA 8.7.1 IIIA 8.7.2
7.2	**Analytical Methodology (Food Crops and Tobacco)**			
7.2.1	Supervised Residue Trial Analytical Methodology	860.1300 860.1340 860.1360	171-4a,b 171-4c,d 171-4m	IIIA 5.3
7.2.2	Enforcement Analytical Methodology	830.1800 860.1300 860.1340 860.1360	62-3 171-4a,b 171-4c,d 171-4m	IIIA 5.3
7.2.3	Inter-laboratory Analytical Methodology	860.1300 860.1340 860.1360	171-4a,b 171-4c,d 171-4m	IIIA 5.3
7.2.4	Multi-residue Analytical Methodology Evaluation	860.1300 860.1340 860.1360	171-4a,b 171-4c,d 171-4m	IIIA 5.3
7.2.5	Storage Stability of Working Solutions in Analytical Methodology	860.1300 860.1340 860.1360	171-4a,b 171-4c,d 171-4m	IIIA 5.3
7.3	Freezer Storage Stability Tests	860.1380 860.1850	165-1 171-4 171-4(e)	IIIA 8.1.1
7.4	**Crop Residue Data**			
7.4.1	Supervised Residue Trial Study	860.1500	171-4	IIIA 8.3.1 IIIA 8.3.2 IIIA 8.3.3
7.4.2	Residue Decline Study	860.1500	171-4	IIIA 8.3.1 IIIA 8.3.2 IIIA 8.3.3
7.4.3	Confined Crop Rotation Trial Study	860.1500	171-4	IIIA 8.6
7.4.4	Field Crop Rotation Trial Study	860.1200 860.1900	165-2 171-3	IIIA 8.6

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
7.4.5	Processed Food/Feed	860.1520 860.1540	171-4 171-5	IIIA 8.5.1 IIIA 8.5.2 IIIA 8.5.3 IIIA 8.5.4
7.4.6	Residue Data for Crops Used as Livestock Feed (if needed for forage crops)	860.1500	171-4	IIIA 8.3.1 IIIA 8.3.2 IIIA 8.3.3
7.5	Livestock, Poultry, Egg and Milk Residue Data (from feeding of treated crops)	860.1300 860.1480	171-4 171-4(c)	IIIA 8.2 IIIA 8.4.1 IIIA 8.4.2 IIIA 8.4.3
7.6	Livestock, Poultry, Egg and Milk Residue Data (external application)	860.1300 860.1480	171-4 171-4(c)	IIIA 8.2 IIIA 8.4.1 IIIA 8.4.2 IIIA 8.4.3
7.7	Tobacco Residue Data	860.1500	171-11	IIIA 8.3.4
7.8	Other Studies/Data/Reports	860.1100 860.1300 860.1400 860.1480 860.1550 860.1560 860.1850	165-1 171-2 171-4 171-4(c) 171-6 171-7	IIIA 5.9 IIIA 8.2 IIIA 8.4 IIIA 8.4.4 IIIA 8.5 IIIA 8.5.4 IIIA 8.9
7.8.1	Other Studies/Pyrolysis Study	—	—	IIIA 8.9
8	**Environmental Chemistry and Fate**			
8.1	Summary	—	—	—
8.2	**Laboratory Studies**			
8.2.3	**Laboratory Studies of Transformation**			
8.2.3.1	Summary	—	—	—
8.2.3.6	Special Studies Related to Use-Pattern or Formulation	—	—	IIIA 9.10.1
8.2.4	**Laboratory Studies of Mobility**			
8.2.4.1	Summary	—	—	—
8.2.4.6	Special Studies Related to Use-Pattern or Formulation	—	—	IIIA 9.10.1
8.3	**Field Studies of Dissipation/Accumulation [may be small- or large-scale]**			
8.3.1	Summary	—	—	—
8.3.2	**Terrestrial**			
8.3.2.1	Canada	835.6100	164-1	IIIA 9.2.1 IIIA 9.2.2 IIIA 9.2.3

