requirements of section 17 of FIFRA, or to properly dispose of the existing stocks in accordance with all applicable law.

3. *Distribution or sale of products bearing instructions for use on indoor sites.* The distribution or sale of existing stocks by the registrant of any product listed in Table 1 or 2 that bears instructions for use at or on any indoor sites (except mushroom houses), shall not be lawful under FIFRA as of the effective date of the cancellation order, except for shipping stocks for export consistent with the requirements of section 17 of FIFRA, or properly disposing of the existing stocks in accordance with all applicable law.

4. *Retail and other distribution or sale of existing stock of products for indoor use.* The distribution or sale of existing stocks by any person other than the registrants of products listed in Table 1 or 2 bearing instructions for any indoor uses except mushroom houses will not be lawful under FIFRA after December 31, 2002, except for shipping stocks for export consistent with the requirements of section 17 of FIFRA, or properly disposing of the existing stocks in accordance with all applicable law.

5. *Use of existing stocks.* EPA intends to permit the use of existing stocks of products listed in Table 1 or 2 until such stocks are exhausted, provided such use is in accordance with the existing labeling of that product.

**List of Subjects**

Environmental protection, Pesticides and pests.

Dated: December 19, 2001.

**Lois A. Rossi,**

*Director, Special Review and Registration Division, Office of Pesticide Programs.*

[FR Doc. 02–225 Filed 1–3–02 8:45 am]

**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

**[PF–1059; FRL–6812–2]**

## Notice of Filing a Pesticide Petition to Establish a Tolerance for a 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–1059, must be received on or before February 4, 2002.

**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–1059 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7740; e-mail address: giles-parker.cynthia@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 | 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'' 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–1059. 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–1059 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–1059. 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: December 17, 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.

*PP IF06300*

EPA has received a pesticide petition (IF06300) from Aventis CropScience, 2 Alexander Drive, Research Trianagle Park, NC 27709 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of fenamidone, and its metabolites RPA 412708, RPA 412636, and RPA 410193 in or on the raw agricultural commodities: Potato, 0.05 parts per million (ppm) tomato, 1.0 ppm; tomato paste, 3.5 ppm, tomato puree, 3.5 ppm, bulb vegetable crop group, 1.5 ppm; cucurbit crop group, 0.1 ppm; head lettuce, 15.0 ppm; leaf lettuce, 20.0 ppm; wheat grain, 0.05 ppm, wheat straw, 0.5 ppm; wheat forage, 0.5 ppm, and wheat hay, 0.5 ppm. Tolerances are also proposed for fenamidone and its metabolite RPA 410193 on imported wine grapes at 0.5 ppm. EPA has determined that the petition 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

*A. Residue Chemistry*

1. *Plant metabolism*. The plant metabolism of fenamidone (RPA 407213) is adequately understood in four distinct crops (lettuce, tomatoes, potatoes, and grapes) to support these tolerances. In all cases, the primary residue was the parent fungicide, RPA 407213. The only significant metabolite was RPA 410193 (~17 of the total radioactive residue (TRR) in grapes, ~9% of the TRR in tomatoes, <1% of the TRR in lettuce (mostly in the wrapper leaves), and <1% of the TRR in potatoes (haulm or tubers)). RPA 412708 and RPA 412636 were minor metabolites reported in the lettuce and potato metabolism studies, and may account for part of the unidentified residue reported in the grape and tomato metabolism studies.

2. *Analytical method*. Although residue levels approaching the proposed tolerances are unlikely, independently validated enforcement methods are available for determining residues of fenamidone and relevant metabolites. Residues are first extracted from the crop matrix by blending or shaking with a mixture of acetonitrile and water. After filtration, an aliquot of the extract is rotary evaporated to near dryness; then diluted with water. Cleanup is accomplished on a HRP polymeric solid phase extraction (SPE) cartridge and an amino SPE cartridge. Residues are quantified by high performance liquid chromotography (HPLC) with tandem mass spectrometric detection (LC/MS/MS). The method limits of quantification (LOQ) are 0.02 ppm for fenamidone, and its metabolites, RPA 412636, RPA 412708, and RPA 410193 in potato tubers, and processed fractions, tomatoes and processed fractions, cucumbers, squash, cantaloupes, head and leaf lettuce, onions, spinach, and wheat raw agricultural commodities and processed fractions.

