December 8, 1998

MEMORANDUM

SUBJECT: Draft Import Tolerance Guidelines.

FROM: Margaret J. Stasikowski, Director
Health Effects Division (7509C)

TO: HED Staff

Attached is a Standard Operating Procedure which is to be used as interim guidance when determining data requirements for tolerance petitions in the absence of a U.S. registration, also known as import tolerances. This SOP describes the minimum data requirements for product chemistry, toxicology, and residue chemistry studies. This draft may be distributed should you receive inquiries on import tolerance data requirements.

OPP is working very closely with Canada and Mexico to develop a NAFTA import tolerance policy. Until the policy is finalized, the data requirements should be considered interim guidance.

If you have any further questions on import tolerances please contact Randy Perfetti (305-5381) or Christine Olinger (305-5406).

December 8, 1998

MEMORANDUM

SUBJECT: Draft Import Tolerance Guidelines.

FROM: Margaret J. Stasikowski, Director
Health Effects Division (7509C)

TO: Lois Rossi, Director
Special and Reregistration Division (7508W)

and

Jim Jones, Director
Registration Division (7503C)

HED has completed a revised Standard Operating Procedure which is to be used as interim guidance when determining data requirements for tolerance petitions in the absence of a U.S. registration, also known as import tolerances. This document describes the minimum data requirements for product chemistry, toxicology, and residue chemistry studies. This draft may found in the HED Policy Database in Lotus Notes and may be distributed should you receive inquiries on import tolerance data requirements.

OPP is working very closely with Canada and Mexico to develop a NAFTA import tolerance policy. Until the policy is finalized, the data requirements should be considered interim guidance.

If you have any further questions on import tolerances please contact Randy Perfetti (305-5381).

cc: J. Housenger
R. McNally
HED Branch Chiefs
R. Perfetti
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GUIDANCE ON IMPORT TOLERANCES

December 1998

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INTRODUCTION

EPA has the authority to establish tolerances for pesticide residues in commodities under Section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA, as amended 1996). A tolerance is the maximum legal limit of a pesticide residue permitted in/on food or animal feed. Most frequently, tolerances are established in conjunction with the registration of a pesticide for use in the United States. Although EPA is responsible for reviewing data submitted in support of a tolerance petition and registration, FDA and USDA are charged with enforcement of tolerances once they have been established.

Increasingly, EPA has been petitioned to establish tolerances for a commodity in the absence of a U.S. registration. These are commonly referred to as "import tolerances", although there is no statutory distinction between "domestic" and "import" tolerances. The term "import tolerances" is used solely for convenience and is used in this document as a definition for a tolerance without a U.S. registration for the pesticide/commodity combination of interest.

This document clarifies how the existing data requirements for product chemistry, residue chemistry, and toxicology studies should be applied to petitions for tolerances on imported commodities. There are no additional types of studies needed for import tolerances; in fact, in a limited number of situations, fewer studies may be required than for tolerances associated with U.S. registrations. Only those studies associated with a tolerance petition, not domestic registrations, are required, resulting in the reduced number of studies. The guideline requirement which requires the most clarification for import tolerances is 860.1500, Crop Field Trials, the core study from which most tolerance values are estimated.

Existing Crop Field Trial guidance for tolerances associated with a domestic use provides specific information on the number and location of field trials, and is based on the U.S. production. In the past, EPA has not had written guidance for the number and location of foreign field trials to support tolerances on imported commodities, but has provided verbal advice instead. This document provides a method for determining the number and location of field trials for new tolerances on imported commodities.

If a registrant has an existing tolerance to support a U.S. use, but intends to withdraw that use and retain the tolerance for import purposes, the Agency may need additional residue data to better determine the dietary exposure of the pesticide to U.S. consumers. In such cases, the registrant or other petitioner is advised to consult with the Agency to determine what studies (if any) are required to support the tolerance under the reregistration or tolerance reassessment program.

The import tolerance petitioner may not need to conduct all new studies to fulfill these requirements, but may be able to rely on existing studies developed for a foreign registration or Codex Maximum Residue Limit (MRL), to support the proposed tolerance. The petitioner should examine existing studies after consulting this guidance and determine whether they are applicable to the U.S. requirements. The petitioner may consult with the Agency before submitting the existing studies. All studies should be in the PR86-5 format, and should contain a statement describing the applicability of the U.S. or OECD Good Laboratory Practices (40 CFR 160). The Agency strongly recommends attaching as an appendix to such studies, a copy of the study evaluation by the registering country or by Codex.

Although this document provides guidance on application of existing data requirements to import situations, we are also proposing a new approach on how data will be considered if a Codex MRL has already been established. If an MRL has been established, and the petition meets certain conditions, the Agency may conduct a limited review of the residue chemistry data.

An earlier version of this document was presented to the FIFRA Science Advisory Panel (SAP) in June 1997. In addition to the SAP, comments were received from the Canada Pest Management Regulatory Agency (PMRA) and the American Crop Protection Association (ACPA). The SAP was supportive of the approach for determining number and location of field trials and encouraged international harmonization to the extent possible. Comments from PMRA and ACPA have been considered and incorporated as appropriate.

These requirements are intended to fulfill an interim need for guidance on how the existing data requirements should be applied to petitions for import tolerances. The U.S. is working with its NAFTA partners, Canada and Mexico, to develop a NAFTA import tolerance policy to facilitate establishment of tolerances in North America, which will be eventually replace this guidance when an agreement is reached.

DESCRIPTION OF REQUIREMENTS FOR AN IMPORT TOLERANCE PETITION

Requirements for a pesticide petition for a tolerance are summarized in 40 CFR § 180.7(b). Each petition must contain seven parts, labeled A through G. The requirements for each section are listed below with a description of the specific information needed to establish an import tolerance.

Section A.

The name, chemical identity, and composition of the pesticide chemical.

