



NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLC sobre plaguicidas
Groupe de travail technique sur les pesticides d'ALENA

**NAFTA Guidance Document
on
Data Requirements for Tolerances
on Imported Commodities**

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US Environmental Protection Agency
Office of Pesticide Programs
(OPP)

Health Canada
Pest Management Regulatory Agency
(PMRA)

Comision Intersecretarial para el Control del Proceso y Uso
de Plaguicidas y Sustancias Toxicas
(CICOPLAFEST)

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I. OBJECTIVE

The purpose of this document is to provide detailed guidance on data requirements that meet the North American Free Trade Agreement (NAFTA) standards for the establishment of pesticide import tolerances or maximum residue levels (MRL) in Canada, Mexico, and the United States. This document has been developed consistently with the goals of NAFTA. A common NAFTA approach to import tolerances will promote trade between North America and the rest of the world.

Under the existing regulations of the importing countries, import tolerance petitioners must submit separate import tolerance/MRL petitions to each of the three NAFTA countries and, as such, must adhere to any specific petition requirements (i.e., formatting, etc.) for each country. However, the common set of data requirements listed herein typically will result in a reduced data set and in a more efficient and cost effective process for petitioners to obtain import tolerances for all of North America. The NAFTA countries encourage the concurrent submission of petitions so that joint review projects can be initiated. The joint review of petitions will help to harmonize the setting of tolerances/MRLs in each country; this will, in turn, allow for free trade within North America.

This document covers those tolerances or MRLs that exist for pesticide chemicals not registered for use on a particular crop in any of the three NAFTA countries. There is no statutory or regulatory distinction between import tolerances and any other tolerance or MRL issued independently by Canada, Mexico, or the United States.

II. CURRENT LEGAL FRAMEWORK IN THE UNITED STATES

A. The Federal Insecticide, Fungicide and Rodenticide Act and The Federal Food, Drug and Cosmetic Act

EPA regulates pesticides under two major statutes: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). FIFRA requires that pesticides be registered (licensed) by EPA before they may be sold or distributed for use in the United States. Under section 408 of the FFDCA, any pesticide residue in or on a food is considered unsafe unless EPA has established a tolerance or tolerance exemption for the pesticide residue. This requirement of a tolerance or tolerance exemption applies equally to domestically-produced and imported food. Any food with pesticide residues not covered by a tolerance or tolerance exemption (or with residues in excess of the tolerance) may be subject to regulatory action by the U.S. government (including seizure). Pesticide tolerances and exemptions are enforced by individual states and the U.S. Food and Drug Administration (FDA) for most foods, and by the U.S. Department of Agriculture (USDA) for meat, poultry, and some egg products.

EPA has an obligation under section 408 of the FFDCA to establish tolerances for pesticide chemicals at levels that are “safe.” EPA also has an obligation to ensure that the tolerances continue to be “safe” over time, since new information may alter EPA’s earlier safety finding under the FFDCA.

B. The *Food Quality Protection Act of 1996*

The *Food Quality Protection Act of 1996* (FQPA) made several changes to FIFRA and FFDCA. Many of these changes affect how tolerances are set, notably: establishing a single, health-based standard (the “reasonable certainty of no harm” standard) for all pesticide residues in food; eliminating past inconsistencies in how raw foods and processed foods were dealt with; specifying a broader assessment of potential risks, with special emphasis on potentially sensitive groups such as infants and children; significantly limiting the extent to which benefits can be used in modifying or maintaining existing tolerances; and requiring reassessment of all existing tolerances in accordance with the new safety standard. All tolerances (including import tolerances) must be evaluated according to this new health standard.

III. CURRENT LEGAL FRAMEWORK IN CANADA

A. *Pest Control Products Act*

In Canada, the Pest Management Regulatory Agency (PMRA) administers the *Pest Control Products Act* (PCPA), which requires that all pest control products be assessed as to their safety, merit, and value. The intent of the legislation is to ensure the acceptability of the risks, safety, merit and value of pest control products used in Canada. This fundamental principle focuses specifically on the protection of human health and the environment and on product performance. Specifically, Section 9 of the Pest Control Products Regulations requires applicants for registration of pest control products to provide data to support the registration of their products.

B. Food and Drugs Act and Regulations

In Canada, the *Food and Drugs Act* (FDA) prohibits the sale and distribution of contaminated and adulterated food. Regulations indicate that an adulterant is ‘unacceptable’ (e.g., in the case of agricultural chemicals) whenever the residue exceeds the prescribed Maximum Residue Limit (MRL) set forth in Table II, Division 15 of the Food and Drugs Act and Regulations.

Part B, Division 15 of the *Food and Drugs Act* and Regulations authorizes PMRA to establish, modify or maintain MRLs for pesticide residues in or on food. Once established, an MRL applies equally to both domestically produced and imported food.

Any food with pesticide residues not covered by a tolerance specifically named in the Act is subject to the following provision:

B.15.002. A food is adulterated if an agricultural chemical or any of its derivatives is present therein or has been added thereto, singly or in any combination, in an amount exceeding 0.1 parts per million

and may be subject to regulatory action by the Canadian Government.

Pesticide MRLs are enforced by Canadian Food Inspection Agency for all foods including meat, milk, poultry and egg products.

C. Food Safety

The PCPA provides the Minister of Health broad discretionary authority to determine information requirements, principles, policies and standards to be applied in the evaluation and re-evaluation of pest control products.

Today, the PMRA must take into account the North American context created through NAFTA. In particular, the PMRA must stay current with both the U.S. Environmental Protection Agency pesticide reregistration program and the activities in the U.S. that are related to the *Food Quality Protection Act* (FQPA). PMRA has an obligation under Part B, Division 15 of the *Food and Drugs Act* and Regulation to ensure that the MRLs continue to be “safe”, since new information may alter PMRA’s earlier safety finding under the PCP Act.

Thus the PMRA will review pesticide active ingredients and their end-use products on the basis of updated data and scientific information to determine whether, and under what conditions, their continued registration is acceptable.

IV. CURRENT LEGAL FRAMEWORK IN MEXICO

The Intersecretarial Commission for the Control of the Production and Use of Pesticides, Fertilizers, and Toxic Substances (CICOPLAFEST - a commission composed of representatives from the ministries involved in pesticide regulation - the Ministries of Health, Environment, Agriculture, and Trade) regulates pesticides under three major statutes: la Ley General de Salud (General Health Law), la Ley Federal de Sanidad Vegetal (Federal Vegetable Sanitation Law), and la Ley General del Equilibrio Ecológico y Protección al Ambiente (Ecological Equilibrium and Environmental Protection Law).

CICOPLAFEST registers pesticides and establishes maximum Residue Limits (MRL) on food by assessing and reviewing pesticide registration applications and data, but also accepts EPA tolerances or Codex MRLs.

V. IMPORT TOLERANCE DATA REQUIREMENTS FOR THE NAFTA COUNTRIES

A. General Information

The product chemistry, residue chemistry, and toxicology data requirements in this section apply to the establishment of import tolerances/MRLs in each of the NAFTA countries¹.

The import tolerance/MRL petitioner may not need to conduct new studies to fulfill the data requirements. Interested parties may support a new import tolerance/MRL in the NAFTA countries with studies developed for a registration in another country, and/or for a Codex MRL, provided that the petitioner is able to demonstrate to each of the NAFTA countries the applicability of the studies to the requirements in this document. The petitioner or other interested parties may consult with the NAFTA countries before submitting the existing studies. All studies must be formatted in accordance with requirements of the country to which the package is being submitted. The NAFTA countries strongly recommend that petitioners attach a copy of the study evaluation by the registering country or by Codex to the study report as an appendix.

Additionally, Canada and the U.S. are involved in a joint review project. Under the joint review process, Canada carries out review of the efficacy data to establish the lowest application rate that provides appropriate effectiveness against the target pest. Reviews of studies conducted under this agreement would be applicable to import tolerances in all three NAFTA countries.

If a Codex MRL has been established, the NAFTA countries may conduct a more limited review of the residue chemistry data under certain conditions. The NAFTA countries are more likely to adopt MRLs similar to Codex MRL levels if MRLs for the pesticide are already established on other commodities with a contemporary robust database. Standard data and review requirements would be applied where exposure and/or risk to any subpopulation from the pesticide is high. An EPA-specific detailed description of how the U.S. may consider Codex MRLs as they relate to data requirements can be found in Unit VIII of the U.S. Import Tolerances Guidance document (65 FR 35069). Mexico accepts Codex MRLs on commodities for domestic consumption.

