(vvv) * * *

(1) Amend the West Virginia program to be consistent with 30 CFR 701.11(e)(2) by clarifying that the exemption at CSR 38–2–3.8(c) does not apply to the requirements to restore the land to approximate original contour.

* * * * *

(iiii) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend the term ''recreational uses'' at W.Va. Code 22–3–13(c)(3) to mean ''recreational facilities use'' at SMCRA section 515(c)(3).

* * * * *

(qqqq) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to delete the proviso from W. Va. Code 22–3–23(c)(2)(C) which provides that Phase III bond can be released if the quality of postmining untreated discharge water is better than or equal to the premining water quality discharged from the site.

(rrrr) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–2.31.b. to clearly define forestry to mean a postmining land use used or managed for the long term production of wood or wood products in accordance with the Federal definition of forestry under the definition of land use at 30 CFR 701.5.

(ssss) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–3.25 to: (1) add the word ''reinstatement'' to the phrase ''transfer, assignment, or sale'' in the second sentence of subdivision CSR 38–2–3.25.a.4., and (2) amend 38–2–3.25.b. to provide that in no event can a reinstated permit be approved in advance of the close of the public comment period.

(tttt) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to make it clear that at CSR 38–2–7.4.a.1., only commercial forestry postmining use and not forestry postmining use may be approved for areas receiving a variance from the AOC requirements.

(uuuu) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to either remove the phrase, ''except for ponds and impoundments located below the valley fills,'' from its regulations at CSR 38–2–7.4.b.1.C.5 or revise the language to clarify that ponds and impoundments below the fill that are left in place must meet the requirements of CSR 38–2–5.5.

(vvvv) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to delete the phrase ''except for those areas with a slope of at least 50%'' from its regulations at CSR 38–2–7.4.1.D.2. Furthermore, the State must define the terms O and Cr soil horizons.

(wwww) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–7.4.b.1.D.6. to provide that the substitute material is equally suitable for sustaining vegetation as the existing topsoil and the resulting medium is the best available in the permit area to support vegetation.

(xxxx) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to: (1) delete the word ''excessive'' at CSR 38–2–7.4.b.1.G.1.; and (2) provide that at CSR 38–2–7.4.b.1.G.1., lesser or no vegetative cover may only be authorized by the Director when mulch or other soil stabilizing practices have been used to protect all disturbed areas and it has been demonstrated that the reduced vegetative cover is sufficient to control erosion and air pollution attendant to erosion regardless of slope.

(yyyy) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to amend CSR 38–2–7.4.b.1.G.3. to require the repair of all rills and gullies that disrupt the approved postmining land use or the establishment of vegetative cover or cause or contribute to a violation of water quality standards for the receiving stream.

(zzzz) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–7.4.b.1.H.2. by deleting ''7.4.d.1.G.1.'' in two places and replacing the deleted citation with ''7.4.b.1.H.1.''

(aaaaa) By October 17, 2000, West Virginia WVDEP must consult with and obtain the approval of the West Virginia Division of Forestry on the new stocking standards for commercial forestry and forestry at CSR 38–2–7.4.b.1.I.

(bbbbb) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–7.4.b.1.I.2., or otherwise amend the West Virginia program, to delete the phrase, ''where there is potential for excessive erosion on slopes greater than 20%.''

(ccccc) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–7.4.b.1.I.2. to delete the words ''rock cover.''

(ddddd) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to amend CSR 38–2–7.4.b.1.I.2. to correct the citation error by deleting ''7.4.d.1.G.1.'' and replacing the deleted citation with ''7.4.b.1.H.1.''

(eeeee) By October 17, 2000, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption to delete the term ''commercial forestry'' at CSR 38–2–14.12.a.1.

[FR Doc. 00–20800 Filed 8–17–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301032; FRL–6599–4]

RIN 2070–AB78

Fosetyl–Al; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of fosetyl–Al in or on cranberries. Interregional Research Project Number 4 (IR4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act, (FFDCA) as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective August 18, 2000. Objections and requests for hearings, identified by docket control number OPP–301032, must be received by EPA on or before October 17, 2000.

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 control number OPP–301032 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–3194; e-mail address: brothers.shaja@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/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301032. 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 June 21, 2000 (65 FR 38535) (FRL–6558–9), EPA issued a notice pursuant to section 408 of the 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 a pesticide petition (PP) for tolerance by IR–4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390. This notice included a summary of the petition prepared by Aventis, 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 a tolerance for residues of the fungicide fosetyl–Al, aluminum tri(*O*–ethyl phosphonate), in or on cranberries at 0.5 part per million (ppm).

