application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. An additional copy must be sent to Director, Division of Project Review, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not filed comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–13622 Filed 5–31–00; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[OPP–170005; FRL–6559–3]

Pesticides; Guidance on Pesticide Import Tolerances and Residue Data for Imported Food; Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice and request for comment.

SUMMARY: This document provides detailed guidance on applying current U.S. data requirements for the establishment or continuance of tolerances for pesticide residues in or on imported foods. The purpose of this guidance is to promote greater transparency and provide clear guidance to interested parties on how to obtain an import tolerance. This guidance includes information on how to adapt data requirements for U.S. food uses to import tolerances, both for establishing new import tolerances and for modifying or maintaining existing U.S. tolerances for import purposes when U.S. uses or registrations are canceled. The Agency is soliciting comments on the approach reflected in this detailed guidance.

In addition, the Agency expects to consider certain information on pesticide use outside the U.S. and resulting pesticide chemical residues in or on imported food to establish or modify tolerances when there is a corresponding U.S. registration and use. EPA may also require additional information and/or data to better characterize the nature of residues in or on imports when such information and/or data are necessary to make the required safety finding during registration, reregistration, or tolerance reassessment. This would apply to a limited number of cases when imported commodities comprise a high percentage of U.S. consumption; domestic residue data are not likely to be representative of growing conditions in other countries; and U.S. consumers would likely be exposed to significant residues in imported foods. The Agency is developing criteria to implement this requirement and is soliciting comments.

In addition to meeting the requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), this guidance has been developed consistent with the goals of the North American Free Trade Agreement (NAFTA), including minimizing trade irritants among the NAFTA countries. This document also addresses the U.S. obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures.

DATES: Comments, identified by the docket number OPP–170005, must be received on or before July 31, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Kimberly Lowe, Office of Pesticide Programs, Special Review and Reregistration Division (7508C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, telephone number: 703–308–8059; fax number: 703–308–8041, e-mail address: lowe.kimberly@epa.gov

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

You may be affected by this notice if you sell, distribute, manufacture, or use pesticides for agricultural applications, process food, distribute or sell food, or implement governmental pesticide regulations. Potentially affected categories and entities may include, but are not limited to the following:

Category	NAICS Codes	Examples of Potentially Affected Entities
Food manufacturers	311	Commercial food processors
Pesticide manufacturers	32532	Pesticide registrants Pesticide producers

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this table could also be affected. If you have any questions regarding the applicability of this action to a particular entity, you can consult with the person listed under ''FOR FURTHER INFORMATION CONTACT.''

II. How Can I Get Additional Information or Copies of this Document or Other Documents?

1. *Electronically.* You may obtain electronic copies of this document and various support documents from the EPA Internet Home Page at http://www.epa.gov/. On the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**— Environmental Documents.'' You can also go directly to the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/.

2. *In person or by phone.* If you have any questions or need additional information about this action, you may contact the technical person identified in the ''FOR FURTHER INFORMATION CONTACT'' section. In addition, the official record for this notice, including the public version, has been established under docket control number OPP–170005, (including comments and data submitted electronically as described

below). A public version of this record, including printed, paper versions of any electronic comments, which does not include any information claimed as CBI, is available for inspection in Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Public Information and Records Integrity Branch telephone number is 703–305–5805.

III. How Can I Respond to This Notice?

A. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. Be sure to identify the appropriate docket number (i.e., ''OPP–170005'') in your correspondence.

1. *By mail*. Submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

3. *Electronically*. Submit your comments and/or data electronically by e-mail to: opp-docket@epa.gov. Do not submit any information electronically that you consider to be Confidential Business Information (CBI). Submit electronic comments as an ASCII file, avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on standard computer disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number OPP–170005. Electronic comments on this notice may also be filed online at many Federal Depository Libraries.

B. How Should I Handle CBI Information that I Want to Submit to the Agency?

You may claim information that you submit in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult with the technical person identified in the ''FOR FURTHER INFORMATION CONTACT'' section.

IV. Guidance on Import Tolerances

A. Introduction

This document describes the EPA guidance regarding pesticide residues in or on imported foods. In particular, by this document, EPA is informing interested parties of the steps they must take to obtain a new import tolerance (a tolerance that does not have a related U.S. registration) or to maintain an existing tolerance as an import tolerance when the corresponding domestic use has been canceled. In addition, EPA is proposing guidance identifying the information and data that EPA believes are necessary to accurately reflect residues in or on imported food for certain tolerances with corresponding domestic uses and to make a safety finding for those tolerances. The same food safety standards apply to tolerances proposed for both domestically-produced and imported food; as a result, domestic and foreign growers are treated equally. Interested persons are invited to comment on any aspect of this document, and in particular, on the questions raised in Unit IV.G.

EPA intends to achieve several objectives by describing its historical, current, and proposed process for establishing, modifying and maintaining tolerances with no corresponding domestic registration and for tolerances with domestic registrations:

1. Assure a safe food supply for the general population and sensitive subpopulations in particular, such as infants and children.

2. Target import data requirements to circumstances that are likely to affect the risk assessment.

3. Maintain the Agency's schedule for reassessing tolerances under the Food Quality Protection Act (FQPA).

4. Ensure that tolerance policies remain consistent with international obligations such as the provisions of the World Trade Organization (WTO) Agreements and the North American Free Trade Agreement (NAFTA) chapter on Sanitary and Phytosanitary (SPS) Measures.

5. Promote greater transparency in Agency policies by providing written guidance and soliciting public comment.

A U.S. tolerance (the equivalent of a tolerance is sometimes called a maximum residue limit, or MRL, in other countries) is the maximum residue level of a pesticide permitted in or on food or feed grown in the U.S. and food or feed imported into the U.S. from other countries. Food may not lawfully be sold in, or imported into, the United States if the food contains detectable pesticide residues above the level permitted by a tolerance, or at any level if no tolerance, or exemption from the requirement of a tolerance, has been established. Generally, tolerances are set for raw agricultural commodities and also apply to processed foods derived from the commodities. This is because, in most cases, processing results in residues at or below the levels in the raw commodity; EPA requires processing data to ascertain this. If residues in processed food concentrate to higher levels than in the raw commodity, separate tolerances will need to be established to cover residues in the processed food.

Typically, EPA establishes a tolerance or tolerance exemption for a food commodity at the same time that it registers the use of a pesticide for that commodity in the U.S. Where no U.S. registration exists, interested persons may submit a petition requesting that EPA establish a tolerance or a tolerance exemption for a pesticide residue on a commodity that would allow treated food to be legally imported into the United States. The term ''import tolerance'' is used as a convenience to refer to a tolerance that exists where there is no accompanying U.S. registration. There is no statutory or regulatory distinction between an ''import tolerance'' and any other tolerance issued by EPA.