The data requirements that are most significant for import tolerances/MRLs are for Field Trials (Canadian Regulatory Directive 98-02, Residue Chemistry Guidelines, and Canadian DACO Guideline No. 7.4.1; Mexican Residue Chemistry Guidelines, Section 9; U.S. Guideline No. 860.1500) and the adequacy of the Toxicology data for those pesticides not already registered for a particular use in the respective NAFTA countries. For registered pesticides, the Field Trials are typically the most significant data requirements for establishing a new tolerance/MRL. See Section V. D. 1. of this document for further information.

Please note that more data requirements may apply to an import tolerance/MRL than would be required by Mexico to obtain a tolerance/MRL in Mexico alone. Mexico has expressed willingness to accept for review studies developed in accordance with Canadian Residue Chemistry Guidelines (98-2), as discussed on page 7 of the Report of the May 24-26, 1999, Technical Working Group meeting in San Antonio.

B. Description of Format and Data Requirements for an Import Tolerance Petition

Specific tolerance/MRL petition requirements (i.e., formatting, etc.) for each country must be adhered to, and separate import tolerance/MRL petitions must be submitted to each of the three NAFTA countries.

In Canada the Registration Hand Book provides information on the registration process for pest control products in Canada and general guidance for making registration submissions. For further details on specific registration procedures and data requirements, consult the various guideline documents and regulatory directives published by the Pest Management Regulatory Agency (PMRA) and Health Canada (<http://www.hc-sc.gc.ca/pmra-arla/english/pubs/book-e.html> Provides additional information).

In Canada petitioners are encouraged to use the data report templates. These templates can be retrieved from the PMRA website (<http://www.hc-sc.gc.ca/pmra-arla>).

Generally, each petition must contain seven parts. The requirements for each section are listed below with a description of the specific information needed to establish an import tolerance/MRL.

1. Name, chemical identity, and composition of the pesticide chemical

Table 1 lists the full complement of product chemistry data that may be required to support an import tolerance/MRL. Detailed guidance on the conduct of the individual studies may be found in the guidelines.

Canadian chemistry requirements have been harmonized with those of the U.S. EPA as described in the *Code of Federal Regulations* (CFR) 40 CFR §158, and the *Product Properties Test Guidelines* 830 Series. The petitioner must disclose the inert ingredients in the formulation. Residue and safety data for inert ingredients may be required if the inert ingredients are of concern to any of the NAFTA countries. For example, if List 1 inert ingredients are present under U.S. EPA's inert ingredient classification system, the U.S. EPA will conduct a dietary risk assessment for the inert ingredient of concern. (A reference for the EPA inert classification system may be found at the end of this document.)

In Canada, any pesticides that contain a toxic formulant, contaminant, or microcontaminant that is toxic within the meaning of section 64 in the Canadian Environmental Protection Act 1999, or those that meet criteria of the Federal Toxic Substances Management Policy (TSMP) or are subject to the Montreal Protocol of ozone-depleting substances will be subject to the PMRA Formulant Policy (<http://www.hc-sc.gc.ca/pmra-arla/english/pdf/spn/spn2000-01-e.pdf>) and the PMRA's strategy for implementing the Toxic Substances Management Policy (TSMP) (<http://www.hc-sc.gc.ca/pmra/english/pdf/dir/dir9903-e.pdf>). The Formulant Policy is based on the approach followed by the U.S. EPA and represents another step in harmonization of pesticide regulation.

2. Amount, frequency, and time of application of the pesticide chemical

For all countries in which a pesticide chemical is marketed and may result in residues in food exported to North America, the petitioner must submit a description of the use of the pesticide chemical. It is preferable to submit copies of labels translated to English, French, and Spanish. The information must include, but is not limited to, the maximum single application rate, the maximum annual application rate, application timing (as it relates to plant growth stage), re-treatment interval, application tank-mix preparation, volume of spray mix per unit area, application equipment, and the pre-harvest interval (PHI). The application rates should be expressed in units of pounds active ingredient per acre (or kilograms per hectare). If the pesticide chemical is applied directly to livestock, then the use information should include a description of the application method (dip, spray, ear tag, etc.), amount of active ingredient applied per unit body weight, re-treatment intervals, maximum application rate per year, and the pre-slaughter interval.

3. Safety data

Toxicology data required to support an import tolerance are the same as those required to support a domestic tolerance in the United States or Canada; however, registration for domestic use additionally requires acute toxicity studies and studies reflecting the dermal or inhalation routes of exposure. In the case of pesticides having at least one tolerance associated with a U.S. or Canadian registration, this data subset would already exist. Toxicology data requirement guidelines are given in Table 2; Section V.C. of this document provides further information.

4. Results of the test on the amount of residue remaining, including a description of the analytical method used.

Studies conducted under the U.S. OPPTS 860 series (formerly 171-4) are listed in this section (Table 3). These include metabolism studies, analytical methods used, information relating to the storage stability of the parent compound and metabolites of concern on the appropriate commodity, and magnitude of residue studies. Specific requirements are further described below in the section on residue chemistry studies.

5. Practicable methods for removing residue

This section is primarily of concern if the proposed tolerance results in an unacceptable risk, when assuming that residues will be ingested at the proposed tolerance level. The petitioner may conduct studies describing reduction of residues through typical practices, including washing, peeling, cooking, etc.

6. Proposed tolerance for the pesticide chemical, if applicable

The petitioner must propose a tolerance based on the maximum residues found in the magnitude of residue studies. Each NAFTA country may individually choose to adopt the Codex MRL, if one has been established.

7. Reasonable grounds in support of the petition

The petitioner should present a rationale describing how the residue data support the proposed tolerance. A detailed discussion of the information that should be presented may be found in U.S. OPPTS Guideline 860.1560.

C. Toxicology Data Requirements

The NAFTA countries require the submission of complete toxicology studies for import tolerances. This applies even if the studies have previously been submitted to the Joint Meeting on Pesticide Residues (JMPR). The NAFTA countries will each conduct an independent review of the data to the extent necessary to comply with the laws of each individual country. Summaries and/or JMPR reviews are not an acceptable substitute, although they may be submitted as supplemental materials, as may reviews by other countries. However, in the future, harmonization of test guidelines and data evaluations may allow the NAFTA countries to use toxicology data reviews from other countries for hazard identification and risk assessment.

Please note that the United States and Canada are conducting joint pesticide reviews, the results of which apply to both countries. In this instance, an acceptable joint Canadian-U.S. data review would satisfy the data requirements for all three NAFTA countries.

Table 2 lists the toxicology data that are required to support an import tolerance/MRL in each of the NAFTA countries. The petitioner is urged to refer to the U.S. regulations at 40 CFR part 158 for the test substance(s) and conditions under which each study is required. Detailed guidance on the conduct of the individual studies may be found in the guidelines. In addition to the required studies, the NAFTA countries welcome the submission of additional studies to support an import tolerance/MRL if the study or studies have been conducted to satisfy the registration/tolerance-setting requirements of one or more other countries. The NAFTA countries also individually reserve the right to require any study, including special studies, if deemed necessary to assess the human hazard, dietary risk, mode of toxicity, or other aspect of the chemical in question.

D. Residue Chemistry Data Requirements

Table 3 lists the Residue Chemistry studies required to support an import tolerance/MRL in each of the NAFTA countries. The data required to support an import tolerance/MRL are essentially the same as for a tolerance/MRL associated with a U.S. or Canadian registration, but fewer studies may be required under certain conditions. More detailed guidance for each type of study may be obtained from the list of references at the end of this Unit. Following is a description of the differences in data requirements (compared to requirements for a tolerance associated with a domestic use in Canada or the United States) for field trials, processing studies, and livestock studies.

1. Field Trials (Canadian Regulatory Directive 98-02; AMIFAC Residue Chemistry Guidelines Section 9., Crop Field Trials; U.S. OPPTS Guideline No. 860.1500)

Field trials are conducted to determine the maximum residue that may be expected in or on a raw agricultural commodity as a result of the legal use of a pesticide. The trials must reflect label directions that would be expected to result in the maximum residue levels (e.g. the maximum label rates, maximum number of applications, minimum re-treatment interval, and minimum pre-harvest interval).

Tables 4 and 5 can be used to determine the number of field trials that should be conducted to establish an import tolerance in each of the NAFTA countries. The number of field trials recommended was derived from the number required for a tolerance associated with a U.S. registration, *and also takes into consideration the maximum consumption of the commodity as a percentage of the U.S., Canadian, or Mexican diet and the maximum relative amount imported into the U.S., Canada, or Mexico from outside of North America.* Detailed instructions on determining the number and location of field trials and examples are provided in Appendix I of this document. Table 6 provides information on the relative significance of different foods in the U.S. and Canadian diets.

