

(8) For any storm water discharge associated with small construction activity identified in paragraph (b)(15)(i) of this section, see § 122.21(c)(1). Discharges from these sources, other than discharges associated with small construction activity at oil and gas exploration, production, processing, and treatment operations or transmission facilities, require permit authorization by March 10, 2003, unless designated for coverage before then. Discharges associated with small construction activity at such oil and gas sites require permit authorization by March 10, 2005.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2002-0348; FRL-7292-6]

Aluminum tris (O-ethylphosphonate); Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the fungicide aluminum tris (O-ethylphosphonate) (fosetyl-Al) in or on onion, green. The Interregional Research Project #4 (IR-4), Center for Minor Crop Management, Rutgers, The State University of New Jersey, 681 U. S. Highway #1 South, North Brunswick, NJ 08902-3390 requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective March 10, 2003. Objections and requests for hearings, identified by docket ID number OPP-2002-0348, must be received on or before May 9, 2003.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: jackson.sidney@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. 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. Potentially affected entities may include, but are not limited to:

- Crop production (NAIC code 111)
- Animal production (NAIC code 112)
- Food manufacturing (NAIC code 311)
- Pesticide manufacturing (NAIC code 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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in OPP-2002-0348. 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 Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2002-0348. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml/00/Title_40/40cfr180_00.html, a beta site currently under development.

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An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of January 2, 2003 (68 FR 103) (FRL-7282-5), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 2E6366) by IR-4, Center for Minor Crop Management, Rutgers, The State University of New Jersey, 681 U. S. Highway #1 South, North Brunswick, NJ 08902-3390. That notice included a summary of the petition prepared by Bayer CropScience, the registrant.

The petition requested that 40 CFR 180.415 be amended by establishing a tolerance for residues of the fungicide fosetyl-Al, aluminum tris (O-ethylphosphonate), in or on onion, green at 10 parts per million (ppm). There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of fosetyl-Al on onion, green at 10 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data on fosetyl-Al and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fosetyl-Al are discussed in the **Federal Register** of August 18, 2000 (65 FR 50431) (FRL-6599-4) as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies reviewed. Please refer to this document should you desire detailed toxicological information on fosetyl-Al.

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF ($RfD = NOAEL / UF$). Where an additional safety factors (SF) is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA SF.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = $NOAEL / exposure$) is calculated and compared to the LOC.

The linear default risk methodology (Q^*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q^* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q^* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer} = \text{point of departure} / \text{exposures}$) is calculated. A summary of the toxicological endpoints for fosetyl-Al used for human risk assessment is discussed in Unit III. B. of the final rule on fosetyl-Al tolerances published in the **Federal Register** on August 29, 2002 (67 FR 55339) (FRL-7195-1).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.415) for the residues of fosetyl-Al, in or on a variety of raw agricultural commodities. Residues of fosetyl-Al are currently regulated under 40 CFR 180.415(a) in bushberry subgroup, and juneberry, lingonberry, and salal, at 40 ppm; caneberries, fresh ginseng root, pineapple, pineapple fodder and forage

at 0.1 ppm; onions (dry bulb) at 0.5 ppm, macadamia nuts at 0.2 ppm; cranberry at 0.5 ppm; fruit, citrus, group at 5.0 ppm; pea, succulent at 0.3 ppm; tomatoes and bananas at 3.0 ppm; pome fruit at 10 ppm; cucurbit vegetables group at 15 ppm; avocados at 25 ppm; hops, dried at 45 ppm; brassica (cole) leafy vegetables group at 60 ppm; strawberries at 75 ppm; turnip, roots at 15 ppm; turnip, tops at 40 ppm; and leafy vegetables (except brassica vegetables) group at 100 ppm. Time-limited tolerances associated with a section 18 request for the residues of fosetyl-Al have been granted in/on peas, succulent at 1.0 ppm under 40 CFR 180.415(b) which expired September 31, 2000. Additionally, tolerances are established in 40 CFR 180.415(c) for residues of fosetyl-Al in/on asparagus at 0.1 ppm and grapes at 10 ppm in conjunction with regional registrations. Risk assessments were conducted by EPA to assess dietary exposures from fosetyl-Al in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No appropriate endpoint attributable to a single exposure (dose) of fosetyl-Al was identified from the oral toxicity studies including developmental toxicity studies in rats and rabbits. Therefore, fosetyl-Al is not expected to pose an acute risk.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, the Dietary Exposure Evaluation Model (DEEM) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The Tier 1 (assuming tolerance level residues and 100% crops treated for all commodities) chronic dietary exposure assessment was conducted for all supported fosetyl-Al food uses. Chronic dietary exposure estimates were provided for the general U.S. population and various population subgroups.

iii. *Cancer.* The Agency concludes that pesticidal use of fosetyl-Al is unlikely to pose a carcinogenic hazard to humans. Therefore, a cancer dietary exposure analysis for fosetyl-Al was not performed.