With this document, EPA provides further clarification of its requirements for import tolerances, and proposes a modification of its approach to registration to permit greater consideration of residues in or on imported food in establishing or maintaining tolerances or tolerance exemptions for food uses registered in the U.S. This document explains the need for foreign residue data for both purposes and a process for the early notification of other countries of the potential for revocation of tolerances following cancellation of a related U.S. registration. This Notice also explains that EPA intends to make use of existing information to the greatest extent appropriate, including data (and associated reviews) that may have been submitted in support of MRLs established by the international Codex Alimentarius Commission, or to regulatory authorities in Canada, Mexico, or other countries.

Also, the U.S. is working with its NAFTA partners in developing import tolerance policies and other related policies that will maintain and enhance food safety while minimizing trade irritants. The publication of U.S. import tolerance guidance is one step in this process.

The remainder of this unit provides information on the legal basis for requiring data for import tolerances and how import tolerances fit in with EPA's general policies on pesticides; a general description of the data requirements for import tolerances; an outline of the types of screening information on residues in or on imported food that EPA is proposing to require; and a brief discussion of EPA's obligations under such international agreements as the WTO and NAFTA SPS Agreements. Unit V. of this Notice provides more specific information on how to apply existing U.S. data requirements to tolerances that do not have corresponding registration for U.S. food uses.

B. Statutory Basis for Guidance

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. Section 408 of the FFDCA authorizes EPA to establish, modify, or maintain tolerances or tolerance exemptions for pesticide residues in or on food. Once established, a tolerance or tolerance exemption applies equally to domestically-produced and imported food. Any food with pesticide residues not covered by a tolerance or tolerance exemption (or with residues in excess of the tolerance) may be subject to regulatory action by the U.S. government (including seizure). Pesticide tolerances and exemptions are enforced by individual states and the U.S. Food and Drug Administration (FDA) for most foods, and by the U.S. Department of Agriculture (USDA) for meat, poultry, and some egg products.

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

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

In granting new tolerances and reassessing existing tolerances to determine if they meet FQPA standards, EPA must consider available information on aggregate non-occupational exposure from the pesticide (including exposure from food, drinking water, and pesticides used in and around the home), cumulative effects from pesticides with a common mechanism or mode of toxicity; the potential increased susceptibility of infants and children or other sensitive subpopulations; and the potential for estrogenic or other endocrine effects.

Three additional provisions of FFDCA as amended by FQPA are particularly important for this import tolerance guidance: Section 408(b)(4) International Standards; section 408(f) Special Data Requirements; and section 408(l)(2) Revocation of Tolerance or Exemption Following Cancellation of Associated Registrations.

In establishing a tolerance, FFDCA section 408(b)(4) requires EPA to determine if the Codex Alimentarius Commission has established a maximum residue level. If EPA does not adopt the Codex level, then the Agency must publish a notice for public comment explaining the reasons for the deviation.

If EPA needs additional data to support the continuance of a tolerance or exemption, but there are no U.S. registrants from whom the Agency can obtain the data under FIFRA, EPA may require data under section 408(f) of FFDCA, and EPA intends to use that authority to impose data requirements. Section 408(f) of FFDCA allows the Agency to publish a Notice in the **Federal Register** describing the type of data needed and inviting persons willing to submit the necessary data to support the tolerance to identify themselves. Tolerances may be revoked if no person commits to supply the necessary data or if the appropriate data are not submitted in a timely manner.

Finally, section 408(l) requires EPA to revoke a tolerance within 180 days of the cancellation of a FIFRA use if the use was canceled for dietary risk reasons.

Companies and others interested in supporting a tolerance for import purposes should familiarize themselves with the changes in FFDCA brought about by FQPA, since these changes will affect how potential risks are assessed and, ultimately, the Agency's decision on whether to grant a tolerance.

C. Summary of Guidance

To establish or modify a tolerance, or to maintain an existing tolerance, EPA must determine that the proposed or existing tolerance is safe under section 408 of the FFDCA as amended by FQPA. This safety finding is based, among other things, on information about the toxicity of the pesticide, likely residues in or on the food in question, and consumption patterns. For new tolerances with no accompanying U.S. registrations, the Agency will continue to require that tolerance petitioners provide EPA with the information and/or data that EPA needs to make the required safety finding. This usually will include residue data representative of the pesticide's use in other countries that export food to the U.S.

In addition, as domestic uses are canceled during the pesticide reregistration process, or for any other reason (other than dietary risk), EPA will consider requests for modifying or maintaining the corresponding tolerance to allow the continued import of treated food into the U.S. As stated above, EPA is required to make a safety finding and may determine that additional data reflecting foreign use patterns and likely residues in or on imported food are necessary for EPA to conclude that the tolerance is safe. For example, if a tolerance has not been reassessed and the corresponding domestic registration is being or has been canceled, old data may not reflect current use patterns, including uses abroad. To determine what data are necessary, EPA will consider information such as that described in Unit IV.D. Therefore, it is important that the data requirements for import tolerances be clearly stated and that the international community understands the need for these data to ensure the safety of imported food for the American public.

Similarly, in those cases where EPA establishes or maintains a tolerance where there is a corresponding registered U.S. food use, the Agency typically has not estimated the specific

contribution to the diet of residues in or on imported food. This is because EPA assumes that residues in or on imported food will be the same as residues in or on food that is domestically-produced; information such as monitoring data is generally consistent with that assumption. However, in some instances this assumption may under- or overestimate residues in or on imported food, and, as such, may under- or overestimate the overall risks from consumption of the imported food. Therefore, the Agency expects to consider additional data and/or information about pesticide use in other countries and residues in or on imported food. Such information may indicate the need to require additional data and/or information when necessary to support the establishment or reassessment of tolerances with corresponding domestic registrations (i.e., to make the required safety finding) such as information on foreign use patterns and residues in or on imported food. Such a requirement for additional information would apply in a limited number of cases in which imported commodities comprise a high percentage of U.S. consumption, domestic residue data are not likely to be representative of growing conditions in other countries, and U.S. consumers would likely be exposed to significant residues in imported foods.

Accordingly, the Agency is issuing current guidance for establishing import tolerances and maintaining or modifying tolerances where the domestic use has been canceled, and soliciting comments on further guidance for determining when data on imported foods are necessary to support establishment of tolerances for selected domestic registrations. Generally, EPA intends to use the same kinds of information and general concepts to determine whether additional data reflecting residues in or on imported food are necessary to modify or maintain a tolerance where the use has been canceled and to establish, modify, or maintain a tolerance with a corresponding U.S. registered use.