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
8.3.2.2	Northern U.S.	835.6100	164-1	IIIA 9.2.1 IIIA 9.2.2 IIIA 9.2.3
8.3.2.3	Other	835.6100	164-1	IIIA 9.2.1 IIIA 9.2.2 IIIA 9.2.3
8.3.3	**Aquatic**			
8.3.3.1	Canada	835.6200	164-2	IIIA 9.2.4
8.3.3.2	Northern U.S.	835.6200	164-2	IIIA 9.2.4
8.3.3.3	Other	835.6200	164-2	IIIA 9.2.4
8.3.4	Special Studies Related to Intended Use-Pattern	—	—	—
8.4	**Storage, Disposal and Decontamination**			
8.4.1	Summary	860.1520 860.1540 40CFR 165.8 (a)-(c) 40CFR 165.9 (a)-(d)	40CFR 165.9 (a)-(d) 171-3 171-4 171-5	IIIA 4.5.1 IIIA 4.5.2 IIIA 4.5.3 IIIA 4.8.2 IIIA 8.5.1 IIIA 8.5.2 IIIA 8.5.3 IIIA 8.5.4
8.5	**Other Environmental Fate Studies**			
8.5.1	Summary	—	—	—
8.5.2	Incineration-thermal Decomposition at High and Low Temperatures	—	—	IIIA 4.7 IIIA 4.8.1 IIIA 9.10.1
8.6	Other Studies/Data/Reports	—	—	IIIA 4.9 IIIA 5.9 IIIA 8.9 IIIA 9.10.1 IIIA 9.10.2
9	**Environmental Toxicology**			
9.1	Summary	—	—	—
9.2	**Non-Target Terrestrial Invertebrates**			
9.2.1	Summary	—	—	—

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
9.2.8	Laboratory Studies	—	—	IIIA 10.2.1.5 IIIA 10.2.1.6 IIIA 10.4.2.1 IIIA 10.4.2.2 IIIA 10.4.3 IIIA 10.4.4 IIIA 10.4.7 IIIA 10.5.1 IIIA 10.5.1.1 IIIA 10.5.1.2 IIIA 10.6.2 IIIA 10.6.3 IIIA 10.6.6 IIIA 10.10.1
9.2.9	Field Studies	—	—	IIIA 10.4.5 IIIA 10.4.6.1 IIIA 10.4.6.2 IIIA 10.4.6.3 IIIA 10.5 IIIA 10.5.1.3 IIIA 10.5.1.4 IIIA 10.6.4 IIIA 10.6.5 IIIA 10.10.2
9.3	**Non-Target Freshwater Invertebrates**			
9.3.1	Summary	—	—	—
9.3.5	Laboratory Studies	850.1010 850.1075 850.4400	72-2 72-1 123-2	IIIA 10.2.1.3 IIIA 10.2.1.4 IIIA 10.2.2 IIIA 10.2.6 IIIA 10.2.6.1 IIIA 10.2.6.2 IIIA 10.10.1
9.3.6	Field Studies	850.1950	72-7	IIIA 10.2.3 IIIA 10.2.4 IIIA 10.10.2
9.4	**Non-Target Marine Invertebrates**			
9.4.1	Summary	—	—	—
9.4.6	Laboratory Studies	850.1025 850.1035 850.1045 850.1055 850.1075	72-3	IIIA 10.2.1.7 IIIA 10.2.1.8 IIIA 10.2.1.9 IIIA 10.2.1.10 IIIA 10.2.2.4 IIIA 10.2.6 IIIA 10.2.6.3 IIIA 10.10.1