Petitioners usually reference product chemistry studies which were submitted in

support of a product registration to fulfill these requirements. Table 1 lists guideline numbers for product chemistry studies along with the information needed specifically for import tolerances. The petitioner must disclose the inert ingredients in the formulation. Residue and safety data for List 1 inerts may be required if present in the formulation, so that a dietary risk assessment for the inert could be done by the Agency. (A reference for the inert classification system may be found at the end of this document.)

Section B.

The amount, frequency, and time of application of the pesticide chemical.

The petitioner must submit a description of the use of the pesticide chemical in all foreign countries in which the chemical is marketed and exported to the U.S. for the subject crop. It is preferable to submit copies of the labels (which have been translated to English). 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 the plant growth stage), retreatment 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, retreatment intervals, maximum application rate per year, and the pre-slaughter interval.

Section C.

Safety data.

Toxicology data required to support an import tolerance are largely the same as those required to support a domestic tolerance with the notable exceptions of most acute toxicity studies and studies reflecting administration via the dermal or inhalation routes. In the case of pesticides having at least one tolerance associated with a U.S. registration, this data subset would already have been submitted to the Agency. Toxicology data requirement guidelines are given in Table 2.

Section D.

The results of test on the amount of residue remaining, including a description of the analytical method used.

Studies conducted under the OPPTS 860 series (formerly 171-4) are listed in this section. These include metabolism studies, analytical methods used, information relating to the storage stability of the parent 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.

Section E.
Practicable methods for removing residue that exceeds any proposed tolerance.
This section is primarily of concern if the proposed tolerance results in an unacceptable risk, when it is assumed that residues will be ingested at the proposed tolerance level. The petitioner may conduct studies describing reduction of residues through typical consumer practices, including, washing, peeling, cooking, etc.

Section F.
Proposed tolerance for the pesticide chemical if tolerances are proposed.
The petitioner must propose a tolerance based on the maximum residues found in the magnitude of residue studies. The Agency may choose to adopt the Codex MRL, if one has been established, as described in the following section on residue chemistry studies.

Section G.
Reasonable grounds in support of the petition.
The petitioner should present the rationale of how the residue data support the proposed tolerance. A detailed discussion of the information which should be presented may be found in OPPTS Guideline 860.1560.

TOXICOLOGY DATA REQUIREMENTS

Table 2 lists the full complement of toxicology data required to support a tolerance as listed at 40 CFR Part 158. Whether or not a given study is required to support an import tolerance is noted as are several explanatory footnotes. The petitioner is urged to refer to 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 references cited at the end of this document. Note that the Agency welcomes the submission of studies not required to support an import tolerance if they have been conducted to satisfy the registration / tolerance-setting requirements of one or more countries outside of the U.S. Also note that the Agency reserves the right to require any study, including special studies, if deemed necessary to assess the human hazard depending on the properties, mode of toxicity, or other aspects of the pesticide in question.

RESIDUE CHEMISTRY DATA REQUIREMENTS

Table 3 lists the Residue Chemistry studies required to support tolerances as outlined in 40 CFR 158. The data requirements to support an import tolerance are essentially the same as for a tolerance associated with a U.S. 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 document. Following is a description of the differences in data requirements (from a petition associated with a domestic use) for crop field trials, processing studies, and livestock studies.

860.1500 Crop Field Trials

Crop field trials are conducted to determine the maximum residue which may be expected in/on a raw agricultural commodity as a result of the legal use of the pesticide. The trials must reflect label directions which would be expected to result in the maximum residue levels, e.g. the maximum label rates, maximum number of applications, minimum retreatment interval, and minimum pre-harvest interval.

The Agency has prepared two tables (refer to Tables 4 and 5), for determining the number of field trials which should be conducted for an import tolerance. 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 consumption of the commodity as a percentage of the U.S. diet and the relative amount imported into the U.S. (percent imported averaged over five years). Detailed instructions on determining the number and location of field trials and examples are provided in Appendix I of this document. A table with information on relative significance of each crop in the U.S. diet may be found in Appendix IV.

The U.S. and Canada utilize zone maps for determining where field trials should be conducted for tolerances associated with a domestic registration. In the absence of zone maps developed for other countries using similar principles (as were used for the North American maps), the Agency has decided to request data on a country-by-country basis. Trials should be conducted in countries in relative proportion to the amount each country imports into the United States. Only those countries in which the pesticide is marketed or proposed to be marketed need be represented. Trials will generally need to be conducted in all such countries which export at least 5% of the total amount of a commodity imported into the U.S. The petitioner should seek Agency approval if substitution of data from one country to another is desired. All major growing areas within a country should be represented, as is required for U.S. registrations in 860.1500. At least two individually composited samples must be taken from each test plot and analyzed.

All major formulation classes should be represented. Petitioners are referred to the section on formulations in the residue chemistry OPPTS Test Guidelines,

860.1500(e)(2)(x). For the major classes a full set of trials must be conducted for each 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 PHI which 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 of the total number of trials is warranted; petitioners are advised to consult the guidelines or Agency staff if a reduced 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 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).

Data generated in the United States or countries other than where the petitioner has existing or proposed uses may be substituted for up to half of the required number of foreign trials, but a minimum of three trials must be from the 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 foreign regions and regions represented by the U.S. (or other) data. The burden of proof is on the petitioner.

In the case of tolerances to cover treated commodities imported from Canada or Mexico only, it may be acceptable for >50% of the trials to be conducted in the United States. As part of the harmonization process under the NAFTA, the crop field trial regions in the U.S. guidelines have been extended into Canada and efforts are in progress to do the same into Mexico. This would allow trials in the U.S. to support registration and tolerances in Canada and Mexico or vice versa. As a result, among these three countries, for certain crops most or all the field trials could be in a different country than the one in which the tolerance is to be established. For example, if a tolerance is desired to cover the export of cranberries from Canada to the U.S., most of the trials could be conducted in the northern regions of the U.S. even though the pesticide is to be registered in Canada. Similarly, for certain crops being imported from Mexico, many of the trials could be done in the southwestern U.S. In the future, if other countries develop zone maps employing similar concepts as were used for the NAFTA countries, and the regions and cultural practices are demonstrated to be substantially similar to U.S. regions, then the Agency may consider substitution of U.S. data for those

countries as well.