The U.S. and Canada use zone maps to determine where field trials should be conducted for tolerances/MRLs associated with domestic registration. Mexico completed its zone maps in 2001 and is looking to implement their use in 2003. These maps divide North America into regions where growing conditions are similar; thus, field trials conducted within the same zone are considered interchangeable. In the future, if other countries develop zone maps employing similar concepts and regions and cultural practices are demonstrated to be substantially similar to North American regions, then the NAFTA countries may consider direct substitution of North American data with data from corresponding regions within other countries.

In the absence of zone maps for other countries, the NAFTA countries request data on a country-by-country basis. Trials should be conducted in countries in relative proportion to the amount each country exports into North America. Only those countries in which the pesticide is marketed or proposed to be marketed need to be represented. Trials will generally need to be conducted in all countries whose exports comprise at least *5% of the total amount of a specific commodity imported into any of the North American countries where a tolerance is being sought.* The petitioner should seek approval from each of the NAFTA countries if substitution of data from one country to another is desired, and the NAFTA countries will evaluate the adequacy of the residue trial data on a case-by-case basis. All major growing areas within a country should be represented. At least two individually composited samples must be taken from each test plot and analyzed.

Half of the required number of foreign field trials may be substituted with data generated in the United States, Canada, Mexico, or additional countries other than those where the petitioner has existing or proposed uses; but at least three trials must have been performed in the NAFTA countries in which the pesticide is marketed. The petitioner should demonstrate that crop cultural practices, climatological conditions, and use patterns are substantially similar between the

subject regions and regions represented by the North American (or other) data. The burden of proving similarity is on the petitioner.

All major formulation classes should be represented. Petitioners are referred to the section on formulations in the residue chemistry EPA OPPTS Test Guidelines, 860.1500(e)(2)(x). A full set of trials must be conducted for each major class. For later season uses, it will likely be necessary to conduct trials on the different formulations within a class. If a petitioner has a chemical with a 2-day pre-harvest interval (PHI) that is formulated as an emulsifiable concentrate and a wettable powder, a full set of trials would be required for both formulations, unless side-by-side plots at a few sites show comparable residues from such products. In the latter case some reduction in the total number of trials may be warranted. Petitioners are advised to consult the guidelines and each of the three NAFTA countries individually if a reduction in the number of trials is intended.

For crops requiring eight or more trials, the number of trials may be reduced up to 25% if metabolism studies indicate that residues are likely to be below the limit of quantitation. If some trials show quantifiable residues, then the full number of trials must be conducted. The limit of quantitation should be sufficiently low from an analytical chemistry standpoint and for risk assessment purposes. The 25% reduction in the number of field trials may not be applied to representative commodities used to support crop group tolerances. For additional information, the petitioner is advised to consult OPPTS Guideline 860.1500(e)(2)(viii).

Generally, a minimum of three trials are required for any crop; however, a petitioner may conduct fewer than three trials if there is a low dietary intake of commodity and if the amount imported is relatively small. In such cases, a greater number of samples would be required from the test plot. Petitioners should consult U.S. EPA OPPTS Guideline 860.1500 and Canada DACO Guideline 7.4.4 *and* submit to each of the NAFTA countries a protocol for review and comment.

Petitioners interested in establishing import tolerances for a crop group are advised to consult with the NAFTA countries for direction on number and location of trials for representative commodities within the crop group.

2. Processing Studies (U.S. OPPTS Guideline No. 860.1520; Canadian DACO Guideline No. 7.4.5)

Processing studies must be conducted if there is likely to be processing of the commodity once it has been imported into North America or if the processed commodity itself is imported into North America. Table 1 of the U.S. residue chemistry testing guidelines (OPPTS Guideline No. 860.1000) and Table 1 in Appendix A of Section 8 of Canadian residue chemistry guidelines list the processed commodities for which data are required. The petitioner is advised to consult the NAFTA countries in which the import tolerance/MRL is sought if the petitioner believes a processing study is not necessary when it normally would be required. In a processing study, the raw agricultural commodity (RAC) is processed in a manner simulating typical commercial practice. The RAC should have detectable residues so a concentration factor may be calculated. Exaggerated rates and/or reduced pre-harvest intervals may be necessary to ensure the RAC to be processed bears quantifiable residues.

3. Nature of the Residue - Animals (U.S. OPPTS Guideline No. 860.1300; Canadian DACO Guideline No. 6.2)

If the raw agricultural commodity or processed commodity associated with the crop to be treated in the subject petition could be used as an animal feed, oral livestock metabolism and magnitude of residue studies are required. Dermal metabolism studies are required if the pesticide is marketed as a dermal treatment for livestock in countries that export a significant quantity of animal products to North America. The purpose of these studies is to determine the identity of the biotransformation products of the pesticide. Ruminant and poultry studies are normally required. The NAFTA countries will assume that all feed items included in Table 1 of the U.S. residue chemistry testing guidelines (OPPTS Guideline No. 860.1000) and Table 1 in Appendix A of Section 8 of Canadian residue chemistry guidelines are feed items for import tolerance purposes. Any claims that these items are not significant feed items in the country(ies) of concern will be considered only if they are convincingly documented by the petitioner.

Livestock metabolism, magnitude of residue, and/or analytical method studies would not be required under the following conditions: i) if animal metabolism studies indicate that there is no reasonable expectation of finite residues in the animal commodity; ii) if it is unlikely that the imported plant commodity or its processed products would be significant feed items (in North America or the exporting country); or iii) if there are no significant exports of livestock-derived food products or commodities from the countries of interest to the NAFTA countries and the commodity is not a feed item in the NAFTA countries.

E. Good Laboratory Practice Considerations

All submissions for NAFTA pesticide tolerance/MRL petitions should be in accordance with any Good Laboratory Practices (GLP) considerations for each of the NAFTA countries. If the study deviates from GLPs, a statement must be included in the study stating any deviations and the effect on the study. Any deviations should be duly noted in the report.

F. Conclusion

Data requirements for a NAFTA pesticide import tolerance have been outlined in this document. Before conducting any toxicology, product chemistry, or residue chemistry studies, prospective petitioners are strongly urged to consult the appropriate U.S. and Canadian guidelines. The U.S. and Canadian residue chemistry guidelines have been harmonized (Canadian Directive 98-02). Petitioners should submit protocols to the NAFTA countries for review and comment if they have any questions regarding study design and conduct. The NAFTA countries will attempt to harmonize tolerances/MRLs with each other to the maximum extent possible, consistent with the laws of each country and their obligations under the World Trade Organizations's Agreement on the Application of Sanitary and Phytosanitary Measures and NAFTA. Our mutual objective is to work toward greater harmonization in international fora.

VI. REFERENCES

A. United States

PR Notice 86-5, "Standard Format for Data Submitted Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA)," July 29, 1986.¹

PR Notice 96-1, "Tolerance Enforcement Methods - Independent Laboratory Validation by Petitioner," February 7, 1996.²

OPPTS Test Guidelines, Series 830, Product Chemistry (August 1996).³

OPPTS Test Guidelines, Series 860, Residue Chemistry (August 1996).⁴

OPPTS Test Guidelines, Series 870, Health Effects (August 1998).⁵

54 FR 48314; November 22, 1989, List 1 and 2 Inert Ingredients.

65 FR 35069; June 1, 2000, Pesticides; Guidance on Pesticide Import Tolerances and Residue Data for Imported Food.

Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation - Human and Domestic Animals. Series 84, Mutagenicity. Addendum 9. (1991).⁶

B. Canada

References for Developing Chemistry Data

Applicants should ensure that they have the latest editions of the following documents.

Available electronically from http://www.epa.gov/opppmsd1/PR_Notices

Available electronically from
http://www.epa.gov/docs/OPPTS_Harmonized/830_Product_Properties_Test_Guidelines/

Available electronically from
http://www.epa.gov/docs/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/

Available electronically from
http://www.epa.gov/docs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/

Available from the National Technical Information Service under order number PB91-158394INZ. To order, call 1-800-553-6847 or e-mail orders@ntis.fedworld.gov

1. Agriculture Canada, Guidelines for Determining Environmental Chemistry and Fate of Pesticides, Trade Memorandum T-1-255, 1987.
2. American Society for testing and Materials, Annual Book of ASTM Standards; ASTM, Philadelphia, PA, U.S.
3. Association of Official Analytical Chemists, Official Methods of Analysis of AOAC-International; AOAC-International, Arlington, VA, U.S.
4. Collaborative International Pesticide Analytical Council, CIPAC Handbooks, CIPAC, Hatching Green, Harpenden, Hertfordshire, England, 1970-1995.
5. Organisation for Economic Co-operation and Development, Guidelines for Testing of Chemicals, OECD 101-117; OECD, Paris, France, 1981-1995.
6. United States Environmental Protection Agency, Product Properties Test Guidelines (830 Series); U.S. Government Printing Office, Washington, DC, U.S., 1996.
7. United States Environmental Protection Agency, EPA Manual of Chemical Methods for Pesticides and Devices, 2nd edition; AOAC, Arlington, VA, U.S., 1992

VII. TABLES

The data requirements for a MRL to support the import of foods for a pesticide that is not registered for domestic use in Canada are shown in Table 1A.