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 tolerance for residues of fosetyl–Al on cranberries at 0.5 ppm. EPA's assessment of 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 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1–SUBCHRONIC, CHRONIC AND OTHER TOXICITY

Study Type	Results
21–Day Dermal Toxicity–Rat	NOAEL =1,500 mg/kg/day highest dose tested (HDT) LOAEL = 1,500 mg/kg/day
3–Month Oral–Rat	NOAEL = 482 mg/kg/day 5,000 ppm LOAEL = 1,250 mg/kg/day 25,000 ppm, based on a slight increase in extramedullary hematopoiesis of the spleen.
3–Month Oral–Dog	NOAEL =250 mg/kg/day 10,000 ppm LOAEL = 1,250 mg/kg/day 50,000 ppm, based on decreased serum potassium levels at the HDT.
Chronic Feeding– 2–Year– Dog	NOAEL = 250 mg/kg/day LOAEL = 500 mg/kg/day, based on testicular degeneration (spermatocytic and/or spermatidic giant cells in the lumen of the seminiferous tubules.
Chronic toxicity/Carcinogenicity–Rat	NOAEL = 400 mg/kg/day LOAEL = 1,500 mg/kg/day, increased urine protein and urinary bladder pathology (tumors).
Carcinogenicity–Mouse	NOAEL (systemic)= 409 mg/kg/day 2,500 ppm LOAEL (systemic)= 1672 mg/kg/day 5,000 ppm, based on slight increases in white blood cells.
Developmental Toxicity–Rabbits	Maternal NOAEL = 125 mg/kg/day LOAEL = 250 mg/kg/day, based on decreased mean body weight Developmental NOAEL = 500 mg/kg/day HDT LOAEL > not established
Developmental Toxicity–Rats	Maternal NOAEL = 1,000 mg/kg/day LOAEL = 4,000 mg/kg/day, based on decreased mean body weights and body weight gain, and increased maternal death Developmental NOAEL = 1,000 mg/kg/day LOAEL = 4,000 mg/kg/day, based on decreased litter and mean fetal body weight, increased resorptions, malformations and skeletal variations.
3–Generation Reproductive Toxicity–Rats	Parental/Systemic NOAEL = 300 mg/kg/day LOAEL = 600 mg/kg/day, based on decreased body weight gains of the F2b generation, and urinary tract changes in adults Reproductive (offspring) NOAEL = 300 mg/kg/day Reproductive (offspring) LOAEL = 600 mg/kg/day, based on decreased litter and pup body weight (Day 8) in both matings of each generation. *In utero* (developmental) NOAEL is > 1,200 mg/kg/day at the HDT.
Gene Mutation–*Salmonella* DNA Repair– *E. Coli* Point Mutation UDS–Hamster Micronucleus Assay Mice Reverse mutation–*S. Cerevisiae* Metabolism–Rat	Non–mutagenic (±) activation. Non–mutagenic and negative (+) activation. Non–mutagenic (±) activation. Non–mutagenic Non–mutagenic First study: (Fosetyl–Al tech.): rapidly metabolized to give mainly carbon dioxide (60%) recovered from exhaled air. About 26% was excreted in the urine containing a larger mount of the metabolite phosphite (phosphorus acid). Only 3–4% was in the feces as the phosphite metabolite. Second study: (Phosphorous acid phosphite metabolite): mainly excreted in the urine (59–65%) and feces (30–32%).

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the 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 intra species 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 x 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.

TABLE 2–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	None	None	None
Chronic Dietary (Non–Cancer)	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 in Dogs. Based on testicular degeneration (spermatocytic and or spermatidic giant cells in the lumen of the seminiferous tubules) in 2/6 males.
Short–Term Dermal (1 to 7 days) (Residential)	None	None	21–Day dermal in the Rat. No dermal or systemic toxicity was seen at the Limit–Dose following repeated dermal applications to Rats.
Intermediate–Term Dermal (1 week to several months) (Residential)	None	None	21–Day dermal in the Rat. No dermal or systemic toxicity was seen at the Limit–Dose following repeated dermal applications to Rats.
Long–Term Dermal (several months to lifetime) (Residential)	dermal (or oral) study NOAEL= 250 mg/kg/day (dermal absorption rate 17%)	None	2–Year Chronic in Dogs. Based on testicular degeneration (spermatocytic and or spermatidic giant cells in the lumen of the seminiferous tubules) in 2/6 males.
Inhalation (Any time period) (Residential)	inhalation (or oral) study NOAEL= 250 mg/kg/day	None	2–Year Chronic in Dogs. Since the dose identified is from an oral study (chronic dog), route–to–route extrapolation (CCC) should be followed based on use and application rate.
Cancer (oral, dermal, inhalation)	Fosetyl–Al is *unlikely* to pose a carcinogenic hazard to humans. The RFD approach is used for quantification of human risk which is identical to the chronic assessment.	None	

