NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada

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US Environmental Protection Agency
Office of Pesticide Programs
(OPP)

Health Canada
Pest Management Regulatory Agency
(PMRA)

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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 and the United States. This document has been developed consistently with the goals of NAFTA. A common NAFTA approach to import tolerances/MRLs will promote trade between North America and the rest of the world. This guidance began as a project of the three NAFTA countries; however, due to new regulations and resulting resource constraints in Mexico, it is at this time only a bilateral effort by the US and Canada.

Under the existing regulations of the importing countries, import tolerance/MRL petitioners must submit separate import tolerance/MRL petitions to Canada and the U.S. and must adhere to any specific petition requirements (i.e., formatting, etc.) for either country. However, the common set of data requirements cited herein typically will result in a reduced data set and in a more efficient and cost effective process for petitioners to obtain import tolerances/MRLs for Canada and the U.S.

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

This document presents the guidelines for obtaining import tolerances/MRLs as they exist today. As the NAFTA Technical Working Group (TWG) continues to work toward further harmonizing data requirements across NAFTA countries, there will be future opportunity to refine the guidance provided in this document. The information in this document will therefore be updated in the future, as needed, and through whichever means is most appropriate to meet the specific need (e.g., the list of required data will be updated through the websites listed in Section VII.A., Data Requirements to Establish Import Tolerances/MRLs in each of the NAFTA Countries).

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

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 Fedral de Sanidad Vegetal (Federal Plant Health Law), and la Ley General del Equilibrio Ecológico y Protección al Ambiente (Ecological Equilibrium and Environmental Protection Law).

The Regulation in Matter of Registration, Import and Export Authorizations and Export Certificates for Pesticides, Nutrients for Plants and Toxic or Dangerous Substances and Materials is a new regulation in Mexico that has been in force since March 29, 2005. This Regulation specifies that the Federal Commission for the Protection Against Health Risks (known as COFEPRIS) registers pesticides and establishes Maximum Residue Limits (MRLs) for food by assessing and reviewing pesticide registration applications and data. The Regulation also indicates that until further guidelines are established in a Mexican Official Standard (as called for under Article 12), Mexico may accept tolerances established by the U.S. Environmental Protection Agency , Codex Alimentarius, or in their absence, those established by the European Union or one of its member countries, as long as such country is the largest importer of the agriculture product.

COFEPRIS is currently focused on implementing this new domestic regulation. As such, Mexico is not in a position to adopt this NAFTA import tolerance guidance document, although this may be considered in the future.

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 Canada and the United States. 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 U.S. and Canada with studies developed for a registration in another country, and/or for a Codex MRL, provided that the petitioner is able to demonstrate to both countries the applicability of the studies to the requirements in this document. The petitioner or other interested parties may consult with the two 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. Canada and the U.S. 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.

If a Codex MRL has been established, Canada and the U.S. may conduct a more limited review of the residue chemistry data under certain conditions. Canada and the U.S. 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).

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; U.S. Guideline No. 860.1500) and the adequacy of the Toxicology data for those pesticides not already registered for a particular use in Canada or the U.S. 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.

B. Description of Format and Data Requirements for an Import Tolerance/MRL 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 Canada and the U.S. The Organization for Economic Cooperation and Development submission format is acceptable for both countries.

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.pmra-arla.gc.ca/english/pubs/pubs-e.html provides additional information).

In Canada and the U.S., petitioners are encouraged to use the data report templates. These templates can be retrieved from the PMRA website (http://www.pmra-arla.gc.ca) and the EPA website at http://www.epa.gov/pesticides/regulating/studyprofile_templates/studyprofile_templatelist_original.htm.

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

Section VII. A. of this document lists websites where the full complement of product chemistry data that may be required to support an import tolerance/MRL can be found. 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 *U.S. 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, formulants used in pest control products are regulated under the Formulants Program. For more information, refer to Regulatory Directive 2004-01, Formulants Program or the latest version. The Formulant Program 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 Canada or the U.S., the petitioner must submit a description of the use of the pesticide chemical. It is necessary to submit copies of registered/approved labels translated to the appropriate language of the recipient country (e.g., English and French for Canada). 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 of 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.

