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. The 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).

H. Petitions for Judicial Review

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 7, 1999. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Transportation conformity, Transportation-air quality planning, Volatile organic compounds.

Dated: June 9, 1999.

W. B. Hathaway,

Acting Regional Administrator, Region 6.

Title 40, part 52, of the Code of Federal Regulations is amended to read as follows:

PART 52—[AMENDED]

Subpart SS—Texas

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671 *et seq.*

2. In § 52.2270 the table in paragraph (c) is amended by removing section 114.27 and adding section 114.260 to read as follows:

§ 52.2270 Identification of plan.

* * * * *

(c) * * *

EPA APPROVED REGULATIONS IN THE TEXAS SIP

State citation	Title/subject	State approval/submittal date	EPA approval date	Explanation
*	*	*	*	*
Chapter 114 (Reg 4)—Control of Air Pollution from Motor Vehicles				
*	*	*	*	*
Section 114.260	Transportation Conformity.	12/10/98	July 8, 1999, 64 FR 36794.	1. No action is taken on the portions of 30 TAC 114.260 that contain 40 CFR 93.102(c), 93.104(d) ,93.109(c)–(f), 93.118(e), 93.120(a)(2), 93.121(a)(1), and 93.124(b). 2. TNRCC order (Docket No.98–0418 RUL) November 23, 1998.
*	*	*	*	*

[FR Doc. 99–17202 Filed 7–7–99; 8:45 am]
BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300892; FRL–6090–3]

RIN 2070–AB78

Fosetyl-Al; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the fungicide fosetyl-Al (aluminum tris(O-ethyl phosphonate)) in or on the raw agricultural commodities bananas at 3.0 parts per million (ppm), blueberries at 40 ppm, grapes at 10 ppm, and macadamia nuts at 0.20 ppm. Rhone-Poulenc Ag Company and the Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective July 8, 1999. Objections and requests for hearings must be received by EPA on or before September 7, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300892], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300892], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or

ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300892]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 249, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–7740; e-mail: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 7,1998 (63 FR 36s681) (FRL–5795–6) and January 29, 1999 (64 FR 4650) (FRL–6055–8), EPA issued notices pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of pesticide petitions (PP#5E4434, 5E4559, 7E4872) for tolerances by Interregional Research project Number 4 (IR–4), New Jersey Agricultural Research Station, Rutgers University, New Brunswick, New Jersey 08903, and pesticide petition (PP#8E4969) for a tolerance by Rhone-Poulenc Ag Company, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. These notices included summaries of the petitions prepared by Rhone-Poulenc Ag Company, the registrant. There were no comments received in response to the notices of filing.

The petitions requested that 40 CFR 180.415 be amended by establishing tolerances for the fungicide fosetyl-Al, in or on bananas at 3.0 ppm, blueberries at 40 ppm, grapes at 10 ppm, and macadamia nuts at 0.20 ppm. Since the tolerance for blueberries expired on December 31, 1998, after the notice of filing was published in the **Federal Register**, this rule re-establishes the blueberry tolerance, with an expiration date of December 31, 2000. Registration for use of fosetyl-Al on grapes will be limited to areas east of the Rocky Mountains, based on the geographical representation of the residue data submitted. Persons seeking geographically broader registration should contact the Registration Division at the address provided above.

I. Background and Statutory Findings

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) 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) 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 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances November 26, 1997 (62 FR 62961), (FRL–5754–7).

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), 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 fosetyl-Al and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances of fosetyl-Al on bananas at 3.0 ppm, blueberries at 40 ppm, grapes at 10 ppm, and macadamia nuts 0.20 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its 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 this unit.

[Technical grade fosetyl-Al has low acute oral (IV), dermal (III), and inhalation (III) toxicity. It is non-irritating to the skin (IV) and severely irritating to the eyes (I). It is not a skin sensitizer. There were no acute neurotoxicity tests performed. The acute oral LD_{50} for rats is >5,000 milligrams per kilogram (mg/kg), the acute dermal LD_{50} for rats is >3,000 mg/kg, and the acute inhalation LC_{50} for rats is 1.73 milligrams per liter (mg/l).

