

**§ 165.1312 Security Zone; Portland Rose Festival on Willamette River.**

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(d) *Enforcement period.* This section is enforced annually in June from the first Wednesday in June falling on the 4th or later through the following Monday in June. The event will be 6 days in length and the specific dates of enforcement will be published each year in the **Federal Register**. In 2005, the zone will be enforced on Wednesday, June 8, through Monday, June 13.

Dated: June 1, 2005.

**Paul D. Jewell,**

*Captain, U.S. Coast Guard, Captain of the Port, Portland, OR.*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 9, 23, 163, 177, 178, 179, and 180**

[OPP-2003-0176; FRL-7706-9]

**Updating Generic Pesticide Chemical Tolerance Regulations**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is updating generic provisions of its procedural regulations pertaining to pesticide chemical tolerances and exemptions from the requirement of a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act. This update is necessary due to various changes made in the underlying statute by the Food Quality Protection Act of 1996. The amendments are primarily administrative in nature. EPA believes that these revisions will clarify the regulations and reduce confusion for users.

**DATES:** This final rule is effective August 8, 2005.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number OPP-2003-0176. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket/>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard

copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:**

Jonathan Fleuchaus, Office of General Counsel, Mail code 2333A, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564-5628; fax number: (202) 564-5644; e-mail address: [fleuchaus.jonathan@epa.gov](mailto:fleuchaus.jonathan@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturer (NAICS 311)
- Pesticide manufacturer (NAICS

32532)

This listing 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 unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Access Electronic Copies of this Document and Other Related Information?*

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgrst/>. A frequently updated electronic version of 40 CFR is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

**II. Background**

In the **Federal Register** of October 8, 2004 (69 FR 60320) (FRL-7308-2), EPA proposed to amend various sections of 40 CFR parts 9, 23, 163, and 177-180 pertaining to pesticide chemical tolerances to make them consistent with

the changes to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, contained in the Food Quality Protection Act of 1996 (FQPA). These proposed changes were primarily procedural in nature.

Two substantive comments were received on the proposal. EPA's response to these two comments is contained in Unit IV. In brief, neither of these comments objected to the changes proposed by EPA; rather, the commenters argued that EPA should have made further changes to the tolerance regulations. As explained in Unit IV., EPA believes that certain additional changes in this regulation are merited based on the comments.

Further, as explained in Unit III., EPA has identified several additional minor changes to the tolerance regulations that help to conform the existing tolerance regulations to the changes made by the FQPA.

Accordingly, other than the modifications identified in Units III. and IV., EPA is adopting in the final rule its revisions to the FFDCA tolerance regulations as proposed.

**III. Additional Changes To Tolerance Regulations Identified by EPA**

EPA proposed to amend 40 CFR 178.37(c) by removing language that specified that the effective date for an order responding to objections "must not be earlier than the 90th day after it is published unless the order contains findings as to the existence of emergency conditions that necessitate an earlier effective date." See 40 CFR 178.37(c). The 90-day limitation on effectiveness was drawn directly from FFDCA section 408 prior to its amendment by the FQPA. Specifically, prior section 408(d)(5) stated that "[n]o order [following a hearing on a tolerance regulation] shall take effect prior to the ninetieth day after its publication, unless the Administrator finds that emergency conditions exist necessitating an earlier effective date, in which event the Administrator shall specify in the order of his findings as to such conditions." 21 U.S.C. 346a(d)(5) (1994). That language, however, was dropped from section 408 upon its amendment by the FQPA. See 21 U.S.C. 346a(g)(2)(C). Similar language requiring a 90-day delay in effectiveness also appears in 40 CFR 179.105(b)(ii). EPA inadvertently missed this obsolete requirement in 40 CFR part 179 in issuing its proposal. Because removal of this language is consistent with the revised statute and the proposal, EPA is deleting the 90-day limitation on effectiveness from 40 CFR 179.105(b)(ii) as well as from 40 CFR 178.37(c).

The second change identified by EPA is to amend the authority citation for parts 9, 23, 178, and 179 to delete the reference to FFDCA section 409. Following the FQPA's consolidation of the authority over pesticide chemicals in section 408, these parts no longer rely on, or pertain to, FFDCA section 409.

The third change identified by EPA is to amend 40 CFR 180.7(h) to include among the options that the Administrator has in ruling on a petition to establish, modify, or revoke a tolerance the option of denying the petition. This option was explicitly added by the FQPA in section 408(d)(4)(A)(iii).

Finally, EPA has added a definition for the abbreviation "FFDCA" in part 180, and revised the definitions for "pesticide chemical" and "pesticide chemical residue" to adopt the modifications to these definitions enacted by the Antimicrobial Regulation Technical Correction Act of 1998, Public Law 105-324, 112 Stat. 3035, and to cross-reference the existing regulatory exceptions to these definitions in 40 CFR 180.4.

#### IV. Response to Comments

##### A. Comment Concerning Filing Time for Judicial Review

Edward C. Gray questioned whether the proposed amendments to 40 CFR 23.10 would clarify when a party needs to file a judicial challenge to a final order on a tolerance regulation or petition denial so that party would come within the 10-day window prescribed in 28 U.S.C. 2112 to address the "races to the courthouse" problem. Pertinent background information helps to explain Mr. Gray's concern.

Section 2112 of Title 28 of the United States Code addresses various procedural requirements pertaining to judicial review of agency orders including what United States Circuit Court of Appeals will hear a case when a challenge to an agency order or rule is filed in multiple circuit courts. Prior to the 1988 amendments to 28 U.S.C. 2112, section 2112 specified that if review of an agency order or rule was sought in more than one circuit, the circuit where a petition for review was first filed would hear the challenge. To avoid the "races to the courthouse" that were produced under this procedure, section 2112 was amended in 1988 to establish a random selection scheme to deal with filings in multiple circuits. S.Rep. No. 100-263, pp. 2-4, 1987 U.S.C.A.N. 3198, 3198-3201 (1987). Under amended section 2112, if an agency receives two or more petitions for review involving at least two circuits

within 10 days of "issuance of an order," the agency is required to notify the judicial panel on multi-district litigation of the fact that there have been multiple filings and provide the panel with the petitions. 28 U.S.C. 2112(a)(3). The judicial panel is then required to select by "random" one of the circuits in which a petition was filed to hear all of the petitions.