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
9.4.7	Field Studies	850.1950	72-7	IIIA 10.2.3 IIIA 10.2.4 IIIA 10.10.2
9.5	**Fish**			
9.5.1	Summary	—	—	—
9.5.4	Laboratory Studies	850.1010 850.1025 850.1035 850.1045 850.1055 850.1075 850.4400	72-1 72-2 72-3 123-2	IIIA 10.2.1.1 IIIA 10.2.1.2 IIIA 10.2.2 IIIA 10.2.2.1 IIIA 10.2.2.4 IIIA 10.2.5.1 IIIA 10.2.5.2 IIIA 10.2.5.3 IIIA 10.10.1
9.5.5	Field Studies	850.1950	72-7	IIIA 10.2.3 IIIA 10.2.4 IIIA 10.10.2
9.6	**Wild Birds**			
9.6.1	Summary	—	—	—
9.6.4	Laboratory Studies	850.2100	71-1	IIIA 10.1.1 IIIA 10.1.2 IIIA 10.1.6 IIIA 10.1.8 IIIA 10.1.9 IIIA 10.10.1
9.6.5	Field Studies	850.2500	71-5	IIIA 10.1.7 IIIA 10.10.2
9.6.6	Special studies related to the intended use-pattern (TGAI and EP)	—	—	IIIA 10.10.1 IIIA 10.10.2
9.7	**Wild Mammals**			
9.7.1	Summary	850.2400	71-3	—
9.7.2	Field Studies	850.2500	71-5	IIIA 10.3.3 IIIA 10.10.2
9.8	**Non-Target Plants**			
9.8.1	Summary	—	—	—
9.8.6	Laboratory Studies	850.1010 850.1075 850.4100 850.4150 850.4200 850.4225 850.4250 850.4400 850.5400	72-2 72-1 122-1 123-1 123-2	IIIA 10.2.1.11 IIIA 10.2.2 IIIA 10.8.1.1 IIIA 10.8.1.2 IIIA 10.8.1.3 IIIA 10.8.2.1 IIIA 10.10.1

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
9.8.7	Field Studies	850.4300 850.4450	124-1 124-2	IIIA 10.8.1.4 IIIA 10.8.2 IIIA 10.8.2.2 IIIA 10.10.2
9.9	Other Studies/Data/Reports	—	—	IIIA 10.10.1 IIIA 10.10.2
10	**Value (applicable to each pest/site or host combination)**			
10.1	Value Summary	—	—	—
10.2	**Efficacy Studies**			
10.2.1	Mode of Action	Form 830.1550 830.1670 860.1200 875.2700 40CFR 156.10 (i)(c)(2)(iii) 8570-4(15)	Form 40CFR 156.10 (i)(c)(2)(iii) 8570-4(15) 61-1 61-3 171-2	IIIA 1.6 IIIA 3.2
10.2.2	Description of Pest Problem	40CFR 156.10 (i)(c)(2)(iii) 860.1200 875.1700 875.2700	40CFR 156.10 (i)(c)(2)(iii) 171-2	IIIA 3.1 IIIA 3.3.1 IIIA 3.3.2
10.2.3	**Efficacy Trials**			
10.2.3.1	Summary	860.1200 875.1700 875.2700	171-2	IIIA 3.3.3 IIIA 3.4 IIIA 3.5 IIIA 3.6 IIIA 3.7.1 IIIA 3.7.2 IIIA 3.7.3 IIIA 3.7.4 IIIA 3.7.5
10.2.3.2	Efficacy: Laboratory, Growth Chamber Trials	860.1200 875.1700 875.2700	171-2	IIIA 3.3.3 IIIA 3.4 IIIA 3.5 IIIA 3.6 IIIA 3.7.1 IIIA 3.7.2 IIIA 3.7.3 IIIA 3.7.4 IIIA 3.7.5 IIIA 6.1.1