A. Table 1A. Product Chemistry Data Requirements to Establish Import Tolerances in Canada

Data Code	Requirement Title	Data Required	When Required
0	Index	R	
1	Label	R	
2	Chemistry requirements for the registration of a technical grade of active ingredient (TGAI) or an integrated system product.		
2.1	Applicant's Name and Office Address	R	
2.2	Manufacturer's Name and Office Address and Manufacturing Plant's Name and Address	R	
2.3	Product Trade Name	R	
2.3.1	Other Names	R	
2.4	Common Name	R	
2.5	Chemical Name	R	
2.6	Chemical Abstracts Registry Number	R	
2.7	Structural Formula	R	
2.8	Molecular Formula	R	
2.9	Molecular Weight	R	
2.10	Canadian Patent Status	R	
2.11	Manufacturing Methods for the TGAI		
2.11.1	Manufacturing Summary	R	
2.11.2	Description of Starting Materials	R	
2.11.3	Detailed Production Process Description	R	
2.11.4	Discussion of Formation of Impurities	R	
2.12	Specifications		
2.12.1	Establishing Certified Limits	CR	A justification must be provided if standard limits are not met.
2.12.2	Control Product Specification Form	R	
2.13	Preliminary Analysis		
2.13.1	Methodology/Validation	R	
2.13.2	Confirmation of Identity	R	
2.13.3	Batch Data	R	
2.13.4	Impurities of Toxicological Concern	CR	If applicable
2.14	Chemical and Physical Properties		
2.14.1	Colour	R	
2.14.2	Physical State	R	
2.14.3	Odour	R	

Data Code	Requirement Title	Data Required	When Required
2.14.4	Melting Point / Melting Range	CR	If solid at room temperature.
2.14.5	Boiling Point / Boiling Range	CR	If liquid at room temperature.
2.14.6	Density or Specific Gravity	R	
2.14.7	Water Solubility (mg/L)	R	
2.14.8	Solvent Solubility (mg/L)	R	
2.14.9	Vapour Pressure	R	
2.14.10	Dissociation Constant	R	
2.14.11	Octanol/Water Partition Coefficient	R	
2.14.12	pH	R	
2.14.13	UV/Visible Absorption Spectra	R	
2.14.14	Stability (Sunlight, Temperature, Metals)	R	
2.14.15	Storage Stability Data	R	
2.15	Other Studies/Data/Reports/Foreign Reviews	CR	If available
3	Chemistry Requirements for the Registration of Manufacturing Concentrates and End-Use Products 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	R	
3.1.2	Formulating Plant's Name and Address	R	
3.1.3	Trade Name	R	
3.1.4	Other Names	R	
3.2	Formulation Process		
3.2.1	Description of Starting Materials	R	
3.2.2	Description of the Formulation Process	R	
3.2.3	Discussion of the Formation of Impurities of Toxicological Concern	CR	If applicable.
3.3	Specifications		
3.3.1	Establishing Certified Limits	R	
3.3.2	Additional Product Specific Requirements		
3.3.2.1	Granules and Baits	CR	If applicable.
3.3.2.2	Seed Coatings	CR	If applicable.
3.3.3	Control Product Specification Form	R	
3.4	Product Analysis		
3.4.1	Enforcement Analytical Method	R	
3.4.2	Impurities of Toxicological Concern	CR	If applicable.
3.5	Chemical and Physical Properties		
3.5.1	Colour	R	
3.5.2	Physical State	R	
3.5.3	Odour	R	
3.5.4	Formulation Type	R	
3.5.5	Container Material and Description	R	
3.5.6	Density or Specific Gravity	R	
3.5.7	pH	R	

Data Code	Requirement Title	Data Required	When Required
3.5.8	Oxidizing or Reducing Action (Chemical Incompatibility)	R	
3.5.9	Viscosity	R	
3.5.10	Storage Stability Data	R	
3.5.11	Flammability	R	
3.5.12	Explosibility	R	
3.5.13	Miscibility	R	
3.5.14	Corrosion Characteristics	R	
3.5.15	Dielectric Breakdown Voltage	R	
3.6	Other Studies/Data/Reports/Foreign Reviews	CR	If available
4	Toxicology		
4.1	Summaries - Toxicology Profile	R	Input to assessment of toxicity to wildlife
4.2	Acute Studies - TGAI		
4.2.1	Acute Oral	R	
4.3	Short-Term Studies -TGAI		
4.3.1	Short-Term Oral (90 day) (rodent)	R	Could be a satellite study of 4.4.1
4.3.2	Short-Term Oral (6-12 month) (Non-rodent, e.g. dog)	R	
4.4	Long-Term Studies TGAI		
4.4.1	Chronic (rodent)	R	4.4.1 and 4.4.2 could be combined as 4.4.4
4.4.2	Oncogenicity (rodent species 1)	R	See 4.4.1
4.4.3	Oncogenicity (rodent species 2)	R	
4.4.4	Combined Chronic/Oncogenicity (rodent)	CR	See 4.4.1
4.5	Special Studies TGAI		
4.5.1	Multigeneration-Reproduction (rodent)	R	
4.5.2	Teratogenicity (rodent)	R	
4.5.3	Teratogenicity (non-rodent)	R	
4.5.4	Genotoxicity: Microbial Point Mutation	CR	Required if 4.5.5 is not submitted
4.5.5	Genotoxicity: Mammalian (cell) Point Mutation	CR	Required if 4.5.4 is not submitted
4.5.6	Genotoxicity: <i>In vitro</i> Chromosomal Aberrations	R	
4.5.7	Genotoxicity: <i>In vivo</i> Chromosomal Aberrations	R	
4.5.8	Other Genotoxicity Studies	CR	Depending on results from 4.5.4 to 4.5.7
4.5.9	Metabolism/Toxicokinetics in Mammals (laboratory animal)	R	
4.5.10	Acute Delayed Neurotoxicity	CR	Required if there is neurotoxic potential
4.5.11	Short-Term Neurotoxicity	CR	See 4.5.10
4.8	Other Studies/Data/Reports/Foreign Reviews	CR	If available

Data Code	Requirement Title	Data Required	When Required
6	Metabolism/Toxicokinetics Studies (TGAI or EP)		
6.1	Summaries	R	Input to assessment of toxicity to wildlife
6.2	Livestock	CR	Depends on end use of crop and by-products
6.3	Plants	R	
6.4	Other Studies/Data/Reports/Foreign Reviews	CR	If available
7	Food, Feed and Tobacco Residue Studies EP		
7.1	Summaries	R	Input to assessment of wildlife exposure
7.2	Analytical Methodology (Food Crops & Tobacco)		
7.2.1	Supervised Residue Trial Analytical Methodology	R	
7.2.2	Enforcement Analytical Methodology	R	
7.2.3	Inter-laboratory Analytical Methodology Validation	R	
7.2.4	Multi-residue Analytical Methodology Evaluation	R	
7.2.5	Storage Stability of Working Solutions in Analytical Methodology	R	
7.3	Freezer Storage Stability Tests	R	If stored for more than 30 days and/or volatile or labile study required
7.4	Crop Residue Data		
7.4.1	Supervised Residue Trial Study	R	
7.4.2	Temporal Residue Trial Study	CR	Depends on size of crop
7.4.3	Confined Crop Rotation Trial Study	CR	See 7.4.2
7.4.4	Field Crop Rotation Trial Study	CR	Depends on cropping practice
7.4.5	Processed Food/Feed	CR	If applicable
7.4.6	Residue Data for Crops used as Livestock Feed	CR	If applicable
7.5	Livestock, Poultry, Egg and Milk Residue Data (from feeding of treated crops)	CR	Depends on end use of crop and by-products
7.7	Tobacco Residue Data	CR	
7.8	Other Studies/Data/Reports/Foreign Reviews	CR	If available