A minimum of three trials are required for any crop. In certain cases 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 OPPTS Guideline 860.1500 or submit a protocol for comment by the Agency.

A table in Appendix III lists the number of field trials and locations for commodities for which import tolerances are most frequently requested. Petitioners interested in establishing import tolerances for a crop group are advised to consult with the Agency for direction on number and location of trials for each representative commodity within the crop group.

860.1520 Processing Studies

Processing studies must be conducted if there is likely to be processing of the commodity once it has been imported into the U.S. or if the processed commodity is imported into the U.S. Table 1 of the residue chemistry testing guidelines (860.1000) lists the processed commodities for which data are required. The petitioner is advised to consult the Agency if they believe 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 raw agricultural commodity to be processed bears quantifiable residues.

860.1300 Nature of the Residue - Animals

If the raw agricultural or processed commodities associated with the crop to be treated in the subject petition could be used as an animal feed then 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 which have significant export of animal products to 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. The EPA will assume that all feed items included in Table 1 of 860.1000 are feed items for import tolerance purposes. Any claims that these items are not significant feed items in the country(s) 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 the imported plant commodity or its processed products would be significant feed items (in the U.S. or exporting country); or iii) there are not significant imports of livestock commodities from the countries of interest into the U.S.

JMPR/CODEX CONSIDERATIONS

The Agency requires the submission of complete toxicology studies comprising the requisite import tolerance data base even if they had previously been submitted to the Joint Meeting on Pesticide Residues (JMPR). The Agency will conduct an independent review of the data. Summaries and/or JMPR reviews are not an acceptable substitute, although they may be submitted as supplemental materials. In the future however, harmonization of OECD test guidelines and data evaluations may allow the Agency to use toxicology data reviews from other countries for hazard identification and risk assessment.

If a Codex MRL has been established, the Agency may consider a petition with limited review of the residue chemistry data under certain conditions. A detailed description of the conditions and an overview of how the Agency may consider Codex MRLs as they relate to the data requirements may be found in Appendix II of this document. EPA is more likely to accept Codex MRL levels as tolerance levels with limited review if U.S. tolerances for the pesticide are already established on other commodities. Standard data and review requirements would be applied where exposure and/or risk from the pesticide is high.

GOOD LABORATORY PRACTICE CONSIDERATIONS

As described in 40 CFR §160.1(a) and §160.3(4) all submissions for pesticide registrations and tolerance petitions should be in accordance with Good Laboratory Practices (GLP). 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.

SUBMITTAL OF SAMPLES

Registrants and petitioners are normally required to submit samples of the pesticide technical grade active ingredient (TGAI) under guideline 830.1900 and analytical standards of the parent compound and regulated metabolites under 860.1650. Unless the TGAI is to be registered in the U.S., petitioners for an import tolerance are not required to submit samples of the product as this is a requirement for registration of a

product. However the petitioners are still required to submit the analytical standard under 860.1650 as this is a requirement of a pesticide tolerance petition.

CONCLUSION

The requirements for a pesticide tolerance in the absence of a U.S. registration (i.e. import tolerance) have been outlined in this document. Before conducting any toxicology, product chemistry, or residue chemistry study, the petitioner is strongly urged to consult the series 870, 830, and 860 OPPTS guidelines. Petitioners should submit protocols for EPA comment if they have any questions regarding study design and conduct. The Agency will attempt to harmonize with international standards to the extent possible to facilitate establishment of U.S tolerances.

REFERENCES

PR Notice 96-1, "Tolerance Enforcement Methods - Independent Laboratory Validation by Petitioner", February 7, 1996.[1]

OPPTS Test Guidelines, Series 830, Product Chemistry (August 1996).[2]

OPPTS Test Guidelines, Series 860, Residue Chemistry (August 1996).[3]

OPPTS Test Guidelines, Series 870, Health Effects (August 1998).[4]

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[1]Available electronically from http://www.epa.gov/opppmsd1/PR_Notices/pr96-1.html.

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

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

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

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

Table 1. Product Chemistry Data Requirements for Import Tolerances

Guideline No.	Guideline Title	Application to Import Tolerances	Test Substance
830.1550	Product Identity	No - Product Specific Requirement	N / A
830.1600 830.1620 830.1650	Description of Manufacturing Process	Yes	TGAI[1]
830.1670	Discussion on Formation of Impurities	Yes - Agency is especially concerned with impurities of toxicological concern (e.g. dioxins, HCB, nitrosamines)	TGAI
830.1700	Preliminary Analysis	Yes	TGAI
830.1750	Certified Limits	No - Product Specific Requirement	N / A
830.1800	Enforcement Analytical Methods	No - Product Specific Requirement	N / A
830.6302	Color	Yes	TGAI
830.6303	Physical State	Yes	TGAI
830.6304	Odor	Yes	TGAI
830.7200	Melting Point	Yes	TGAI
830.7220	Boiling Point	Yes	TGAI
830.7300	Density	Yes	TGAI
830.7840 830.7860	Solubility	Yes	TGAI or PAI[1]
830.7950	Vapor Pressure	Yes	TGAI or PAI
830.7370	Dissociation Constant	Yes	TGAI or PAI
830.7550 830.7560 830.7570	Octanol / Water Partition Coefficient	Yes	PAI
830.7000	pH	Yes	TGAI
830.6313	Stability	Yes	TGAI
830.6314	Oxidation / Reduction	No - Product Specific Requirement	N / A

830.6315	Flammability	No - Product Specific Requirement	N / A
830.6316	Explodability	No - Product Specific Requirement	N / A
830.6317	Storage Stability	No - Product Specific Requirement	N / A
830.6319	Miscibility	No - Product Specific Requirement	N / A
830.6320	Corrosion Characteristics	No - Product Specific Requirement	N / A
830.6321	Dielectric Breakdown Voltage	No - Product Specific Requirement	N / A
830.7100	Viscosity	No - Product Specific Requirement	N / A
830.7050	UV / Visible Absorption	No - Product Specific Requirement	N / A

