ENVIRONMENTAL PROTECTION AGENCY

[PF–1019; FRL–6780–2]

Notice of Filing a Pesticide Petition to Establish a Tolerance fora Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1019, must be received on or before June 23, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1019 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 PF–1019. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, 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 Highway, 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.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1019 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1019. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 9, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Reseach Project Number 4 (IR-4)

PP 5E4434 and 0E6219

EPA has received pesticide petitions (5E4434 and 0E6219) from the Interregional Reseach Project Number 4 (IR-4), New Jersey Agricultural Experiment Station, Rutgers University, New Brunswick, NJ 08903 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of the fungicide, aluminum tris (O-ethylphosphonate) (referred to in this document as fosetyl-Al) in or on the raw agricultural commodities as follows:

1. PP 5E4434 proposes the establishment of tolerances for the bushberrysubgroup, and lingonberry, salal, and juneberry at 40 parts per million (ppm).

2. PP 0E6221 proposes the establishment of tolerances for turnip roots and tops (leaves) at 50 ppm, peas (succulent) at 0.3 ppm, and citrus at 5 ppm.

EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of these petitions. Additional data may be needed before EPA rules on these petitions.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of fosetyl-Al in plants is adequately understood. Adequate data on the nature of the residues in plants, including identification of major metabolites and degradates of fosetyl-Al, are available. Radiolabeled studies on the uptake, translocation and metabolism in plants show that the chemical proceeds through hydrolytic cleavage of the ethyl ester. The major residues are fosetyl-Al, phosphorus acid, and ethanol. The tolerances are established for the parent only, that is fosetyl-Al.

2. *Analytical method*. Adequate methods are available for enforcement purposes. There are two analytical methods acceptable for determining residues of fosetyl-Al in plants: a gas chromatography method is available for enforcement of tolerance in pineapple and is listed as Method I in PAM, Vol. II; a gas chromatography/phosphorus specific flame photometric detector (FPD-P) method (Rhone-Poulenc Method No. 163) for citrus has undergone a successful method tryout on oranges and has been sent to the Food and Drug Administration for inclusion in PAM as Method II.

3. *Magnitude of residues*. Magnitude of residue data are adequate for the proposed commodities.

B. Toxicological Profile

1. *Acute toxicity*. A complete battery of acute toxicity studies for fosetyl-Al technical has been conducted. The lethal doseLD_{50} from the acute oral rat is 5.4 grams/kilograms (g/kg) and the LD_{50} from an acute dermal rabbit study is>2 g/kg. The LD_{50} for a rat inhalation study is >1.73 milligrams/liter (mg/L). The acute oral rat and primary dermal irritation studies indicate category IV toxicity. A guinea pig dermal sensitization study shows fosetyl-Al is not a skin sensitizer. The primary eye irritation study in rabbits shows fosetyl-Al to be an eye irritant with Category I toxicity.

2. *Genotoxicity*. Fosetyl-Al is neither mutagenic nor genotoxic. The genetic toxicity potential of fosetyl-Al was assessed in several assays. Eight mutagenicity tests performed with fosetyl-Al were negative. The tests included two Ames assays with*S. typhimurium*, two phase induction assays using*E. coli*, two micronucleus studies in mice, one DNA repair assay using *E. coli* and one mutation assay in *Saccharomyces cerevisiae*.

3. *Reproductive and developmental toxicity*. Fosetyl-Al is not a reproductive toxicant and shows no evidence of estrogenic or androgenic related effects.

i. In a three generation reproduction study, fosetyl-Al was administered to rats at dietary levels of 0, 6,000, 12,000 or 24,000 ppm. No adverse effects on reproductive performance or pup survival were observed in any dose group. The lowest observed adverse effect level (LOAEL) was established at 12,000 ppm based on effects on animal weights and urinary tract changes. The no observed adverse effect level (NOAEL) for all effects was 6,000 ppm.

ii. A developmental study in rats dosed via oral gavage at 500, 1,000 or 4,000 mg/kg/day showed a developmental NOAEL of 1,000 mg/kg. At 4,000 mg/kg, there was maternal toxicity, as evidenced by effects on animal weights, maternal deaths, increased resorptions, and delayed fetal ossification.

iii. A rabbit developmental study showed no toxic effects at oral doses up to 500 mg/kg. Effects of fosetyl-Al on fetal development were observed only in the rat at a dose producing severe maternal toxicity. In the absence of maternal toxicity, no adverse effects on fetal development were observed, i.e. at

1,000 mg/kg/day in rats or at 500 mg/kg/day in rabbits.