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 (RACs) with tolerances ranging from 0.1 ppm for asparagus, caneberries, ginseng, and pineapples to 100 ppm for leafy vegetables (excluding Brassica). Other significant registrations include Brassica leafy vegetables, citrus, cucurbits, strawberries, and tomatoes. In addition, a timelimited tolerance is currently in effect for blueberries (40 ppm) in conjunction with an emergency exemption under section 18 of FIFRA. 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 fooduse pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. A toxicological endpoint for acute dietary toxicity was not selected. Therefore, a risk assessment for dietary food exposure was not conducted.

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 1989–1991 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 cPAD used for the chronic dietary analysis was 2.5 mg/kg/day. As the 10X safety factor was removed, the cPAD is equal to the RfD.

Dietary exposure for various subgroups of the U.S. population was estimated through the use of the (DEEM™) software. As the risk estimate was low for even the most highly exposed subpopulation, no anticipated residues were used. EPA 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., cranberries).

iii. *Cancer*. Fosetyl–Al is unlikely to pose a carcinogenic hazard to humans. Therefore, a cancer risk assessment was not conducted.

2. *Dietary exposure from drinking water*. Fosetyl–Al is not expected to reach ground or surface water under most conditions. If it does reach 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 g/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.

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 Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI–GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening–level assessment for surface water. The GENEEC model is a subset of the PRZM/ EXAMS model that uses a specific high–end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a % 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. of this preamble.

Based on the GENEEC and SCI–GROW2 models the estimated EECs of fosetyl–Al for chronic exposures are estimated to be 9.0 ppb for surface water and 0.00038 ppb for ground water. The chronic GENEEC value is adjusted (divided) by a factor of three when comparing the EEC for surface water to nonacute DWLOCs. This results in a chronic exposure estimate for surface water at 3 ppb.

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. The risk assessment was not conducted using the following residential exposure assumptions: Under the brand names CHIPO® Aliette WDG and Aliette® HG. CHIPO® Aliette WDG, the above uses are sold to professional applicators only which includes lawn care operators (LCO). For this reason, all residential uses of CHIPO® Aliette WDG are applied by the LCO. The use of Fosetyl–Al directly by the homeowner constitutes a minor use of the product since only small quantities of Aliette® HG are sold in the market. Short–term and intermediate–term exposures may occur for residential handlers and for post–application activities. Because the EPA did not select applicable short–term and intermediate–term dermal endpoints, a dermal risk assessment is not required. Long–term or chronic dermal exposure is not expected for residential uses.

In addition, EPA did not recommend a risk assessment for incidental hand–to–mouth ingestion by toddlers. While incidental ingestion of residues by toddlers may occur, no acute RfD was identified. Risk from intermediate–term incidental ingestion by toddlers is assessed by comparing exposure to the NOAEL from an oral study selected for either short or intermediate–term dermal or inhalation risk assessment. However, EPA reviews indicated that incidental hand–to–mouth ingestion is not a concern because the chronic oral endpoint (testicular degeneration) is unlikely to be relevant to toddlers and chronic oral exposure because fosetyl–Al has a relatively short half–life. EPA does not believe that the criteria for a quantitative risk has been met, therefore, no assessment of incidental ingestion was conducted.

Inhalation risk for non–occupational (e.g., residential) handlers is possible from mixing, loading and applying fosetyl–Al to turf using a lowpressure handwand. A risk assessment was conducted which assumes an application rate of 0.42 lb/ai per 1,000 ft^2 and 10,000 ft^2 area treated per day. The unit exposure was calculated at 0.03 (µg/lb/ai) with an absorption factor of 100% and a body weight of 70 kg. The daily dose, which is equal to the application rate x area treated x unit exposure x absorption factor /body weight, is 0.0018 mg/kg/day. The short–and intermediate–term MOE equal to the short–term and intermediate–term NOAEL/ daily dose is 1.4 million for this activity, and is below EPA's level of concern for nonoccupational inhalation risk.

