Commodity	Parts per million	Expiration/Revocation Date
Cattle, meat	0.60	7/31/05
Cattle, meat byproducts, except kidney	0.50	7/31/05
Goat, fat	0.30	7/31/05
Goat, kidney	4.0	7/31/05
Goat, meat	0.60	7/31/05
Goat, meat byproducts, except kidney	0.50	7/31/05
Hog, fat	0.30	7/31/05
Hog, kidney	4.0	7/31/05
Hog, meat	0.60	7/31/05
Hog, meat byproducts, except kidney	0.50	7/31/05
Horse, fat	0.30	7/31/05
Horse, kidney	4.0	7/31/05
Horse, meat	0.60	7/31/05
Horse, meat byproducts, except kidney	0.50	7/31/05
Milk	3.0	7/31/05
Sheep, fat	0.30	7/31/05
Sheep, kidney	4.0	7/31/05
Sheep, meat	0.60	7/31/05
Sheep, meat byproducts, except kidney	0.50	7/31/05

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0144; FRL–7195–1]

Fosetyl-Al; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the fungicide, fosetyl-Al aluminum tris (*O*-ethylphosphonate) in or on bushberry subgroup, lingonberry, salal and juneberry at 40 parts per million (ppm); turnip tops at 40 ppm; turnip roots at 15 ppm; succulent pea at 0.3 ppm; and citrus fruit group at 5.0 ppm. 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 August 29, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0144 must be received on or before October 28, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0144 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; 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 affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. 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.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0144. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity

Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of May 23, 2001 (66 FR 28479) (FRL–6780–2), EPA issued a notice 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 and 0E6221) 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. This notice included a summary of the petition prepared by Rhone-Poulenc Ag Company, Research Triangle Park, NC 27709, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.415 be amended by establishing tolerances for residues of the fungicide fosetyl-Al, aluminum tris (*O*-ethylphosphonate), in or on bushberry subgroup 13B, lingonberry, salal and juneberry at 40 ppm: turnip tops at 40 ppm and turnip roots at 15 ppm; succulent pea at 0.3 ppm; and citrus fruit group 10 at 5.0 ppm. Additionally, this rule deletes the previously established tolerance under 40 CFR 180.415(a) for citrus at 0.5 ppm. The higher citrus fruit group tolerance was requested in support of registration for a shorter pre-harvest interval for use of fosetyl-Al on citrus.

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 (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. 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 and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerances for residues of fosetyl-Al on bushberry subgroup, lingonberry, salal, and juneberry at 40 ppm; turnip tops at 40 ppm; turnip roots at 15 ppm; succulent pea at 0.3 ppm; and citrus fruit group at 5.0 ppm. EPA's assessment of exposures and risks associated with establishing the tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data 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.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (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 factor 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 Safety Factor.

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} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for fosetyl-Al used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FOSETYL-AL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary	Not applicable	Not applicable	No effects attributable to a single exposure (dose) were observed from the oral toxicity studies including developmental toxicity studies in rats and rabbits.
Chronic dietary all populations	NOAEL = 250 mg/kg/day UF = 100 Chronic RfD = 2.5 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD/FQPA SF = 2.5 mg/kg/day	2-Year chronic toxicity-dogs LOAEL = 500 mg/kg/day based on increased incidence of testicular degeneration
Short-term (1 to 30 days) and intermediate-term (1 to 6 months) Incidental oral (Residential)	NOAEL = 300 mg/kg/day	LOC for MOE = 100 (Residential) FQPA SF = 1x	3-Generation reproductive toxicity - rat LOAEL = 600 mg/kg/day based on decreased litter and pup body weight (on day 8) in both matings of each generation, F1 and F2
Short- and intermediate-term dermal (Residential)	None	Not applicable	No hazard identified. Risk assessment not performed.
Long-term dermal (greater than 6 months) (Residential)	Oral NOAEL = 250 mg/kg/day	LOC for MOE = 100 (Residential)	2-Year chronic toxicity-dog LOAEL = 500 mg/kg/day based on increased incidence of testicular degeneration
Short- and intermediate-term inhalation (Residential)	Oral study NOAEL= 300 mg/kg/day	LOC for MOE = 100 (Residential)	3-Generation reproductive toxicity - rat Parental (systemic) LOAEL = 600 mg/kg/day based on decreased body weight gains of F2b generation, and urinary tract changes in adults
Long-term inhalation (several months to lifetime) (Residential)	Oral study NOAEL = 250 mg/kg/day	LOC for MOE = 100 (Residential)	2-Year chronic toxicity - dog LOAEL = 500 mg/kg/day based on increased incidence of testicular degeneration
Cancer (oral, dermal, inhalation)	Classification: Unlikely to pose a carcinogenic hazard to humans.		