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
10.2.3.3	Efficacy: Small-scale Trials (Field, Greenhouse)	860.1200 875.1700 875.2700	171-2	IIIA 3.3.3 IIIA 3.4 IIIA 3.5 IIIA 3.6 IIIA 3.7.1 IIIA 3.7.2 IIIA 3.7.3 IIIA 3.7.4 IIIA 3.7.5 IIIA 6.1.2
10.2.3.4	Efficacy: Operational Trials	—	—	IIIA 6.1.3
10.3	**Adverse Effects on Use Site**			
10.3.1	Summary	—	—	—
10.3.2	Non-Safety Adverse Effects (e.g., to crop, site of application (discolouration, corrosion), etc.)	870.7200	85-2	IIIA 6.2.1 IIIA 6.2.2 IIIA 6.2.3 IIIA 6.2.5 IIIA 7.10
10.3.3	Damage to Rotational Crops	860.1200 875.1700 875.2700	171-2	IIIA 3.8.1 IIIA 3.8.2 IIIA 3.8.3
10.4	Economics	—	—	IIIA 6.3
10.5	**Sustainability**	—	—	—
10.5.1	Survey of Alternatives (chemical and non-chemical)	—	—	IIIA 6.4.1
10.5.2	Compatibility with Current Management Practices Including IPM	—	—	IIIA 6.4.2
10.5.3	Resistance Management	—	—	IIIA 6.2.8
10.5.4	Contribution to Risk Reduction	—	—	IIIA 6.4.3
10.6	Other Studies/Data/Reports	—	—	IIIA 1.7 IIIA 3.10 IIIA 6.5
12.5	**Foreign Reviews**	—	—	—
12.5.3	Foreign Reviews of Chemistry Requirements for MAs and EPs	—	—	—
12.5.4	Foreign Reviews of Toxicology	—	—	—
12.5.5	Foreign Reviews of Exposure (Occupational and/or Bystander)	—	—	—
12.5.6	Foreign Reviews of Metabolism/Toxicokinetics Studies	—	—	—
12.5.7	Foreign Reviews of Food, Feed and Tobacco Residue Studies	—	—	—

Canadian DACO Number	TITLE	EPA		OECD
		OPPTS	OPP	
12.5.8	Foreign Reviews of Environmental Chemistry and Fate	—	—	—
12.5.9	Foreign Reviews of Environmental Toxicology	—	—	—
12.5.10	Foreign Reviews of Value	—	—	—
12.7	Comprehensive Data Summaries	—	—	—

Appendix V Required numbers of copies of information supporting submissions for pest control products for Category A submissions*

Applicants should contact the PMRA for specific data requirements

Part Number	Data or Information	Total Number of Copies	
		Paper	Fully Electronic **
0	Index	2[1]	1
1	Label	4[1]	1
2	Chemistry TGAI[2]	2	1
3	Chemistry EP[2]	2	1
4	Toxicology[2]	2	1
5	Exposure[2]	2	1
6	Metabolism[2]	2	1
7	Residue[2]	2	1
8	Environmental chemistry or fate[2]	2	1
9	Environmental toxicology[2]	2	1
10	Value[2]	2	1
12.7	Comprehensive Data Summaries[2]	2[1]	1

* This table may be applied to submissions of other Category types, e.g., Category B with the exception that the Comprehensive Data Summaries are not required. As with Category A submissions, it is not necessary to submit copies when a Part does not appear on the applicable DACO table.

** Only one (1) paper copy of the complete dossier is required when submitting a fully electronic dossier. Please refer to Section 5.4 for details.

[1] One electronic copy as well as hard (paper) copies in the prescribed format are required. (Note: requirements for the label will be subject to changes identified in LPS2003-01*Labe1 Process Changes Part 1: Overview* and LPS2003-02 *Label Process Changes Part 2: Guidance for Industry*)

[2] It is not necessary to submit copies when a Part does not appear on the applicable DACO table.

Appendix VI Description of data codes for evaluation of occupational, residential and bystander exposure (DACO Section 5.0)

The following is a description of the data codes (DACOs) for evaluation of occupational, residential and bystander exposure and an overview of approaches for addressing these DACOs. Applicants and registrants may request a presubmission consultation to discuss such matters as study design.

NOTE: Each report must be identified with the title, date, author(s), telephone number of author(s) or person(s) who can answer technical questions about the report.