1. *Current guidance for establishing, modifying, or maintaining import tolerances*—a. *Establishing new tolerances with no accompanying U.S. registration.* EPA will continue to require toxicology data and data representative of residues in or on imported foods in making the required safety findings. EPA generally requires the same toxicology data and residue data as are needed for U.S. food uses, except that the data requirements covering residues in or on imported food are geared to use conditions in the exporting countries. In the past, these data have been required on a case-by-case basis. Unit V. of this Notice provides more detailed written guidance on the data requirements to establish a tolerance for import purposes.

b. *Modifying or maintaining tolerances for imported food following cancellation of U.S. uses.* Registered pesticide uses may be canceled for a variety of reasons including internal business reasons, dietary risk concerns, or non-dietary risk concerns. In many cases, a tolerance is no longer needed after a registered use in this country is canceled, and EPA routinely proposes to revoke such tolerances. However, use in other countries may continue and, unless a use was canceled due to dietary risk concerns, EPA will consider requests (normally by petition) to modify or maintain a tolerance as an ''import tolerance.'' EPA plans to use a variety of means to provide an opportunity for interested parties to support the modification or maintenance of a tolerance in these circumstances. In cases where a cancellation of a pesticide is for dietary risk reasons, FFDCA section 408(1) requires revocation of the tolerances within 180 days of the cancellation.

When a pesticide is canceled based on non-dietary risk concerns, such as adverse effects on non-target species, the corresponding tolerance may be maintained provided that there is a need for the tolerance because the pesticide is used outside of the U.S. on commodities intended for the U.S. market and a proponent of the tolerance supplies sufficient data or information to demonstrate that a tolerance meets the food safety requirements of FFDCA. EPA's tolerance setting authority is based on food safety considerations. The Agency has no authority to regulate pesticide use in other countries. At the same time, however, EPA promotes public health and environmental protection worldwide by providing information designed to encourage safer, well-informed pest control decisions on an international level, consistent with the Agency's mandates under FIFRA. This includes Agency actions based on non-dietary as well as dietary risks. Whenever EPA takes significant cancellation actions based on non-dietary risks, EPA will notify other countries and share information with other regulatory authorities for their use in deciding whether conditions in their countries warrant continued use of the pesticide. Where appropriate, EPA will also propose to include pesticides canceled, whether or not for non-dietary concerns in the international system of information exchange known as the ''prior informed consent'' system.

When a registrant requests that a registered use be deleted voluntarily, the Agency will propose to cancel that use in a **Federal Register** Notice in accordance with section 6(f) of FIFRA. Following the cancellation of a use, EPA will typically propose to revoke the tolerance. To provide interested parties an early notification of the potential revocation of the tolerance, the section 6(f) Notice will inform the public that once the use is canceled, the Agency may propose to revoke the tolerance unless there is a request to modify or maintain it as an import tolerance. In addition, the interested party must commit to supply the information necessary for the Agency to make a safety finding. The Notice will state the Agency's willingness to consider requests to modify or maintain a tolerance following the cancellation of the accompanying registration and indicate the process for doing so. Interested parties may notify EPA of their interest in supporting maintenance or modification of a tolerance to cover residues in or on imported food in comments on the Notice. EPA will also provide the public with information on the EPA web site (www.epa.gov/pesticides) about the potential loss of the related tolerance and about how to maintain a tolerance as an import tolerance if the corresponding use is canceled. These notices will also be provided to other countries through the WTO notification process.

If EPA receives a request to modify or maintain a tolerance in response to a section 6(f) Notice, the interested party may identify or provide (consistent with relevant provisions of FIFRA) existing domestic or foreign data and the Agency will determine if the data are sufficient. EPA will consider the kind of information specified in Unit IV.D. to determine if additional data and/or information are needed (and data requirements must be satisfied) to support continuation of the tolerance. If so, the Agency may issue a Notice under section 408(f) of FFDCA informing the public of the data requirements and stating the time period for submitting the required data. Persons supporting the maintenance or modification of tolerances to cover residues in or on imported food have the burden of demonstrating the relevance of any existing domestic data to foreign growing conditions.

If EPA does not receive any indication of support for an import tolerance following the cancellation of the registered food use, the Agency will publish a **Federal Register** Notice that

proposes to revoke the tolerance. The Notice will again give interested parties the opportunity to come forward to support the maintenance of the tolerance. To avoid the issuance of the final tolerance revocation, interested parties must demonstrate a need to retain the tolerance and commit to support the tolerance. Retaining the tolerance may likely require submission of data so that EPA can make safety findings under FFDCA. EPA's data requirements for import tolerances are further described in Unit V.

2. *Further guidance under development regarding U.S. registration with an import component.* The Agency expects to require information on residues in or on imported food in a limited number of circumstances when registering new U.S. uses and when reassessing tolerances as required by FQPA. In the past, EPA has not expressly considered the unique contribution of residues in or on imported food when establishing (or reassessing) tolerances with accompanying U.S. registrations. Currently, EPA assumes that the residues in imported commodities will be the same as in domestically-produced commodities. Additional information will be required when EPA's assumption that residues in or on imported foods will be the same as residues in or on domestic foods is not expected to be correct and/or additional data to better reflect residues in or on imports are necessary to support the safety finding. Because, in this instance, EPA's assumption may under- or overestimate risks from imported food, and existing monitoring programs may not provide sufficient information in all cases to support the assumption and safety finding, the Agency is developing criteria to help determine the circumstances in which residue data based on pesticide use on crops destined for import into the U.S. should be required. When imported foods may contribute significantly to dietary exposure to the pesticides, those interested in establishing or supporting continuation of a tolerance with a U.S. registered food use must provide basic screening information about potential residues in imported foods, as discussed below, so that the Agency can determine if additional data are needed.

It is important to emphasize that the Agency expects that additional data will be needed in very limited cases where a high percentage of the commodity is imported potentially resulting in substantial dietary exposure. EPA is seeking comment on the adequacy and appropriateness of requiring this information, as well as on the specific questions posed on this issue later in this document. While seeking comment on this document and developing more formal guidance, the Agency reserves the right to require data based on pesticide use in other countries on a case-by-case basis, e.g., when a high percentage of the commodity is imported, and, thus, such information is clearly necessary to make the required safety findings under FFDCA.

D. Screening Information

The following types of screening information will be considered in establishing or reassessing a tolerance or tolerance exemption to help the Agency decide if additional information or data are needed on imported foods, regardless of whether the data are supporting import tolerance or a domestic registration with a significant import component:

- What international tolerances or MRLs exist?
- Which countries export the commodity to the U.S.?
- Major seasonal variations in imports of the commodity.
- Percent of U.S. consumption which is imported.
- Percent of crop treated in the exporting countries.
- Significance of the food in the U.S. diet (see Table 10 in Unit VII.).
- Effect of processing on the residues.
- Available information on levels of residues found in samples of imported food (based on FDA, USDA, or other monitoring data).
- Other information that would help the Agency determine if residues in or on imported food are likely to contribute significantly to dietary exposure or risk in the U.S. or to differ significantly from residues in or on domestically-produced foods.