Prior to the 1988 amendment to 28 U.S.C. 2112, various agencies, including EPA, promulgated rules in an attempt to mitigate "races to the courthouse" to challenge agency orders and rules. In 40 CFR part 23, EPA generally specified that the time and date of the entry or promulgation of an order or rule for the purpose of judicial review is 1 p.m. eastern time on the date that is 2 weeks after the date on which the order or rule is published in the **Federal Register**. Although these regulations did not eliminate races to the courthouse, they at least provided all parties with fair notice of when the starting gun would be fired. A specific provision in 40 CFR part 23 addressed orders issued under the FFDCA. See 40 CFR 23.10.

Upon amendment of section 2112 in 1988, EPA promulgated a new section to 40 CFR part 23 specifying the manner in which service of petitions should be filed with the Agency so that the EPA could comply with section 2112's new requirement that an agency, whose order or rule is challenged in more than one circuit court, file the multiple petitions for review with the judicial panel on multi-district litigation. In promulgating this new section of 40 CFR part 23, EPA made clear that, out of consideration of fairness to all parties, it intended to leave in place the existing sections of 40 CFR part 23 establishing a 2-week delay between publication of an order or regulation and the time when the order or regulation could be challenged. As EPA explained: "In other words, agency actions covered under these sections will continue to be deemed 'final' for purposes of judicial review (and the ten-day period for petitions for review to enter the random selection process will begin) at 1:00 p.m. fourteen days after the date of publication or date of signature." (53 FR 29320) (August 3, 1988).

40 CFR 23.10 currently specifies that "the time and date of the entry of an order" issued under the FFDCA is 2 weeks after publication. EPA's proposed amendment to 40 CFR 23.10 principally involved conforming the statutory references in 40 CFR 23.10 to the FQPA's structural change of moving the judicial review provision in FFDCA section 408 from subsection (i) to

subsection (h). EPA did not propose to change the "time and date of the entry of an order" language.

Mr. Gray contends that, because EPA's regulations speak in terms of "entry" of an order and the United States Code uses the word "issuance," there could be confusion about when a petition for review must be filed to come within the 10-day window provided by 28 U.S.C. 2112. Mr. Gray suggests deleting 40 CFR 23.10 and amending the relevant portions of 40 CFR parts 178, 179, and 180 to make clear that an order or regulation is considered "issued" at the time of publication. As Mr. Gray explains, a court may determine that "issuance" occurs prior to "entry," thus penalizing those filers who delay action based on 40 CFR 23.10. Alternatively, a party who files within 10 days of publication may have the filing ruled to be premature, and thus not within 28 U.S.C. 2112's 10-day window, if a court treats "issuance" and "entry" as equivalent under 40 CFR 23.10.

In light of Mr. Gray's comments, EPA has reviewed again the statutory provisions in section 408 pertaining to the timing of judicial review; the requirements in 28 U.S.C. 2112; EPA's existing regulations on judicial review of FFDCA actions in 40 CFR parts 178, 179, and 180, and on "races to the courthouse" in part 23; and EPA's proposals with regard to these regulations.

This review has revealed an oversight in EPA's proposal with regard to the timing of the filing for petitions for judicial review. Prior to the passage of the FQPA, section 408 specified that petitions for judicial review must be filed "within sixty days after *entry* of [an appropriate] order." 21 U.S.C. 346a(i) (1994) (emphasis added). FQPA amended this language to specify in section 408(h) that a petition must be filed "within 60 days after *publication* of [an appropriate] order or regulation." 21 U.S.C. 346a(h)(1) (emphasis added). EPA's existing regulations in parts 23, 178, and 179 pertaining to judicial review for section 408 orders reflect the focus on "entry," as opposed to "publication," in the pre-FQPA statute. See 40 CFR 178.65 and 179.125. In proposing to amend its FFDCA regulations, EPA overlooked this change. Correcting 40 CFR parts 178 and 179 to reflect the change to "publication" as the starting point for the running of the 60-day clock is easy enough. EPA proposed that these provisions retain existing language stating that various EPA orders shall be final and reviewable "as of the date of entry of the order, which shall be

determined in accordance with §§ 23.10 and 23.11 of this chapter,” and that petitions for judicial review must be filed within 60 days of the “entry of the order.” In the final rule, EPA is amending 40 CFR 178.65 and 179.125 to state that the specified orders and regulations are final and reviewable “upon publication” and that petitions for review must be filed within 60 days from “publication.” The reference to 40 CFR part 23 is dropped because the statute now establishes publication as the date from which the 60-day clock for filing petitions for judicial review begins to run.

As to 40 CFR 23.10, the matter is only slightly more complicated. EPA believes two changes are appropriate here. First, to bring 40 CFR 23.10 into step with 28 U.S.C. 2112, the reference in 40 CFR 23.10 to “entry” of an order is being changed to “issuance” of an order. Second, 40 CFR 23.10 is amended to make clear that it is not defining the date of issuance of an order for the purposes of determining the time for filing a judicial review petition under FFDCA section 408(h) but rather for the purposes of determining the date upon which the 10-day clock established in 28 U.S.C. 2112 begins to run. Although there is some merit to Mr. Gray’s suggestion to simply delete 40 CFR 23.10, EPA believes that it is clearer to retain 40 CFR 23.10 with the substitution of the term “issuance” for “entry.” Additionally, EPA is reluctant to reverse, in the context of action pertaining to a single statute, the prior Agency-wide decision to retain the additional 2-week period prior to the beginning of the 28 U.S.C. 2112 10-day clock. The revised 40 CFR 23.10 is amended to read:

Unless the Administrator otherwise explicitly provides in a particular order, the time and date of the issuance of a regulation under section 21 U.S.C. 346a(e)(1)(C), or any order under 21 U.S.C. 346a(f)(1)(C) or 21 U.S.C. 346a(g)(2)(C), or any regulation that is the subject of such an order, shall, for purposes of 28 U.S.C. 2112, be at 1 p.m. eastern time (standard or daylight, as appropriate) on the date that is for a **Federal Register** document, 2 weeks after the date when the document is published in the **Federal Register**, or for any other document, 2 weeks after it is signed.