¹R = Required; CR = Conditionally required

B. Table 1B. Product Chemistry Data Requirements to Establish Import Tolerances in the U.S.

U.S. OPPTS Guideline No.	Study Title	Test Substance ¹
830.1600 830.1620 830.1650	Description of Manufacturing Process	TGAI
830.167	Discussion on Formation of Impurities ²	TGAI
830.17	Preliminary Analysis	TGAI
830.6302	Color	TGAI
830.6303	Physical State	TGAI
830.6304	Odor	TGAI
830.72	Melting Point	TGAI
830.722	Boiling Point	TGAI
830.73	Density	TGAI
830.7840 830.7860	Solubility	TGAI or PAI
830.795	Vapor Pressure	TGAI or PAI
830.737	Dissociation Constant	TGAI or PAI
830.7550 830.7560 830.7570	Octanol/Water Partition Coefficient	PAI
830.7	pH	TGAI
830.6313	Stability	TGAI

¹ TGAI = technical grade active ingredient; PAI = pure active ingredient

² U.S. EPA is especially concerned with impurities of toxicological concern (e.g., dioxins, HCB, nitrosamines)

C. Table 2. Toxicology Data Requirements to Establish Import Tolerances in Each of the NAFTA Countries

U.S. OPPTS Guideline No.	Study Title
870.11	Acute oral toxicity - rat
870.31	90-Day Oral Toxicity - rodent
870.315	90-Day Oral Toxicity - non-rodent
870.37	Developmental toxicity study
870.38	Multi-Generation Reproduction
870.41	Chronic Toxicity
870.42	Carcinogenicity study
870.43	Combined chronic toxicity/ carcinogenicity
870.5100 – 870.5915	Mutagenicity ¹
870.62	Neurotoxicity screening battery
870.7485	Metabolism and pharmacokinetics

¹An initial battery of the following three tests must be conducted: 1) Ames assay (*S. typhimurium*), 2) Mammalian cells in culture forward gene mutation assay, and 3) *in vivo* cytogenetics assay. Details of the screening protocol may be found in Addendum 4 to the U.S. OPPTS Guideline Series 870.

²418 Delayed neurotoxicity of organophosphorous substances following acute exposure.

419 Delayed neurotoxicity of organophosphorous substances 28 day repeated dose study.

424 Neurotoxicity study in rodents.

D. Table 3. Residue Chemistry Data Requirements to Establish Import Tolerances in Each of the NAFTA Countries

U.S. OPPTS Guideline No.	Canadian DACO Guideline No.	Study Title	Required for Import Tolerance? ¹
860.13	6.3	Nature of the Residue - Plants	R
860.13	6.2	Nature of the Residue - Animals	CR ²
860.134	7.2.1	Residue Analytical Methods - Plants and Animals	R
860.136	None	Multiresidue Methods	R
860.138	7.3	Storage Stability	R
860.148	7.5	Magnitude of Residue - Meat, Milk, Poultry, and Eggs	CR ³
860.15	7.4.4	Crop Field Trials	R
860.152	7.4.5	Processing Studies	CR ⁴

¹R = Required; CR = Conditionally Required

²Required if subject crop is an animal feed item, or if the pesticide will be applied directly to livestock exported to the U.S.

³May not be required if crop is not an animal feed item, or if livestock metabolism studies indicate no potential for finite residues in edible commodities. Refer to text of this document for additional information.

⁴May not be required if crop is not likely to be processed after export to the U.S., or if processed commodity is not shipped to the U.S. Refer to text of this document for additional information.

⁵One or more of DACO Guidelines 7.4.2-7.4.4 may be applicable under some circumstances.

E. Table 4. Number of Field Trials Required to Establish Import Tolerances in Each of the NAFTA Countries

(Use this table if less than 75% of the crop available for consumption is imported)¹

Maximum Required No. of Field Trials for a U.S. Registration	Maximum Percentage of Commodity Available for Consumption (in Canada, Mexico, or the United States) That is Imported (Weight Basis)		
	0 – 10%	10 – 35%	35 – 75%
20	5	16	20
16 (15) ²	5	12	16
12	3	8	12
8 (9) ²	3	5	8
5 (6) ²	3 ³	3	5
3	2 ³	3 ³	3

¹ The number of trials determined using this table may be reduced by 25% for crops needing 8 or more trials if metabolism studies and all the trials show residues less than the limit of quantitation of the analytical method. Crops being used as representative commodities to obtain crop group tolerances may not be reduced by an additional 25% even if metabolism studies and all the trials show residues of less than the limit of quantitation.

² The numbers in parentheses refer to the number of trials required for representative crops being used toward a crop group tolerance. As described in 860.1500, the number of field trials required for representative commodities that are being used to support a crop group tolerance is 25% less than the number required to support a tolerance of a single commodity, provided that greater than eight trials are required for the tolerance.

³ Fewer than three trials may be conducted if the dietary consumption is very low and a relatively small amount of the commodity is imported into North America. Four independent samples must be collected from each test plot if fewer than three trials are conducted. Petitioners should either consult the guidelines or contact each of the NAFTA countries before proceeding if they believe that fewer trials are warranted.

F. Table 5. Number of Field Trials Required to Establish Import Tolerances in Each of the NAFTA Countries

(Use this table if greater than 75% of the crop available for consumption is imported) ¹

Maximum Percent of Diet ²	No. of Trials Required
0 – 0.05	3
0.05 – 0.2	8
0.2 – 1.0	12
>1.0	16

¹The number of trials determined using this table may be reduced by 25% for crops needing eight or more trials if metabolism studies and all the trials show residues less than the limit of quantitation of the analytical method and the crops are not being used as representative commodities to obtain crop group tolerances.

²Highest percentage in the North American diet for *any of the following subgroups*: U.S. general population, U.S. children ages 1 to 6, U.S. infants; Canadian general population, Canadian children ages 1 to 6, Canadian infants. Information on percentages in the diet may be found in Table 6.

³Fewer than three trials may be conducted if the dietary consumption is very low and a relatively small amount of the commodity is imported into the North America. Four independent samples must be collected from each test plot if less than three trials are conducted. Petitioners should either consult the residue chemistry guidelines or contact the NAFTA countries before proceeding if they believe that fewer trials are warranted.

G. Table 6. Percent in Diet Values and Number of Field Trials Required for a Tolerance Associated with a Canadian or U.S. Domestic Registration for Most Commodities

Crop	Percent Contribution from Crop Total Exposure (1994 - 1998) ¹			No. of Field Trials for a Canadian Registration	No. of Field Trials for a U.S. Registration
	All Population	Infants	1 to 6		
Acerola	0	0	0		12
Alfalfa sprouts	0.0018	0	0		NA ³
Almonds	0.00902	0	0.00513		5
Apples	2.45117	4.09358	6.36119	12	16
Apricot	0.04148	0.14791	0.06418	3	5
Artichokes – globe	0.00361	0	0.0009	3	3
Artichokes – jerusalem	0	0	0	3	3
Asparagus	0.01984	0.00338	0.00856	5	8
Avacados	0.01804	0.00135	0.00685		5
Banana	0.64751	0.9719	1.008		5

Crop	Percent Contribution from Crop Total Exposure (1994 - 1998) ¹			No. of Field Trials for a Canadian Registration	No. of Field Trials for a U.S. Registration
	All Population	Infants	1 to 6		
Barley	0.22185	0.02229	0.01968	16	12
Beans – dry ⁴	0.19479	0.01824	0.17285	5	125
Beans – lima	0.03066	0.0027	0.02567	8	85
Beans – succulent ⁴	0.26333	0.2965	0.31061	5	85
Beets – garden	0.01443	0.00473	0.00513	5	5
Beets – sugar	0.52667	0.45387	0.54678	5	12
Blackberries	0.00721	0.00338	0.0077	3	36
Blueberries	0.02705	0.02094	0.03423	8	8
Boysenberries	0.0018	0	0.00428	2	2
Broccoli	0.1984	0.05268	0.16943	5	8
Broccoli – chinese (Gai Lon)	0	0	0	2	2
Brussels sprouts	0.00541	0.00203	0.00257	2	3
Buckwheat	0.0018	0	0	5	5
Cabbage – green and red	0.12445	0.00405	0.04706	5	8
Cabbage, Chinese/celery/bok choy	0.01263	0	0.00513	2	3
Canola oil (rape seed oil)	0.01263	0.0007	0.01027	16	8
Carambola (starfruit)	0	0	0		2
Carrots	0.33368	0.76928	0.34313	5	8
Casabas	0.0018	0	0		3
Cashews	0.00361	0	0.0017		NA ³
Cassava (yuca blanca)	0.00361	0.02837	0.00428		22
Cauliflower	0.03427	0.00338	0.02139	5	8
Celery	0.10822	0.01418	0.0676	5	8
Cherries (sweet and sour)	0.0469	0.02026	0.06247	5	87
Chestnuts	0	0	0		3
Chicory	0.00361	0	0.00171	2	22
Chocolate (cocoa bean)	0.06854	0.0027	0.08043		3
Coconut	0.05591	1.03268	0.02396		5
Coffee	0.04509	0	0.0009		5
Collards	0.01984	0.00203	0.02054		5
Corn – field	2.88224	2.09778	3.26274	5	20
Corn/pop	0.0487	0.00135	0.04706	12	3
Corn/sweet	0.33187	0.05808	0.42014	8	12
Cottonseed	0.05591	0.01216	0.0676		12
Crabapples	0	0	0	3	3
Cranberries	0.06493	0.02904	0.0676	3	5
Crenshaws	0	0	0	3	3
Cucumbers	0.17135	0.00338	0.11637	5	8
Currants	0	0	0	2	22
Dandelion-greens	0	0	0	1	12