Following are two examples of how the Agency may use the above information in determining the need for further data:

Example 1. A petitioner seeks a U.S. registration and tolerance for a new pesticide use on cranberries. Less than 1% of cranberries consumed in the U.S. are imported. Almost all imports are from Canada, where growing conditions (e.g., use patterns, weather conditions, soil type) are similar to those in the U.S. Cranberries account for an extremely low percentage of the U.S. diet. In this case, EPA would probably not require submission of foreign residue data because dietary exposure to residues in imported cranberries is very low and EPA determines that U.S. field trials would be representative of growing conditions in Canada.

Example 2. A petitioner seeks to maintain a tolerance for residues of a pesticide in bananas following the cancellation of the banana use in the U.S. The vast majority of bananas consumed in the U.S. are imported. Bananas are imported from Central and South America, and cultural practices for bananas grown in the U.S. differ from those in Latin America. Existing residue data consist of five U.S. field trials in Hawaii and Puerto Rico. Bananas represent a relatively high percentage of the U.S. diet, especially for children. To assess the safety of the tolerance, EPA would likely require submission of additional residue data based on the pesticide's use in major banana exporting countries for the following reasons: Most of what is consumed in the U.S. is imported and EPA has no data on such foreign uses; cultural practices in other countries appear to differ from those in the U.S.; and bananas represent a relatively high percentage of the diet of a potentially sensitive subpopulation (children). The tolerance petitioner would not necessarily have to conduct new trials; however, since there may be existing, reliable residue data that supported a Codex submission or an MRL approved by another regulatory body.

These examples are only for illustrative purposes to suggest how the Agency might use the screening information in deciding whether to require additional residue data. Other factors that would likely affect the Agency's decision include the toxicity of the chemical, available information on conditions of pesticide use in exporting countries, and available monitoring data.

E. Data Requirements

Import tolerances generally require the same types of data as are needed for tolerances with U.S. registrations, including toxicology data, residue chemistry data, and data representative of actual growing conditions. EPA needs these data to assess the potential dietary risk and to make the required safety finding. EPA does not require worker exposure and environmental fate and effects data to establish import tolerances since these data are not needed to assess dietary risk, although they would be required if the pesticide were to be registered for use in the U.S. The data requirements described in Unit V. interpret 40 CFR part 158 for purposes of characterizing residues in or on imports, and are intended to apply to all new tolerance petitions where there is no U.S. registration and to requests to modify or maintain a tolerance for imports where the

corresponding U.S. use has been canceled.

The data requirements described in this Notice are the existing EPA field trial guidance for U.S. registrations adapted to growing conditions in other countries. In the past, EPA did not have written guidance for the number and location of field trials to support tolerances for residues in or on food imported from other countries. Rather, the Agency provided case-by-case advice on adapting the data requirements to import situations. Unit V. provides written guidance on how to determine the number and location of field trials for new tolerances on imported commodities.

F. Consistency with International Obligations

1. *Codex*. The Codex Alimentarius Commission of the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Food Standards Program establishes international food standards, including maximum pesticide residue limits, to protect public health and promote international trade. It is EPA's policy to harmonize its tolerances with the levels established by Codex provided that the Agency has sufficient information to make a determination that the Codex Maximum Residue Limits (MRLs) will be protective of the health of the U.S. public and meet FFDCA standards. FQPA requires EPA to publish a notice for public comment whenever the Agency establishes a tolerance that differs from an established Codex MRL. EPA may set a tolerance that differs from the Codex MRL if EPA explains the reason for the difference. For example, EPA may determine that the Codex MRL does not meet FFDCA standards or is inadequate in light of pesticide use practices in the U.S.

2. *International trade agreements*. The U.S. is a party to both the North American Free Trade Agreement (NAFTA) and the World Trade Organization (WTO) Agreements. Both agreements contain provisions applicable to Sanitary and Phytosanitary (SPS) Measures that include food safety measures such as tolerances. Under these agreements, individual countries have the right to establish levels of protection for human, animal, or plant life or health that they deem appropriate and to implement measures that will achieve these levels of protection. Measures are to be based on available international standards, including Codex MRLs, but may be more stringent than international standards if there is a scientific justification or to achieve a greater level of protection. Measures are to be based on scientific principles, not be maintained without sufficient scientific evidence, and be based on an assessment, as appropriate to the circumstances, of the risks; may not arbitrarily or unjustifiably discriminate between domestic and imported goods or goods from different importers; and are to be established through an open, transparent process. The NAFTA further states explicitly that efforts toward greater harmonization and equivalence in regulatory standards are to be undertaken ''without reducing the level of protection of human, animal, or plant life or health.''

As stated in this Notice, EPA's policy is to harmonize its tolerances with Codex MRLs to the extent possible, provided that the MRLs achieve the level of protection required under FFDCA. Publication of this Notice will enhance the transparency of EPA's requirements governing pesticide residues in imported foods by providing better guidance on the type of data needed to support a tolerance. The tolerance policies outlined in this Notice are nondiscriminatory and designed to ensure that both domestically-produced and imported foods meet the food safety standards (level of protection) established by the FFDCA. The same food safety standards apply to domestically-produced and imported foods.

3. *NAFTA activities*. As part of NAFTA, a North American Pesticide Initiative was created to improve cooperation and sharing of data reviews for pesticides among the three countries. The U.S. is participating with its NAFTA partners (Canada and Mexico) in harmonizing data requirements and policies to the extent possible. Canada and the U.S. have made substantial progress in harmonizing their data requirements and have established zone maps to permit pesticide residue data from one country to be used by the other for estimating MRLs and tolerances. A similar effort is underway to develop zone maps that will permit the use of data from similar growing regions in Mexico and the U.S. In addition, this U.S. import tolerance guidance is intended to form the basis for a NAFTA guidance on import tolerances. EPA has been working with its NAFTA partners in developing this guidance.

G. Request for Comments

The Agency is interested in comments on this Notice and, in particular, on its proposed guidance for requiring data and information on potential residues in or on imported foods when there is a corresponding U.S. registration. EPA is specifically soliciting comments on the following questions:

1. Under what circumstances should EPA require data reflecting growing conditions in other countries when a pesticide also has U.S. registration for the same food use?

2. Do the data requirements outlined in this Notice provide a sufficient basis for making the food safety determination required by the FFDCA?

3. If a commenter believes that data reflecting growing conditions in other countries should not be required when a pesticide is registered for the same use in the U.S., how should the Agency account for potential exposure to residues in or on imported foods in conducting its dietary risk assessments?

4. Should EPA be concerned with potential shifts in the sources of imported foods and changes in pesticide use practices in exporting countries over time? If so, how frequently should data needs be reassessed? (After an initial tolerance is granted, the crop in question could be grown in other countries that have different application methods and climate, possibly resulting in different residues in or on imported food.)