2. *Dietary exposure from drinking water.* Fosetyl-Al is not expected to reach ground water or surface water under most conditions.

Based on screening models, FQPA Index Reservoir Screening Tool (FIRST) and Screening Concentrations in Ground Water (SCI-GROW), the estimated environmental concentrations (EECs) of fosetyl-Al for acute exposures are estimated to be 0.0086 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 0.00003 ppb for surface water and 0.006 ppb for ground water.

3. From non-dietary exposure.

Fosetyl-Al is currently registered for use on the following residential non-dietary sites: Lawn, turf, and ornamental plants under the brand names CHIPO® Aliette WDG and Aliette® HG. CHIPO® Aliette WDG is sold to professional applicators only, which includes lawn care operators (LCO). Because all residential uses of CHIPO® Aliette WDG are applied by the LCO, a residential applicator exposure assessment for this product was not performed. Short- and intermediate-term dermal, inhalation, and oral exposures to fosetyl-Al may occur from residential handling/postapplication activities.

For a detailed discussion of fosetyl-Al risk assessment, see Unit III. C. 3. of the final rule on fosetyl-Al tolerances published in the **Federal Register** on August 29, 2002 (67 FR 55339).

4. Cumulative exposure to substances with a common mechanism of toxicity.

Section 408(b)(2)(D)(v) of the FFDCFA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether fosetyl-Al has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, fosetyl-Al does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fosetyl-Al has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCFA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* The developmental and reproductive toxicity data did not indicate increased quantitative or qualitative susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

3. *Conclusion.* There is a complete toxicity data base for fosetyl-Al and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X safety factor to protect infants and children should be reduced to 1X. The FQPA factor was reduced because the toxicology data base is complete; the developmental and reproductive toxicity data did not indicate increased quantitative or qualitative susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; a developmental neurotoxicity study is not required by the Agency; and the exposure assessment, which assumes the theoretical maximum residue contribution will not underestimate the potential dietary (food and water) and non-dietary exposures for infants and children resulting from the use of fosetyl-Al.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates drinking water level of concerns (DWLOC) which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is

available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* The acute aggregate risk assessment takes into account exposure estimates from dietary consumption of fosetyl-Al (food and drinking water). However, no appropriate endpoint attributable to a single dose (exposure) was identified in oral toxicity studies for fosetyl-Al. Therefore, fosetyl-Al is not expected to pose an acute risk.

2. *Chronic risk.* The chronic aggregate risk assessment takes into account average exposure estimates from food, drinking water, and residential uses. However, based on the use pattern, no chronic residential exposures are expected. Therefore, the chronic aggregate risk assessment will consider exposure from food and drinking water only. Chronic risk estimates resulting from aggregate exposure to fosetyl-Al in food and water are below Agency's LOC.

Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fosetyl-Al from food will utilize 4% of the cPAD for the U.S.

population, 5% of the cPAD for infants and 8% of the cPAD for children 1–6 years old, subpopulation at greatest exposure. Based the use pattern, chronic residential exposure to residues of fosetyl-Al is not expected. In addition, there is potential for chronic dietary exposure to fosetyl-Al in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 1 of this unit:

TABLE 1.—DWLOCs FOR CHRONIC (NON-CANCER) EXPOSURE TO FOSETYL-AL

Population Subgroup ¹	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb) ²	Ground Water EEC (ppb) ²	Chronic DWLOC (ppb) ³
U.S. Population	2.5	4	0.00003	0.006	84,000
Children (1–6 years old)	2.5	8	0.00003	0.006	23,000
All infants (< 1 year old)	2.5	5	0.00003	0.006	24,000
Female (13–50 years old)	2.5	3	0.00003	0.006	73,000

1 Within each of these subgroups, the subpopulation with the highest food exposure having an adequately representative number of samples was selected. Default body weights are: General U. S. population, 70 kg; females (13 plus years old), 60 kg; and, All Infants/Children, 10 kg.