EPA believes that, under this language it will be clear, that the 10-day window created by 28 U.S.C. 2112 will not begin to run until 2 weeks after publication of the FFDCA rule or order in the **Federal Register**. At the same time, EPA regulations in 40 CFR parts 178 and 179 make clear that the 60-day period for seeking judicial review of an order or regulations under section 408(h)(1) begins upon publication of the order or

regulation. No change is required in 40 CFR part 180 because the provision addressing judicial review in that part does not address the timing for the filing of a petition.

On a related matter, EPA would note that its interpretation of section 408(h)(5) as mandating the exclusivity of the judicial review provision in section 408(h) as to tolerance-related issues was confirmed by a federal district court in *New York v. EPA*, No. 03 Civ. 7155 (GEL) (S.D.N.Y. July 29, 2004). In that case, the court held that parties wishing to challenge tolerances or tolerance reassessment decisions finding a tolerance to be safe must first exhaust the petition procedures in section 408(d), and the objection procedures in subsection 408(g), before seeking judicial review.

#### *B. Comment on Pesticide Residues in Processed Foods*

The Pesticide Policy Coalition, representing various food, agriculture, and pesticide manufacturer organizations, filed a detailed comment regarding pesticide residues in processed food. The PPC raised two issues with regard to EPA’s tolerance regulations. First, the PPC is concerned that EPA’s traditional practice of evaluating the need for and establishing tolerances for only a select group of dried commodities means that many dried commodities may have violative pesticide residues. Second, the PPC is concerned that EPA’s proposal did not respond to the FQPA’s removal of the “ready to eat” requirement from a provision addressing the legality of pesticide residues in processed foods. The PPC suggests that EPA’s lack of action will result in dehydrated or concentrated products, such as juice concentrates, being found to be adulterated even though when rehydrated they would be fully in compliance with the applicable regulations.

1. *Background.* Traditionally, pesticide chemical tolerances on foods have been set primarily on raw agricultural commodities rather than processed foods. In the 1954 law establishing the modern system of pesticide tolerances, such tolerances were only authorized as to raw agricultural commodities. See 21 U.S.C. 346a(b) (1994). Although later amendments to the FFDCA pertaining to food additives did establish a similar system that included authority for tolerances for pesticide residues in processed food, these amendments were crafted in such a manner that tolerances for pesticides in processed foods were rarely necessary in comparison to the

need for raw food tolerances. See 21 U.S.C. 321(s) and 348 (1994).

Specifically, in seeking to coordinate action under the pesticides provision (section 408) and the food additives provision (section 409), Congress provided in section 402 that:

... where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the food shall, notwithstanding the provisions of section 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity . . . .

21 U.S.C. 342(a)(2)(C) (1994). In sum, this provision applied the tolerance level for a pesticide residue in raw food to processed food derived from that raw food. The provision became known as the “flow-through” provision because it permitted, in most cases, legal residues in a raw food to flow-through to the processed commodity without adulterating that latter commodity. A similar version of the “flow-through” provision was contained in the FQPA.

Given the “flow-through” provision, the only processed foods that need tolerances are those processed foods in which pesticide residues concentrate during processing to levels higher than the tolerance in the raw food. An increase in the concentration of residues can occur during processing in a number of processing operations including dehydration or drying of a raw food and separation of a raw food into its component parts. These processing operations may lead to all or most of the pesticide residues in the overall raw food being primarily allocated to a single component of the food, as processed, with the effect that the concentration of residues in that component (on a weight to weight basis) exceeds the concentration in the original raw food. For example, when apples are processed into juice, two commodities are created: Apple juice and apple pomace, an animal feed. The concentration of pesticide residues in the juice or pomace may be higher on a weight to weight basis than in the whole apple if the pesticide residue is either highly soluble in water or the reverse because in those circumstances the residue tends to partition unequally between the juice and the pomace rather than being equally distributed between them.

EPA determines the need for processed food tolerances by requiring the submission of food processing studies in the registering of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, and when establishing corresponding section 408 tolerances under the FFDCA. See 40 CFR 158.340. Food processing studies for a pesticide document the residue level of the pesticide in a treated raw commodity and the residue level in various processed commodities that can be derived from the raw commodity. In the Office of Prevention, Pesticides and Toxic Substances (OPPTS) Test Guidelines, EPA has provided guidance on which processed commodities, if any, food processing data should be submitted so that EPA can determine whether a processed food tolerance is needed. EPA, *OPPTS Harmonized Test Guidelines, Series 860, Residue Chemistry*, OPPTS Harmonized Guideline 860.1000 Table 1 (August 1996) (listing raw commodities and processed foods for which processing data is recommended). The criteria EPA has used for designating processed food on which processing data should be submitted relate both to the likelihood of an increase in concentration during processing and the significance of the processed commodity in the American diet. OPPTS Harmonized Guideline 860.1000(m).

When in 1996 Congress amended the FFDCA to, among other things, consolidate pesticide tolerance authority in section 408, it moved the flow-through provision to section 408 with minor changes. One of these minor changes was the dropping of the requirement in the flow-through provision that specified that residues in processed foods be judged against the raw food tolerance only when the processed food is at the "ready to eat" stage.

Although the legislative history regarding this change is sparse, EPA believes the reason the change was made was due to concerns with the phrase raised by EPA following the difficulties it had in applying the ready-to-eat requirement in the context of several legal and administrative challenges to various processed food tolerances or to uses which allegedly needed such tolerances. One of the issues that arose in this dispute was EPA's interpretation of the "ready to eat" requirement in the flow-through provision. When EPA looked into the questions surrounding its implementation of the ready-to-eat requirement, it discovered that, due to the wide variety in consumers' diets, it

was difficult to define what foods are ready to eat, and for foods that are not ready to eat, the stage when they become ready to eat. See 60 FR 31300, 31306 (June 14, 1995) ("EPA envisions that this definition [of ready-to-eat food] may be difficult to apply in many instances."). Given the problems with the ready-to-eat concept it is not surprising that EPA sought and Congress agreed to dropping the phrase from the statute.