The subchronic toxicity studies included a 21-day dermal toxicity study in rats whose no observed adverse effect level (NOAEL) was greater than the limit dose of 1,000 milligrams per kilogram per day (mg/kg/day). The NOAEL was 1,500 mg/kg/day, the highest dose tested (HDT) and the lowest observed adverse effect level (LOAEL) was >1,500 mg/kg/day. The other subchronic studies were two 3-month oral toxicity studies, one using dogs and the other using rats. Treatment-related effects included slightly increased medullary hematopoiesis in the spleen of rats and decreased serum potassium in dogs, both at LOAELs of 1,250 mg/kg/day. The NOAELs were 482 and 250 mg/kg/day in rats and dogs, respectively.

The following chronic toxicity and/or carcinogenicity studies were performed. In a chronic toxicity feeding study using dogs, the NOAEL of 250 mg/kg/day was based on testicular degeneration (spermatocytic and/or spermatidic giant cells in the lumen of the seminiferous tubules) at the LOAEL of 500 mg/kg/day. In a combined chronic toxicity/carcinogenicity study using rats, the NOAEL of 400 mg/kg/day was based on urinary bladder pathology (tumors) and increased urine protein at the LOAEL of 1,500 mg/kg/day. In a carcinogenicity study in mice, the NOAEL of 409 mg/kg/day was based on a slight increase in white blood cells at the LOAEL of 1,672 mg/kg/day. There was no evidence of carcinogenicity in the mouse. The Agency classified fosetyl-Al as a Group C carcinogen (possible human carcinogen). A subsequent review concluded that fosetyl-Al was not amenable to classification using the current Agency guidelines and determined that the tumors produced in rats occurred under extremely high doses, under conditions not anticipated to occur outside of the experimental lab. Therefore, it was concluded that fosetyl-Al is not likely to pose a carcinogenic hazard to humans.

Results from five acceptable mutagenicity studies indicate that fosetyl-Al was not mutagenic in bacterial or cultured mammalian cells and did not cause DNA damage in bacterial or primary rat hepatocytes.

Therefore, the available data indicate that fosetyl-Al is not a mutagen.

In a developmental toxicity study using rats, maternal toxicity occurred at four times the limit dose. The maternal LOAEL was 4,000 mg/kg/day, based on decreased mean body weights and body weight gain, and increased maternal mortality, and the NOAEL was 1,000 mg/kg/day (limit dose). The developmental LOAEL was also 4,000 mg/kg/day, based on decreased litter and mean fetal body weight, increased resorptions, malformations, and skeletal variations, and the developmental NOAEL was 1,000 mg/kg/day (limit dose). In a developmental toxicity study using rabbits there was no evidence of developmental toxicity at the HDT of 500 mg/kg/day, so the NOAEL is considered to be 500 mg/kg/day and the LOAEL was not established. In this same study the maternal LOAEL was 250 mg/kg/day, based on decreased mean body weight, and the NOAEL was 125 mg/kg/day. A three-generation reproductive toxicity study using rats did not indicate any concern for pre- or post-natal effects in offspring or for reproductive effects. The parental/systemic LOAEL was 600 mg/kg/day, based on decreased body weight gains of the F_{2b} generation, and urinary tract changes in adults, and the parental/systemic NOAEL was 300 mg/kg/day. In this same study the reproductive (offspring) LOAEL was 600 mg/kg/day, based on decreased litter and pup body weight (day 8) in both matings of each generation, and the reproductive (offspring) NOAEL was 300 mg/kg/day. The *in utero* (developmental) NOAEL in this study was >1,200 mg/kg/day (the HDT). Therefore, there was no evidence of increased sensitivity due to prenatal or postnatal exposure to fosetyl-Al.

A dermal absorption factor is required only for long-term dermal risk assessment due to the selection of an oral value. The Agency estimated a dermal absorption factor of 17% based on the ratio of the oral LOAEL (250 mg/kg/day), and the dermal LOAEL (1500 mg/kg/day) in rabbits. Two metabolism studies using rats were evaluated. The first study showed that fosetyl-Al technical was rapidly metabolized to carbon dioxide (60%, recovered in exhaled air), and phosphite (phosphorous acid) (29 to 30%, excreted in the urine and feces). The second study examined metabolism of the phosphite metabolite, showing most of it to be excreted in the urine (59–65%) and feces (30 to 32%).

Overall, the quality of the toxicology data base is good and the confidence in the hazard and dose responses is high. There are no toxicology data gaps.

B. Toxicological Endpoints

1. *Acute toxicity.* No appropriate endpoint attributable to a single dose exposure was identified in acute oral toxicity studies. Therefore, an acute Reference Dose (RfD) was not established.