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) 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. A list of these requirements can be found in the 40 CFR 158. 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/MRL results in an unacceptable risk, when assuming that residues will be ingested at the proposed tolerance/MRL level. The petitioner may conduct studies describing reduction of residues through typical practices, including washing, peeling, cooking, etc.

6. Proposed Tolerance/MRL for the Pesticide Chemical, If Applicable

The petitioner must propose a tolerance/MRL based on the maximum residues found in the magnitude of residue studies. Canada and the U.S. 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/MRL. A detailed discussion of the information that should be presented may be found in U.S. OPPTS Guideline 860.1560.

C. Toxicology Data Requirements

Canada and the United States require the submission of complete toxicology studies for import tolerances/MRLs. This applies even if the studies have previously been submitted to the Joint Meeting on Pesticide Residues (JMPR). The two 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 evaluation reports may allow Canada and the U.S. 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.

Section VII.A. of this document lists the websites where the toxicology data required to support an import tolerance/MRL in Canada and the U.S. can be found. 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 individual studies may be found in the guidelines. In addition to the required studies, Canada and the U.S. 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/MRL-setting requirements of one or more other countries. The two 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

Section VII.A. of this document lists websites where the Residue Chemistry studies required to support an import tolerance/MRL in Canada and the U.S. can be found. 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 cited in Section VI. 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; 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 1, 2, 3, and 4 can be used to determine the number of field trials that should be conducted to establish an import tolerance/MRL in Canada and the United States. 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. or Canadian diet and the maximum relative amount imported into the U.S. or Canada 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 3 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. 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 Canada and the U.S. 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, Canada and the U.S. request data on a country-by-country basis. Trials should be conducted in countries in relative proportion to the amount each country exports into either Canada or the U.S. 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 the country where a tolerance is being sought*. The petitioner should seek approval from both countries if substitution of data from one country to another is desired, and both 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, 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 among 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 country 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 both countries a protocol for review and comment.

Petitioners interested in establishing import tolerances/MRLs for a crop group are advised to consult with Canada and the U.S. 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 Canada or the United States, or if the processed commodity itself is imported into either country. 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 Canada or the U.S. The purpose of these studies is to determine the identity of the biotransformation products of the pesticide. Ruminant and poultry studies are normally required. Canada and the U.S. 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 Canada and the U.S. and the commodity is not a feed item in either country.

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 Canada and the U.S. 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 in Canada and the U.S. 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 both countries for review and comment if they have any questions regarding study design and conduct. The two 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 Organization's Agreement on the Application of Sanitary and Pytosanitary 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]

[1]Available electronically from http://www.epa.gov/PR_Notices/pr86-5.html

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

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

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

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

[6]Available from the National Technical Information Service under order number PB91-158394INZ. To order, call 1-800-533-6847 or e-mail orders@ntis.fedworld.gov.

B. Canada

Applicants should ensure that they have the latest editions of the following documents.[7]

American Society for testing and Materials, Annual Book of ASTM Standards; ASTM, Philadelphia, PA, U.S.

Association of Official Analytical Chemists, Official Methods of Analysis of AOAC-International; AOAC-International, Arlington, VA, U.S.

Collaborative International Pesticide Analytical Council, CIPAC Handbooks, CIPAC, Hatching Green, Harpenden, Hertfordshire, England, 1970-1995.

Organisation for Economic Co-operation and Development, Guidelines for Testing of Chemicals, OECD 101-117; OECD, Paris, France, 1981-1995.

United States Environmental Protection Agency, Product Properties Test Guidelines (830 Series); U.S. Government Printing Office, Washington, DC, U.S., 1996.

United States Environmental Protection Agency, EPA Manual of Chemical Methods for Pesticides and Devices, 2nd edition; AOAC, Arlington, VA, U.S., 1992.

Directive DIR98-02. Residue Chemistry Guidelines.

Directive DIR2003- 01. Organizing and Formatting a Complete Submission for Pest Control Products.

Regulatory Note. REG2001-06. Guidance to Applicants for Preparing Electronic Submissions Part I: Overview.

Regulatory Note. REG2004-01. PMRA List of Formulants

[7]Copies of the PMRA Directives are available on the PMRA web site. http://www.pmra-arla.gc.ca/english/pubs/dir-e.html

VII. TABLES AND PETITIONER REQUIREMENTS

A. Data Requirements to Establish Import Tolerances/MRLs in Each of the NAFTA Countries

For a list of current data requirements to obtain an import tolerance in the US, see the U.S. Code of Federal Regulations (40 CFR), Part 158, Data Requirements for Registration:

http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr158_04.html.