2. *Dried foods.* The PPC expressed concern that EPA only considers whether processed food tolerances are necessary in a few dried commodities (e.g., raisins) and does not examine whether pesticide residues may concentrate in other dried commodities. According to the PPC, "[t]oday there are many more forms of dried or otherwise processed foods in commerce than was the case forty or fifty years ago when the tolerance establishment process was developed (e.g., banana chips, sun-dried tomatoes, freeze-dried berries)." EPA has traditionally only focused its tolerance-setting resources on those processed foods that are consumed at a significant enough level that they could meaningfully affect a risk assessment. The PPC, however, notes that EPA's approach may leave food processors with a "regulatory problem" as to certain minor foods in that routine drying of those foods may result in a processed commodity that bears illegal residues even though the raw food prior to drying was well within the applicable pesticide tolerance. The PPC argues that "[a]s a general matter, the drying or other routine processing of a compliant [raw agricultural commodity] should not be regarded as the adulteration of that [raw agricultural commodity] to yield unlawful processed food."

The PPC proposed that EPA issue a tolerance regulation applying to all processed foods that directs the tolerance for any processed food not having a specific tolerance shall be the tolerance level of the applicable raw food tolerance adjusted to "take account of the concentration of the product caused by the drying or other processing of the [raw agricultural commodity]." The PPC argues that such a tolerance regulation is "risk-neutral" because the amount of pesticide consumed as a total amount would be the same whether a food is consumed in its raw or dried form. Additionally, the PPC notes that this approach has been adopted by the European Union.

Although EPA understands that the PPC is concerned about pesticide residues in processed foods, the dried food issue in the PPC's comments goes beyond the scope of the proposed rule.

The proposed rule focused entirely on changes to EPA's regulations in response to the passage of the FQPA or other routine changes (e.g., updating addresses). It does amend the EPA regulation addressing the flow-through provision but only with regard to the changes that were accomplished by the FQPA. Similarly, EPA discussed how it is handling the interpretation of a few tolerance regulations that got caught between a change in EPA policy on "ready-to-eat" foods and the dropping of that requirement by the FQPA. The question of whether EPA has adequate tolerance regulations in place to deal with dried foods, however, is a question that exists independent of any changes in the law effectuated by the FQPA. Put another way, the potential regulatory problem identified by the PPC as to dried foods would be present even if the FQPA had never been passed. Accordingly, EPA will not be adopting the PPC's proposed regulation in this final rule. If the PPC continues to be concerned about the need for additional processed food tolerances for dried commodities, EPA is committed to working with them to explore options for resolution of their concerns.

EPA would note, however, that in response to the PPC's concern about how the deletion of the "ready to eat" language from the statute affects dried foods, EPA is making a change in the rule to address that issue, as discussed in the following section.

3. *Juice concentrates and similar products.* The PPC also is concerned that EPA has not addressed the legality of juice concentrates and similar products in light of the removal from the flow-through provision of the "ready to eat" requirement. The PPC argues that the removal of the "ready to eat" requirement may render these commodities adulterated even if they are produced from below-tolerance raw foods and will have below-tolerance residues when reconstituted and consumed.

As explained above, EPA believes that the "ready to eat" requirement was removed based on EPA's concerns that this vague language complicated both the tolerance establishment program and the enforcement of tolerances in the field. There is no indication that Congress removed the requirement because it thought it was important that concentrated juices be analyzed "as is" to determine whether or not they comply with tolerances applying to raw fruit and fruit juice in the form they are consumed. Obviously, examining whether concentrated apple juice meets a tolerance applicable to apple juice as consumed makes little sense from a risk

perspective. From an administrative standpoint, requiring tolerances for concentrated juices or other similar foods makes equally little sense because separate tolerances might need to be set on a food processor by food processor basis taking into account the degree of concentration used by individual processors in preparing their food products.

Traditionally, FDA has followed the commonsense approach of sampling concentrated apple juice for pesticide residues by either diluting the juice to its normal moisture content or compensating for the lack of normal moisture content in calculating the pesticide concentration in the juice. FDA's approach to sampling concentrated apple juice is spelled out in the section of the Pesticide Analytical Manual, Volume I, addressing the preparation of test samples of food for laboratory analysis of pesticide residues. See FDA, Pesticide Analytical Manual, Volume I, Table 102-b. The Pesticide Analytical Manual builds upon EPA regulations that provide general guidance on how some foods are to be sampled. See 40 CFR 180.1(j). Both EPA's regulations and the FDA guidance are directed at designing food sampling procedures to give a realistic measure of residues to which people are likely to be exposed (e.g., removing shells from nuts and stems from melons and re-hydrating juice concentrates before analyzing) and make sampling practicable for FDA personnel (e.g., analyzing not-ready-to-eat processed food used as an ingredient in other foods on an "as is" basis).

Accordingly, in response to the PPC's comment, EPA is adding an additional provision to its regulations in 40 CFR 180.1(j) regarding food sample preparation that tracks FDA's approach to concentrated products as set forth in the Pesticide Analytical Manual.

### III. Regulatory Assessment Requirements

This rule makes several changes in the EPA regulations governing pesticide tolerances and exemptions from tolerance. The amendments are procedural in nature and, for the most part, correct the CFR so that it is consistent with FFDCA section 408, as amended by the FQPA, and EPA's ongoing implementation of FFDCA. Other than making EPA regulations more accurate, these amendments are not expected to have any impact on regulated parties or the public. Accordingly, these amendments are not subject to review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), as a significant regulatory action.

Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

Since, as detailed above, these amendments will have no detrimental impact on regulated parties or the public, EPA certifies under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) that the amendments will not have a significant impact on a substantial number of small entities.

In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This rule is directed at pesticide manufacturers and

others who seek to establish, modify, or revoke pesticide tolerances and exemptions, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA.

For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

### IV. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

### List of Subjects in 40 CFR Parts 9, 23, 163, 177, 178, 179, 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 24, 2005.

**Suzan B. Hazen,**

*Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.*

Therefore, 40 CFR chapter I is amended as follows:

#### **PART 9—[AMENDED]**

- 1. The authority citation for part 9 is revised to read as follows:

**Authority:** 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

#### **§ 9.1 [Amended]**

- 2. Section 9.1 is amended by removing the entries and center headings for parts 163 and 177 in the table.