2. *Short-and intermediate-term toxicity.* In the 21-day dermal toxicity study using rats, no dermal or systemic toxicity was seen at the limit dose following repeated dermal applications. Therefore, no endpoint value is calculable.

3. *Chronic toxicity.* EPA has established the chronic RfD for fosetyl-Al at 2.5 mg/kg/day. This RfD is based on testicular degeneration (spermatocytic and/or spermatidic giant cells in the lumen of the seminiferous tubules) in 2 of 6 rats. The endpoint was observed in the 2-year chronic toxicity using dogs. In this study the NOAEL was 250 mg/kg/day and the uncertainty factor was set at 100. The FQPA factor was determined to be 1× because:

(1) The toxicology data base is complete.

(2) there is no indication of increased susceptibility of rat or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity studies,

(3) a developmental neurotoxicity study is not required,

(4) food exposure estimates are unrefined (that is, tolerance level residues and 100% crop treated assumed) and likely result in an overestimate of the actual food exposure,

(5) the Agency models used for ground and surface drinking water exposure estimates produce upper-bound concentration estimates,

(6) the current residential use pattern is not of concern since no potential hazard was identified for short- or intermediate-term exposure (no risk assessment is required) and long-term exposure is not expected with this use. As a result of the 1x FQPA factor, the chronic population adjusted dose (CPAD) is the same as the RfD.

4. *Carcinogenicity.* The Agency has determined that fosetyl-Al is unlikely to pose a cancer hazard to humans because the effects produced in rats occurred at extremely high doses, under conditions not anticipated to occur outside of the laboratory. Therefore, under the expected exposure conditions for this use, fosetyl-Al is unlikely to pose a carcinogenic risk to humans.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.415) for residues of fosetyl-Al in or on a variety of raw agricultural commodities. These tolerances range from 0.1 part per million (ppm) on caneberries, fresh ginseng root, and pineapple to 100 ppm on the leafy vegetables (except brassica vegetables) group. A time-limited tolerance for blueberries at 40 parts per million expired on December 31, 1998. Risk assessments were conducted by EPA to assess dietary exposures from fosetyl-Al as follows:

i. *Acute exposure and risk.* 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 dose exposure was identified in oral toxicity studies. Therefore, an acute RfD was not established, and there is no expectation of acute risk.

ii. *Chronic exposure and risk.* Food exposure for various subgroups of the U.S. population was estimated through the use of the Dietary Exposure Evaluation Model (DEEM) software. The DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1991 nationwide Continuing Surveys of Food Intake by Individuals. As the risk estimate was low for even the most highly exposed subpopulation, no anticipated residues were used. The Agency assumed 100% crop treated and tolerance level residues for all crops with tolerances as well as for the crops which are being evaluated in this action (i.e., bananas, grapes, and macadamia nuts). The most highly exposed group, children (1–6 years), is at 6% of the chronic CPAD. Of the female subgroups, females (13+/nursing) has the highest exposure at 4% of the CPAD. The exposure for the U.S. population is 3% of the CPAD. Foods that contribute most to the exposure are: lettuce, apples, tomatoes, broccoli, celery, strawberries, spinach, and cabbage.

The Agency does not consider the chronic dietary food risk to exceed the Agency's level of concern.

iii. *Short- and intermediate-term exposure and risk.* Since no dermal or systemic toxicity was seen at the limit dose following repeated dermal applications in the 21-day toxicity study using rats, no endpoint value was calculated and there is no expectation of short- or intermediate-term risk.

iv. *Cancer exposure and risk.* Carcinogenicity risk assessments are required for a food-use pesticide if a toxicological study has indicated the possibility of cancer occurring as a result of an exposure (usually chronic).

The Agency has concluded that fosetyl-Al is unlikely to pose a carcinogenic hazard to humans. Therefore, this risk assessment is not appropriate.