Crop	Percent Contribution from Crop Total Exposure (1994 - 1998) ¹			No. of Field Trials for a Canadian Registration	No. of Field Trials for a U.S. Registration
	All Population	Infants	1 to 6		
Dates	0.00361	0.00135	0.00513		3
Dill	0	0	0	2	22
Eggplant	0.01263	0	0.00257	3	3
Elderberries	0	0	0	3	3
Endive – curley and escarole	0.00541	0	0.00171	3	3
Figs	0.00541	0.0007	0.00513		3
Filberts (hazelnuts)	0	0	0	2	3
Flax seed	0	0	0	8	5
Garlic	0.01082	0.00135	0.00856	3	3
Ginger	0	0	0		22
Ginseng	0	0	0	2	3
Gooseberries	0	0	0	3	3
Grapefruit	0.25792	0.11549	0.10268		8
Grapes	1.13269	0.76185	2.10157	5	12
Guava	0.00361	0.0007	0.00513		22
Hops	0.00361	0	0	3	3
Horseradish	0.0018	0	0	3	3
Huckleberries	0	0	0	3	3
Kale	0.00721	0	0.00513	3	3
Kiwi fruit	0.01263	0.00135	0.01369		3
Kohlrabi	0	0	0	3	3
Kumquats	0	0	0	1	12
Leeks	0	0	0	2	3
Lemons	0.4437	0.00946	0.41672		5
Lentils	0.00721	0.0027	0.00428	5	3
Lettuce (head and leaf)	0.43107	0.00135	0.1583	5	88
Limes	0.02345	0.00338	0.02481		3
Loganberries	0	0	0	1	12
Longan fruit	0	0	0	1	12
Lychees	0	0	0	1	12
Macadamia nuts (bush nuts)	0	0	0		3
Maney (mammee apple)	0	0	0		22
Mangoes	0.02525	0.02296	0.03252		3
Melon (inc.cantaloupe and honeydew)	0.17676	0.01824	0.18055	3	5 and 8 ⁹
Millet	0	0	0	5	5
Mint	0	0	0	5	510
Mung beans (sprouts)	0.02525	0.00203	0.01284	8	8
Mushrooms	0.05411	0.00338	0.02909	3	3
Mustard greens	0.00541	0	0.00257	5	511

Crop	Percent Contribution from Crop Total Exposure (1994 - 1998) ¹			No. of Field Trials for a Canadian Registration	No. of Field Trials for a U.S. Registration
	All Population	Infants	1 to 6		
Nectarines	0.03427	0.00743	0.02995	3	8
Oats	0.19479	0.32487	0.36966	16	16
Okra	0.01263	0.0027	0.00685		5
Olives	0.03788	0.0027	0.02653		3
Onions, dry bulb	0.40041	0.13846	0.28067	5	8
Onions – green	0.02705	0.0007	0.01027	2	3
Oranges	4.25121	0.68215	5.83665		16
Palm	0.01082	0.01216	0.01198		NA ³
Papaya	0.00721	0	0.00685		3
Parsley	0.00721	0.00135	0.0077	3	3
Parsnips	0	0	0	3	3
Passion fruit	0.00902	0.0007	0.01797		22
Peaches	0.20381	0.51533	0.29436	5	12
Peanuts	0.22185	0.01486	0.3842	12	12
Pears	0.17676	0.7301	0.29008	5	8
Peas (garden) ⁴	0.17135	0.26678	0.18996	8	85
Peas – succulent/blackeye/ cowpea ⁴	0.01263	0.00135	0.00685	8	55
Pecans	0.00721	0	0.00513		5
Pepper/black	0.0018	0.0007	0.0009		3
Peppers – non-bell	0.09199	0.0027	0.03252	5	3
Peppers – sweet (garden)	0.02705	0.0027	0.00856	5	8
Persimmons	0.00361	0	0.00171		3
Pimientos	0.00361	0	0.00257	2	22
Pineapples	0.28858	0.41199	0.53994		8
Pinenuts	0	0	0		NA ³
Pistachio nuts	0.0018	0	0.00257		3
Plantains	0.02705	0.0027	0.01626		3
Plums	0.07756	0.27826	0.05134	5	8
Pomegranates	0.0018	0	0.00513		3
Potatoes/white	1.67379	0.59773	1.6241	16	16
Pumpkin	0.01443	0.00203	0.00685	5	5
Quinces	0	0	0		3
Radishes – Japanese (daiken)	0	0	0.0009	2	22
Radishes	0.00541	0	0.00171	3	5
Raspberries	0.00721	0.01621	0.00856	5	3
Rhubarb	0.0018	0	0	3	22
Rice	0.4942	0.51803	0.4595		16
Rice – wild	0.0018	0	0.0009		5
Rutabagas	0.0018	0	0	5	3
Rye	0.01082	0	0.00342	8	5

Crop	Percent Contribution from Crop Total Exposure (1994 - 1998) ¹			No. of Field Trials for a Canadian Registration	No. of Field Trials for a U.S. Registration
	All Population	Infants	1 to 6		
Safflower	0	0.0081	0.0009	3	5
Salsify (oyster plant)	0	0	0		3
Sesame seeds	0.0018	0	0	3	3
Shallots	0	0	0	2	12
Snowpeas	0.01263	0	0.00513	3	3
Sorghum (including milo)	0	0	0		12
Soybean	0.80263	1.64797	0.74359	12	20
Spinach	0.06313	0.06484	0.04022	3	8
Squash – summer	0.06674	0.0385	0.03936	5	5
Squash – winter	0.02525	0.22221	0.01198	5	5
Strawberry	0.12084	0.01959	0.15574	5	8
Sugar Apples (sweetsop)	0	0	0		22
Sugar – cane	0.61324	0.52141	0.64711		8
Sunflower	0.00902	0	0.00428	5	8
Sweet potatoes (incl. yams)	0.06132	0.29988	0.04278		8
Swiss chard	0.0018	0	0	3	3
Tangelos	0	0	0		3
Tangerines	0.01623	0.00608	0.02567		5
Taro-root	0.0018	0.00675	0		22
Tea	0.01082	0	0.00342		NA ³
Tomatoes	3.83637	0.64095	3.7676	12	16
Turnips	0.01443	0.00135	0.01027	5	5
Walnuts	0.00721	0.0007	0.00685	3	3
Water chestnuts	0.00721	0	0.00171		NA³
Watercress	0.0018	0	0	2	22
Watermelon	0.25612	0.03107	0.30377		8
Wheat	2.94897	0.47548	3.2713	20	20
Yambean tuber (jicama)	0	0	0.0009		NA³
Yautia (tannier)	0	0	0		22

¹If one or two field trials are required, then four samples must be collected from each test plot.

²The percent in diet figures for peas, beans, and dry beans include different varieties that may require separate field trials. Petitioners are advised to consult 860.1500 for additional information on numbers of field trials for individual varieties.