For a list of current data requirements to obtain an import tolerance in Canada, see:

1. Canada. Guidelines for Developing a Toxicological Database for Chemical Pest Control Products, Regulatory Directive DIR2005-01. http://www.pmra-arla.gc.ca/english/pdf/dir/dir2005-01-e.pdf.

2. Canada. Residue Chemistry Guidelines. Regulatory Directive DIR98-02. http://www.pmra-arla.gc.ca/english/pubs/dir-e.html. The data requirements of these Residue Chemistry Guidelines are considered to be those data necessary to evaluate and assess the nature of the residues that may result from the proposed uses petitioned for, or for support of a MRL/tolerance to cover residues in an imported food.

3. Canada. Overview Data Table. Requirements for Terrestrial Food Crops. http://www.pmra-arla.gc.ca/english/pdf/daco/EnglishEP/USC_14_EP_1.m.pdf

B. Table 1. Number of Field Trials Required to Establish Import Tolerances/MRLs 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 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.

C. Table 2. Number of Field Trials Required to Establish Import Tolerances/MRLs 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[3]
0-0.05	3
0.05-0.2	8
0.2-1.0	12
>1.0	16

[1] The 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.

[2] Highest 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 4.

[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 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.

D. Table 3. 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)			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
Barley	0.22185	0.02229	0.01968	16	12
Beans - dry[1]	0.19479	0.01824	0.17285	5	12[2]
Beans - lima[1]	0.03066	0.0027	0.02567	8	8[2]
Beans - succulent[1]	0.26333	0.2965	0.31061	5	8[2]
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	3[3]
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

Crop	Percent Contribution from Crop Total Exposure (1994 - 1998)			No. of Field Trials for a Canadian Registration	No. of Field Trials for a U.S. Registration
	All Population	Infants	1 to 6		
Casabas	0.0018	0	0		3
Cashews	0.00361	0	0.0017		NA
Cassava (yuca blanca)	0.00361	0.02837	0.00428		2[4]
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	8[5]
Chestnuts	0	0	0		3
Chicory	0.00361	0	0.00171	2	2[4]
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	2[4]
Dandelion-greens	0	0	0	1	1[4]
Dates	0.00361	0.00135	0.00513		3
Dill	0	0	0	2	2[4]
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		2[4]

Crop	Percent Contribution from Crop Total Exposure (1994 - 1998)			No. of Field Trials for a Canadian Registration	No. of Field Trials for a U.S. Registration
	All Population	Infants	1 to 6		
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		2[4]
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	1[4]
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	8[6]
Limes	0.02345	0.00338	0.02481		3
Loganberries	0	0	0	1	1[4]
Longan fruit	0	0	0	1	1[4]
Lychees	0	0	0	1	1[4]
Macadamia nuts (bush nuts)	0	0	0		3
Maney (mammee apple)	0	0	0		2[4]
Mangoes	0.02525	0.02296	0.03252		3
Melon (inc. cantaloupe and honeydew)	0.17676	0.01824	0.18055	3	5 and 8[7]
Millet	0	0	0	5	5
Mint	0	0	0	5	5[8]
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	5[9]
Nectarines	0.03427	0.00743	0.02995	3	8
Oats	0.19479	0.32487	0.36966	16	16

Crop	Percent Contribution from Crop Total Exposure (1994 - 1998)			No. of Field Trials for a Canadian Registration	No. of Field Trials for a U.S. Registration
	All Population	Infants	1 to 6		
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
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		2[4]
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)[1]	0.17135	0.26678	0.18996	8	8[2]
Peas - succulent/ blackeye/ cowpea[1]	0.01263	0.00135	0.00685	8	5[2]
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	2[4]
Pineapples	0.28858	0.41199	0.53994		8
Pinenuts	0	0	0		NA
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	2[4]

Crop	Percent Contribution from Crop Total Exposure (1994 - 1998)			No. of Field Trials for a Canadian Registration	No. of Field Trials for a U.S. Registration
	All Population	Infants	1 to 6		
Radishes	0.00541	0	0.00171	3	5
Raspberries	0.00721	0.01621	0.00856	5	3[3]
Rhubarb	0.0018	0	0	3	2[4]
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
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	1[4]
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		2[4]
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		2[4]
Tea	0.01082	0	0.00342		NA
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	33
Water chestnuts	0.00721	0	0.00171		NA