2. *From drinking water.* A Drinking Water Level of Comparison (DWLOC) is a theoretical upper limit on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, drinking water, and through residential uses. A DWLOC will vary depending on the toxicological endpoint, drinking water consumption, and body weights. Different populations will have different DWLOCs. The Agency uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, it is used as a point of comparison against conservative model estimates of a pesticide's concentration in water. DWLOC values are not regulatory standards for drinking water. They do have an indirect regulatory impact through aggregate exposure and risk assessments.

i. *Acute exposure and risk.* No appropriate endpoint attributable to a single dose exposure was identified in oral toxicity studies. Therefore, an acute RfD was not established, and there is no expectation of acute risk.

ii. *Chronic exposure and risk.* Of all of the crops for which fosetyl-Al is registered, its use on turf produces the highest estimated environmental concentrations (EECs). As a result, the EECs generated from use on turf are the ones used for comparison with the DWLOCs in this risk assessment. For surface water, the Agency's Generic Estimated Environmental Concentration (GENEEC) model has provided a 56-day EEC of 9 µg/L. As no data were available on the aerobic aquatic metabolism of fosetyl-Al (a GENEEC input), the aerobic soil metabolism half-life of 3 hours (0.125 day) was multiplied by a factor of 2 to use as a GENEEC input. Multiplying by 2 to account for a change in medium (aerobic soil to aerobic aquatic conditions) is a standard practice for surface water modeling in the absence of data when the pesticide is stable to hydrolysis. For ground water, the Screening Concentration in Ground Water (SCI-GROW2) model-derived concentration of 4.6×10^{-3} micrograms per liter (µg/L) can be used for chronic risk assessment. For this risk assessment, the surface water EEC of 9 µg/L was compared with the DWLOCs to determine whether or not fosetyl-Al residues in drinking water result in an unacceptable dietary exposure. The surface water EEC was chosen because it exceeds the ground water EEC.

Fosetyl-Al is not expected to reach ground or surface water under most conditions. Even if it reaches surface water, it is expected to degrade rapidly. In ground water, it could persist because of potentially low microbial content. Biodegradation is the only apparent means of fosetyl-Al dissipation. Fosetyl-Al rapidly degrades in both aerobic and anaerobic soil to degradates that are widespread in nature (Al^{+3}, phosphate, and ethanol). Under almost all uses, the degradation is expected to be so rapid that fosetyl-Al will not have time to move in soil, despite being highly soluble in water (120 µg/L) and potentially mobile in soil. As it is stable to abiotic hydrolysis, fosetyl-Al could persist in pristine receiving waters with low microbial content.

Parent fosetyl-Al is the only compound included in EFED's assessment. At this time the Agency has no reason to believe that there are toxicologically significant degradates to be included in the risk assessment.

The modeling results lead to the following maximum water exposures and the following DWLOCs for the U.S. population and three appropriate subgroups:

1. For the U.S. population the maximum water exposure would be 2.42 mg/kg/day and the DWLOC would be 85,000 µg/L.

2. For the females (13+) subgroup, the maximum water exposure would be 2.40 mg/kg/day and the DWLOC would be 72,000 µg/L.

3. For the infants/children subgroup, the maximum water exposure would be 2.34 mg/kg/day and the DWLOC would be 23,000 µg/L.

4. For the non-Hispanic other than Black or White subgroup, the maximum water exposure would be 2.40 mg/kg/day and the DWLOC would be 84,000 µg/L.

The Agency therefore concludes that the residues in water, as estimated by the models, are not a significant contribution to aggregate exposure.

iii. *Short- and intermediate-term toxicity.* Since no dermal or systemic toxicity was seen at the limit dose following repeated dermal applications in the 21-day toxicity study using rats, no endpoint value is calculable and therefore no risk analysis can be performed.

iv. *Cancer exposure and risk.* The Agency has concluded that fosetyl-Al is unlikely to pose a carcinogenic hazard to humans. Therefore, this risk assessment is not appropriate.

3. *From non-dietary exposure.* Fosetyl-Al is currently registered for use on the following residential non-food sites: lawn, turf, and ornamental plants.

i. *Acute exposure and risk.* No appropriate endpoint attributable to a single dose exposure was identified in oral toxicity studies. Therefore, an acute RfD could not be calculated, and there is no expectation of acute risk.

ii. *Chronic exposure and risk.* Long-term (chronic) exposure is not expected for residential uses. In addition, the Agency does not consider incidental hand-to-mouth ingestion by toddlers a concern since chronic exposure via this route is highly unlikely and because fosetyl-Al has a relatively short half-life.

iii. *Short- and intermediate-term exposure and risk.* Since no dermal or systemic toxicity was seen at the limit dose following repeated dermal applications in the 21-day toxicity study using rats, no endpoint value is calculable and therefore no risk analysis can be performed.

iv. *Cancer exposure and risk.* The Agency has concluded that fosetyl-Al is unlikely to pose a carcinogenic hazard to humans. Therefore, this risk assessment is not appropriate.