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

Table 2. Toxicology Data Requirements for Import Tolerances

Guideline Reference Number	Study Title	Application to Import Tolerance	Footnote No.
81-1	Acute oral toxicity - rat	Yes	
81-2	Acute dermal toxicity	No	1, 2
81-3	Acute inhalation toxicity - rat	No	1, 2
81-4	Primary eye irritation - rabbit	No	1, 2
81-5	Primary dermal irritation	No	1, 2
81-6	Dermal sensitization	No	1, 2
81-7	Acute delayed neurotoxicity - hen; organophosphates only	Yes	
81-8	Acute neurotoxicity - rat screening battery	Yes	
82-1	90-Day feeding studies - rodent and nonrodent	Yes	
82-2	21-day dermal toxicity	No	2
82-3	90-day dermal toxicity	No	2
82-4	90-Day inhalation - rat	No	2
82-6	28-Day neurotoxicity - hen; organophosphates only	Yes	
82-7	90-Day neurotoxicity - rat screening battery	Yes	
83-1	Chronic feeding - rodent and nonrodent	Yes	
83-2	Oncogenicity study - two species	Yes	
83-3	Teratogenicity - rodent and nonrodent	Yes	
83-4	Reproduction, two-generation	Yes	
84-2	Salmonella typhimurium reverse mutation assay	Yes	
84-2	Detection of gene mutations in mammalian cells in culture	Yes	

84-2	In vivo mammalian cytogenetics tests: Erythrocyte micronucleus assay	Yes	
84-2	In vitro mammalian cytogenetics	Yes	3
85-1	General metabolism	Yes	
85-2	Dermal penetration	No	2
86-1	Domestic animal safety	No	4

[1]Study used largely to determine appropriate hazard statements required on U.S. pesticide product labels.
[2]Study reflects a route of exposure (dermal or inhalation) not expected to be applicable to dietary exposure, the only exposure route assumed to be relevant to U.S. citizens via imported foods/feeds.
[3]May be required depending on the assay selected to fulfill the 84-2 requirement for "Detection of gene mutations in mammalian cells in culture".
[4]Study is applicable only to direct application to domestic animals as opposed to dietary exposure via treated feed.

Table 3. Residue Chemistry Data Requirements for Import Tolerances

Guideline No.	Study Title	Required for Import Tolerance?[1]
860.1300	Nature of the Residue - Plants	R
860.1300	Nature of the Residue - Animals	CR[2]
860.1340	Residue Analytical Methods - Plants and Animals	R
860.1360	Multiresidue Methods	R
860.1380	Storage Stability	R
860.1480	Magnitude of Residue - Meat, Milk, Poultry, and Eggs	CR[3]
860.1500	Crop Field Trials	R
860.1520	Processing Studies	CR[4]
860.1850	Confined Rotational Crop	NR
860.1900	Field Rotational Crop	NR

1. R = Required; CR = Conditionally Required; NR = Not Required.
2. Required if subject crop is an animal feed item, or if the pesticide will be applied directly to livestock exported to the U.S.
3. May 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.
4. May 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.

Table 4. Number of Field Trials Required for an Import Tolerance (Less than 75% of Crop Available for Consumption Imported into U.S.)[1,2]

Required No. of Field Trials for a U.S. Registration	Percentage of U.S. Consumption Imported (Weight Basis)		
	0 - 10%	10 - 35%	35 - 75%
20	5	16	20
16,15	5	12	16
12	3	8	12
9,8	3	5	8
6,5	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 and the crops are not being used as representative commodities to obtain crop group tolerances.

[2] Representative crops being used for crop group tolerances require 25% fewer trials than indicated in Table IV-1 if the latter specifies 8 or more trials for the individual crop. Therefore, the 15, 9, and 6 trials in the left hand column refer only to representative crops being used toward a crop group 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 the U.S. Four independent samples must be collected from each test plot if less than three trials are conducted. Petitioners should either consult OPPTS Guideline 860.1500 or contact the Agency before proceeding if they believe that fewer trials are warranted.

Table 5. Number of Field Trials Required for an Import Tolerance (Greater than 75% of Crop Available for Consumption Imported into U.S.) [1]

Maximum Percent in U.S. Diet [2]	No. of Trials Required
0 - 0.05	3 [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 8 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 U.S. Diet for any of the following subgroups: general population, children 1-6, and infants. Information on percentages in the diet may be found in Table IV-1 of this document.

[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 U.S. Four independent samples must be collected from each test plot if less than three trials are conducted. Petitioners should either consult OPPTS Guideline 860.1500 or contact the Agency before proceeding if they believe that fewer trials are warranted.

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 which must be conducted using Tables 4, 5, and IV-1

(1) Average the amount of the crop imported into the U.S. for the last five years (on a weight basis) from the countries in which the product is registered or intended to be registered. Averaging over the previous five years allows for seasonable variability. Information on production may be obtained from the U.S. Dept. of Agriculture, the U.S. Dept. of Commerce, and various private sources. All forms of the commodity which are imported (in significant amounts) must be taken into consideration including (but not limited to) juice, juice concentrate, wine, and fresh fruit. The source of the production information should be reported.

(2) Using the value determined in step (1), calculate the percent of the crop imported into the U.S. relative to the total amount available for consumption in the U.S. If less than 75% of the commodity available for consumption in the U.S. is imported, proceed to step (3). If greater than 75% of the commodity available for consumption in the U.S. is imported, proceed to step (4).

(3) Refer to Tables 4 and IV-1. Determine the number of field trials required for a U.S. registration for the commodity of interest from Table IV-1. Using that value and the percentage imported into the U.S., determine the minimum number of field trials required for an import tolerance using Table 4. Go to Step (5).