2 Estimate for the highest use rate was chosen.

3 DWLOC (µg/L) = [Maximum water exposure (mg/kg/day) X body wt (kg) divided by (10⁻³ mg/µg) X water consumed daily (L/day)]. µg/L = parts per billion. Default daily drinking rates are 2 L/day for Adults and 1 L/day for Infants/Children.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

The short-term aggregate risk assessment estimates risks likely to result from 1 to 30 day exposure to fosetyl-Al residues from food, drinking water, and residential pesticide uses. High-end estimates of residential exposure are used in the short-term assessment, while average values are used for food and drinking water exposure (i.e. chronic exposures).

A short-term risk assessment is required for adults because there is a residential handler inhalation exposure

scenario. In addition, a short-term risk assessment is required for infants and children because there is a residential post-application oral exposure scenario. As no short- or intermediate-term dermal endpoint was established, there is no dermal component to these aggregate risk assessments.

Fosetyl-Al is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for fosetyl-Al.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated

result in aggregate MOEs of 3,300 for adults, 570 for children ages 1–6 years old, and 650 for all infants < 1 year old. These aggregate MOEs do not exceed the Agency’s level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of fosetyl-Al in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency’s level of concern, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO FOSETYL-AL

Population Subgroup	Aggregate MOE (Food + Residential) ¹	Aggregate Level of Concern (LOC) ²	Surface Water EEC (ppb) ³	Ground Water EEC (ppb) ³	Short-Term DWLOC (ppb) ⁴
Adults	3,300	100	0.00003	0.006	102,000
Children (1–6 years old)	570	100	0.00003	0.006	25,000
All infants (<1 year old)	650	100	0.00003	0.006	25,000

1 Aggregate MOE = [NOAEL (300 mg/kg/day) ÷ (Avg Food Exposure + Residential Exposure)]

2 The LOC is 100, based on interspecies and intraspecies safety factors totaling 100.

3 The crop producing the highest level was used.

4 DWLOC(µg/L) = [Maximum water exposure (mg/kg/day) x body weight (kg) ÷ water consumption (L) x 10⁻³ mg/µg] For adults, a 70 kg body weight was used, for children, 10 kg.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term risk assessment was not performed since adult residential handler scenarios are not expected to occur for longer than a short-term timeframe (more than 30 days of continuous exposure) and intermediate-term exposure is not likely

to occur for infants and children (residential post-application oral exposure scenario) because fosetyl-Al has a very short half-life (less than 3 hours in aerobic soil).

5. *Aggregate cancer risk for U.S. population.* The Agency concludes that pesticidal uses of fosetyl-Al are not likely to pose a carcinogenic hazard to humans. Therefore, an aggregate cancer risk assessment was not performed.

6. *Determination of safety.* Based on these risk assessments, EPA concludes

that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to fosetyl-Al residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate analytical method is available for enforcement of the proposed tolerances in/on onion, green. The method is Method I in PAM II, which uses diazomethane as the

methylating agent and quantitation of fosetyl-Al by GC/FPD. The method may be requested from: Francis Griffith, Analytical Chemistry Branch, Environmental Science Center, Environmental Protection Agency, 701 Mapes Road, Fort George G. Mead, MD 20755-5350; telephone number: (410) 305-20905; e-mail address: griffith.francis@epa.gov.

B. International Residue Limits

There is no established or proposed maximum residue limit (MRL) or tolerance for fosetyl-Al in or on onion, green for Canada, Mexico, or Codex.

V. Conclusion

Therefore, the tolerance is established for residues of fosetyl-Al, aluminum tris (O-ethylphosphonate), in or on onion, green at 10 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2002-0348 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before May 9, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of

the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in

Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP-2002-0348, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). 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 final 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 tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. 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 final rule directly regulates growers, food processors, food handlers and food retailers, 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.

VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, 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 to 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 this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: February 28, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.415 is amended by alphabetically adding an entry for "Onion, green" to the table in paragraph (a) to read as follows:

§ 180.415 Aluminum tris (O-ethylphosphonate); tolerance for residues.
(a) * * *

Commodity	Parts per million	Expiration/Revocation Date
Onion, green	10.0	None

* * * * *

[FR Doc. 03-5616 Filed 3-7-03; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 03-431; MM Docket No. 01-254; RM-10264; RM-10375; RM-10376]

Radio Broadcasting Services; Atoka, Haileyville and Clayton, OK

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document dismisses a petition for rule making filed at the request of Maurice Salsa ("Salsa") proposing the allotment of FM Channel 290A at Atoka, Oklahoma, as that community's second local FM transmission service (RM-10264). See 66 FR 52733, October 17, 2001. In response to a counterproposal filed on behalf of Keystone Broadcasting, this