³These bean/pea commodities include more than one type of bean/pea. The specific commodities included in each of these groups are shown below. The specific representative commodity for which field trials should be run in each case are those representative commodities provided in crop subgroup in 40 CFR 180.41. Bean, edible podded: include those commodities listed in subgroup 6-A as *Phaseolus* spp., *Vigna* spp., jackbeans, soybeans, (immature seed), and sword bean. Pea, edible podded: include those

commodities listed in subgroup 6-A as *Pisum* spp. an pigeon pea. Bean, succulent shelled: include those commodities listed in subgroup 6-B as *Phaseolus* spp., *Vigna* spp., and broad bean. Pea, succulent shelled: include those commodities listed in subgroup 6-B as *Pisum* spp. and pigeon pea. Bean, dried shelled (except soybean): include those commodities listed in subgroup 6-C as *Lupinus* spp., *Phaseolus* spp., *Vigna* spp., guar and lablab beans. Pea, dried shelled: include those commodities listed in subgroup 6-C as *Pisum* spp., lentil, and pigeon pea. A minimum of three trials in required for field pea forage and hay with Austrian winter pea the preferred cultivar. Field pea seeds will be considered dried shelled peas and require a minimum of five trials. The number of trials required for dried shelled pea is based on combined acreage and consumption of dried garden pea (*Pisum* spp.) and lentil.

⁴ A minimum of five trials (and ten samples) is required on any one blackberry or any one raspberry if a tolerance is sought on “caneberries.” A minimum of three trials (and six samples) is required if a tolerance is sought only on blackberries or only on raspberries.

⁵ Eight trials each for sweet and sour cherries are required.

⁶ Eight trials each for head and leaf lettuce are required.

⁷ Five trials are required for honeydew melons and eight trials are required for cantaloupe. A tolerance for muskmelons may be contained using residue data for cantaloupes.

⁸ A tolerance for mint may be obtained using residue data for spearmint and/or peppermint. If a tolerance is sought for either spearmint or peppermint separately, five trials are still required.

⁹ A minimum of eight trials (and 16 samples) are required on mustard greens if a tolerance is sought on the crop subgroup leafy Brassica greens.

H. Table 7. Canadian Regulatory Directive - Dir98-02 Section 9 - Crop Field Trials 9-7

Determination of Number of Field Trials for a Canadian Registration

Step 1

Assign a base number of field trials to each crop as follows:

1995		
Hectares	Acres	Base Number of Field Trials
> 4,046,860	> 10,000,000	16
> 404,690 ≤ 4,046,860	> 1,000,000 ≤ 10,000,000	12
> 121,410 ≤ 404,690	> 300,000 ≤ 1,000,000	8
> 12,140 ≤ 121,410	> 30,000 ≤ 300,000	5
> 810 ≤ 12,140	> 2,000 ≤ 30,000	3
> 81 ≤ 810	> 200 ≤ 2,000	2
> 81	≤ 200	1

Step 2

Increase the base number one level, i.e., 8 to 12 or 12 to 16, etc., if the area exceeds 121,410 hectares (3,000 acres) and the dietary share is 0.40% or more.

(wheat, oats, potatoes)

Step 3

Decrease the base number one level if the area exceeds 121,410 hectares (300,000 acres) and the dietary share is less than 0.10%.

(tame hay, flaxseed, dry field peas, lentil, mustard seed, corn for silage, canary seed)

Step 4

Increase the base number one level if the area is 121,410 hectares (300,000 acres) or less and the dietary share is 0.02% or more.

(All fruits and vegetables are affected except cranberries, saskatoon berries, green onions and shallots, Brussels sprouts, radishes, Chinese cabbage and other ethnic leafy vegetables, leeks, hazelnuts and filberts)

Step 5

A minimum of 16 field trials is required if the area is more than 121,410 hectares (300,000 acres) and the dietary share is more than 1.00%.

(wheat, oats*, potatoes)

*Oats was found to exceed the 1.00% diet criterion when using the infant diet, but not when using the diet of the general population. See *Estimation of Dietary Share*.

Step 6

A minimum of twelve field trials is required if the area is 121,410 hectares (300,000 acres) or less and the dietary share is more than 1.00%.

(apples, tomatoes)

After note

The U.S. methodology includes a step where the base number is reduced by one level if 90% of the crop is grown in one region. This step was omitted from the Canadian Guideline because only one crop, soybeans, would be affected.

VIII. APPENDICES

Appendix I: Instructions for Determining Number and Location of Field Trials

Following is a step-by-step guide to calculating the minimum number of field trials that must be conducted using Tables 4, 5, and 6.

Determine the minimum number of field trials required to obtain an import tolerance for each NAFTA country individually, based on the percent crop imported value in each country and the percent of crop available for consumption that is imported in each country, as described below. If a tolerance associated with a pesticide registration already exists in one or two NAFTA countries, only calculate the potential number of field trials for the remaining NAFTA country(ies). Of the three (or fewer) potential numbers of field trials determined using this appendix, along with Tables 4, 5, and 6, the greatest number is the number of field trials required to obtain a NAFTA tolerance.

- (1) Average the amount of the crop imported for the last five years (on a weight basis) from the foreign countries in which the pesticide is marketed. Averaging over a five year period allows for seasonal variability. Information on U.S. agricultural imports may be obtained from the U.S. Dept. of Agriculture, the U.S. Dept. of Commerce, and various private sources. Information on Canadian agricultural imports may be obtained from Industry Canada, Statistics Canada, Agri-Food Canada and various private sources in Canada. All forms of the commodity that are imported (in significant amounts) must be taken into consideration including (but not limited to) juice, juice concentrate, wine, and fresh produce. The source of the import information should be reported.
- (2) Using the three values determined in step (1), calculate the percent of the crop imported into the each of the NAFTA countries relative to the total amount available for consumption. If less than 75% of the commodity available for consumption is imported, proceed to step (3). If greater than 75% of the commodity available for consumption is imported, proceed to step (4).
- (3) Refer to Tables 4 and 6. Determine the number of field trials required for a U.S. registration for the commodity of interest from Table 6. Using this number and the percent of the crop available for consumption that is imported, determine the minimum number of field trials required for an import tolerance in each NAFTA country for which a tolerance is being requested using Table 4. Go to Step (5).
- (4) Refer to Tables 5 and 6 to determine the number of field trials required to obtain an import tolerance for a commodity for which imports are greater than 75% of the total commodity available for consumption. The maximum percentage in the diet for any commodity and any population subgroup may be found in Table 6. Determine the minimum number of

field trials in each NAFTA country for which a tolerance is being requested from Table 5 using the percentage in diet value. Go to Step (5).

- (5) Determine the countries in which the field trials should be conducted. All countries (in which the pesticide is marketed or intended to be marketed) must be represented if the amount that they export to North America represents 5% or more of imports of the subject crop into any of the three NAFTA countries in which a tolerance is being sought. A greater number of total trials and trials per country than that determined in steps 3 and 4 may be required to ensure that all relevant countries and the major growing regions within the individual countries are represented.

Note 1: The number determined in steps 3 and 4 is only the minimum number of field trials required. Additional trials may be required to ensure all major formulation classes are represented.

Note 2: If the subject pesticide is not marketed or intended to be marketed in one of the top two or three countries that export the subject crop to North America, then the total percent imported should not include the countries in which the pesticide is not marketed or intended to be marketed.

- (B)-1 The XYZ Pesticide company intends to register a new insecticide for oranges in most countries, but is not pursuing a U.S. use.

1) Approximately 21% of all oranges available in the U.S. (as juice or fresh fruit) over the last five years were imported. Referring to Table 4, sixteen field trials are required for a U.S registration. Using Table 4, oranges fall in the range of 10-35% imported; therefore a minimum of twelve trials (24 samples) must be conducted.

2) The countries which import fresh fruit and juice are listed in Table 8, along with the amount imported. Considering only the countries in which the pesticide is marketed and represent greater than 5% of the U.S. imports, nine trials should be done in Brazil, and three should be done in Mexico.

Table 8. Countries That Export Oranges and Amounts Exported

Trading Country	Orange Juice, (Thousand liters)	Weight Orange Juice (Thousand lb)	Weight Fresh Market Oranges (Thousand lb)	Total Weight Imported (Thousand lb)	Percent Imported Total
Brazil	1,042,756	2,294,063	--	2,294,065	80.73
Mexico	140,403	308,887	29,938	338,825	11.92
Belize	29,784	65,525	--	65,525	2.31
Costa Rica	12,891	28,360	--	28,360	1.00
Honduras	12,440	27,368	--	27,368	0.96
Other (<1% from each country)	9,769	21,492	7,050	28,542	1.00
Spain	--	7	26,332	26,339	0.93
Morocco	--	0	12,841	12,841	0.45
Australia	--	0	9,691	9,691	0.34
Dominican Republic	--	0	6,873	6,873	0.24
Israel	--	0	3,312	3,312	0.12
Total	1,248,043	2,745,702	96,037	2,841,741	100.00

Appendix II:
**Examples of application of the NAFTA Guidance Document for
Tolerances/Maximum Residue Limits in/on Imported Commodities**

NOTE : NUMERICAL VALUES FOR PRODUCTION, CONSUMPTION, AND RELATIVE AMOUNT IMPORTED ARE ESTIMATES FOR CANADA AND MEXICO; THESE ARE NOT KNOWN VALUES AND WILL NEED TO BE CHANGED WHEN DATA ARE RECEIVED FROM MEXICO AND CANADA. ESTIMATES ARE USED FOR ILLUSTRATIVE PURPOSES ONLY AND SHOULD NOT BE USED IN OFFICIAL PUBLICATIONS.