5. Pesticides with U.S. registrations require periodic review under U.S. laws to ensure that the data supporting the registration (and associated tolerances) continue to meet up-to-date scientific standards. How should EPA ensure that import tolerances, which have no corresponding U.S. registrations, are similarly reviewed and updated? (The Agency notes that FFDCA requires a review of tolerances after five years whenever anticipated residue data are used in risk assessment.)

6. What criteria should be used in deciding if further data are needed to better capture the imported food contribution to dietary risk when there is a tolerance with a corresponding domestic registration?

V. Import Tolerance Data Requirements

The data requirements in this Unit apply to the following two scenarios discussed in Unit IV:

1. Establishing new tolerances with no accompanying U.S. registration.

2. Modifying or maintaining tolerances for imported food following cancellation of U.S. uses.

This part clarifies how existing U.S. food use pesticide data requirements for product chemistry, residue chemistry, and toxicology studies apply to petitions for tolerances to cover residues in or on imported commodities (scenario 1). These data requirements also serve as target data requirements for scenario 2.

There are no additional types of studies needed for import tolerances, compared to tolerances that do have corresponding domestic registrations. In general, fewer studies are required than for tolerances associated with U.S. registrations because only those studies specifically associated with a tolerance petition are required. The guideline requirement that requires the most clarification for import tolerances is OPPTS Guideline 860.1500, Field Trials. These are the core studies from which most tolerance values are estimated.

If a registrant has an existing tolerance and registered U.S. use, but intends to withdraw the registered use and maintain the tolerance for import purposes, the Agency may need additional residue data to better determine the dietary exposure of U.S. consumers to the pesticide. In such cases, the registrant or other proponent of the tolerance is advised to consult with the Agency to determine what studies are required to support the tolerance.

The import tolerance petitioner may not need to conduct new studies to fulfill the data requirements. Interested parties may support a new import tolerance, or support maintenance or modification of an existing tolerance, with studies developed for a registration in another country, for a Codex MRL, and/or in support of the previous U.S. registration and tolerance, provided that they are able to demonstrate the applicability of the studies to the requirements in this Notice. The petitioner or other interested parties may consult with the Agency before submitting the existing studies. All studies must be formatted in accordance with PR Notice 86-5, and, as such, should contain a statement describing the applicability of the U.S. (40 CFR part 160) or Organization for Economic Cooperation and Development (OECD) requirements for Good Laboratory Practices. The Agency strongly recommends that petitioners attach a copy of the study evaluation by the registering country or by Codex to the study report as an appendix.

An earlier version of the import tolerances data requirements included in this unit was presented to the FIFRA Science Advisory Panel (SAP) in June 1997. The SAP was supportive of the approach for determining number and location of field trials and encouraged international harmonization to the extent possible. In addition to the SAP, comments have been received from Canada's Pest Management Regulatory Agency (PMRA) and the American Crop Protection Association (ACPA) and taken into consideration in this Notice.

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

Tolerance petition requirements 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. This information is the same as or similar to information needed to support an existing tolerance where the corresponding U.S. use has been canceled.

1. *Section A—The name, chemical identity, and composition of the pesticide chemical.* Petitioners usually reference product chemistry studies that 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 inert ingredients may be required if List 1 inerts are present in the formulation so that a dietary risk assessment for the inert can be done by the Agency. (A reference for the inert classification system may be found at 54 FR 48314, November 22, 1989)

2. *Section B—The 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 the U.S., the petitioner must submit a description of the use of the pesticide chemical. It is preferable to submit copies of labels 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 plant growth stage), re-treatment interval, application tank-mix preparation, volume of spray mix per unit area, application equipment, and the pre-harvest interval (PHI). The application rates should be expressed in units of pounds active ingredient per acre (or kilograms per hectare). If the pesticide chemical is applied directly to livestock, then the use information should include a description of the application method (dip, spray, ear tag, etc.), amount of active ingredient applied per unit body weight, re-treatment intervals, maximum application rate per year, and the pre-slaughter interval.

3. *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 in Unit VI.

4. *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 Guideline 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 compound and metabolites of concern on the appropriate commodity, and magnitude of residue studies. Specific requirements are further described below in the section on residue chemistry studies.

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

6. *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.

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

B. Toxicology Data Requirements

Table 2 in Unit VI. 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 Unit. In addition to the required studies, 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. The Agency also reserves 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 pesticide in question.

C. Residue Chemistry Data Requirements

Table 3 in Unit VI. lists the Residue Chemistry studies required to support tolerances as outlined in 40 CFR part 158. The data required 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 Unit. Following is a description of the differences in data requirements (compared to requirements for a tolerance associated with a domestic use) for field trials, processing studies, and livestock studies.

1. *Field Trials (OPPTS Guideline 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 the 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 PHI.

The Agency has prepared two tables (Tables 4 and 5 in Unit VI.), that can be used to determine the number of field trials that 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 5 years). Detailed instructions on determining the number and location of field trials and examples are provided in Unit VII. of this document. Table 10 in Unit VII. provides information on relative significance of each food in the U.S. diet.

The U.S. and Canada use zone maps to determine where field trials should be conducted for tolerances associated with a domestic registration. These maps divide North America into regions where growing conditions are similar. Field trials conducted within the same zone are considered interchangeable. In the absence of zone maps for other countries developed using similar principles, the Agency requests data on a country-by-country basis. Trials should be conducted in countries in relative proportion to the amount each country exports into the United States. 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 that export at least 5% of the total amount of a specific 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 OPPTS Guideline 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 Guideline, 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 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 of the total number of trials may be warranted. Petitioners are advised to consult the guidelines or Agency staff if a reduced number of trials is intended.

For crops requiring 8 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).

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 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 more than 50% of the trials to be conducted in the U.S. As mentioned above, 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 underway 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 of the field trials could be conducted in a different country than the one in which the pesticide use is registered. 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, 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.

Generally, 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 review and comment by the Agency.

Table 9 in Unit VII. 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.

2. *Processing Studies (OPPTS Guideline 860.1520).* 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 (OPPTS Guideline 860.1000) lists the processed commodities for which data are required. The petitioner is advised to consult the Agency 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 PHIs may be necessary to ensure that the RAC to be processed bears quantifiable residues.

3. *Nature of the Residue—Animals (OPPTS Guideline 860.1300).* 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 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. EPA will assume that all feed items included in Table 1 of OPPTS Guideline 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 exports of livestock-derived food products or commodities from the countries of interest to the U.S. and the commodity is not a feed item in the U.S.

D. JMPR/Codex Considerations

The Agency requires the submission of complete toxicology studies for import tolerances even if they have 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. However, in the future, 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 conduct a more 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 Unit VIII. 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.

E. 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.

F. Submittal of Samples

Registrants and petitioners are normally required to submit samples of the pesticide technical grade active ingredient (TGAI) under OPPTS Guideline 830.1900 and analytical standards of the parent compound and regulated metabolites under OPPTS Guideline 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 because this is a requirement only for the registration of a product. However, the petitioners are still required to submit the analytical standard under OPPTS Guideline 860.1650 because this is a requirement for a pesticide tolerance petition.

