Pesticide Registration Manual:

Chapter 11 - Tolerance Petitions

Tolerances and Exemptions from Tolerances

This chapter provides information on definitions, interpretative regulations and procedures for filing a petition for establishment of a tolerance or an exemption from the requirement of a tolerance. Read more about tolerances.

Under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA is responsible for regulating the amount of pesticide residues that can remain in or on food or feed commodities as the result of a pesticide application. A tolerance is the maximum residue level of a pesticide (usually measured in parts per million, or ppm) that legally can be present in food or feed.

- If residues of a pesticide exceed the established tolerance, or no tolerance has been established, the crop is considered adulterated and may be seized by the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), or a state enforcement agency.

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCA by, among other things, consolidating EPA's authority for establishing, modifying, and revoking pesticide tolerances under FFDCA section 408. EPA no longer establishes tolerances for pesticides in processed food/feed commodities under FFDCA section 409. Now all tolerances for raw agricultural commodities (RACs) and processed food/feed commodities (if required) are established under FFDCA section 408. Subsequently, the Antimicrobial Regulation Technical Corrections Act (ARTCA) of 1998 amended the FFDCA by excluding certain antimicrobial pesticides from FFDCA section 408. Tolerances for residues of those pesticides are set by FDA under FFDCA section 409.

- As EPA amends or renews tolerances in accordance with FQPA, the Agency will issue those amendments and renewals in 40 CFR Part 180.

Pesticide Tolerances

Foods in interstate commerce containing pesticide residues must be covered by pesticide tolerances. Pesticide residues may result from:

- direct treatment of target crop or treatment to seed stock with a pesticide (whether that treatment occurs in the United States or a foreign country);
- use of antimicrobial pesticides in food processing (under ARTCA, tolerances for many antimicrobial uses are set by FDA under FFDCA section 409);

- inadvertent carryover of residues in the soil to rotational or replacement crops;
- runoff and spray drift;
- consumption of treated commodities by livestock (including primary or secondary residues in meat, milk, poultry, and eggs); and
- post-harvest applications.

Tolerances for residues in raw commodities apply to those same residues in processed commodities. If the residues in processed commodities may exceed the residues in the raw commodity, a separate processed food tolerance is needed.

Registration of a pesticide is not, however, a prerequisite for establishing a tolerance. For example, EPA may establish a temporary tolerance under FFDCA section 408(r) to permit the experimental use of a non-registered pesticide, or EPA may establish a tolerance for a pesticide residue resulting from the use of the pesticide in food or feed production in a foreign country.

New Pesticide Registrations and Amendments to Existing Registrations

A tolerance or the exemption from the requirement of a tolerance must be established for each active and inert ingredient in the formulation before a pesticide can be registered for use on a food or feed crop, or for use in a food processing or storage area. In addition, an amendment to an established tolerance may be required if an amendment is proposed for a currently registered use that might result in residue levels higher than the established tolerance. Examples include an increase in the dosage rates and/or an increase in the frequency of application. To enable the Agency to establish or amend a tolerance or tolerance exemption, a tolerance petition needs be submitted.

Temporary Tolerances for Experimental Use Permits

An applicant must obtain a temporary tolerance or exemption from the requirement of a tolerance to accompany an experimental use permit (EUP) for uses that have not been registered if the crop(s) treated during the EUP is (are) not destroyed or otherwise prevented from entering food or feed in interstate commerce

Under FFDCA section 408(r), EPA may establish a temporary tolerance or exemption from the requirement of a tolerance on its own initiative or at the request of any person who holds an EUP. A temporary tolerance allows participants in the EUP program to market or use commodities harvested from the EUP test plots.

- The petition for the temporary tolerance must be submitted with the application for the experimental use permit (Chapter 12).

Tolerances for Use of Pesticides Under an Emergency Exemption

A time-limited tolerance or exemption from the requirement must be established for pesticides approved for use on food or feed crops under emergency exemptions according to FIFRA section 18).

Import Tolerances

Residues of a pesticide not registered for use in the United States may be present in raw agricultural commodities (RACs) and processed foods produced abroad and imported into this country if a tolerance has been established for those residues and the residues are within the tolerance.

- Under FFDCA section 408, these imported commodities are considered adulterated unless the Agency has established a tolerance for the pesticide on that commodity and the residues are within the tolerance.

The requirements of section 408 of the FFDCA apply equally to domestically produced and imported food and feed found to contain pesticide residues. Therefore, even though the use of a pesticide in a foreign country is not subject to EPA registration requirements under FIFRA, a pesticide residue in imported food or feed must conform with a tolerance or tolerance exemption established by EPA.