#### **PART 23—[AMENDED]**

- 3. The authority citation for part 23 is amended to read as follows:

**Authority:** Clean Water Act, 33 U.S.C. 1361(a), 1369(b); Clean Air Act, 42 U.S.C. 7601(a)(1), 7607(b); Resource, Conservation and Recovery Act, 42 U.S.C. 6912(a), 6976; Toxic Substances Control Act, 15 U.S.C. 2618; Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136n(b), 136w(a); Safe Drinking Water Act, 42 U.S.C. 300j–7(a)(2), 300j–9(a); Atomic Energy Act, 42 U.S.C. 2201, 2239; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(a), 346a, 28 U.S.C. 2112(a), 2343, 2344.

- 4. Section 23.10 is revised to read as follows:

#### **§ 23.10 Timing of Administrator's action under the Federal Food, Drug, and Cosmetic Act.**

Unless the Administrator otherwise explicitly provides in a particular order, the time and date of the issuance of a regulation under section 21 U.S.C. 346a(e)(1)(C), or any order under 21 U.S.C. 346a(f)(1)(C) or 21 U.S.C. 346a(g)(2)(C), or any regulation that is the subject of such an order, shall, for purposes of 28 U.S.C. 2112, be at 1 p.m. eastern time (standard or daylight, as appropriate) on the date that is for a **Federal Register** document, 2 weeks after the date when the document is published in the **Federal Register**, or for any other document, 2 weeks after it is signed.

#### **PART 163—[REMOVED]**

- 5. Part 163 is removed.

#### **PART 177—[REMOVED]**

- 6. Part 177 is removed.

#### **PART 178—[AMENDED]**

- 7. The authority citation for part 178 is revised to read as follows:

**Authority:** 21 U.S.C. 346a, 371(a); Reorg. Plan No. 3 of 1970.

- 8. Section 178.20 is amended by revising paragraph (a) to read as follows:

#### **§ 178.20 Right to submit objections and requests for a hearing.**

(a) On or before the 60th day after the date of publication in the **Federal Register** of an order under part 180 of this chapter establishing, modifying, or revoking a regulation, or denying all or any portion of a petition, a person adversely affected by such order or petition denial may submit, in accordance with § 178.25, one or more written objections to the order (or to the action that is the subject of the order).

\* \* \* \* \*

- 9. Section 178.25 is amended by revising paragraphs (a)(7) and (b)(2) to read as follows:

#### **§ 178.25 Form and manner of submission of objections.**

(a) \* \* \*

(7) Be received by the Hearing Clerk not later than the close of business of the 60th day following the date of the publication in the **Federal Register** of the order to which the objection is taken (or, if such 60th day is a Saturday, Sunday, or Federal holiday, not later than the close of business of the next government business day after such 60th day).

\* \* \* \* \*

(b) \* \* \*

(2) For personal delivery, the Office of the Hearing Clerk is located at: Room 104, Crystal Mall #2, 1801 S. Bell St., Arlington, VA.

- 10. Section 178.35 is amended as follows:

a. By revising the section heading.  
b. By revising paragraph (a).  
c. By revising “rule” to read “order” in paragraph (b).

#### **§ 178.35 Modification or revocation of regulation or prior order.**

(a) If the Administrator determines upon review of an objection or request for hearing that the regulation or prior order in question should be modified or revoked, the Administrator will publish an order setting forth any revision to the regulation or prior order that the Administrator has found to be warranted.

\* \* \* \* \*

- 11. Section 178.37 is amended by revising the introductory text of paragraph (a) and paragraph (c) to read as follows:

#### **§ 178.37 Order responding to objections on which a hearing was not requested or was denied.**

(a) The Administrator will publish in the **Federal Register** an order under FFDCA section 408(g)(2)(B) or section 408(g)(2)(C) setting forth the Administrator's determination on each denial of a request for a hearing, and on each objection submitted under § 178.20 on which:

\* \* \* \* \*

(c) Each order published under paragraph (a) of this section must state its effective date.

- 12. Section 178.65 is revised to read as follows:

#### **§ 178.65 Judicial review.**

An order issued under § 178.37 is final agency action reviewable in the courts as provided by FFDCA section 408(h), as of the date of publication of the order in the **Federal Register**. The failure to file a petition for judicial review within the period ending on the 60th day after the date of the publication of the order constitutes a waiver under FFDCA section 408(h) of the right to judicial review of the order and of any regulation promulgated by the order.

#### **§ 178.70 [Amended]**

- 13. Section 178.70 is amended by removing paragraphs (a)(2) and (a)(3) and redesignating existing paragraphs (a)(4) through (a)(8) as paragraphs (a)(2) through (a)(6), respectively.

#### **PART 179—[AMENDED]**

- 14. The authority citation for part 179 is revised to read as follows:

**Authority:** 21 U.S.C. 346a, 371(a); Reorg. Plan No. 3 of 1970.

#### **§ 179.20 [Amended]**

- 15. Section 179.20(a)(3) is amended by removing the phrase “§ 177.81 or”.

#### **§ 179.24 [Amended]**

- 16. Section 179.24 is amended by removing “177,” and removing the comma after “178” in paragraph (a).

#### **§ 179.83 [Amended]**

- 17. Section 179.83 is amended by revising “parts 177, or 180” to read “part 180” in paragraph (a)(1).
- 18. Section 179.91 is amended by revising paragraph (b) to read as follows:

**§ 179.91 Burden of going forward; burden of persuasion.**

\* \* \* \*

(b) The party or parties who contend that a regulation satisfies the criteria of section 408 of the FFDCA has the burden of persuasion in the hearing on that issue, whether the proceeding concerns the establishment, modification, or revocation of a tolerance or exemption from the requirement for a tolerance.

■ 19. Section 179.105 is amended by revising paragraph (b)(1)(ii) to read as follows:

**§ 179.105 Initial decision.**

\* \* \* \*

(b) \* \* \*

(i) \* \* \*

(ii) A conclusion that changes in the order or regulation are warranted, the language of the order or regulation as changed, and an effective date for the order or regulation as changed.