3. *Magnitude of residues*—i. *Cucurbit crops*. The magnitude and decline of residues of fenamidone were determined on cucumber, cantaloupe, and summer squash, the representative commodities for the cucurbit vegetable

crop group. Nine field trials were conducted on each crop during 1999. EXP 10623A, a suspension concentrate end use formulation containing 500 g fenamidone per liter, was applied as six broadcast applications, each at the maximum rate of 0.178 lb ai/acre (200 g ai/A/ha). Applications were made approximately 5 days apart. The target pre-harvest interval (PHI) was 14 days. Residues of fenamidone RPA 407213 were detected in two of nine trials of cucumbers at levels of 0.022 to 0.041 ppm, with the metabolite RPA 412708 measured in only one trial at 0.028 ppm. Quantifiable residues of fenamidone were measured in eight of nine trials of cantaloupes at levels ranging from 0.021 to 0.098 ppm, with no quantifiable residues of metabolites detected. Residues of parent fenamidone were found in only one of nine summer squash trials at 0.039 to 0.077 ppm with no quantifiable residues of any metabolites detected.

ii. *Tomato*. Seventeen residue trials were conducted in 1999–2000. EXP 10623A, a suspension concentrate containing 500 g fenamidone per liter, was applied as four broadcast applications of 0.268 lb ai/acre (300 g ai/ha) each or six broadcast applications of 0.178 lb ai/acre (200 g ai/A) each, for a maximum seasonal use rate of 1.068 lb ai/acre (1,200 g ai/ha). Applications were made approximately 5 days apart. The target PHI was 14 days. Cherry tomatoes were grown at 4 of the 18 trials. Trace residues of the fenamidone metabolite RPA 410193 were detected in tomatoes from only one trial, on cherry tomatoes, at levels of 0.023 to 0.028 ppm. Measurable residues of the parent fungicide, fenamidone were found in tomatoes from 15 of the 17 harvestable trials at levels ranging from 0.044 to 0.800 ppm. The residues did not seem to correlate with the application scenario. The extent of potential residue concentration in processed tomato fractions was estimated by processing tomatoes after application of fenamidone at 5X the maximum seasonal use rate. Fenamidone residues concentrated in tomato puree by a factor of about 2.2 and in tomato paste by a factor of about 3.5. When corrected to account for the exaggerated application rate, residue levels were 0.089 ppm in whole tomato fruit, 0.198 ppm in tomato puree and 0.316 ppm in tomato paste.

iii. *Lettuce*. In 2000, nine residue trials were conducted with fenamidone on leaf lettuce and nine trials were conducted on head lettuce. EXP 10623A was applied as four broadcast applications of 0.268 lb ai/acre (300 g ai/ha) each, for a maximum seasonal use rate of 1.068 lb ai/acre (1,200 g ai/ha). Applications were made approximately 5 days apart. The target PHI was 2 days. Residues of the parent fungicide, fenamidone (RPA 407213) were found in/on leaf lettuce from all nine trials at levels ranging from <LOQ to 17.5 ppm. Low levels of the metabolites RPA 410193 and RPA 412708 were found in five of the nine trials of leaf lettuce at levels up to 0.049 ppm. The metabolite RPA 412636 was found in one sample of leaf lettuce at a level of 0.031 ppm. Residues of the parent fungicide, fenamidone RPA 407213 were found in/on head lettuce from all nine trials at levels ranging from 0.815 to 11.7 ppm with the wrapper leaves, and from <LOQ to 2.90 ppm with the wrapper leaves removed. Low levels of the metabolite RPA 410193 were found in four of the nine trials of head lettuce with wrapper leaves at levels up to 0.029 ppm but not detected after the wrapper leaves were removed. Low levels of the metabolite RPA 412708 were found in five of the nine trials of head lettuce with wrapper leaves at levels up to 0.047 ppm but found in samples from only two trials after the wrapper leaves were removed. The metabolite RPA 412636 was found in head lettuce from only one trial at a level of 0.031 ppm before the wrapper leaves were removed and not at all after the wrapper leaves were removed.