Example 1A. Oranges

Pesticide XYZ will be registered as an insecticide in Brazil only to control a pest unique to that country. Canada, Mexico, and the US all receive imports of orange products from Brazil.

Step 1. Determine minimum number of trials for each country.

Canada

Two assumptions will be made in this example in the absence of Canadian specific data: 1) most of the orange products consumed in the Canada are imported, and 2) Canadian consumption of orange products is similar to the US.

Greater than 75% of the orange products available for consumption in Canada are imported, so Table 5 would be used to determine the minimum number of field trials required for an import tolerance. The population subgroup with the greatest consumption of orange products is children, ages 1-6, with an average of 1.65% in the diet. Therefore 16 field trials would be required for an orange import tolerance in Canada.

Mexico

Assume in this example that most of the orange products consumed in Mexico are grown in Mexico and that most of the imports are from Brazil. Approximately 5% of the orange products available for consumption in Mexico are imported, and virtually all of the imports are from Brazil. Table 4 would be used to determine the minimum number of field trials. Sixteen field trials are required in the US for oranges; assuming 5% imported, then the 0-10% column would be used. Five field trials would be required for an orange import tolerance in Mexico.

United States

Approximately 17% of all oranges available in the U.S. (as juice or fresh fruit) over the last five years were imported from Brazil. Referring to Table 6, 16 field trials are required for a U.S registration. Using Table 4, oranges fall in the range of 10-35% imported; therefore a minimum of twelve trials must be conducted.

The maximum number of field trials of any of the three countries is 16, so the import tolerance petitioner would conduct 16 trials to support the tolerance/MRL.

Step 2. Determine the Locations of the Crop Field Trials

Since the pesticide will be marketed only in Brazil, all of the field trials should be conducted in Brazil in locations representing the major growing areas. Field trials would need to be conducted at the maximum application rate and minimum pre-harvest interval (PHI).

Under limited circumstances, up to a 25% reduction in the number of field trials is acceptable. If the total number of field trials is 8 or greater, the petitioner may reduce the number of field trials if the residues in each duplicate sample are non-detectable.

Example 1B.

The XYZ Pesticide company intends to register a new insecticide for oranges in most countries, but is not pursuing a U.S. use.

- 1) Approximately 21% of all oranges available in the U.S. (as juice or fresh fruit) over the last five years were imported. Referring to Table 6, sixteen field trials are required for a U.S registration. Using Table 4, oranges fall in the range of 10-35% imported; therefore a minimum of twelve trials (24 samples) must be conducted.
- 2) The countries which import fresh fruit and juice are listed in Table 8 along with the amount imported. Considering only the countries in which the pesticide is marketed and represents greater than 5% of the U.S. imports, nine trials should be done in Brazil and three should be done in Mexico.

Example 2. Bananas

Step 1. Determine minimum number of trials for each country

Markis Corporation is planning to market a nematicide for use on bananas in all countries except the US.

Canada and United States

Greater than 75% of the bananas available for consumption in Canada and the US are imported, so Table 5 would be used to determine the minimum number of field trials need for an import tolerance. Assuming consumption of bananas in the US and Canada is similar, the population subgroup with the greatest consumption of bananas is 1.008% for infants. Therefore twelve field trials would be required for a banana import tolerance in Canada and the US.

Mexico

Mexico normally requires two field trials for a domestic registration of bananas.

The total number of field trials required would be twelve.

Step 2. Determine the Locations of the Crop Field Trials

For the purposes of this example, assume that US and Canada get bananas from the same countries in the same relative amounts. Many bananas enter Canada via the U.S. as a transit route.

Table 9 shows countries that export bananas to the U.S. The relative number of field trials in each trading country should be proportional to the relative amount imported. Accordingly, the trials should be conducted in the following countries:

Country	Number of Trials
Columbia	2 trials
Costa Rica	3 trials
Ecuador	3 trials
Honduras	2 trials
Mexico	2 trials

Although the US would normally recommend that a trial to be conducted in Guatemala as well, the NAFTA TWG on pesticides would recommend substituting a second trial in Mexico to fulfill the Mexican Government's requirements. Climatic differences between the two countries would not be so great as to result in vastly different pesticide residues.

Table 9. Bananas Imported to the United States (1991-1995 average)

Trading Country	Import Quantity (thousand lbs)	IMPORT QUANTITY (%)
Ecuador	2,076,329	25.55
Costa Rica	1,994,840	24.55
Columbia	1,312,890	16.16
Honduras	1,032,646	12.71
Guatemala	866,371	10.66
Mexico	559,385	6.88
Panama	191,409	2.36
Venezuela	11,416	0.14
Other Countries	81,366	1.00
Total	8,126,652	100.01

Appendix III: Definitions of terminology

Note: Italicized text found in a definition indicates that the term is also defined in this appendix.

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

Diastereomer: *stereoisomers* not related as mirror images.

Enantiomer: one of a pair of molecular species that are non-superimposable mirror images of each other.

End-use product: a product containing *active ingredient(s)*, and usually *formulant(s)*, that is labeled with instructions for direct pest control use or application.

Formulant: any substance or group of substances other than an *active ingredient* that is intentionally added to a pest control product to improve its physical characteristics, e.g., sprayability, solubility, spreadability, and stability.

Formulation: the process of mixing, blending, or diluting one or more *active ingredients* with one or more *formulants*, typically without an intended chemical reaction, to obtain a distinct *manufacturing-use product* or an *end-use product*.

Formulation type: the physical form of the pest control product. These are listed in the Registration Handbook.

Guarantee: the typical or *nominal concentration* of an ingredient that is expected to be present in a representative sample of a pest control product at the time of its production.

Impurity: any substance in a control product other than an *active ingredient* or a *formulant*, e.g., contaminants, residual starting materials, reaction products, degradation products or products added for purposes of extraction or purification.

Integrated system product: may be used in manufacture of an *end-use product* or may itself be an *end-use product*; formed in a manufacturing process in which the ISP:

- (a) contains an *active ingredient* that is not isolated due to physical limitations or uncertainty as to the specific active component(s); or

-
- (b) is purposely left as a mixture of components due to manufacturing or integrity considerations.

Manufacturing concentrate: a product containing a registered *technical grade of active ingredient(s)* and *formulant(s)* intended for further reformulating and/or repackaging into *end-use products*.

Manufacturing-use product: products for manufacturing use only which include *technical grade of active ingredients* and *manufacturing concentrates*. They may also include *integrated system products* when they are used for reformulating or repackaging.

Nominal concentration: the typical amount, or *guarantee*, of an ingredient that is expected to be present in a representative sample of a pest control product at the time of its production.

Starting material: any substance, including reactants, solvents and catalysts, used to manufacture or purify a pest control product.

Stereoisomers: *isomers* having identical atomic connectivities and differing only by the spatial arrangements of their atoms or groups. Subclasses are *enantiomers* and *diastereomers*.

Technical active ingredient: see *technical grade of active ingredient*.

Technical grade of active ingredient: contains the *active ingredient* and normally contains *impurities* that are by-products of the manufacturing process.

Acronym List

CAS	Chemical Abstracts Service
CIPAC	Collaborative International Pesticides Analytical Council
CPSF	Control Product Specification Form
CR	Conditionally Required
CV	Coefficient of Variation
DACO	Data Code
EAM	Enforcement Analytical Method
EPA	Environmental Protection Agency (United States)
EP	End-Use Product
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act (EPA)
ID	Identify
ISP	Integrated System Product
IUPAC	International Union of Pure and Applied Chemistry
LOD	Limit of Detection
LOQ	Limit of Quantitation
MA	Manufacturing Concentrate
MP	Manufacturing-Use Product
MSDS	Material Safety Data Sheet
OECD	Organisation for Economic Co-operation and Development
PCPA	Pest Control Product Act
PMRA	Pest Management Regulatory Agency
QC	Quality Control
R	Required
TGAI	Technical Grade of Active Ingredient
USC	Use-Site Category