\* \* \* \*

■ 20. Section 179.125 is amended by revising paragraph (a) to read as follows:

**§ 179.125 Judicial review.**

(a) The Administrator's final decision is final agency action reviewable in the courts as provided by FFDCA section 408(h), as of the date of publication of the order in the **Federal Register**. The failure of a person to file a petition for judicial review within the period ending on the 60th day after the date of the publication of the order constitutes a waiver under FFDCA section 408(h) of the right to judicial review of the order and of any regulation promulgated by the order.

\* \* \* \*

**§ 179.130 [Amended]**

■ 21. Section 179.130 is amended by removing paragraphs (a)(2) and (a)(3) and redesignating existing paragraphs (a)(4) through (a)(12) as paragraphs (a)(2) through (a)(10), respectively.

**PART 180—[AMENDED]**

■ 22. The authority citation for part 180 continues to read as follows:  
**Authority:** 21 U.S.C. 321(q), 346(a) and 371.

■ 23. Section 180.1 is amended as follows:

■ a. By adding text to reserved paragraph (c).

■ b. By removing paragraph (d).

■ c. By redesignating existing paragraphs (e) through (p) as paragraphs (d) through (o), respectively.

■ d. By revising newly designated paragraphs (e), (j), and (n).

■ e. By revising the introductory text and adding a new paragraph (10) to newly designated paragraph (i).

**§ 180.1 Definitions and interpretations.**

\* \* \* \*

(c) *FFDCA* means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301–392.

\* \* \* \*

(e) Where a raw agricultural commodity bearing a pesticide chemical residue that has been exempted from the requirement of a tolerance, or which is within a tolerance permitted under FFDCA section 408, is used in preparing a processed food, the processed food will not be considered unsafe within the meaning of FFDCA sections 402 and 408(a), despite the lack of a tolerance or exemption for the pesticide chemical residue in the processed food, if:

(1) The pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section;

(2) The pesticide chemical residue has been removed to the extent possible in good manufacturing practice; and

(3) The concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue on the raw agricultural commodity.

\* \* \* \*

(i) Unless otherwise specified in this paragraph or in tolerance regulations prescribed in this part for specific pesticide chemicals, the raw agricultural commodity or processed food to be examined for pesticide residues, shall consist of the whole raw agricultural commodity or processed food.

\* \* \* \*

(10) For processed foods consisting primarily of one ingredient and sold in a form requiring further preparation prior to consumption (e.g., fruit juice concentrates, dehydrated vegetables, and powdered potatoes), the processed food to be examined for residues shall be the whole processed commodity after compensating for or reconstituting to the commodity's normal moisture content, unless a tolerance for the concentrated or dehydrated food form is included in this part. If there exists a tolerance for a specific pesticide on the processed food in its concentrated or dehydrated food form, for the purpose of determining whether the food is in compliance with that tolerance, the processed food to be examined for residues shall be the whole processed commodity on an "as is" basis.

\* \* \* \*

(j) The term *pesticide chemical* shall have the meaning specified in FFDCA section 201(q)(1), as amended, except as provided in § 180.4.

\* \* \* \*

(n) The term *pesticide chemical residue* shall have the meaning specified in FFDCA section 201(q)(2), as amended, except as provided in § 180.4.

\* \* \* \*

**§ 180.2 [Removed]**

■ 24. Section 180.2 is removed.

■ 25. The undesignated center heading that precedes § 180.7 and § 180.7 are revised to read as follows:

**Procedure for Filing Petitions Seeking the Establishment, Modification, or Revocation of Tolerances or Exemptions**

**§ 180.7 Petitions proposing tolerances or exemptions for pesticide residues in or on raw agricultural commodities or processed foods.**

(a) Petitions to be filed with the Agency under the provisions of FFDCA section 408(d) shall be submitted in duplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall be accompanied by an advance deposit for fees described in § 180.33. The petition shall state the petitioner's mail address to which notice of objection under FFDCA section 408(g)(2) may be sent. The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(b) Petitions shall include the following information:

(1) An informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition. Both a paper and electronic copy of the summary should be submitted. The electronic copy should be formatted according to the Office of Pesticide Programs' current standard for electronic data submission as specified at <http://www.epa.gov/oppfead1/eds/edsgoals.htm>.

(2) A statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under FFDCA section 408(d)(3) and as a part of a proposed or final regulation issued under FFDCA section 408.

(3) The name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue.



(4) Data showing the recommended amount, frequency, method, and time of application of the pesticide chemical.

(5) Full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations.

(6) Full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used. (See § 180.34 for further information about residue tests.)

(7) Proposed tolerances for the pesticide chemical residue if tolerances are proposed.

(8) Practicable methods for removing any amount of the residue that would exceed any proposed tolerance.

(9) A practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed.

(10) If the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food.

(11) Such information as the Administrator may require to make the determination under FFDCa section 408(b)(2)(C).

(12) Such information as the Administrator may require 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.

(13) Information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue.

(14) 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.

(15) Such other data and information as the Administrator requires by regulation to support the petition.

(16) Reasonable grounds in support of the petition.

(c) The data specified under paragraphs (b)(1) through (b)(16) of this section should be on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with

an earlier application, the present petition may incorporate it by reference to the earlier one.

(d) Except as noted in paragraph (e) of this section, a petition shall not be accepted for filing if any of the data prescribed by FFDCa section 408(d) are lacking or are not set forth so as to be readily understood. The availability to the public of information provided to, or otherwise obtained by, the Agency under this part shall be governed by part 2 of this chapter. The Administrator shall make the full text of the summary referenced in paragraph (b)(1) of this section available to the public in the Environmental Protection Agency Electronic Docket at <http://www.epa.gov/edocket> no later than publication in the **Federal Register** of the notice of the petition filing.

(e) The Administrator shall notify the petitioner within 15 days after its receipt of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. If petitioner desires, the petitioner may supplement a deficient petition after notification as to deficiencies. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified.