(4) Refer to Tables 5 and IV-1 for commodities for which the U.S. imports greater than 75% available for U.S. consumption. The maximum percentage in the diet for any commodity may be found in Table IV-1. Determine the minimum number of field trials 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 which they export to the U.S. is equivalent to at least 5% of the U.S. imports (for the subject crop). A greater number of trials 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 required. Additional trials may be required to ensure all major formulation classes are represented.

Note 2: If the petitioner does not market or does not intend to market the subject pesticide in one of the top two or three countries which exports the subject crop to the U.S. then the total percent imported should not include the countries in which the pesticide is not marketed or intended to be marketed.

Examples of Calculating Number of Field Trials

Several examples are provided below illustrating different considerations when calculating the numbers of field trials.

(A) The ABC Chemical Company markets a granular nematicide all over the world for use on bananas. They would like the U.S. to establish a tolerance for their chemical, but no Codex MRL has been set.

1) Approximately 99.8% of all bananas available in the U.S. are imported. The highest consumption level for any population sub-group is 0.96% for infants. Referring to Table 5, a minimum of 12 trials would be required.
2) Table I-1 below lists the countries and amounts of bananas imported into the U.S. To ensure that all countries in which >5% of the amount imported are represented, and that the countries with the most production are equally represented, twelve trials will have to be conducted (and 24 treated samples analyzed). Both bagged and unbagged samples need to be analyzed for bananas. Petitioners have the option of analyzing one bagged sample and one unbagged sample from each site.

Costa Rica	3 trials	Ecuador	3 trials
Honduras	2 "	Guatemala	1 "
Colombia	2 "	Mexico	1 trial

Table I-1. 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

(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 IV-1, 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 I-2 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.

(B)-2 The registrant also intends to register another insecticide on oranges in Mexico only, but does not intend to market it elsewhere.

1) Approximately 3% of all oranges available in the U.S. (as juice or fresh fruit) over the last five years were imported from Mexico. Referring to Table IV-1, sixteen field trials are required for a U.S registration. Using Table 4, oranges fall in the range of 0-10% imported, Therefore a minimum of five trials (10 samples) must be conducted. All five trials would be conducted in Mexico.

Table I-2 Quantity of Oranges and Orange Juice Imported into U.S.

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	--[2]	2,294,061	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	--[3]	-7	26,332	26,325	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	1,248,040	2,745,689	96,035	2,841,723	100.00

[1] Assumption each liter of orange juice weighs 2.2 lbs.
[2] Fresh market oranges imported from this country represents less than 1% of the total orange imports and is 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.

(C) MSR Pesticides has petitioned the Agency for an import tolerance on cherries for an insecticide used to kill an insect found only in warmer climates. They have proposed conducting only three trials using only the WP formulation, but an emulsifiable concentrate is registered as well.

1) Approximately 2.3% of all cherries available for U.S. consumption over the last five years have been imported. However, since the pesticide will not be marketed in Canada, the percent imported into the U.S. drops to 2%. Eight trials are required for a tolerance with a U.S. registration, according to Table IV-1. Referring to Table 4 a minimum three trials are required for an import tolerance. However since both formulations should be tested, a minimum of six trials (12 treated samples) are required, three with each formulation.
2) Table I-3 shows the amount imported into the U.S. Normally trials would be required for both Chile and Canada, but the pest controlled by the product is only found in warmer climates. Therefore all six trials should be conducted in Chile.

Table I-3 Amount of Cherries Imported into the U.S.

Trading Country	Average Amt Fruit/yr. (short tons)	% of Imports
Chile	1633	85.50
Canada	252	13.19
Swaziland	12	0.63
Others (<1% each)	13	0.68
Total	1,910	100.00

APPENDIX II

Consideration of Codex MRLs When Establishing Import Tolerances

The 1996 amendments to FFDCA codify a long-standing Agency policy to harmonize U.S. tolerances with Codex Maximum Residue Limits (MRLs) to the extent possible. Recent trade agreements such as NAFTA and GATT [the latter implemented by the World Trade Organization (WTO)] encourage the use of international standards such as Codex MRLs. In fact, provisions of the GATT agreement state that countries meet their WTO trade obligations when they apply certain international standards such as Codex MRLs. Countries who apply stricter national standards may be challenged in the WTO as creating artificial trade barriers. The burden of proof that they are not falls on the country applying the stricter standard. Stricter standards may be acceptable if based on sound science.

When establishing new tolerances (including import tolerances), or reassessing existing ones, the Agency takes into consideration the Codex MRL level and the metabolite(s) included in the Codex MRL definition. If U.S. use patterns or risk assessments permit, the tolerance will be modified to harmonize with the Codex level. If the tolerance and the Codex level do not agree, the Agency must explain why they cannot be harmonized, in accordance with FQPA.

In the context of establishing import tolerances, four common situations are presented below which take into consideration the presence or absence of U.S. tolerances and Codex MRLs. The effect of Codex MRLs on data requirements are described, as well as harmonization of existing tolerances with MRLs.

A U.S. tolerance and Codex MRL have been established for the chemical/commodity of concern.

This situation might occur either when there is no on-going action on the U.S. use or tolerance, when a U.S. registration is withdrawn, a chemical is going through the reregistration process, or the tolerance is being reassessed as a result of FQPA requirements. Depending upon the status of the database, additional data may be required before an existing tolerance can be reassessed or the import tolerance petition can be assessed. The registrant should review this guidance for number and location of field trials when determining if additional studies are needed to support the tolerance.