4. *Subchronic toxicity.* In subchronic studies, no significant toxicity was observed even at doses exceeding the limit of 1,000 mg/kg/day.

i. A 21–day dermal study in rabbits showed mild to moderate skin irritation and a NOAEL of 1.5 g/kg/day.

ii. A 90–day feeding study in rats showed a NOAEL of>5,000 ppm; the LOAEL was 25,000 ppm with extramedullary hematopoiesis in the spleen.

iii. A 90–day dog feeding study showed a NOAEL of 10,000 ppm and a LOAEL at 50,000 ppm, at which the test animals had a lower serum potassium level than untreated animal.

5. *Chronic toxicity.* Chronic toxicity studies have been conducted in dogs and rats.

i. *Dog.* Fosetyl-Al was fed to dogs for 2 years at concentrations of 0, 10,000, 20,000, and 40,000 ppm. The NOAEL was 10,000 ppm, equivalent to 250 mg/kg/day. The LOAEL was 20,000 ppm based on a slight degenerative effect on the testes. These testicular changes, as well as a few scattered clinical changes, were seen in the high dose dogs. No effects were observed in the urinary tract.

ii. *Rat.* Fosetyl-Al was administered via a mixture in the diet to CD rats at target levels of 0, 2,000, 8,000, and 30,000/40,000 ppm for approximately 2 years. Based on these levels, respective doses were 100, 400 and 2,000/1,500 mg/kg/day. After 2 weeks at 40,000 ppm, this dietary level was reduced to 30,000 ppm due to the occurrence of red coloration of the urine and a decrease in body weight gain. Although these findings were no longer apparent after week 2, analytical verification of dietary levels revealed that the highest dietary level ranged from approximately 38,000 to 61,000 ppm during the first 32 weeks of the study. No significant differences in body weight or food consumption were noted at 2,000 or 8,000 ppm. No biologically significant differences were observed in ophthalmoscopy, hematology, clinical chemistry, or urinalysis for treated and control animals. Calculi in the urinary bladder were observed for several male and female rats in the high dose group. Non-neoplastic findings consisted of epithelial hyperplasia and inflammation in the urinary bladders of males at 30,000/40,000 ppm. Increased incidences of hydronephrosis, inflammation, and epithelial hyperplasia in the kidney were also observed in males from the high dose group. Females from the same group exhibited increased incidences of epithelial hyperplasia in the urinary bladder and hydronephrosis in the kidney. The NOAEL in the chronic rat study was 8,000 ppm (400 mg/kg/day). The lowest NOAEL for chronic effects of fosetyl-Al is 10,000 ppm (250 mg/kg/day) based on the dog study. This NOAEL is based on minor changes at 20,000 ppm. In the rat, calculi in the urinary bladder and related histopathological changes in the bladder and kidneys of males and females were observed at 30,000/40,000 ppm.

6. *Carcinogenicity.* Long-term feeding studies were conducted with technical grade fosetyl-Al in mice and rats and with monosodium phosphite, the primary urinary metabolite of fosetyl-Al, in rats. These studies, and a mechanistic study in rats, are described below:

i. *Rat.* In addition to the chronic studies previously noted, calculi in the urinary bladder were also observed for several male and female rats at 30,000/40,000 ppm. Microscopic examination revealed transitional cell carcinomas and papillomas in the urinary bladders of high dose males. A statistically significant increase in adrenal pheochromocytomas (benign and malignant combined) was observed in males at 8,000 and 30,000/40,000 ppm. The adrenal slides were independently reread by two consulting pathologists who found no significant dose-related increases in the incidence of pheochromocytomas or hyperplasia.