(f) A notice of the filing of a petition for a pesticide chemical residue tolerance that the Administrator determines has met the requirements of paragraph (b) of this section shall be published in the **Federal Register** by the Administrator within 30 days after such determination. The notice shall state the name of the pesticide chemical residue and the commodities for which a tolerance is sought and announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall explicitly reference the specific address in the Agency's Electronic Docket (<http://www.epa.gov/edocket>) where the full text of the summary required in paragraph (b) of this section and refer interested parties to this document for further information on the petition. The full text of the summary may be omitted from the notice.

(g) The Administrator may request a sample of the pesticide chemical at any time while a petition is under consideration. The Administrator shall specify in its request for a sample of the pesticide chemical, a quantity which it deems adequate to permit tests of analytical methods used to determine

residues of the pesticide chemical and of methods proposed by the petitioner for removing any residues of the chemical that exceed the tolerance proposed.

(h) The Administrator shall determine, in accordance with the Act, whether to issue an order that establishes, modifies, or revokes a tolerance regulation (whether or not in accord with the action proposed by the petitioner), whether to publish a proposed tolerance regulation and request public comment thereon under § 180.29, or whether to deny the petition. The Administrator shall publish in the **Federal Register** such order or proposed regulation. After receiving comments on any proposed regulation, the Administrator may issue an order that establishes, modifies, or revokes a tolerance regulation. An order published under this section shall describe briefly how to submit objections and requests for a hearing under part 178 of this chapter. A regulation issued under this section shall be effective on the date of publication in the **Federal Register** unless otherwise provided in the regulation.

■ 26. Section 180.8 is revised to read as follows:

**§ 180.8 Withdrawal of petitions without prejudice.**

In some cases the Administrator will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a tolerance or the tolerance requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification and the obtaining of additional data. This withdrawal may be without prejudice to a future filing. A deposit for fees as specified in § 180.33 shall accompany the resubmission of the petition.

■ 27. Section 180.9 is revised to read as follows:

**§ 180.9 Substantive amendments to petitions.**

After a petition has been filed, the petitioner may submit additional information or data in support thereof, but in such cases the petition will be given a new filing date.

**§§ 180.10, 180.11 and 180.12 [Removed]**

■ 28. Sections 180.10, 180.11 and 180.12 are removed.

■ 29. The undesignated center heading that precedes § 180.29, and § 180.29 are revised to read as follows:



**Establishment, Modification, and Revocation of Tolerance on Initiative of Administrator; Judicial Review; Temporary Tolerances; Modification and Revocation of Tolerances; Fees**

**§ 180.29 Establishment, modification, and revocation of tolerance on initiative of Administrator.**

(a) Upon the Administrator's own initiative, the Administrator may propose, under FFDC section 408(e), the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance, or a regulation modifying or revoking an existing tolerance or exemption.

(b) The Administrator shall provide a period of not less than 60 days for persons to comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(c) After reviewing any timely comments received, the Administrator may by order establish, modify, or revoke a tolerance regulation, which order and regulation shall be published in the **Federal Register**. An order published under this section shall state that persons may submit objections and requests for a hearing in the manner described in part 178 of this chapter.

(d) Any final regulation issued under this section shall be effective on the date of publication in the **Federal Register** unless otherwise provided in the regulation.

■ 30. Section 180.30 is revised to read as follows:

**§ 180.30 Judicial review.**

(a) Under FFDC section 408(h), judicial review is available in the United States Courts of Appeal as to the following actions:

(1) Regulations establishing general procedures and requirements under FFDC section 408(e)(1)(C).

(2) Orders issued under FFDC section 408(f)(1)(C) requiring the submission of data.

(3) Orders issued under FFDC section 408(g)(2)(C) ruling on objections to establishment, modification, or revocation of a tolerance or exemption under FFDC section 408(d)(4), or any regulation that is the subject of such an order. The underlying action here is Agency disposition of a petition seeking the establishment, modification, or revocation of a tolerance or exemption.

(4) Orders issued under FFDC section 408(g)(2)(C) ruling on objections to the denial of a petition under FFDC section 408(d)(4).

(5) Orders issued under FFDC section 408(g)(2)(C) ruling on objections to the establishment, modification, suspension, or revocation of a tolerance or exemption under FFDC section 408(e)(1)(A) or (e)(1)(B). The underlying action here is the establishment, modification, suspension, or revocation of a tolerance or exemption upon the initiative of EPA including EPA actions pursuant to FFDC sections 408(b)(2)(B)(v), 408(b)(2)(E)(ii), 408(d)(4)(C)(ii), 408(l)(4), and 408(q)(1).

(6) Orders issued under FFDC section 408(g)(2)(C) ruling on objections to the revocation or modification of a tolerance or exemption under FFDC section 408(f)(2) for noncompliance with requirements for the submission of data.

(7) Orders issued under FFDC section 408(g)(2)(C) ruling on objections to rules issued under FFDC sections 408(n)(3) and 408(d) or (e) regarding determinations pertaining to State authority to establish regulatory limits on pesticide chemical residues.

(8) Orders issued under FFDC section 408(g)(2)(C) ruling on objections to orders issued under FFDC section 408(n)(5)(C) authorizing States to establish regulatory limits not identical to certain tolerances or exemptions.

(b) Any issue as to which review is or was obtainable under paragraph (a) of this section shall not be the subject of judicial review under any other provision of law. In part, this means that, for the Agency actions subject to the objection procedure in FFDC section 408(g)(2), judicial review is not available unless an adversely affected party exhausts these objection procedures, and any petition procedures preliminary thereto.

■ 31. Section 180.31 is revised to read as follows:

**§ 180.31 Temporary tolerances.**

(a) A temporary tolerance (or exemption from a tolerance) established under the authority of FFDC section 408(r) shall be deemed to be a tolerance (or exemption from the requirement of a tolerance) for the purposes of FFDC section 408(a)(1) or (a)(2) and for the purposes of § 180.30.

(b) A request for a temporary tolerance or a temporary exemption from a tolerance by a person who has obtained or is seeking an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act shall be accompanied by such data as are available on subjects outlined in § 180.7(b) and an advance deposit to cover fees as provided in § 180.33.

(c) To obtain a temporary tolerance, a requestor must comply with the petition procedures specified in FFDC section 408(d) and § 180.7 except as provided in this section.