Shipments of imported food/feed items found to have pesticide residues for which a tolerance or exemption from the requirement of a tolerance has not been issued will be held up and the importer required to:

1. file for a tolerance or exemption from a tolerance;
2. return the shipment to the country of origin; or
3. destroy the shipment.

Registrants who wish to submit an import tolerance petition under NAFTA (North American Free Trade Agreement) should refer to the NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada (December 2005) announced in the *Federal Register* on April 5, 2006 (71 FR 17099). This document finalized the requirements originally proposed in the Federal Register on April 16, 2003 (68 FR 18638). For more information, see the "Questions and Answers at the NAFTA Guidance on Data Requirements for Pesticide Import Tolerances" Web page developed by EPA.

Tolerance-Setting Requirements for Inert Ingredients

Inert ingredients in pesticide product formulations are regulated under both FIFRA and FFDCA (Chapter 8).

Inert ingredients in products labeled for food use must have a tolerance or exemption from tolerance before the product can be registered. Under the FFDCA, both the active and inert ingredients in a pesticide need a tolerance or an exemption from tolerance. Further, regulations found in 40 CFR 152.50(i) require that inert ingredients, as well as active ingredients, in a pesticide product must have all needed tolerances or exemptions for tolerances before the pesticide can be registered under FIFRA. A statement must be submitted indicating whether a tolerance or exemption from the requirement of a tolerance has been issued by the Agency under section 408 of FFDCA if the proposed labeling bears instructions for use of the product on food or feed crops or if the intended use of the product may result directly or indirectly in pesticide residues in or on food or feed.

If a tolerance or exemption from the requirement of a tolerance has not been issued for such residues, an application must be accompanied by a petition for establishment of appropriate tolerances or exemptions from the requirement of a tolerance in accordance with 40 CFR Part 180 (tolerance or exemption petitions).

- EPA will not register a pesticide product for food/feed uses unless all of the inert ingredients in the product have been approved for use under the FFDCA on food/feed items.
- Refer to 40 CFR 180.910 – 180.960 for a listing of the inert ingredients that have been approved for use under the FFDCA on food/feed items.

Adjuvants

If the use of an adjuvant may result in detectable residues on food, the applicant should contact the EPA product manager or registration ombudsman (Chapter 21) prior to submitting the application to discuss the potential need for a tolerance.

Antimicrobials

EPA has jurisdiction for certain food contact sanitizing solutions under FIFRA and FFDCA section 408. Permitted active and inert components of food contact sanitizing solutions are found in 40 CFR 180.940, 180.950 and 180.960.

Filing a Petition

Procedures for filing a petition requesting the establishment or amendment of a tolerance, a temporary tolerance, an exemption from the requirement of a tolerance, or a temporary exemption from a tolerance are described in detail in 40 CFR 180.7 and below in the section titled "Completing the Application".

Additional information concerning requests for temporary tolerances, or a temporary exemption from a tolerance in conjunction with an experimental use permit, can be found in 40 CFR 180.31.

There is no application form for petitions. Requests must contain the information listed in 40 CFR 180.7. Please refer to PR Notice 97-1 for information on filing a tolerance petition under FQPA. General information on the format recommended by the Agency to submit this information is provided below.

Completing the Application

In order to assure expeditious processing, the petition should present the information required in 40 CFR 180.7 in the following format:

Summary

The Federal Food, Drug and Cosmetic Act requires that the petitioner submit an informative summary of the petition and the data, and any other information and arguments submitted or cited in support of the petition (40 CFR 180.7(b)(1) and (2)). Both a paper and electronic copy of the summary should be submitted. The electronic copy should be formatted according to OPP's current standard for electronic data submission and the Notice of Filing. The petition must include a statement that the petitioner agrees that such summary and any information it contains may be published as part of the notice of filing of the petition to be published under FFDCA section 408(d)(3) and as part of a proposed or final regulation issued under FFDCA section 408. The Agency will use this summary to provide the

public with information concerning the petition. The summary will be included in the EPA's electronic public docket, and the Notice of Filing of the petition published in the Federal Register will refer interested parties to the summary in the docket.

Section A

Include the name, chemical identity, and composition of the pesticide chemical (40 CFR 180.7(b)(3)). For EPA to assess the composition of the pesticide, information is required on the manufacturing process, chemical analysis of the active ingredient, certified limits for ingredients of a product, and analytical methods to determine the composition of the pesticide. Please refer to 40 CFR 158.300 - 158.355 and Product Chemistry Data Requirements and OPPTS Harmonized Guidelines Series 830 for more detailed information.