When the import tolerance petition is being assessed, the Agency will make every attempt to harmonize with the Codex level in all their aspects, including the numerical level and definition of residue. Assessment of the import tolerance petition will need to take into account whether the existing U.S. tolerance supports an existing U.S. use for

the commodity in question or whether the U.S. tolerance has been (or is proposed to be) retained to accommodate foreign uses after a U.S. use has been canceled. If an existing U.S. tolerance exceeds the Codex MRL and is sufficient to cover the import use, there is no need for a revision to accommodate the import use. Under this circumstance an assessment should be made to determine whether the U.S. tolerance can be lowered to the Codex level and still accommodate any existing U.S. use and/or the import tolerance needs. If that is not possible, the review should recommend that the relevant information be provided to Codex in order to support a higher Codex limit. If the Codex MRL exceeds the existing U.S. tolerance or the proposed import tolerance, then the Codex MRL may be adopted as the U.S. tolerance, provided dietary intake estimates (TMRC or anticipated residues) would not result in an unreasonable risk. If adoption of the Codex MRL (i.e. using the best estimate of dietary intake) would result in an unreasonable risk, reviews should request that this information be provided to Codex. Further assessment will then be needed to determine an appropriate level for import tolerance purposes.

A Codex MRL has been established for the chemical/commodity of concern, but there is no U.S. Tolerance.

This applies to proposed tolerances with no U.S. registration for the commodity of interest. Normally under these circumstances the full range of data must be provided to support an import tolerance. Product chemistry data and an acceptable tolerance enforcement method must be submitted. At the same time, efforts should be made to harmonize with the Codex MRL.

Under the conditions listed below the petitioner may propose the Codex MRL as the tolerance level, and a limited data review of the residue chemistry data may be done by the Agency.

(i) The dietary exposure to the pesticide residue will be low, either due to low consumption of the commodity in the U.S. diet, or non-detectable residues in higher consumption commodities.

(ii) A U.S. use(s) or U.S. tolerance(s) for the subject commodity(s) has not been canceled, suspended, revoked or denied or is not under consideration for the same as a result of human dietary risk concerns.

(iii) Increases in risk resulting from the importation of the subject commodity(s) are acceptable.

(iv) An acceptable analytical method is submitted with the petition (i.e., the procedure should undergo an independent lab validation and an EPA lab

validation if it is not already approved for enforcement, and multi-residue method testing of the parent and residues of concern should be provided).

(v) U.S./Codex commodity and residue definitions are or can be made compatible.

If the above criteria are not met, standard data and review requirements would be applied. The Agency may consider limited review for higher consumption commodities if exposure is expected to be minimal, for example if all residues are non-detectable. In either case, a dietary risk assessment will be done using the Codex MRL level. If the risk is acceptable, then the Codex MRL level will be established as the tolerance. If the apparent risk is not acceptable based on use of the Codex MRL in the risk assessment, additional data may be required if the exposure assessment needs to be further refined.

An assessment will need to be made as to whether the Codex MRL will accommodate the import tolerance need. If the Codex MRL is not high enough to accommodate the import tolerance need, the Agency review should recommend that the petitioner provide the relevant data to Codex to support a revised Codex limit.

A U.S. tolerance has been established but there is no Codex MRL for the chemical/commodity of concern.
Assessment of the import tolerance need will need to take into account whether the existing U.S. tolerance supports an existing U.S. use for the commodity in question or whether the U.S. tolerance has been retained to accommodate foreign uses after a U.S. use has been canceled. If the former, the assessment will need to determine whether the existing U.S. tolerance will accommodate the import tolerance need and if not, whether data requirements outlined elsewhere in this guidance have been met. If the U.S. tolerance has been retained after cancellation of U.S. uses, the assessment will need to determine whether the petition provides sufficient data as defined elsewhere in this document to support the import tolerance need. Up to 50% of the data may be U.S. data if adequately justified.

In either case, the Agency review should recommend that the petitioner provide the relevant data to Codex to support a Codex limit for the subject commodities.

Neither a Codex MRL nor a U.S. tolerance has been established for the chemical/commodity of concern.
All toxicology and product and residue chemistry studies as described in this document are required for establishment of the import tolerance. U.S. import tolerances will be established provided that the use does not result in an unreasonable

dietary risk.

The Agency review should recommend that the petitioner provide the relevant data to Codex to support a Codex limit for the subject commodities.

Examples:

Listed below are two examples on the use of Codex MRLs and other factors used to decide whether the Agency can consider a limited review of an import tolerance petition.

(A) ABC Company has petitioned for an import tolerance for an insecticide used on olives. There are U.S. tolerances and registrations for several other commodities, and a Codex MRL has been established for olives. The U.S. tolerance expression and the Codex MRL definition are compatible. There are no dietary risk concerns with the existing tolerances. There is an acceptable enforcement method in the FDA Pesticide Analytical Manual for plant commodities.

Only a limited review of this chemical would be required initially. Olives are a low consumption commodity, 0.033% of the U.S. diet. A risk assessment would be done using the Codex MRL. If the risk was acceptable, no further submission of residue chemistry data would be required.

(B) MRE Chemicals would like to obtain an import tolerance for an organophosphate insecticide on lima beans, and no tolerance has been established in the U.S. for this commodity. This chemical is undergoing reregistration in the U.S. and is used on several commodities. Dietary risk concerns have delayed the Reregistration Eligibility Decision. A Codex MRL has been established and the company has proposed conducting a risk assessment using the Codex MRL without submitting data. The U.S. tolerance expression for other commodities includes the parent, a sulfoxide, and a sulfone metabolite. The Codex MRL includes the parent only.

This situation is not a good candidate for a petition with a limited review. Although it involves a low consumption food item (0.036% of the U.S. diet), there is an existing risk concern with the chemical. Additionally, the tolerance expression is different than the Codex MRL expression, which requires consideration of harmonization in the residue chemistry assessment.

APPENDIX III

Table III-1 Number of Field Trials Required for Commodities for which Import Tolerances are Commonly Requested

Commodity	Number of Field Trials Required	Countries in Which Trials Should be Conducted [1]
Coffee	8	Brazil (3), Columbia (3), Mexico (2)
Grapes	8	Chile (3), Italy (2), France (1), Mexico (1), Argentina (1)
Oranges	12	Brazil (9), Mexico (3)
Bananas	12	Ecuador (3), Costa Rica (3), Columbia (2), Honduras(2), Guatemala (1), Mexico (1)
Apples	12	Argentina (5), Germany (4), Chile (3)
Stone Fruit Peaches Cherries Plums	 3 3 5 [2]	 Chile (3) Chile (2), Canada (1) Chile (5) [2]
Tomatoes	12	Mexico (10), Italy (1), Chile (1)
Mangoes	3	Mexico
Kiwi	3	Chile (2), New Zealand (1)

[1] The number in the parentheses indicates the number of trials which should be conducted in the country specified.