The NOAEL for fosetyl-Al in the chronic rat study was 8,000 ppm; however, a subsequent mechanistic study in rats conducted with dietary levels of 8,000, 30,000 and 50,000 ppm demonstrated that the massive doses of 30,000 and 50,000 ppm fosetyl-Al alter calcium/phosphorous homeostasis resulting in severe acute renal injury, similar to that observed in the chromic rat study, and the formation of calculi in kidneys, ureters, and bladder. Under conditions of chronic exposure, these effects could lead to the formation of bladder tumors as seen in the chronic rat study. At 8,000 ppm, no evidence of renal injury was observed, a result consistent with the absence of bladder tumors. Thus, the bladder tumors induced by fosetyl-Al were the result of acute renal injury followed by a chronic toxic reaction rather than a true carcinogenic effect. An carcinogenicity study in rats was conducted with monosodium phosphite administered via dietary mixture at levels of 2,000, 8,000, and 32,000 ppm. No evidence of carcinogenicity was observed in this study.

ii. *Mouse.* A 2–year feeding/carcinogenicity study was conducted in mice fed diets containing fosetyl-Al at 0, 2,500, 10,000, or 20,000/30,000 ppm. The 20,000 ppm dose was increased to 30,000 ppm during week 19 of the study. The NOAEL for all effects was 20,000/30,000 ppm (3,000/4,500 mg/kg/day). There were no carcinogenic effects observed under the conditions of this study.

iii. The Office of Pesticide Programs', Health Effects Division, Carcinogenicity Peer Review Committee (CPRC) concluded in their report of June 29, 1993 that the pesticidal use of fosetyl-Al is unlikely to pose a carcinogenic hazard for humans given that: Tumors develop in rats under extreme conditions that are unlikely to be achieved other than under laboratory conditions (at a dose in excess of the EPA dose limit for carcinogenicity studies); tumors in rats are believed to develop only at doses that produce stones; human dietary exposure to fosetyl-Al is only about one-500,000th of the NOAEL for stone formation in the rat (the most sensitive experimental model); and the dose of fosetyl-Al which can be absorbed dermally by applicators is also probably too low to result in stone formation. EPA has therefore chosen to use the Reference Dose (RfD) to quantify dietary risk to humans.

7. *Animal metabolism.* Rat metabolism studies showed that most of the radiolabel rapidly appeared in exhaled carbon dioxide. There was also some radiolabel excreted in the urine as phosphite, along with a smaller amount as the unchanged parent compound. It appears that fosetyl-Al is essentially completely absorbed after ingestion and extensively hydrolyzed to carbon dioxide which is exhaled. The phosphite is excreted in the urine without further oxidation to phosphate. Aluminum does not appear to be absorbed to a significant extent from the gastrointestinal trac.

8. *Metabolite toxicology.* There are no metabolites of toxicological concern. The tolerances are established for the parent only, that is fosetyl-Al.

9. *Endocrine disruption.* No evidence of estrogenic or androgenic effects were noted in any study with fosetyl-Al. No adverse effects on mating or fertility indices and gestation, live birth, or weaning indices were noted in a three-generation rat reproduction study at doses well above EPA's limit of 1,000 mg/kg/day. Therefore, Aventis Crop Science concludes that fosetyl-Al does not have any effect on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure.* EPA has established the chronic RfD for fosetyl-

Al at 2.5 mg/kg/day. This RfD is based on a NOAEL of 250 mg/kg/day from a 2–year feeding study in dogs and the use of a 100 fold safety factor to account for interspecies and intraspecies differences. No appropriate endpoint attributable to a single dose exposure was identified in oral toxicity studies. Therefore, an acute RfD was not established and there is no expectation of acute risk. Since no dermal or systemic toxicity was seen at the limit dose following repeated dermal applications in the 21–day toxicity study using rats, no endpoint value was calculated for short- and intermediate-term exposure and risk. The Agency has concluded that fosetyl-Al is unlikely to pose a carcinogenic hazard to humans. Therefore, a cancer exposure and risk assessment is not appropriate.

i. *Food*. For all currently registered uses of fosetyl-Al, chronic food exposure for various subgroups of the U.S. population was estimated by EPA through the use of the Dietary Exposure Evaluation Model (DEEM) software. The DEEM analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-1991 nationwide Continuing Surveys of Food Intake by Individuals. As the risk estimate was low for even the most highly exposed subpopulation, no anticipated residues were used. One hundred percent crop treated and tolerance level residues were assumed for all crops. Based on the results of this conservative analysis, exposure to fosetyl-Al residues from the proposed uses is expected to be minimal. Aventis Crop Science concludes that dietary exposure to fosetyl-Al resulting from the currently registered and the proposed uses of the product will be well below the Agency's level of concern.