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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 November 26, 1997 (62 FR 62961) (FRL–5754–7).

D. Aggregate Risks and Determination of Safety for the U.S. Population

1. *Acute risk.* No appropriate endpoint attributable to a single dose exposure was identified in oral toxicity studies. Therefore, an acute RfD was not

established, and their is no expectation of acute risk.

2. *Chronic risk.* Chronic risk estimates associated with exposure to fosetyl-Al in food and water do not exceed HED's level of concern. The DEEM chronic exposure analysis showed that for the U.S. general population, 3% of the CPAD is occupied by dietary (food) exposure. For the most highly exposed subgroup, children 1–6 years old, 6% of the CPAD is occupied by dietary (food) exposure. The estimated average concentrations of fosetyl-Al in surface and ground water are less than HED's DWLOC for fosetyl-Al as a contribution to chronic aggregate exposure. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fosetyl-Al residues.

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

Since no dermal or systemic toxicity was seen at the limit dose following repeated dermal applications in the 21-day toxicity study using rats, no endpoint value is calculable and therefore no risk analysis can be performed.

4. *Aggregate cancer risk for the U.S. population.* The Agency has concluded that fosetyl-Al is unlikely to pose a carcinogenic hazard to humans. Therefore, this risk assessment is not appropriate.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fosetyl-Al residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children.* The Agency has determined that the FQPA factor should be 1x because:

1. The toxicology data base is complete.

2. There is no indication of increased susceptibility of rat or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity studies.

3. A developmental neurotoxicity study is not required.

4. Food exposure estimates are expected to be unrefined (that is, tolerance level residues and 100% crop treated assumed) and will likely result in an overestimate of the actual dietary exposure.

5. The Agency models used for ground and surface drinking water exposure estimates produce upper-bound concentration estimates.

6. The current residential use pattern is not of concern since no potential hazard was identified for short- or intermediate-term exposure (no risk assessment is required) and long-term exposure is not expected with this use. As a result of the 1x FQPA factor, the CPAD is the same as the RfD.

FFDCA section 408 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 database 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined inter- and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

2. *Acute risk.* No appropriate endpoint attributable to a single dose exposure was identified in oral toxicity studies. Therefore, an acute RfD was not established, and there is no expectation of acute risk.

3. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to fosetyl-Al from food will utilize up to 6 percent of the RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Despite the potential for exposure to fosetyl-Al in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. *Short- and intermediate-term risk.* Since no dermal or systemic toxicity was seen at the limit dose following repeated dermal applications in the 21-day toxicity study using rats, no endpoint value is calculable and therefore no risk analysis can be performed.

5. *Aggregate cancer risk for U.S. population.* The Agency has concluded that fosetyl-Al is unlikely to pose a carcinogenic hazard to humans. Therefore, this risk assessment is not appropriate.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to fosetyl-Al residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in plants is adequately understood. The residue of concern is parent fosetyl-Al. This conclusion was based on the results of metabolism studies performed on the following commodities: pineapples, grape vines, tomatoes , citrus, and apples. Residues of fosetyl-Al are not systemic; therefore, residues will be on the surface of plants. There are no feed items associated with preexisting tolerances or with bananas, grapes, or macadamia nuts; therefore, the nature of the residue in animals is not germane to this action. Section 40 CFR 180.6(a)(3) applies to this action. That is, it is not possible to establish with certainty whether finite residues will be incurred in animal commodities, but there is no reasonable expectation of finite residues.

B. Analytical Enforcement Methodology

Adequate methodology is available for enforcement of the proposed tolerances in/on bananas, blueberries, grapes, and macadamia nuts.

The gas chromatography/flame photometric detection, phosphorous-specific (GC/FPD-P) method is adequate to enforce the proposed tolerances on bananas and grapes. This method is an adaptation of the tolerance enforcement method for fosetyl-Al on pineapples (Pesticide Analytical Method (PAM) II, Food and Drug Administration, June 1986). The limit of quantitation (LOQ) and limit of detection (LOD) for the method are 0.10 and 0.05 ppm, respectively.

Method SOP–90113, dated 6/8/90 (a modified version of Rhone-Poulenc method 163) is used for the blueberry analysis. The method has been approved for publication in PAM II.