[2] The number of field trials for plums may be reduced to 3 if a tolerance for the stone fruits crop group is proposed.

Appendix IV

Table IV-1 Percent in Diet Values and Number of Field Trials Required for A Tolerance Associated with a U.S. Registration for Most Commodities

Raw Agricultural Commodity	% Contribution to Total Exposure			No. of Field Trials for Tolerance with A U.S. Registration
	1989-91 US Population	1989-91 Children 1-6	1989-91 Infants	
Acerola	0.000000	0.000000	0.000000	1[1]
Almonds	0.007583	0.000043	0.000000	5
Apples	1.808737	4.012164	1.969677	16
Apricot	0.027213	0.032773	0.048144	5
Artichokes-Jerusalem	0.000000	0.000000	0.000000	3
Artichokes-globe	0.005846	0.001192	0.000000	3
Asparagus	0.023181	0.001589	0.000000	8
Atemoya	0.000000	0.000000	0.000000	1[1]
Avocados	0.017335	0.005760	0.000000	5
Banana	0.577720	0.791826	0.957257	5
Barley	0.178596	0.023041	0.013825	12
Beans - Dry[2]	0.180813	0.133279	0.005965	12[3]
Beans - Succulent[2]	0.320303	0.392089	0.220857	8[3]
Beans - Lima- Dry & Succulent[2]	0.036485	0.029198	0.008702	8[3]
Beets - Garden - Total	0.018545	0.010687	0.035230	5
Bitter Melon	0.000000	0.000000	0.000000	5
Blackberries - Total	0.006047	0.007746	0.000211	3[4]
Blueberries	0.026205	0.025126	0.011018	8
Boysenberries	0.003024	0.005264	0.000140	2[1]
Broccoli, chinese (Gai Lon)	0.000000	0.000000	0.000000	2[1]
Broccoli	0.229796	0.276191	0.008562	8
Brussels Sprouts	0.009071	0.000596	0.000983	3
Buckwheat	0.001209	0.000596	0.000000	5
Cabbage-green and Red	0.146949	0.081040	0.001895	8
Cabbage-chinese/celery/ bok Choy	0.003225	0.003575	0.000000	3
Calabaza	0.000000	0.000000	0.000000	2[1]
Canola Oil, Rape Seed Oil	0.009071	0.007746	0.001053	8
Carambola (Starfruit)	0.000000	0.000000	0.000000	2[1]
Carob	0.000000	0.000199	0.000000	3
Carrots	0.352959	0.302509	0.683836	8
Casabas	0.000403	0.000000	0.000000	3
Cassava (Yuca Blanca)	0.003024	0.002483	0.014387	2[1]
Cauliflower	0.039912	0.013805	0.000070	8
Celery	0.121550	0.087495	0.003439	8
Cherries (sweet & sour)	0.040517	0.042605	0.014036	8[5]
Chestnuts	0.000000	0.000000	0.000000	3

Raw Agricultural Commodity	% Contribution to Total Exposure			No. of Field Trials for Tolerance with A U.S. Registration
	1989-91 US Population	1989-91 Children 1-6	1989-91 Infants	
Chicory(french/belgian Endive)	0.004435	0.000695	0.000000	2 [1]
Chocolate (Cocoa bean)	0.067125	0.089978	0.002737	3
Coconut	0.056844	0.018075	1.023086	5
Cocoyam (tanier)	0.000000	0.000000	0.000000	2 [1]
Coffee	0.052006	0.000199	0.000000	5
Collards	0.023383	0.007746	0.000000	5
Corn/pop	0.047370	0.036249	0.000000	3
Corn/sweet	0.430767	0.556453	0.043863	12
Corn	1.828693	2.117263	0.883428	20
Cottonseed	0.052006	0.057006	0.004703	12
Crabapples	0.000000	0.000000	0.000000	3
Cranberry	0.052813	0.045883	0.005053	5
Crenshaws	0.000000	0.000000	0.000000	3
Cress-upland	0.000000	0.000000	0.000000	1 [1]
Cucumbers	0.145941	0.084717	0.000983	8
Currants	0.000000	0.000000	0.000000	2 [1]
Dandelion-greens	0.000202	0.000000	0.000000	1 [1]
Dates	0.002419	0.001887	0.002948	3
Dill	0.000000	0.000000	0.000000	2 [1]
Eggplant	0.006249	0.001589	0.000000	3
Elderberries	0.000000	0.000000	0.000000	3
Endive-curly and Escarole	0.005443	0.000695	0.000000	3
Figs	0.004838	0.004767	0.000000	3
Filberts (Hazelnuts)	0.000403	0.000497	0.000000	3
Flax Seed	0.000000	0.000000	0.000000	5
Garlic	0.009272	0.007945	0.000842	3
Genip (Spanish Lime)	0.000000	0.000000	0.000000	1 [1]
Ginger	0.000403	0.000298	0.000000	2 [1]
Ginseng	0.000000	0.000000	0.000000	3
Gooseberries	0.000000	0.000000	0.000000	3
Grapefruit	0.255799	0.059290	0.000772	8
Grapes	0.694629	1.213610	0.449785	12
Guar Beans	0.000000	0.000000	0.000000	3
Guava	0.002217	0.001688	0.000000	2 [1]
Hops	0.002217	0.000000	0.000000	3
Horseradish	0.000806	0.000298	0.000000	3
Huckleberries	0.000000	0.000000	0.000000	3
Kale	0.005039	0.005959	0.000000	3
Kiwi Fruit	0.007257	0.011818	0.000000	3
Kohlrabi	0.000000	0.000000	0.000000	3
Kumquats	0.000000	0.000000	0.000000	1 [1]
Leeks	0.000000	0.000000	0.000000	3