iv. *Potato*. Eighteen residue trials were conducted with fenamidone on potatoes in 1999. EXP 10623A, a suspension concentrate containing 500 g fenamidone per liter, was applied as four broadcast applications of 0.268 lb ai/acre (300 g ai/ha) each or six broadcast applications of 0.178 lb ai/acre (200 g ai/ha) each, for a maximum seasonal use rate of 1.068 lb ai/acre (1200 g ai/ha). Applications were made approximately 5 days apart. The target PHI was 14 days. No quantifiable residues of fenamidone or metabolites were found in any potato tuber sample above the LOQ (0.02 ppm). The extent of potential residue concentration in processed potato fractions was estimated by processing potatoes after application of fenamidone at 5X the maximum seasonal use rate. The potato fractions included flakes, chips and wet peel. There were no measurable residues in the potato tuber or the potato chips despite the exaggerated application rate. Only parent fungicide, fenamidone RPA 407213, residues were found in the wet peel at levels of 0.043 to 0.049 ppm with an estimated concentration factor of 4.6. Trace residues of two fenamidone metabolites were found only in the potato flake fraction, RPA 412708 at 0.029 to 0036 ppm and RPA 412636 at 0.026 ppm. When corrected to account for the exaggerated application rate, residue levels of processed fractions were < the RAC LOQ of 0.02 ppm.

v. *Onions*. The magnitude and decline of fenamidone residues was determined on both dry bulb and green onions. There were eight harvestable trials of dry bulb onions and four harvestable trials of green onions. EXP 10623A, a suspension concentrate containing 500 g fenamidone per liter, was applied as six broadcast applications of 0.178 lb ai/acre (200 g ai/ha) each, for a maximum seasonal use rate of 1.068 lb ai/acre (1200 g ai/ha). Applications were made approximately 7 days apart. The target PHI was 7 days. Trace residues of the fenamidone metabolite RPA 412636 were detected in dry bulb onions from only one trial, at levels of 0.027 to 0.035 ppm. Measurable residues of the parent fungicide, fenamidone (RPA 407213), were found in dry bulb onions from only two of the eight harvestable trials at levels ranging from 0.021 to 0.126 ppm. Residues of the parent fungicide, fenamidone RPA 407213, were found in scallions collected from all four green onion trials at levels of 0.221 to 1.10 ppm. Low levels, up to 0.058 ppm, of each of the metabolites were detected in scallions from some of the four green onion trials.

vi. *Wheat*. Twenty–two residue trials were conducted with fenamidone on wheat in the 1999–2000 season. At each trial, a single broadcast application of the fenamidone was made to bare soil at 1.068 lb ai/acre (1,200 g ai/ha) in the fall (September-October 1999), which is the maximum recommended seasonal use rate. The test substance was EXP 10623A, a soluble concentrate containing 500 g fenamidone per liter. The winter wheat was planted 30 days after application and was harvested the following summer of 2000. Storage stability studies indicate that fenamidone and its metabolites are stable for the length and condition of storage (see 6.1.1 Stability of Residues During Storage of Samples for details). No quantifiable residues were found in any UTC samples. No residues of fenamidone or metabolites were found in wheat grain from any of the 22 trials. The limit of detection was 0.006 ppm. Low but quantifiable levels of the metabolite RPA 412636 were found in wheat forage from 10 of the 22 trials. The residues of RPA 412636 ranged from 0.021 to 0.071 ppm in the wheat forage tissue. Residues of the metabolite RPA 412708 were measurable 0.031 to 0.071 ppm in wheat forage from 3 of the 22 trials. Measurable levels of the metabolite RPA 412636 were found in

wheat hay from 16 of the 22 trials. The residues of RPA 412636 ranged from 0.022 to 0.321 ppm in the wheat hay tissue. Residues of the metabolite RPA 412708 were measured at the LOQ of 0.020 ppm in 1 sample of wheat hay from 44 samples from the 22 trials. Measurable residues of the metabolite RPA 412636, ranging from 0.022 to 0.200 ppm, were found in wheat straw from 14 of the 22 trials.