G. Conclusion

Data requirements for a pesticide tolerance in the absence of a U.S. registration (i.e., import tolerance) have been outlined in this part. Before conducting any toxicology, product chemistry, or residue chemistry studies, prospective petitioners are strongly urged to consult the OPPTS Guideline series 870, 830, and 860. Petitioners should submit protocols to EPA for review and comment if they have any questions regarding study design and conduct. The Agency will attempt to harmonize U.S. tolerances with international standards to the maximum extent possible, consistent with the food safety standards of the FFDCA, and is continuing to work towards greater harmonization in international fora.

VI. Tables

The following tables are provided as additional information and are referenced in this guidance document.

TABLE 1.—PRODUCT CHEMISTRY DATA REQUIREMENTS FOR IMPORT TOLERANCES

Guideline No.	Study Title	Application to Import Tolerances	Test Substance [1]
830.1550	Product Identity	No—Product Specific Requirement	N/A
830.1600 830.1620 830.1650	Description of Manufacturing Process	Yes	TGAI
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

TABLE 1.—PRODUCT CHEMISTRY DATA REQUIREMENTS FOR IMPORT TOLERANCES—Continued

Guideline No.	Study Title	Application to Import Tolerances	Test Substance [1]
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	Water Solubility	Yes	TGAI or PAI
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	Applicable to Import Tolerance	Footnote Number
870.1100	Acute oral toxicity—rat	Yes	
870.1200	Acute dermal toxicity	No	1, 2
870.1300	Acute inhalation toxicity—rat	No	1, 2
870.2400	Acute eye irritation—rabbit	No	1, 2
870.2500	Acute dermal irritation	No	1, 2
870.2600	Skin sensitization	No	1, 2
870.3100	90-Day Oral Toxicity—rodent	Yes	
870.3150	90-Day Oral Toxicity—non-rodent	Yes	
870.3200	21-Day dermal toxicity	No	2

TABLE 2.—TOXICOLOGY DATA REQUIREMENTS FOR IMPORT TOLERANCES—Continued

Guideline Reference Number	Study Title	Applicable to Import Tolerance	Footnote Number
870.3250	90-Day dermal toxicity	No	2
870.3465	90-Day inhalation—rat	No	2
870.3700	Developmental toxicity study	Yes	
870.3800	Multi-Generation Reproduction	Yes	
870.4100	Chronic Toxicity	Yes	
870.4200	Carcinogenicity study	Yes	
870.4300	Combined chronic toxicity/carcinogenicity	Yes	
870.5100 to 870.5915	Mutagenicity	Yes	3
870.6200	Neurotoxicity screening battery	Yes	
870.7200	Companion animal safety	No	4
870.7485	Metabolism and pharmacokinetics	Yes	
870.7600	Dermal penetration	No	2

[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] An initial battery of the following three tests must be conducted: (1) Ames assay (*S. typhimurium*), (2) Mammalian cells in culture forward gene mutation assay, and (3) *in vivo* cytogenetics assay. Details of the screening protocol may be found in Addendum 4 to the Series 84 guidelines, Document PB91-158394, available from the National Technical Information Service.
[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]

Required No. of Field Trials for a U.S. Registration	Percentage of Commodity Imported into U.S. (Weight Basis)		
	0–10%	10–35%	35–75%
20	5	16	20
16 (15) [2]	5	12	16

TABLE 4.—NUMBER OF FIELD TRIALS REQUIRED FOR AN IMPORT TOLERANCE (LESS THAN 75% OF CROP AVAILABLE FOR CONSUMPTION IMPORTED INTO U.S.) [1]—Continued

Required No. of Field Trials for a U.S. Registration	Percentage of Commodity Imported into U.S. (Weight Basis)		
	0–10%	10–35%	35–75%
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 OPPTS Guideline 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 greater than 8 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 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 of 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 ages 1 to 6, and infants. Information on percentages in the diet may be found in Table 10 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.

VII. Instructions for Determining Number and Location of Field Trials

Following is a step-by-step guide to calculating the minimum number of field trials that must be conducted using Tables 4 and 5 in Unit VI. and Table 10 in this unit.

1. Average the amount of the crop imported into the U.S. for the last 5 years (on a weight basis) from the countries in which the pesticide is marketed. Averaging over the previous 5 years allows for seasonal variability. Information on agricultural imports 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 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 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 Table 4 in Unit VI. and Table 10 in this unit. Determine the number of field trials required for a U.S. registration for the commodity of interest from Table 10. 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 Table 5 in Unit VI. and Table 10 in this unit. 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 10. Determine the minimum number of field trials from Table 5 in Unit VI. 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 the U.S. represents 5% or more of U.S. imports of the subject crop. 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 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 that export 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. These are for illustrative purposes only. Before submitting data or conducting field trials, petitioners should consult with the Agency.

i. The ABC Chemical Company markets a granular nematicide for use on bananas. This pesticide is marketed in major banana producing countries. ABC Chemical Company would like the U.S. to establish a tolerance for their chemical. No Codex MRL has been set.

a. 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% of the diet for infants. Referring to Table 5 in Unit VI., a minimum of 12 trials would be required.

b. Table 6 below lists the countries and amounts of bananas imported into the U.S. To ensure that all countries that account for greater than 5% of the amount imported are represented, and that the countries with the most production are most heavily represented, 12 trials will have to be conducted (and 24 treated samples analyzed) distributed among exporting companies as listed below. 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 trials
Guatemala—1 trial
Colombia—2 trials
Mexico 1—trial

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

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

a. Approximately 21% of all oranges available in the U.S. (as juice or fresh fruit) over the last 5 years were imported. Referring to Table 10 in this unit, 16 field trials are required for a U.S registration. Using Table 4, oranges fall in the range of 10-35% imported; therefore a minimum of 12 trials (24 samples) must be conducted.

b. The countries that export fresh fruit and juice to the U.S. are listed in Table 7 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.

iii. 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 5 years were imported from Mexico. Referring to Table 10 below, 16 field trials are required for a U.S registration. Using Table 4 in Unit VI, oranges fall in the range of 0-10% imported, Therefore a minimum of 5 trials (10 samples) must be conducted. All 5 trials would be conducted in Mexico.

TABLE 7.—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	(see footnote 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	(see footnote 3)	—	26,332	26,325	0.93
Morocco	—	0	12,841	12,841	0.45
Australia	—	0	9,691	9,691	0.34

TABLE 7.—QUANTITY OF ORANGES AND ORANGE JUICE IMPORTED INTO U.S.—Continued

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
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] 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.

iv. MRE 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.

a. Approximately 2.3% of all cherries available for U.S. consumption over the last 5 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 10 in Unit VII. Referring to Table 4 in Unit VI., a minimum of 3 trials are required for an import tolerance. However since both formulations should be tested, a minimum of 6 trials (12 treated samples) are required, 3 with each formulation.

b. Table 8 below 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 8.—AMOUNT OF CHERRIES IMPORTED INTO THE U.S.