DACO 5.2 Use description or scenario

This includes information which fully describes the use of the product and human activity associated with its use. Qualitative information which will help characterize exposure should be included here and can be divided into mixer/loader/applicator and postapplication categories. The sources of the information should be cited (label, growers groups, surveys, custom applicators, agricultural experts and associations, databases). Where relevant, specific information should be provided for different product users (such as farmers, homeowners, custom applicators, pest control operators). All numerical values should be reported as fully as possible, specifying whether they are minima, maxima or means.

Handler (mixer/loader/applicator)

- Site of application: the sites to which the pesticide is to be applied (geographical locations, areas in buildings)

- Information to characterize amount handled: For agricultural products, area of crop (ha) that can be treated in a work day, including typical and maximum areas (that is, the number of hectares of a crop that can be treated in a typical day by a farmer or by a custom applicator). For non-agricultural products, such as home and garden products and antimicrobials, typical and maximum surface areas treated or other parameters to characterize amount of product handled in a day.

- Timing of application: Description of typical application rates, number of applications per season, frequency of applications, and seasonal variations, if applicable. For agricultural products, summarize when the product is to be applied relative to standard cultivation practices, crop height at application, and so on. For non-agricultural products, summarize relevant parameters (for a material preservative, the typical and maximum volume of material produced at a facility per day, for example).

- Method of application: Typical methods of application employed, description of equipment used (open or closed cab, nozzle size, pressure used, high volume or low volume equipment for greenhouse uses, width of spray swath for residential aerosol sprays).

- Individuals involved: Typical tasks of individuals (whether the same or a different person mixes, loads and applies).

- Mixing/loading method: Tasks involved in mixing and loading, equipment used (open or closed mixing and loading), duration and frequency of mixing/loading, number of mix/load cycles typical per work day.

- Clean-up and repair activities: Tasks involved in clean-up and repair, duration and frequency of these tasks, who performs these tasks.

- Personal protective equipment: Description of personal protective equipment (devices and apparel) recommended on label, and typical practice.

- Formulation: Physical and chemical properties of active ingredient and formulation that may influence exposure, such as vapour pressure, water solubility, ionization constants, octanol–water partition coefficient, and particle size distribution, if applicable.

Post-application

- Cropping practices for agricultural products: How the crop is cultivated, if applicable (are the crops staked, what practices are used for weed control).

- Re-entry intervals: If applicable, science-based re-entry interval should be presented. If there is no re-entry interval, the reason for not establishing one should be presented.

- Re-entry activities: Identify potential re-entry activities (such as harvesting, pruning, thinning, children playing on treated lawns, children playing on treated surfaces in homes) together with a description of the nature of the activity (tools used and the intensity of contact with treated surfaces, for example). Include varietal differences of crops, if applicable.

- Timing, frequency and duration of re-entry activities: Describe when each re-entry activity is carried out (time of season relative to product application), as well as frequency (how often a day/week/year) and duration of these activities (minutes, hours).

- Individuals re-entering treated areas: Describe individuals re-entering treated areas (individuals re-entering treated turf may include landscape workers, individuals entering for recreational purposes, and so on; individuals re-entering treated agricultural fields may include farmers, scouters, seasonal contract workers and the like).

- Principal sources of exposure: Intensity or degree of contact with treated surface (soil, foliage, carpets, lawns, air); principal body parts that come in contact with treated surface (hands, legs, feet) should be specified.

- Personal protective equipment: Describe personal protective equipment (devices and apparel) recommended on label and typical practice for individuals re-entering treated areas.

DACO 5.3 Pesticide Handlers' Exposure Database Assessment

An exposure assessment conducted using the current version of Pesticide Handlers' Exposure Database (PHED). Refer to the PHED User Guide and Reference Manual for guidance in using and reporting PHED data (provided with PHED software).