Raw Agricultural Commodity	% Contribution to Total Exposure			No. of Field Trials for Tolerance with A U.S. Registration
	1989-91 US Population	1989-91 Children 1-6	1989-91 Infants	
Lemons	0.056441	0.034164	0.000561	5
Lentils	0.003628	0.001589	0.000000	3
Lettuce (Head & Leaf)	0.412020	0.161881	0.002456	8[6]
Limes	0.008869	0.004866	0.000211	3
Loganberries	0.000000	0.000000	0.000000	2[1]
Longan	0.000000	0.000000	0.000000	1[1]
Lotus Roots	0.000000	0.000298	0.000000	1[1]
Lychees	0.000000	0.000000	0.000000	1[1]
Macadamia Nuts (Bush Nuts)	0.000000	0.000000	0.000000	3
Maney (Mammee Apple)	0.000000	0.000000	0.000000	2[1]
Mangoes	0.008869	0.003476	0.004070	3
Melon (inc. Cantaloupe & Honeydew)	0.138079	0.062468	0.000000	5 and 8[7]
Millet	0.000202	0.000000	0.000000	5
Mint	0.000000	0.000000	0.000000	5[8]
Mulberries	0.000202	0.000397	0.000000	3
Mung Beans (Sprouts)	0.026205	0.034859	0.000491	8
Mushrooms	0.059263	0.041811	0.001404	3
Mustard Greens	0.005846	0.001390	0.014036	5[9]
Nectarines	0.026608	0.015791	0.000000	8
Oats	0.230602	0.455352	0.287037	16
Okra	0.016328	0.007449	0.000000	5
Olive	0.032655	0.021253	0.000983	3
Onion - Dry Bulb	0.333809	0.242921	0.038178	8
Onions-green	0.018747	0.011421	0.000211	3
Orange	1.155632	1.651185	0.246403	16
Papaya	0.007660	0.001589	0.000000	3
Parsley	0.006652	0.007349	0.001263	3
Parsnips	0.000605	0.000000	0.000000	3
Passion Fruit	0.017134	0.037739	0.000070	2
Pawpaws	0.000000	0.000000	0.000000	3
Peaches	0.263056	0.343327	0.655904	12
Peanuts	0.154407	0.265266	0.005614	12
Pears	0.218508	0.240934	1.361074	8
Peas- dried[2]	0.009474	0.006157	0.005053	5[3]
Peas -succulent[2]	0.235239	0.265862	0.167029	8[3]
Pecans	0.006249	0.006157	0.000140	5
Pepper/black	0.001209	0.001092	0.001053	3
Peppers-sweet(garden)	0.080025	0.044890	0.002386	8
Peppers - non-bell	0.019754	0.006357	0.000000	3
Persimmons	0.000403	0.000000	0.005334	3
Pimento	0.003628	0.004270	0.000070	2[1]

Raw Agricultural Commodity	% Contribution to Total Exposure			No. of Field Trials for Tolerance with A U.S. Registration
	1989-91 US Population	1989-91 Children 1-6	1989-91 Infants	
Pineapple	0.160656	0.218192	0.144431	8
Pistachio	0.001411	0.000000	0.000000	3
Plantains	0.013304	0.004866	0.003720	3
Plum	0.062690	0.061972	0.124360	8
Pomegranates	0.000000	0.000000	0.000000	3
Potato	1.791805	1.587823	0.217278	16
Pumpkin	0.010684	0.016784	0.015580	5
Quinces	0.000000	0.000000	0.000000	3
Radishes	0.010684	0.002681	0.000000	5
Radishes-Japanese (daikon)	0.000000	0.000000	0.000000	2 [1]
Raspberries	0.007861	0.003476	0.011650	3 [4]
Rhubarb	0.011691	0.007051	0.000000	2 [1]
Rice	0.463422	0.486456	0.652956	16
Rice-wild	0.001814	0.000199	0.000000	5
Rutabagas-tops and roots	0.002217	0.000000	0.000000	3
Rye	0.013707	0.006853	0.000000	5
Safflower-seed and oil	0.000202	0.000000	0.000000	5
Salsify(oyster Plant)	0.000000	0.000000	0.000000	3
Sesame	0.000403	0.000497	0.000000	3
Shallots	0.000000	0.000000	0.000000	1 [1]
Snowpeas	0.006854	0.005264	0.000000	3
Sorghum (Including Milo)	0.000000	0.000000	0.000000	12
Soybeans	0.801061	0.710290	1.257067	20
Spinach	0.053216	0.052835	0.034037	8
Squash-summer	0.079824	0.042804	0.000000	5
Squash-winter	0.038703	0.015791	0.459189	5
Strawberry	0.099578	0.107954	0.001263	8
Sugar Cane	0.520065	0.576415	0.312933	8
Sugar Apples (Sweetssop)	0.000000	0.000000	0.000000	2 [1]
Sugar-beet	0.443458	0.491502	0.271878	12
Sunflower	0.007055	0.007449	0.000000	8
Sweet Potatoes (Incl. Yams)	0.055433	0.026219	0.355252	8
Swiss Chard	0.001008	0.000099	0.000000	3
Tangelos	0.000000	0.000000	0.000000	3
Tangerine	0.011490	0.016883	0.000000	5
Taro-root	0.002016	0.001092	0.014808	2 [1]
Tomato	1.662796	1.485630	0.218331	16
Turnip	0.021367	0.009931	0.000421	5
Walnuts	0.006854	0.005760	0.000140	3
Watercress	0.001209	0.000000	0.000000	2 [1]
Watermelon	0.141506	0.203096	0.012422	8
Wheat	2.983519	3.370301	0.360305	20

Footnotes

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

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

3.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. and 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 is required for field pea forage and hay with Austrian winter pea the preferred cultivar. Field pea seeds will be considered dried shelled peas and required 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 10 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 obtained 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) is required on mustard greens if a tolerance is sought on the crop subgroup leafy Brassica greens.