Environmental Management (1601F), 401 M Street, SW, Washington, D.C. 20460. There will also be an opportunity for the public to make comments directly to the committee during the first day of the meeting. Requests to make public comments must be submitted no later than March 1,1999 to Gwendolyn Whitt, at the address above or faxed to (202)-260–6882.

FOR FURTHER INFORMATION CONTACT: Gwendolyn Whitt, Designated Federal Officer, NACEPT, at (202) 260–9484.

Dated: January 21, 1999.

Gordon Schisler,

Deputy Director, Office of Cooperative Environmental Management.

[FR Doc. 99–2199 Filed 1–28–99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[PF–853; FRL–6055–8]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by the docket control number PF–853, must be received on or before March 1, 1999.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Hoyt Jamerson, Registration Support Branch, Registration Division (7505), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 268, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–9368; e-mail: jamerson.hoyt@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain 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 supports granting of the petitions. Additional data may be needed before EPA rules on the petitions.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–853] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (PF–853) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: January 21, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petitions is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petitions was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summaries with minor editing. 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 Research Project Number 4 (IR-4)

PP 5E4434, 5E4559 and 7E4872,

EPA has received pesticide petitions (5E4434, 5E4559, and 7E4872) from the Interregional Research Project Number 4 (IR-4), Center for Minor Crop Pest Management, Technology Center of New Jersey, Rutgers, the State University of New Jersey, 681 U.S. Highway # 1 South, North Brunswick, NJ 08902-3390, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the fungicide aluminum tris (o-ethylphosphonate) (referred to in this document as fosetyl-Al) in or on certain raw agricultural commodities as follows:

1. EPA has received an amendment to PP 5E4434 from IR-4 proposing to amend the time-limited tolerance established for blueberries at 40 ppm. IR-4 requests that the tolerance for bluberries be amended by extending the expiration date to December 31, 2000. The time extension will allow IR-4 to develop additional magnitude of residue data in support of a permanent tolerance for blueberries.

2. PP 5E4559 proposes the establishment of a tolerance for grapes at 10 parts per million (ppm). Registration for use of fosetyl-Al on

grapes would be limited to areas east of the Rocky Mountains based on the geographical representation of the residue data submitted.

3. PP 7E4872 proposes the establishment of a tolerance for macadamia nuts at 0.3 ppm.

EPA has determined that the petitions contains 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 supports granting of the petitions. Additional data may be needed before EPA rules on the 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. Radio labeled 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. There is no reasonable expectation of residues occurring in eggs, milk, and meat of livestock and poultry since there are no livestock feed items associated with commodities treated with 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 FDA for inclusion in PAM as Method II.

B. Toxicological Profile

1. *Acute toxicity*. A complete battery of acute toxicity studies for fosetyl-Al technical have been conducted. 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. *Genotoxicty*. Fosetyl-Al is neither mutagenic nor genotoxic. The genetic toxicity potential of fosetyl-Al was assessed in several assays.

3. *Reproductive and developmental toxicity*. Rhone-Poulenc concludes that fosetyl-Al is not a reproductive toxicant and shows no evidence of estrogenic or androgenic related effects.

i. In a 3-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 teratology study in rats dosed via oral gavage at 500, 1,000 or 4,000 milligrams/kilogram/day (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 teratology 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, NOAEL 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.

5. *Chronic toxicity*. Chronic feeding studies have been conducted in dogs and rats. The LOAEL for chronic effects of fosetyl-Al is 10,000 ppm (250 mg/kg/day) based on a 2 year feeding study with dogs fed diets containing 0, 10,000, 20,000 and 40,000 ppm. This NOAEL is based on a slight degenerative effect on the testes at the 20,000 ppm dose level. 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 (1,500/2,000 mg/kg/day).

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. In addition, a mechanistic study in rats was conducted with feeding levels up to 50,000 ppm. Fosetyl-Al was administered via admixture 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. After 2 weeks at 40,000 ppm, this dietary level was reduced to 30,000 ppm. Calculi in the urinary bladder were 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. In addition, 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.

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 chronic 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.

A 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 oncogenicity was observed in this study. 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.