Trading Country	Average Amount Fruit/yr. (short tons)	% of Imports
Chile	1,633	85.50
Canada	252	13.19
Swaziland	12	0.63
Others (<1% each)	13	0.68
Total	1,910	100.00

TABLE 9.—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), Colombia (2), Honduras (2), Guatemala (1), Mexico (1)
Apples	12	Argentina (5), Germany (4), Chile (3)
Stone Fruit		
Peaches	3	Chile (3)
Cherries	3	Chile (2), Canada (1)
Plums	5 [2]	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 that 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.

TABLE 10.—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 U.S. Population	1989-91 Children (ages 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
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

TABLE 10.—PERCENT IN DIET VALUES AND NUMBER OF FIELD TRIALS REQUIRED FOR A TOLERANCE ASSOCIATED WITH A U.S. REGISTRATION FOR MOST COMMODITIES—CONTINUED

Raw Agricultural Commodity	% Contribution to Total Exposure			No. of Field Trials for Tolerance with A U.S. Registration
	1989-91 U.S. Population	1989-91 Children (ages 1-6)	1989-91 Infants	
Cherries (sweet & sour)	0.040517	0.042605	0.014036	8 [5]
Chestnuts	0.000000	0.000000	0.000000	3
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

TABLE 10.—PERCENT IN DIET VALUES AND NUMBER OF FIELD TRIALS REQUIRED FOR A TOLERANCE ASSOCIATED WITH A U.S. REGISTRATION FOR MOST COMMODITIES—CONTINUED

Raw Agricultural Commodity	% Contribution to Total Exposure			No. of Field Trials for Tolerance with A U.S. Registration
	1989-91 U.S. Population	1989-91 Children (ages 1-6)	1989-91 Infants	
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
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 (including 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

TABLE 10.—PERCENT IN DIET VALUES AND NUMBER OF FIELD TRIALS REQUIRED FOR A TOLERANCE ASSOCIATED WITH A U.S. REGISTRATION FOR MOST COMMODITIES—CONTINUED

Raw Agricultural Commodity	% Contribution to Total Exposure			No. of Field Trials for Tolerance with A U.S. Registration
	1989-91 U.S. Population	1989-91 Children (ages 1-6)	1989-91 Infants	
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]
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

TABLE 10.—PERCENT IN DIET VALUES AND NUMBER OF FIELD TRIALS REQUIRED FOR A TOLERANCE ASSOCIATED WITH A U.S. REGISTRATION FOR MOST COMMODITIES—CONTINUED

Raw Agricultural Commodity	% Contribution to Total Exposure			No. of Field Trials for Tolerance with A U.S. Registration
	1989-91 U.S. Population	1989-91 Children (ages 1-6)	1989-91 Infants	
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 (including 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

[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 that may require separate field trials. Petitioners are advised to consult OPPTS Guideline 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 5 trials (and 10 samples) is required on any one blackberry or any one raspberry if a tolerance is sought on ''caneberries.'' A minimum of 3 trials (and 6 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 8 trials (and 16 samples) are required on mustard greens if a tolerance is sought on the crop subgroup leafy Brassica greens.

VIII. Consideration of Codex MRLs When Establishing Import Tolerances

The 1996 FQPA amendments to FFDCA codified a longstanding Agency policy to harmonize U.S. tolerances with Codex MRLs to the extent possible. Recent trade agreements such as the NAFTA and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures further encourage the use of international standards such as Codex MRLs.

When establishing or reassessing tolerances (including import tolerances), the Agency takes into consideration the Codex MRL level, the Codex commodity definition, and the metabolite(s) included in the Codex MRL definition. If use patterns and risk assessments permit, the Agency will harmonize tolerances with the Codex levels. If not, the Agency must explain why they cannot be harmonized, in accordance with FQPA.

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 MRL. During tolerance reassessment, the Agency will evaluate whether the U.S. tolerance can be lowered to the Codex level and still accommodate any existing U.S. use and/or import tolerance needs. If that is not possible, relevant information should 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 the data support the safety findings required by the FFDCA at that level.

In the context of establishing import tolerances, four common situations are presented below that take into consideration the presence or absence of U.S. tolerances and Codex MRLs. The potential effects of Codex MRLs on data requirements for import tolerances are described, as are the Agency's approaches to harmonizing new and existing tolerances with MRLs.

1. *A U.S. tolerance and Codex MRL have been established for the chemical/commodity combination of concern.* This situation might be encountered when a U.S. registration is withdrawn or proposed for cancellation and is most likely to occur during the tolerance reassessment or reregistration process. Depending upon the status of the data base, additional data may be required to support maintenance of the U.S. tolerance as an import tolerance. Persons seeking to maintain the tolerance should review this guidance on the required number and location of field trials when determining what additional studies may be needed to support the tolerance.

During the review of the data base, the Agency will make every attempt to harmonize with the Codex level in all respects, including the numerical level and definition of residue.

2. *A Codex MRL has been established for the chemical/commodity combination of concern, but there is no U.S. tolerance.* This situation may occur when a tolerance petition for imported commodities has been submitted and there are no corresponding U.S. registrations for the commodities 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 proposed tolerance levels with Codex MRLs.

If the following conditions are met, the petitioner may propose the Codex MRL as the tolerance level, and the Agency may be able to complete its assessment of the tolerance based on a more limited review of the residue chemistry data:

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 due to minimal expected exposure to residues in higher consumption commodities (for example, if all residues are non-detectable).

ii. A U.S. use(s) or U.S. tolerance(s) for the subject commodity(ies) 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. Residues resulting from the importation of the subject commodity(ies) meet U.S. food safety standards under FFDCA.

iv. An acceptable analytical method is submitted with the petition (i.e., the method should undergo an independent lab validation and an EPA lab validation if it is not already approved for enforcement, and the applicability of multi-residue method testing for the parent compound and residues of concern should be evaluated).

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 apply. In either case, a dietary risk assessment will be done using the Codex MRL. The Codex MRL will be established as the tolerance if FFDCA food safety standards are satisfied.

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, it will not be adopted as the U.S. tolerance level. In these circumstances, data must be provided to support the higher level before EPA can evaluate the establishment of an import tolerance. The Agency would also recommend that the tolerance petitioner provide the relevant data to Codex to support a revised Codex limit.

3. *A U.S. tolerance has been established but there is no Codex MRL for the chemical/commodity combination of concern.* Assessment of the need for an import tolerance will need to take into account whether the U.S. tolerance supports an existing U.S. use for the commodity in question or whether the U.S. tolerance has been maintained to accommodate residues in or on imported commodities 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. If so, no import tolerance petition is necessary. If not, the data requirements outlined in this guidance apply. Persons supporting maintenance or modification of a U.S. tolerance that has been maintained after cancellation of U.S. uses also may need to provide additional data. Residue field trial data requirements may be partly satisfied by U.S. data, if adequately justified.