ii. *Drinking water*. There is no established maximum contaminant level or health advisory level for fosetyl-Al. The potential for ground water and/or surface water contamination by fosetyl-Al and its degradates is expected to be very low, in most cases, due to the rapid degradation of the compound in soil to non-toxic degradates under both aerobic and anaerobic conditions. Under aerobic laboratory conditions, the half-life of fosetyl-Al is between 1 and 1.5 hours in loamy sand, silt loam and clay loam and 20 minutes in sandy loam soil. The degradation proceeds through the hydrolysis of the ethyl ester bond, resulting in the formation of phosphorous acid and ethanol. The ethanol is further degraded into carbon dioxide. Based on the short half-life of fosetyl-Al and the known fate of phosphates under anaerobic conditions, EPA determined that an anaerobic soil metabolism study was not necessary. An anaerobic aquatic soil metabolism study was conducted. When anaerobic conditions were established by flooding soil, the half-life was 40 hours with silty clay loam and 14 hours with sandy loam soil. Aventis Crop Science expects that potential fosetyl-Al residues in drinking water are not a significant contribution to aggregate exposure.

2. *Non-dietary exposure*. Fosetyl-Al is currently registered for residential use on turf and ornamental plants. Chronic exposure is not expected for residential uses. There is also no expectation of acute risk. No appropriate endpoint attributable to a single dose exposure was identified in oral toxicity studies and consequently, an acute RfD cannot be calculated. No endpoint value is calculable for short- and intermediate-term exposure and a risk analysis cannot be performed since no dermal or systemic toxicity was seen at the limit dose following repeated dermal applications in the 21–day toxicity study using rats. The Agency has previously concluded that fosetyl-Al is unlikely to pose a carcinogenic hazard to human. Therefore, a cancer exposure and risk assessment is not appropriate. Thus, Aventis Crop Science concludes that the ornamental and turf uses do not add significantly to the aggregate exposure for fosetyl-Al.

D. Cumulative Effects

Effects associated with fosetyl-Al are unlikely to be cumulative with any other compound. The formation of calculi and bladder tumors in rats is the only significant toxicological effect observed with fosetyl-Al. These effects were observed in rat only at a dose which not only exceeds estimated human exposure by several orders of magnitude but is in excess of the EPA dose limit for carcinogenicity studies. Therefore, an aggregate assessment based on common mechanisms of toxicity is not appropriate as exposure to humans will be well below the levels producing calculi and bladder tumors in rats. Further, considering the rapid elimination of fosetyl-Al in the rat metabolism study, any effects associated with fosetyl-Al are unlikely to be cumulative with any other compound. Based on these reasons, only the potential risks of fosetyl-Al are considered in the exposure assessment.

E. Safety Determination

1. *U.S. population*. Chronic risk estimates associated with exposure to fosetyl-Al in food and water are expected to be well below the Agency's level of concern. The DEEM chronic exposure analysis previously performed by the Agency for all currently registered food uses shows that exposure to fosetyl-Al utilizes 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). This analysis was conducted assuming 100% crop treated and tolerance level residue values for all crops. The contribution of fosetyl-Al residues in surface and ground water to chronic aggregate exposure is expected to be minimal. Therefore, Aventis Crop Science concludes that even when considering the potential incremental risk resulting from the proposed uses, there is a reasonable certainty that no harm will result from aggregate exposure to fosetyl-Al residues.

2. *Infants and children*. No indication of increased susceptibility of rat or rabbit fetuses to *in utero* and/or postnatal exposure was noted in the developmental and reproductive toxicity studies. The Agency has previously determined that no additional safety factor to protect infants and children is necessary for this product.

Using the conservative assumptions described in the exposure section, aggregate exposure to fosetyl-Al from currently registered food uses will utilize up to 6.3% of the RfD for infants and children. Even when considering the potential incremental dietary risk resulting from the proposed uses, the potential for exposure to residues in drinking water and from non-dietary, non-occupational exposure, the aggregate exposure to fosetyl-Al is expected to be well below 100% of the RfD. Aventis Crop Science concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to fosetyl-Al residues.

F. International Tolerances

There are presently no Codex Alimentarius Commission maximum residue levels established for residues of fosetyl-Al.

[FR Doc. 01–12906 Filed 5–22–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1023; FRL–6782–5]

Notice of Filing a Pesticide Petition to Establish a Tolerance fora Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).