A modification of the GC/FPD-P method is adequate to enforce the proposed tolerance on macadamia nuts. This method is similar to the banana method in the extraction, derivitization, separation, and detection steps. Because of the macadamia nut matrix, more-involved cleanup steps are necessary.

Given the similarity of the macadamia nut method, an Agency pesticide method validation (PMV) will not be required. The LOQ and LOD for the method were not specified.

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5229.

C. Magnitude of Residues

1. *Bananas.* With bananas, seven field trials were conducted in Central and South America, from Mexico to Ecuador. These locations represent the climatic regions where bananas are grown for export to the United States. Over 96% of the bananas imported into the U.S. come from these countries. Bananas received two types of treatment: foliar and tree injection. In addition, bagged and unbagged samples were treated. The unbagged samples receiving foliar applications were the only ones with appreciable residues. Fourteen samples were treated at the 0.9x rate. Ten of these samples had quantifiable residues. The average of these ten samples was 0.58 ppm. Residues ranged up to 1.99 ppm. Four samples were treated at the 1.8x rate. The mean for these samples was 0.69 ppm. Residues ranged from 0.38 to 1.22 ppm. Of the unbagged samples receiving injection treatments (0.9x rate, 18 samples total), all samples had residue levels at or below the LOQ of 0.10 ppm. Four unbagged samples received a 1.8x injection treatment. Residue levels were below the LOQ for all four of these samples, as well. Of the 28 bagged samples, 26 had residue levels which were below the LOQ. The other 2 had residues which were slightly over the LOQ (0.11 and 0.13 ppm). A residue decline study was also performed. Mean residues (2 samples at each PHI) in the foliar-treated unbagged samples declined as follows: 0-day pre-harvest interval (PHI), 0.35 ppm; 3-day PHI, 0.22 ppm; 7-day PHI, 0.27 ppm; and 14-day PHI, <0.10 ppm. The Agency has a high level of confidence in the data.

2. *Blueberries.* Sufficient data to support a permanent tolerance for residues of fosetyl-Al in/on blueberries have not yet been submitted by the registrant. However, one study that was performed on blueberries in Michigan was submitted. This study showed a maximum residue of 32.7 ppm of fosetyl-Al in blueberries 30 days after an application of fosetyl-Al at the maximum label rate of 4 lb. active ingredient per acre and supports the time-limited tolerance of 40 ppm in/on blueberies. Two additional acceptable magnitude of residue studies must be submitted before the time-limited tolerance can be converted to a permanant tolerance.

3. *Grapes.* Four field trials were conducted in regions east of the Rocky Mountains, 2 to 3 specimens being collected from each plot. Five additional field trials were conducted west of the Rocky Mountains, three specimens being collected from each of these plots. Although the registration is for regions east of the Rocky Mountains, the tolerance was set at a level (10 ppm) that took into account the higher values which were obtained in the field trials that were performed west of the Rocky Mountains. The petitioner proposed a tolerance of 10 ppm because in extreme drought conditions residues will be higher. Although drought conditions are rare east of the Rocky Mountains, they are still possible. Among the 10 samples from the eastern field trials, one had a residue level below the LOQ of 0.50 ppm and the others had residues ranging from 0.52 to 2.45 ppm. The mean residue levels of these samples was 1.2 ppm. Among the 15 samples from the western field trials, residues ranged from 1.7 to 18 ppm. The Agency has a high level of confidence in the submitted field trial data.

4. *Macadamia nuts.* Despite the fact that only 2 field trials were performed and storage stability was poor, fosetyl-Al is not highly systemic and macadamia nuts have hard, impervious shells. As a result, no residues were expected to be detected, and none were found. Although limited residue data were provided, the Agency is confident that residues will not exceed a 0.20 ppm tolerance. The registrant initially requested that this tolerance be set at 0.3 ppm.

D. International Residue Limits

There are no Codex, Canadian, or Mexican international residue limits established for fosetyl-Al; therefore, the magnitude of the residue is not of concern for this action.

E. Rotational Crop Restrictions

None of the crops affected by this rule is grown in rotation with other crops. Therefore, rotational crop restrictions are unnecessary.

IV. Conclusion

Therefore, tolerances are established for residues of fosetyl-Al in or on bananas at 3.0 ppm, blueberries at 40 ppm, grapes at 10 ppm, and macadamia nuts at 0.20 ppm.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by September 7, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the **''ADDRESSES''** section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this regulation. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator

determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). 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.