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

4. *Neither a Codex MRL nor a U.S. tolerance has been established for the chemical/commodity combination 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 FFDCA food safety standards are met. The Agency also recommends that the petitioner provide the relevant data to Codex to support establishment of a Codex limit for the subject commodities.

Examples:

Following are two examples illustrating the consideration of Codex MRLs and other factors in deciding whether the Agency can conduct a more limited review of an import tolerance petition.

Example 1. 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. and Codex have the same definition of ''olives.'' The U.S. tolerance expression and the Codex MRL definition are compatible. There are no dietary risk concerns with the existing tolerances, and the data base supporting them is up-to-date. There is an acceptable enforcement method in the FDA Pesticide Analytical Manual for plant commodities.

In this case, 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 assessment concludes that there are no dietary risk concerns, no further data would be required.

Example 2. Acme Chemicals would like to obtain an import tolerance for an 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 compound, a sulfoxide, and a sulfone metabolite. The Codex MRL includes the parent only.

This proposed tolerance is not a good candidate for 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 differs from the Codex MRL expression, and the Agency's review must therefore include consideration of harmonization in the residue chemistry assessment.

IX. References

The following is a list of documents that are referenced in this guidance document, and that are available as described in Unit II.

1. PR Notice 96-1, ''Tolerance Enforcement Methods—Independent Laboratory Validation by Petitioner,'' February 7, 1996. (http://www.epa.gov/opppmsd1/PR—Notices)

2. 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. (http://www.epa.gov/opppmsd1/PR—Notices)

3. OPPTS Test Guidelines, Series 830, Product Chemistry (August 1996). (http://www.epa.gov/docs/OPPTS—Harmonized/830—Product—Properties—Test—Guidelines/)

4. OPPTS Test Guidelines, Series 860, Residue Chemistry (August 1996). (http://www.epa.gov/docs/OPPTS—Harmonized/860—Residue—Chemistry—Test—Guidelines/)

5. OPPTS Test Guidelines, Series 870, Health Effects (August 1998). (http://www.epa.gov/docs/OPPTS—Harmonized/870—Health—Effects—Test—Guidelines/)

6. **Federal Register**. 54 FR 48314; November 22, 1989, List 1 and 2 Inert Ingredients.

7. Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation—Human and Domestic Animals. Series 84, Mutagenicity. Addendum 9. (1991). (Available from the National Technical Information Service under order number PB91-158394INZ. To order, call 1–800–553–6847 or e-mail orders@ntis.fedworld.gov.)

X. Intended Legal Effect of this Guidance Document

This document provides detailed guidance for EPA staff and outside parties on how U.S. data requirements apply for the establishment or continuance of tolerances for pesticide residues in or on imported foods. The purpose of this guidance is to promote greater transparency and provide clear guidance to interested parties on how to obtain an import tolerance. As guidance, this document is not binding on either EPA or any outside parties, and this document is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States.

Although this guidance provides information on the applicability of U.S. data requirements for the establishment or continuance of tolerances for pesticide residues in or on imported foods, EPA will depart from its policy where the facts or circumstances warrant. In such cases, EPA will explain why a different course was taken. Similarly, outside parties remain free to assert that the application of this guidance is not appropriate for a specific circumstance or that the circumstances surrounding a specific pesticide demonstrate that this guidance should not be applied.

In addition, the Agency is providing an opportunity for public comment on the guidance provided in this document and may also request feedback through other venues. After reviewing comments received, this document may be revised and the Agency may announce its availability in the **Federal Register**. This guidance may be used by both EPA staff and outside parties in the interim. If additional changes are necessary at some point in the future, the Agency may revise, clarify, or update the text of this guidance without public notice.

XI. Regulatory Assessment

A. General Requirements

As indicated previously, this document provides guidance for EPA staff and outside parties and is not a rulemaking. As such, the regulatory assessment requirements imposed on rulemakings do not apply to this action.

B. Paperwork Reduction Act Notice

Pursuant to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after appearing in the preamble of the final rule, are listed in 40 CFR part 9 and 48 CFR chapter 15, and included on the related collection instrument.

This guidance document does not contain any new information collection requirements that would require additional OMB review and approval. The information collection activities related to the process and informational needs for requesting that the Agency establish or provide an exemption from the establishment of a tolerance or maximum residue level for the use of a pesticide on food or feed crops, which are contained in 40 CFR part 180, are already approved by OMB under OMB control number 2070–0024 (EPA ICR No. 597). The annual respondent burden for the information collection activities in 40 CFR part 180 is estimated to average 1,726 hours per petition, including time for reading the regulations, processing, compiling and reviewing the requested data, generating the request, storing, filing, and maintaining the data.

As defined by the PRA and 5 CFR 1320.3(b), ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of

information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Comments regarding the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, should be sent to the Director, Collection Strategies Division, Office of Environmental Information, U.S. Environmental Protection Agency (Mail Code 2822), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Include the OMB control number in any correspondence, but do not submit the requested information to this address. The requested information should be submitted in accordance with the instructions accompanying the form, or as specified in the corresponding regulation.

XII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Tolerance and tolerances, Import and Imports, Reporting and recordkeeping requirements.

Dated: May 23, 2000.

Marcia E. Mulkey,

Director, Office of Pesticide Programs.

[FR Doc. 00–13708 Filed 5–31–00; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

May 24, 2000.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before July 31, 2000. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications Commissions, 445 12th Street, S.W., Room 1–A804, Washington, DC 20554 or via the Internet to lesmith@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at (202) 418–0217 or via the Internet at lesmith@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–XXXX.

Title: Amendment of the Commission's Rules to Establish New Personal Communications Services, Narrowband PCS.

Form Number: N/A.

Type of Review: New collection.

Respondents: Business or other for-profit; Individuals or households; Not-for-profit institutions; Federal Government; and State, Local or Tribal Government.

Number of Respondents: 1,500.

Estimated Time Per Response: 3.5 hrs. (avg.).

Frequency of Response: On occasion.

Total Annual Burden: 5,250 hours.

Total Annual Costs: $1,050,000.

Needs and Uses: The amendments to the Commission's narrowband Personal Communications Services rules adopted in this proceeding will improve the efficiency of spectrum use, reduce the regulatory burden on spectrum users, encourage competition, and promote service to the largest feasible number of users.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 00–13591 Filed 5–31–00; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission

May 24, 2000.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before July 3, 2000. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Judy Boley, Federal Communications Commission, Room 1–C804, 445 12th Street, SW, DC 20554 or via the Internet to jboley@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judy Boley at 202–418–0214 or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–XXXX.