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 (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *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 MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Pre–natal and post–natal sensitivity*. A three generation reproduction study in rats and developmental toxicity studies in rats and rabbits did not indicate any concern for pre–natal or post–natal effects in

offspring or for reproductive effects. Therefore, there was no evidence of increased sensitivity due to pre–natal or post–natal exposure to fosetyl–Al.

iii. *Conclusion*. There is a complete toxicity data base for fosetyl–Al and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA Safety Factor Committee determined that the 10X factor should be removed from fosetyl–Al for several reasons, including the facts that the toxicology data base is complete and there is no indication of increased susceptibility of rat or rabbit fetuses to *in utero* and/or post–natal exposure in the developmental and reproductive toxicity studies.

E. Aggregate Risks and Determination of Safety

1. *Acute risk*. Acute aggregate risk is based upon the estimated risks from the combined exposures of food and drinking water sources. The EPA did not recommend an acute dietary endpoint for fosetyl–Al, therefore no acute aggregate risk assessment was conducted, and there is no expectation of acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fosetyl–Al from food will utilize 3.1% of the cPAD for the U.S. population, 2.7% of the cPAD for females (13–50) years, 6.3% of the cPAD for children 1–6 years old, and 4.2% of the cPAD for Non–Hispanic (other than black or white). Based on the use pattern, chronic residential exposure to residues of the fosetyl–Al is not expected. In addition, there is potential for chronic dietary exposure to fosetyl–Al in drinking water. After calculating the 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 3. SUMMARY OF DWLOC CALCULATIONS FOR FOSETYL–AL FOR AGGREGATE RISK

Population Subgroup	cPAD mg/kg/day	%cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	2.5	3.1	3	0.00038	84,000
Females (13–50 years)	2.5	2.7	3	0.00038	72,000
Children (1–6 years)	2.5	6.3	3	0.00038	23,000
Non–Hispanic (other than black or white)	2.5	4.2	3	0.00038	84,000

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). Though residential exposure could occur with the use of fosetyl–Al, no toxicological effects have been identified for short–term toxicity. Therefore, the aggregate risk do not exceed the Agency's level of concern.

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). Though residential exposure could occur with the use of fosetyl–Al, no toxicological effects have been identified for intermediate–term toxicity. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population*. Fosetyl–Al is classified non–carcinogenic and is unlikely to pose a carcinogenic hazard to humans. Therefore, no cancer aggregate exposure assessment was done.

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

A detailed description of Rhone–Poulenc's ''Method of Analysis for Fosetyl–Al Residues in Citrus,'' was provided. This procedure is identical to that described in the Pesticide Analytical Manual, Volume II (PAM II). The studies reported in the subject petition validate the method on cranberries fortified at 0.05 ppm, 0.5 ppm and 5.0 ppm. The recoveries ranged from 70 to 91%. The limit of quantitation (LOQ) was reported at 0.05 ppm. EPA concludes that the available GC/FPD–P methodology (PAM II) is adequate for enforcing tolerances and collecting residue data on fosetyl–Al residues in/on cranberries.

B. 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.

V. Conclusion

Therefore, the tolerance is established for residues of fosetyl–Al, aluminum tris(*O*–ethyl phosphonate), in or on cranberries at 0.5 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA 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–301032 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 17, 2000.

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 (1,900), 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. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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 (202) 260–4865.

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–301032, 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 file format 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 tolerance 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). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and LowIncome Populations* (59 FR 7629, February 16, 1994); or require 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 tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

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

requirednformation 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 record keeping requirements.

Dated:August 3, 2000.

James Jones,

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), (346a) and 371.

2. Section 180.415 is amended by adding the commodity ''cranberry'' to the table in paragraph (a) to read as follows:

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

(a) *General.* * * *

Commodity	Parts per million	Expiration/Revocation Date
* * * * *		
Cranberry	0.5	None
* * * * *		

* * * * *

[FR Doc. 00–21081 Filed 8–17–00; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301037; FRL–6737–6]

RIN 2070–AB78

Acibenzolar-S-Methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of acibenzolar-*S*-methyl in or on bananas; Brassica (cole) leafy vegetables; fruiting vegetables; tomato, paste; leafy vegetables (except spinach); and spinach. Novartis Crop Protection, Inc. 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 18, 2000. Objections and requests for hearings, identified by docket control number OPP–301037 must be received by EPA on or before October 17, 2000.

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 control number OPP–301037 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Daniel Kenny, Acting PM–22, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–7546; and e-mail address: kenny.dan@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	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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/.

2.*In person*. The Agency has established an official record for this action under docket control number OPP–301037. 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.