(d) A temporary tolerance or exemption from a tolerance may be issued for a period designed to allow the orderly marketing of the raw agricultural commodities produced while testing a pesticide chemical under an experimental permit issued under authority of the Federal Insecticide, Fungicide, and Rodenticide Act if the Administrator concludes that the safety standard in FFDC section 408(b)(2) or (c), as applicable, is met. Subject to the requirements of FFDC section 408(e), a temporary tolerance or exemption from a tolerance may be revoked if the experimental permit is revoked, or may be revoked at any time if it develops that the application for a temporary tolerance contains a misstatement of a material fact or that new scientific data or experience with the pesticide chemical indicates that it does not meet the safety standard in FFDC section 408(b)(2) or (c), as applicable.

(e) Conditions under which a temporary tolerance is established shall include:

(1) A limitation on the amount of the chemical to be used on the designated crops permitted under the experimental permit.

(2) A limitation for the use of the chemical on the designated crops to bona fide experimental use by qualified persons as indicated in the experimental permit.

(3) A requirement that the person or firm which obtains the experimental permit for which the temporary tolerance is established will immediately inform the Environmental Protection Agency of any reports on findings from the experimental use that have a bearing on safety.

(4) A requirement that the person or firm which obtained the experimental permit for which the temporary tolerance is established will keep records of production, distribution, and performance for a period of 2 years and, on request, at any reasonable time, make these records available to any authorized officer or employee of the Environmental Protection Agency.

■ 32. Section 180.32 is revised to read as follows:

**§ 180.32 Procedure for modifying and revoking tolerances or exemptions from tolerances.**

(a) The Administrator on his/her own initiative may propose the issuance of a regulation modifying or revoking a tolerance for a pesticide chemical

residue on raw agricultural commodities or processed foods or modifying or revoking an exemption from tolerance for such residue.

(b) Any person may file with the Administrator a petition proposing the issuance of a regulation modifying or revoking a tolerance or exemption from a tolerance for a pesticide chemical residue. The petition shall furnish reasonable grounds for the action sought. Reasonable grounds shall include an explanation showing wherein the person has a substantial interest in such tolerance or exemption from tolerance and an assertion of facts (supported by data if available) showing that new uses for the pesticide chemical have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the application of the tolerance or exemption from tolerance may justify its modification or revocation. Evidence that a person has registered or has submitted an application for the registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act will be regarded as evidence that the person has a substantial interest in a tolerance or exemption from the requirement of a tolerance for a pesticide chemical that consists in whole or in part of the pesticide. New data should be furnished in the form specified in § 180.7(b) for submitting petitions, as applicable.

(c) The procedures for completing action on an Administrator initiated proposal or a petition shall be those specified in §§ 180.29 and 180.7, as applicable.

■ 33. Section 180.33 is amended as follows:

- a. In paragraphs (a), (b), (c), and (h) remove the phrase "or request".
- b. Remove paragraph (j) and redesignate existing paragraphs (k) through (p) as paragraphs (j) through (o), respectively.
- c. In newly designated paragraph (j) revise "408(d)(5) or (e)" to read "408(h)".
- d. In newly designated paragraph (l) remove the phrase "Registration Division (7505C)".
- e. In newly designated paragraph (m) remove the phrase "Registration Division, (7505C)".
- f. Revise paragraph (f) and the third sentence to newly designated paragraph (l) to read as follows:

**§ 180.33 Fees.**

(f) Each petition for revocation of a tolerance shall be accompanied by a fee of \$10,125. Such fee is not required when, in connection with the change sought under this paragraph, a petition

is filed for the establishment of new tolerances to take the place of those sought to be revoked and a fee is paid as required by paragraph (a) of this section.

\* \* \* \* \*

(l) \* \* \* A fee of \$2,025 shall accompany every request for a waiver or refund, as specified in paragraph (m) of this section, except that the fee under this paragraph shall not be imposed on any person who has no financial interest in any action requested by such person under paragraphs (a) through (j) of this section. \* \* \*

\* \* \* \* \*

■ 34. Section 180.40 is amended by revising the last sentence in paragraph (f) to read as follows:

**§ 180.40 Tolerances for crop groups.**

\* \* \* \* \*

(f) \* \* \* Processing data will be required prior to establishment of a group tolerance. Tolerances will not be granted on a group basis as to processed foods prepared from crops covered by the group tolerance.

\* \* \* \* \*

■ 35. Section 180.1229 is added to subpart D to read as follows:

**§ 180.1229 Benzaldehyde; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of benzaldehyde when used as a bee repellent in the harvesting of honey.

■ 36. Section 180.1230 is added to subpart D to read as follows:

**§ 180.1230 Ferrous sulfate; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of ferrous sulfate.

■ 37. Section 180.1231 is added to subpart D to read as follows:

**§ 180.1231 Lime; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of lime.

■ 38. Section 180.1232 is added to subpart D to read as follows:

**§ 180.1232 Lime-sulfur; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of lime-sulfur.

■ 39. Section 180.1233 is added to subpart D to read as follows:

**§ 180.1233 Potassium sorbate; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of potassium sorbate.

■ 40. Section 180.1234 is added to subpart D to read as follows:

**§ 180.1234 Sodium carbonate; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of sodium carbonate.

■ 41. Section 180.1235 is added to subpart D to read as follows:

**§ 180.1235 Sodium hypochlorite; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of sodium hypochlorite.

■ 42. Section 180.1236 is added to subpart D to read as follows:

**§ 180.1236 Sulfur; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of sulfur.

■ 43. Section 180.1237 is added to subpart D to read as follows:

**§ 180.1237 Sodium metasilicate; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of sodium metasilicate when used as plant desiccants, so long as the metasilicate does not exceed 4% by weight in aqueous solution.

■ 44. Section 180.1238 is added to subpart D to read as follows:

**§ 180.1238 Oil of lemon; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of oil of lemon when used as a postharvest fungicide.

■ 45. Section 180.1239 is added to subpart D to read as follows:

**§ 180.1239 Oil of orange; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of oil of orange when used as a postharvest fungicide.

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[R06-OAR-2005-NM-0001; FRL-7921-8]

**Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Albuquerque/Bernalillo County**

**AGENCY:** Environmental Protection Agency (EPA).