Applicants are encouraged to use the study profile templates in developing their manufacturing and chemical analysis study documents. These templates provide a summary of the study that if submitted electronically with the study report, can be used by the Agency to efficiently develop its own review of the study and may be found by going to the Study Profile Templates Web page.

Important Note: EPA evaluates the composition data to determine whether impurities could constitute a significant component of the residues in food and feed commodities. Impurities that arise in the manufacture of pesticides can become a residue problem if they are not identified before tolerances are established. Dioxins and nitrosamines are the best-known examples of significant impurities of toxicological concern. If impurities are at levels that may lead to toxicologically significant residues in crops or the environment, then adjustments to the manufacturing process or additional purification steps will be necessary to reduce the impurities to a safe level. Refer to PR Notice 96-8.

Section B

Indicate the amount, frequency, and timing of application of the pesticide chemical (40 CFR 180.7(b)(4)). This refers to the directions for use, dosage rates, number of applications, restrictions, pre-harvest intervals, and times of application proposed for inclusion on the label of the product to be marketed.

Section C

Include the full reports on investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting the tests and investigations (40 CFR 180.7(b)(5)). Refer to 40 CFR 158.500, Toxicology Data Requirements (for antimicrobial pesticides,40 CFR 161.340) and OPPTS Harmonized Guidelines, Series 870, for the types of toxicity data that are needed to support a petition request. The required data are identified under the "Food Crop" headings. Include in this section such information that may be required on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or

other endocrine effects (40 CFR 180.7(b)(12)) and information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue (40 CFR 180.7(b)(13).

Applicants are encouraged to use the study profile templates in developing their toxicity study documents. These templates provide a summary of the study that if submitted electronically with the study report, can be used by the Agency to efficiently develop its own review of the study and may be found by going to the Study Profile Templates Web page.

Section D

Include the results of tests on the amount of residue remaining, including a description of the analytical method used (40 CFR 180.7(b)(6) and 40 CFR 180.7(b)(10)). Information on testing for the amount of residue remaining in the raw agricultural commodity or processed food or feed, when the pesticide is applied according to the proposed label directions, is provided in 40 CFR 180.34 *Tests on the amount of residue remaining*, 40 CFR 158.1400 (for antimicrobial pesticides, 40 CFR 161.240*), Residue Chemistry Data Requirements*, and the OPPTS Harmonized Guidelines, Series 860.

Applicants are encouraged to use the study profile templates in developing their residues and analytical methods study documents. These templates provide a summary of the study that if submitted electronically with the study report, can be used by the Agency to efficiently develop its own review of the study and may be found by going to the Study Profile Templates Web page.

Submitting Analytical Methods for Use in Tolerance Enforcement

Applicants will need to develop and submit accurate and precise analytical methods for identifying and measuring the amount of pesticide residues in the agricultural commodity and processed foods (40 CFR 180.7(b)(9)).

Those methods need to be practical in order to be used in tolerance enforcement and should meet all of the specifications for pesticide residue methods identified in the Residue Chemistry Test Guidelines, OPPTS Series 860.

- The enforcement analytical method cannot be claimed Confidential or Trade Secret.

In addition, petitioners should submit pesticide validation data showing the results from their own (or a contract) laboratory, as well as the results from an additional independent laboratory that confirms those results. Further, it is recommended that tandem-stage MS (e.g., LC-MS/MS or GC-MS/MS) methods monitor two ion transitions to include both identification and confirmation of that identification, as this is the generally recognized standard for regulatory monitoring.

The exact procedure for conducting an independent laboratory validation (ILV) can be found in OPPTS Harmonized Guidelines, Series 860, Guideline 860.1340 and PR Notice 96-1. Additional information can be found in the Residue Analytical Methods Index.

Section E

This section details the practical methods for removing residues that exceed any proposed tolerance (40 CFR 180.7(b)(8)). Tolerances are usually set at levels that are adequate to cover residues that are likely to result from a proposed use without any special processing of the commodities to reduce residues to the tolerance level.

Section F

This section includes proposed tolerances for the pesticide chemical (40 CFR 180.7(b)(7). Tolerances should be proposed in terms that best represent the total residues on the raw agricultural commodity, whether it be the parent pesticide, altered forms of it, or both.

An exemption from the requirement of a tolerance may be proposed when appropriate.

- According to 40 CFR 180.900, an exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no hazard to human health.

When an exemption is proposed, data may be necessary to show the level of residues expected.