Crop	Percent Contribution from Crop Total Exposure (1994 - 1998)			No. of Field Trials for a Canadian Registration	No. of Field Trials for a U.S. Registration
	All Population	Infants	1 to 6		
Watercress	0.0018	0	0	2	2[4]
Watermelon	0.25612	0.03107	0.30377		8
Wheat	2.94897	0.47548	3.2713	20	20
Yambean tuber (jicama)	0	0	0.0009		NA
Yautia (tannier)	0	0	0		2[4]

NA - Not applicable

[1]The 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.

[2]These 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.

[3]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.

[4]If one or two field trials is/are required, then four samples must be collected from each test plot.

[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.

E. Table 4. Calculation Steps To Determine the Required Number of Field Trials for a Canadian or U.S. 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 ≤ 121,140	> 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 (300,000 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 1, 2, and 3.

Determine the minimum number of field trials required to obtain an import tolerance/MRL for Canada and the U.S. 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 of the countries, only calculate the potential number of field trials for that country. Of the three (or fewer) potential numbers of field trials determined using this appendix, along with Tables 1,2, and 3, 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 (or fewer) values determined in step (1), calculate the percent of the crop imported into both countries relative to the total amount available for consumption (this information is available through the U.S. Department of Commerce and U.S. Department of Agriculture). 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 1 and 3. Determine the number of field trials required for a U.S. registration for the commodity of interest from Table 3. 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/MRL in each NAFTA country for which a tolerance is being requested using Table 3. Go to Step (5).

(4) Refer to Tables 2 and 3 to determine the number of field trials required to obtain an import tolerance/MRL 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 3. Determine the minimum number of field trials in the country for which a tolerance is being requested from Table 4 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 country 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.

Table 5. Countries That Export Oranges and Amounts Exported

Trading Country	Orange Juice, (Thousand liters)	Weight Orange Juice (Thousand lb [1])	Weight Fresh Market Oranges (Thousand lb)	Total Weight Imported (Thousand lb)	Percent Imported Total
Brazil	1,042,756	2,294,063	(see footnote 2)	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	7050	28,542	1.00
Spain	(see footnote 3)	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	1,248,046	2,745,703	96,039	2,841,741	100.00

[1]Assuming each liter of orange juice weighs 2.2 lbs.
[2]Fresh market oranges imported from this country represent less than 1% of the total orange imports and are therefore included in the "other" category.
[3]Orange juice imported from this country represents less than 1% of the total orange juice imports and is therefore included in the "other" category.

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; these are not known values and will need to be changed when data are received from 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 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 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 2 would be used to determine the minimum number of field trials required for an import tolerance/MRL. The population subgroup with the greatest consumption of orange products is children, ages 1-6, with an average of 5.83% in the diet. Therefore 16 field trials would be required for an orange import tolerance/MRL in Canada.

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 1, 16 field trials are required for a U.S registration. Using Table 1, 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/MRL 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 1, sixteen field trials are required for a U.S registration. Using Table 3, 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 5 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.

Greater than 75% of the bananas available for consumption in Canada and the US are imported, so Table 2 would be used to determine the minimum number of field trials need for an import tolerance/MRL. Assuming consumption of bananas in the US and Canada is similar, the population subgroup with the greatest consumption of bananas is 1.008% for children 1-6 years old. Therefore twelve field trials would be required for a banana import tolerance/MRL in Canada and the US.

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 6 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 and zonal differences between the two countries would not be so great as to result in vastly different pesticide residues.

Table 6. 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
Colombia	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.

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.

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

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.

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

Acronym List

CIPAC	Collaborative International Pesticides Analytical Council
CR	Conditionally Required
DACO	Data Code
EPA	Environmental Protection Agency (United States)
EP	End-Use Product
LOQ	Limit of Quantitation
MP	Manufacturing-Use Product
OECD	Organisation for Economic Co-operation and Development
PCPA	Pest Control Product Act
PMRA	Pest Management Regulatory Agency
R	Required
TGAI	Technical Grade of Active Ingredient