The Office of Pesticide Programs', Health Effects Division, Carcinogenicity Peer Review Committee (CPRC) concluded that the pesticidal use of fosetyl-Al is unlikely to pose a carcinogenic hazard for humans given that; (i) 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 OPP dose limit for carcinogenicity studies); (ii) tumors in rats are believed to develop only at doses that produce stones; (iii) 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 (iv) 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 tract.

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. NOAEL on mating or fertility indices and gestation, live birth, or weaning indices were noted in a 3-generation rat reproduction study at doses well above EPA's limit of 1,000 mg/kg/day. Therefore, Rhone-Poulenc concludes that fosetyl-Al does not have any effect on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. The calculated potential dietary exposure for the U.S. population is 0.065760 milligram/kilogram/bodyweight/day (mg/kg/bwt/day). Potential exposure for nursing and non-nursing infants less than 1-year old, children aged 1 to 6 years, and children aged 7 to 12 years is calculated to be 0.134076, 0.116682, and 0.069637 mg/kg/bwt/day, respectively. Chronic dietary exposure was estimated using established and proposed tolerance residue levels, 1987 food consumption data, and 100% crop treated.

ii. *Drinking water*. There is no established maximum contaminant level (MCL) or health advisory level (HAL) for fosetyl-Al. Rhone-Poulenc expects the potential for ground water and/or surface water contamination by fosetyl-Al and its degradates 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. 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.

2. *Non-dietary exposure*. Considering that fosetyl-Al is applied by commercial applicators on about 0.03% of available lawn acres (the majority being commercial landscapes), the likelihood of post application exposure occurring, particularly in a residential situation, is extremely low. The use of fosetyl-Al by the homeowner constitutes a minor use of the product since only small quantities are expected to be sold in 1998. Other applications by professional operators, e.g. golf courses, nurseries, sod farms, present only very limited exposure to a limited population of adults but do not pose any exposure to small children. Thus, Rhone-Poulenc concludes that the ornamental and turf uses are not expected to add significantly to the aggregate exposure for fosetyl-Al, and only dietary exposure has been taken into consideration for risk assessment purposes.

D. Cumulative Effects

According to Rhone-Poulenc the 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 OPP 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*. EPA has established an RfD of 3.0 mg/kg/day using a 100 fold safety factor and a NOAEL of 250 mg/kg/bodyweight/day from the two year feeding study in dogs. A chronic dietary risk assessment using established and proposed tolerance residue levels results in utilization of 2.2, 4.5, 3.9, and 2.3% of the RfD for the whole U.S. population, non-nursing infants less than 1 year old, children aged 1 to 6 years, and children aged 7 to 12 years, respectively. Thus, the dietary exposure for fosetyl-Al is well below the RfD of 3.0 mg/kg/day and is negligible for all segments of the population including infants and children. Based on a lack of acute toxicity and the large margins of exposure (MOE) in the chronic dietary assessment, Rhone-Poulenc concludes that fosetyl-Al does not pose any acute dietary risks.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of fosetyl-Al, the available developmental and reproductive toxicity studies and the potential for endocrine modulation were considered.

Developmental toxicity studies in two species indicate that fosetyl-Al has no teratogenic potential at any dose level. Further, NOEAL on fetal development were observed in rabbits at doses up to 500 mg/kg/day or in rats at doses up to 1,000 mg/kg/day. In a 3-generation rat reproduction study, NOAEL on reproductive performance or pup survival were observed up to 24,000 ppm (equivalent to a dose well above EPA's limit dose (LTD) of 1,000 mg/kg/day). Maternal and developmental NOAELs and LELs were comparable in all studies indicating no increase susceptibility of developing organisms. Further, fosetyl-Al has no endocrine-modulation characteristics as demonstrated by the lack of endocrine effects in developmental, reproductive, subchronic, and chronic studies. The probability of non-occupational sources of exposure to fosetyl-Al is negligible. Therefore, based upon the completeness and reliability of the toxicity data and the conservative exposure assessment, Rhone-Poulenc concludes that there is a reasonable certainty that no harm will result to infants and children from exposure to the residues of fosetyl-Al and no additional uncertainty factor is warranted.

F. International Tolerances

There are presently no Codex maximum residue levels established for residues of fosetyl-Al on any crop.

[FR Doc. 99–2202 Filed 1–28–99; 8:45 am]

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