DACO 5.4 Mixer/loader/applicator: passive dosimetry

Passive dosimetry studies estimate the amount of a chemical impinging on the surface of the skin or clothing and the amount of the chemical available for inhalation through the use of appropriate trapping devices. Passive dosimetry studies conducted with surrogate compounds may be acceptable, provided that a rationale is submitted showing that the surrogate study is relevant to the compound of interest with respect to the following areas: formulation type, application method and equipment, mixing method, application rates, application site, personal protective equipment, and packaging. Further, the surrogate study must be conducted according acceptable guidelines. Refer to the *OECD Guidance Document for the Conduct of Studies of Occupational Exposure to Agricultural Pesticides* or the EPA's *OPPTS Test Guideline Series 875, Occupational and Residential Exposure Test Guidelines: Group A, Applicator Exposure Monitoring Test Guidelines* (formerly Subdivision U).

DACO 5.5 Mixer/loader/applicator: biological monitoring

Same as 5.4 above, but biological monitoring uses urine, blood or other biological matrices to measure exposure. The toxicokinetics of the compound must be well understood prior to conducting biological monitoring studies. Surrogate biological monitoring studies would generally not be acceptable as the toxicokinetics differ from compound to compound. However, if the toxicokinetics are sufficiently understood to convert internal to external dose, then biological monitoring data may be acceptable as surrogate data.

DACO 5.6 and 5.7 Postapplication: passive dosimetry and biological monitoring

Same types of studies as 5.4 and 5.5, but postapplication activity is measured for exposure as opposed to mixing/loading/applying activities. Postapplication activities include re-entry into treated crops, greenhouses, treated lawns and homes, and so on. Refer to the EPA's *OPPTS Test Guideline Series 875, Occupational and Residential Exposure Test Guidelines: Group B, Post Application Monitoring Guidelines* (formerly Subdivision K) for guidance on conducting postapplication exposure studies.

If there is potential for nondietary ingestion (such as hand-to-mouth activity of juvenile subpopulations contacting treated surfaces), then this pathway of exposure must also be addressed.

DACO 5.8 In vivo dermal absorption study

An in vivo study, typically conducted with rodents, from which estimates of dermal absorption can be derived. Refer to the U.S. EPA's *OPPTS Test Guidelines Series 870, Health Effects Test Guidelines* (formerly Subdivision F) for guidance on conducting in vivo dermal absorption studies on rodents. If performing in vivo studies on human volunteers or monkeys, refer to the following references:

Feldmann, R.J. and H.I. Maibach, (1974) Percutaneous Penetration of Some Pesticides and Herbicides in Man, *Toxicol. And Appl. Pharmacol.* **28**: 126–132.

Wester, R.C. and H.I. Maibach (1985), In Vivo Percutaneous Absorption and Decontamination of Pesticides in Humans, *J. Toxicol. Environ. Health*, **16**: 25–37.

Data generated using in vitro dermal absorption methodology is currently unacceptable, for lack of sufficient validation. Applicants wishing to submit in vitro data for the purposes of method validation should contact the Health Evaluation Division regarding appropriate strategies and study designs.

DACO 5.9 Dislodgeable/transferable residue

A study which estimates the amount of residue that can be dislodged or transferred from a surface. Media of interest would include foliage, indoor surfaces such as carpets, or the fur of companion animals. This data, in conjunction with transfer coefficients, may be suitable for estimating postapplication exposure. Refer to the *OPPTS Test Guideline Series 875, Occupational and Residential Exposure Test Guidelines: Group B, Post Application Monitoring Guidelines* (formerly Subdivision K) for guidance on conducting these types of study.

DACO 5.10 Ambient air samples

Sampling that measures the amount of pesticide in a given volume of ambient air. Ambient air samples are conducted to estimate inhalation exposure, where such exposure may occur, or to establish appropriate re-entry intervals for indoor studies. Breathing zone samples are preferable for estimating inhalation exposure. Refer to the *OPPTS Test Guideline Series 875, Occupational and Residential Exposure Test Guidelines: Group B, Post Application Monitoring Guidelines* (formerly Subdivision K) for guidance on conducting air sampling.