This section also includes information concerning any maximum residue level established by the Codex Alimentarius Commission for the pesticide chemical residue addressed in the petition. If a Codex maximum residue level has been established for the pesticide chemical residue and the petitioner does not propose that this level be adopted, a statement explaining the reasons for this departure from the Codex level (40 CFR 180.7(b)(14) should be provided.

Section G

This section presents the reasonable grounds in support of the petition. Such reasons should include a rationale of how the residue data support the proposed tolerance, brief discussions on the adequacy of the analytical method with respect to sensitivity and determination of total toxic residues, an explanation of any aberrant residue values reported, an explanation for the omission or substitution of required data or information, discussion of the fate of the pesticide in the environment (i.e., soil persistence, contamination of groundwater or runoff water), and any residue considerations applicable to the proposed use. In addition, a

summary of the grounds for safety of the proposed tolerance, based on the toxicology data submitted under Section C, may also be included.

Important Note: If EPA does not receive all of the items identified above listed in 40 CFR 180.7, the petition and application will be rejected at the end of the 21-day initial content screen under PRIA as described in Chapter 5. Petitioners are encouraged to contact their registration ombudsman with any questions on required testing or formatting prior to submitting an application or petition.

Supporting Data

Three copies of any data required in support of the petition must be submitted in accordance with the data formatting requirements set forth in PR Notice 86-5.

Registration or Amendment under FIFRA Section 3

Except in certain instances, a petition request must be accompanied by an application for registration, an application to amend the registration of a currently registered product, or an experimental use permit for the uses proposed in the petition. A request for an import tolerance generally would not require an accompanying application for registration.

Fee Requirements

Refer to Chapter 5 for detailed information on the Pesticide Registration Improvement Act of 2003 (PRIA), which was reauthorized by the Pesticide Registration Improvement Extension Act of 2012 and how this legislation has created a registration service fee system for specific pesticide registration, amended registration, and tolerance-setting actions.

Fees are assessed for specific EPA review actions for conventional chemical pesticide products, antimicrobial products, and biopesticide products. In return, EPA is obligated to perform certain review functions and make regulatory determinations within a specific timeframe.

Please contact the appropriate Ombudsman for the type of pesticide product (or new active ingredients) or, alternatively, the Product Manager or Branch Chief (Chapter 21) responsible for the pesticide (for existing active ingredients) for questions concerning:

- whether a petition for a tolerance is required;
- the appropriate fee;
- how to submit a request for a petition for a tolerance and/or application for product registration; or
- what data are required to support a petition for tolerance and/or application for product registration.

If the petition request involves a new chemical not yet assigned, then the inquiry should be directed to the Ombudsman.

References Cited in Chapter 11

Refer to Chapter 19 for information on the source of these documents.

Code of Federal Regulation, Title 40

- Part 158 - Data Requirements for Registration
- Part 161 – Data Requirements for Registration of Antimicrobial Pesticides (Currently being revised, refer to last proposed revision in the Federal Register of March 11, 2005 (70 FR 12276)
- Part 180 - Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Foods

Code of Federal Regulation, Title 21

- Part 178 –Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Food Quality Protection Act of August 3, 1996

Federal Food, Drug and Cosmetic Act

- Section 408 – Tolerances and Exemptions for Pesticide Chemical Residues

OPPTS Harmonized Test Guidelines

- 830 Series - Product Properties Test Guidelines
- 860 Series - Residue Chemistry Test Guidelines
- 870 Series - Health Effects Test Guidelines

Federal Register Notices

- NAFTA Guidance Document on Requirements for Tolerances on Imported Commodities in the U.S. and Canada: Notice of Availability (PDF) (1 pp, 139 K, About PDF), April 5, 2006 (71 FR 17099).
- Inert Ingredient Tolerances (PDF) (6 pp, 234 K, About PDF), July 24, 2000 (65 FR 45569)

NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada (December 2005) dated December 2005

PR Notices

- 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)
- PR Notice 96-1 -Tolerance Enforcement Methods – Independent Laboratory Validation by Petitioner
- PR Notice 96-8 - Toxicologically Significant Levels of Pesticide Active Ingredients
- PR Notice 97-1 - Agency Actions under the Requirements of the Food Quality Protection Act

Antimicrobial Regulation Technical Corrections Act of 1998 amending FFDCA

Indexes to Part 180 Tolerance Information for Pesticide Chemicals in Food and Feed Commodities

Pesticides and Food: What the Pesticide Residue Limits are on Food

Food and Feed Commodity Vocabulary