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 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; citrus and cranberry at 0.5 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; 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 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) was identified from the oral toxicity studies including developmental toxicity studies in rats and rabbits. Therefore, an acute reference dose was not established and this risk assessment was not performed.

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 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 in ground water. Biodegradation is the only apparent means of fosetyl-Al dissipation. Fosetyl-Al rapidly degrades in aerobic soil (half-life < 3 hours) and in anaerobic soil (half-life ranging from 14 to 40 hours) to degradates that are widespread in nature (Al^{3+}, PO_4^{3-}, 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 g/L) and potentially mobile in soil. Since 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 the Agency's assessment. The parent compound is also the residue of concern in both plant and livestock commodities.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fosetyl-Al in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of fosetyl-Al.

The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in 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 from residential uses. Since DWLOCs address total aggregate exposure to fosetyl-Al, they are further discussed in the aggregate risk sections in Unit III.E.

Based on the FIRST and SCI-GROW 2 models, the EECs for 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 exposure are estimated to be 0.00003 ppb for surface water and less than 0.006 ppb for ground water.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

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/post-application activities.

Short-term (1 to 30 days) dermal and inhalation exposures may occur to adult residential handlers from mixing, loading and applying fosetyl-Al to turf. However, intermediate-term (1 to 6 months) and long-term (more than 6 months) exposure durations are not likely based on the use pattern. In addition, the Agency did not select applicable short- or intermediate-term dermal endpoints. Therefore, only short-term inhalation exposure assessments for residential handlers from mixing, loading and applying fosetyl-Al to turf were performed. MOEs for short-term inhalation exposures are estimated at 170,000 for mixing loading and applying to turf with low pressure handwands and 140,000 for mixing, loading and applying to turf with hose-end sprayer. Short-term MOEs for inhalation exposure are above 100 and do not exceed EPA's level of concern.

There is potential dermal (adults and children) and oral exposure (children only) during post-application activities. However, because no dermal toxicity endpoints were identified, only incidental oral exposure to children is assessed. The following post-application exposure scenarios resulting from lawn treatment were assessed: (1) Incidental non-dietary ingestion of pesticide residues on lawns from hand-to-mouth transfer; (2) incidental non-dietary ingestion of residues from object-to-mouth activities (pesticide-treated turfgrass); and (3) incidental non-dietary ingestion of soil from pesticide-treated residential areas. The exposure and risk estimates for the three residential exposure scenarios are assessed for the day of application (day ''0'') because it is assumed that children could contact the lawn immediately after application. On the day of application, it was assumed that 5% of the application rate is available from the turfgrass as transferrable residue (20% for object-to-mouth activities). Based on the short half-life (<3 hours in aerobic soil), intermediate-term exposure is not expected. Risks from short-term incidental ingestion by children is assessed by comparing these exposures to the short and intermediate-term incidental oral endpoint (NOAEL = 300 mg/kg/day), based on parental systemic toxicity observed in a 3-generation reproduction study in rats. The short-term MOEs for children from post-application exposure to treated lawns are 1,100 based on oral hand-to-mouth activities; 4,400 from object-to-mouth (turfgrass) exposure; and 330,000 from incidental ingestion of soil from treated lawns. Short-term MOEs are above 100 and do not exceed EPA's level of concern. Intermediate-term exposure is not expected based on the short half-life (less than 3 hours in aerobic soil) and long-term exposure is not expected based on the use pattern.