VI. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300892] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at: opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in **''ADDRESSES''** at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408(d) of the FFDCA in response to petitions 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). 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) (Pub. L. 104–4). Nor does it require special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement

Fairness Act of 1996, 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 Part 180

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

Dated: June 30, 1999.

Peter Caulkins,

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. By revising § 180.415 to read as follows:

§ 180.415 Aluminum tris (O-ethylphosphonate); tolerances for residues.

(a) *General.* Tolerances are established for residues of the fungicide aluminum tris(*O*-ethylphosphonate) in or on the following food commodities:

Commodity	Parts per million	Expiration/Revocation Date
Avocados	25	None
Bananas	3.0	None
Blueberries	40	12/31/00
Brassica (cole) leafy vegetables group.	60	None
Caneberries	0.1	None
Citrus	0.5	None
Cucurbit vegetables group.	15	None
Ginseng root, fresh.	0.1	None
Hops, dried	45	None
Leafy vegetables (except brassica vegetables) group.	100	None
Macadamia nuts.	0.20	None
Pineapple	0.1	None
Pineapple fodder.	0.1	None
Pineapple forage.	0.1	None
Pome fruit	10	None
Onions, dry bulb.	0.5	None
Strawberries	75	None
Tomatoes	3	None

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for residues of the fungicide aluminum tris (*O*-ethylphosphonate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Asparagus	0.1
Grapes	10

(d) *Indirect or inadvertent residues. [Reserved]*

[FR Doc. 99–17351 Filed 7–7–99; 8:45 am]

BILLING CODE 6560–50–F–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 1

[OST Docket No. 1; Amdt. 1–300]

Organization and Delegation of Powers and Duties; Delegations to the Commandant, United States Coast Guard and Administrator, Maritime Administration

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: The Secretary of Transportation delegates to the Commandant, United States Coast Guard, authority to implement new ownership requirements for eligibility of vessels measuring less than 100 feet to receive a fishery endorsement to operate in certain fisheries. The Secretary also delegates the authority to assess penalties for fishery endorsement violations to the Commandant, United States Coast Guard. The authority to issue and implement regulations for vessels 100 feet and greater is delegated to the Administrator, Maritime Administration. This rule adds two new paragraphs to 49 CFR 1.46 and 1.66 to reflect these delegations of authority.

EFFECTIVE DATE: July 8, 1999.

FOR FURTHER INFORMATION CONTACT: Richard Weaver, Chief, Division of Management and Organization, Maritime Administration, MAR–318, Room 7301, 400 Seventh Street, SW., Washington, DC 20590; or Ms. Blane Workie, Office of the General Counsel, C–50, (202) 366–9314, Department of Transportation, 400 Seventh Street SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: The American Fisheries Act (Public Law 105–277) (''the Act'') amends current law regarding the ownership requirements for eligibility of a vessel to receive a fishery endorsement to operate in certain fisheries and under certain terms and conditions. The Secretary delegates to the Coast Guard the authority to issue and administer regulations implementing the new requirements for vessels measuring less than 100 feet. Regulations affecting vessels measuring 100 feet and greater will be developed and administered by the Maritime Administration. The Act requires the publication of these regulations by April 1, 2000.

The Act also outlines procedures for implementation and penalties for non-compliance. The Secretary delegates to the Coast Guard the authority to assess penalties for willful noncompliance with the new requirements under the American Fisheries Act because the Coast Guard has current authority, resources, and expertise to assess penalties.

The delegations should be made to the Commandant and to the Maritime Administrator as provided in this amendment to 49 CFR part 1 because the Coast Guard and the Maritime Administration have the requisite expertise, capability, and responsibility for the duties prescribed in the American Fisheries Act. Indeed, the Coast Guard is currently administering documentation requirements for vessels under 100 feet and has resources in place to effectively carry out the American Fisheries Act. Additionally, the Maritime Administration has a long history of administering certain maritime laws that require detailed scrutiny of ownership and control issues as they relate to U.S. citizenship requirements. The Maritime Administration's oversight of the new requirements for vessels 100 feet and greater is a natural extension of its current administration of citizenship enforcement.

We publish this rule as a final rule, effective on the date of publication. Since this amendment relates to departmental management, organization, procedure and practice, notice and comment are unnecessary under 5 U.S.C. 553(b). Further, since the