DACO 5.11 Glove or clothing penetration data

A study that quantifies penetration or permeation of a pesticide through gloves or protective clothing. Refer to the following references for further guidance:

American Society for Testing and Materials (ASTM), Resistance of Protective Clothing Materials to Permeation by Liquids or Gases, Method F-739-85. ASTM, Philadelphia, 1985.

McBriarty, J.P. and N. Henry, Eds. Performance of Protective Clothing: 4th Vol., ASTM STP 1133. American Society for Testing and Materials, Philadelphia, 1992.

DACO 5.12 Epidemiology

An epidemiology study examines the incidence of disease in specific populations and the influence of environment and lifestyle on disease patterns. Epidemiology may be used as supporting data for a submission in addition to other DACOs. However, the utility of this type of data should be discussed with the Health Evaluation Division before its submission.

DACO 5.13 Package integrity study

A study that investigates package integrity under field conditions. Such studies measure the strength, durability and storage stability of a package and are generally exclusive to water-soluble packages. The study protocol should be discussed with the Health Evaluation Division before conducting the study.

Appendix VII Requests for waiver

Each request for waiver must be submitted under the applicable DACO. The request should include the elements indicated below. A statement should also be included in the *Comments* field of the index to indicate that the item is a request for waiver.

The following elements should be included in a request for waiver:

- DACO number
- Author(s)
- Date of the waiver request
- Brief description of the product
- Explanation detailing why the study is not necessary
- Description of relevant scientific literature which supports the explanation
- Conclusions
- References

Appendix VIII Documents referenced in this directive

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*
DIR96-05	*Comprehensive Data Summaries*
DIR97-01	*Comprehensive Data Summaries*
DIR97-02	*Guidelines for the 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*
DIR2002-02	*The PMRA Initiative for Reduced-Risk Pesticides*

Regulatory Notes

REG2001-06	*Guidance to Applicants for Preparing Electronic Submissions Part I: Overview*
REG2002-04	*Category C Submission Efficacy Reviews*
REG2003-01	*Guidance on Selecting the Correct Category Type for Pest Control Product Submissions*

Label Process Series

LPS 2003-01	*Label Process Changes - Part 1: Overview*
LPS 2003-02	*Label Process Changes - Part 2: Guidance for Industry*

EDDE2001-01	*Guidance to Applicants for Preparing Electronic Submissions Part II: Guidance for Industry during Pilot Stage*
EDDE2001-02	*Guidance to Applicants for Preparing Electronic Submissions Part III: Guidance Evaluator Functional Requirements for Electronic Evaluation*
EDDE2001-03	*Guidance to Applicants for Preparing Electronic Submissions Part IV: Guidance on the Preparation of Documents for Electronic Exchange*

Memoranda

T-1-232	*Product Specific Registration (PSR) Policy: Pesticides*
T-1-245	*Guidelines for Developing a Pesticide Toxicology Data Base*
T-1-255	*Guidelines for Determining Environmental Chemistry and Fate of Pesticides*

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

NOTE: The Pesticide Own Use Import Program (OUI) can be found in the Registration Handbook at Section 16.2.

Pest Control Products Regulations

Food and Drugs Act

OECD Guidelines and Criteria for Industry for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for Plant Protection Products and their Active Substances in Support of Regulatory Decisions in OECD Countries

OECD Guidance Document for the Conduct of Studies of Occupational Exposure to Agricultural Pesticides

OPPTS Test Guideline Series 875	*Occupational and Residential Exposure Test Guidelines: Group A: Applicator Exposure Monitoring Test Guidelines*
OPPTS Test Guideline Series 875	*Occupational and Residential Exposure Test Guidelines: Group B: Post Application Monitoring Guidelines*
OPPTS Test Guidelines Series 870	*Health Effects Test Guidelines*

NAFTA Technical Working Group on Pesticides

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

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OPPTS Test Guidelines Series 870	*Health Effects Test Guidelines*

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