Residential exposures that could reasonably be expected to occur on the same day are combined and compared to the appropriate toxicity endpoint. Because no dermal endpoints were identified, the only multiple-residential exposure scenarios involve children's exposure from oral routes following

turfgrass treatment. For incidental oral exposure to children in residential settings, the three scenarios that would reasonably be expected to occur on the same day are toddler's incidental ingestion of residues on turf from hand-to-mouth activities, mouthing turfgrass and eating soil. The combined short-term daily exposures total 0.34 mg/kg/day, leading to a combined short-term toddler MOE of 880 for incidental oral exposure. This MOE is above the target MOE of 100, and therefore does not exceed EPA's level of concern.

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from the ground application method employed for fosetyl-Al. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast, and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where 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. On this basis, the petitioner must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether fosetyl-Al shares a common mechanism of toxicity with any other substance and, if so, whether any tolerances for fosetyl-Al need to be modified or revoked.

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*. 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 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 margin of exposure (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 account 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 dietary 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 DWLOCs 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 the USEPA Office of Water are used to calculate DWLOCs: 2L/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, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP 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, OPP 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, an acute RfD was not established and no acute risk from exposure to fosetyl-Al is expected.

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 the Agency's level of concern.

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 on 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 and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

TABLE 2.—DWLOCS FOR CHRONIC DIETARY (NON-CANCER) EXPOSURE TO FOSETYL-AL

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
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 (less than 1 year old)	2.5	5	0.00003	0.006	24,000
Females (13-50 years old)	2.5	3	0.00003	0.006	73,000

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 (less than 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 and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO FOSETYL-AL

Population Subgroup	Aggregate MOE (Food + Residential)[1]	Target MOE[2]	Surface Water EEC[3] (ppb)	Ground Water EEC[3] (ppb)	Short-Term DWLOC[4] (ppb)
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 (less than 1 years old)	650	100	0.00003	0.006	25,000

[1]Aggregate MOE = NOAEL (300 mg/kg/day) ÷ (Average Food Exposure + Residential Exposure)
[2]The target MOE 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.

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 turnips (roots and tops), succulent peas, blueberries, and citrus. The method is Method I in PAM II, which uses diazomethane as the methylating agent and quantitation of fosetyl-Al by GC/FPD. The limit of quantitation (LOQ) is 0.05 ppm for turnips and succulent peas and 0.1 ppm for citrus. 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) 305–2905; e-mail address: griffith.francis@epa.gov.

B. International Residue Limits

There are no established or proposed maximum residue limits or tolerances for fosetyl-Al in or on turnip roots and tops, succulent peas, blueberries or citrus fruit for Canada, Mexico, or Codex.

C. Conditions

Registration for succulent pea will be conditional pending the submission of adequate storage stability data for this crop.

V. Conclusion

Therefore, the tolerances are established for residues of fosetyl-Al, aluminum tris (*O*-ethylphosphonate), in or on bushberry subgroup, lingonberry, salal, and juneberry at 40 ppm; turnip tops at 40 ppm; turnip roots at 15 ppm; succulent pea at 0.3 ppm; and citrus fruit group at 5.0 ppm. Since the tolerance for the citrus fruit group at 5.0 ppm supercedes the existing tolerance under 40 CFR 180.415(a) for citrus at 0.5 ppm, the tolerance for citrus at 0.5 ppm is deleted.

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 of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) 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), as was provided in the old FFDCA sections 408 and 409. 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 control number OPP–2002–0144 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 October 28, 2002.

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. 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.

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.

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.2. Mail your copies, identified by docket control number OPP–2002–0144, 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. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. 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. Regulatory Assessment Requirements

This final rule establishes a tolerances under FFDCA section 408(d) 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 FFDCA section 408(d), such as the tolerances 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 FFDCA section 408(n)(4). 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. 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 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: August 16, 2002.

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 374.

2. Section 180.415 is amended by removing the entry for ''Citrus'' and alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

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

(a) * * *

Commodity	Parts per million	Expiration/Revocation Date
* * *	* *	
Bushberry subgroup	40	None
* * *	* *	
Fruit, citrus, group	5.0	None

Commodity	Parts per million	Expiration/Revocation Date
* * *	* *	
Juneberry	40	None
* * *	* *	
Lingonberry	40	None
* * *	* *	
Pea, succulent	0.3	None
* * *	* *	
Salal	40	None
* * *	* *	
Turnip, roots	15	None
* * *	* *	
Turnip, tops	40	None
* * *	* *	

* * * * *

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