vii. *Wine grapes*. Seventeen residue trials were conducted with fenamidone on grapes in the 1997 and 1998 growing seasons in Western Europe. In each case, the fenamidone was applied in combination formulations to be registered in Europe (Fosetyl-Al, mancozeb, copper and/or BAY 12921F). At each trial, multiple broadcast applications of fenamidone were made to grape vines at rates of 0.083 to 0.118 lb ai/acre (93 to 133 g ai/ha) each. Applications were made approximately 7 or 14 days apart. The target PHI was 20 to 40 days. The storage stability studies indicate that fenamidone residues are stable for the length and condition of storage. No quantifiable residues were found in any UTC samples. Measurable residues of the parent fungicide, fenamidone (RPA 407213), were found in fresh grape fruit at levels ranging from 0.047 to 0.71 ppm. The metabolite, RPA 410193 was found at levels ranging from 0.026 to 0.28 ppm. The combined residue in grape fruit was calculated to be 0.067 to 0.84 ppm. Measurable residues of the parent fungicide, fenamidone (RPA 407213), were found in grape juice at levels ranging from <LOQ to 0.110 ppm. The metabolite, RPA 410193 was found at levels ranging from 0.027 to 0.074 ppm. The combined residue in grape juice was calculated to be 0.013 to 0.28 ppm. Measurable residues of the parent fungicide, fenamidone (RPA 407213), were found in grape wine at levels ranging from <LOQ to 0.027 ppm. The metabolite, RPA 410193, was found at levels ranging from <LOQ to 0.34 ppm. The combined residue in grape wine was calculated to be <LOQ to 0.40 ppm. Measurable residues of the parent fungicide, fenamidone (RPA 407213), were found in grape at levels ranging from 0.055 to 0.56 ppm. The metabolite, (RPA 410193) was found at levels ranging from 0.024 to 0.13 ppm. The combined residue in grape was calculated to be 0.11 to 0.71 ppm.

viii. *Dairy cows*. In a guideline feeding study, dairy cows were dosed twice a day for 35 days with technical fenamidone at rates of 0.8, 0.24 and 8.0 ppm based on the diet. No residues were detected in whole milk at a limit of detection of 0.003 ppm. No residues were found in muscle, liver, kidneys or fat at a limit of detection of 0.017 ppm. Based on these findings, no tolerances for fenamidone or its metabolites are proposed in animal commodities.

*B. Toxicological Profile*

1. *Acute toxicity*. A complete battery of acute toxicity studies for fenamidone have been conducted. The acute oral toxicity study in rats resulted in a $LD_{50}$ of >5,000 mg/kg (males) and >2,028 mg/kg (females). The acute dermal toxicity study in rats resulted in a $LD_{50}$ of >2,000 mg/kg for both males and females. The acute inhalation study in rats resulted in a $LC_{50}$ of >5 mg/L for males and females. Fenamidone was not irritating in the primary eye irritation or primary dermal irritation studies. The dermal sensitization study in guinea pigs was negative.

In an acute neurotoxicity study in rats, fenamidone was not neurotoxic at doses up to the limit dose of 2,000 mg/kg. The no observed adverse effect level (NOAEL) was 500 mg/kg for males and 125 mg/kg for females.

2. *Genotoxicty*. Mutagenicity studies conducted include: A *Salmonella typhimurium* reverse mutation assay (negative at the limits of cytotoxicity and solubility with and without activation), *in vitro* unscheduled DNA synthesis test in rat liver (negative at the limits of cytotoxicity), *in vitro* chromosome aberrations test in human lymphocytes (positive at the limits of cytotoxicity and solubility), TK+/- mouse lymphoma assay (positive with activation, negative without), *in vivo* mouse micronucleus test (negative with toxicity at 2,000 mg/kg), and an *in vivo* unscheduled DNA synthesis assay in the rat (negative at up to 2,000 mg/kg with toxicity at the high dose level). Based on the data cited above, fenamidone is not considered to be mutagenic.

3. *Reproductive and developmental toxicity*. A teratology study was conducted with rats administered (orally) fenamidone on gestation days 6–15 at dose levels of 0, 25, 150, or 1,000 mg/kg/day. High dose dams had significantly decreased body weight and food consumption. High dose fetal body weights were less than controls and correlated with slightly delayed skeletal ossification secondary to maternal toxicity. The NOAEL for maternal and developmental toxicity is 150 mg/kg/day. The Lowest observed adversed effect level (LOAEL) was 1,000 mg/kg/day. A teratology study was conducted with rabbits administered (orally) fenamidone on gestation days 6–19 at dose levels of 0, 10, 30, or 100 mg/kg/day. The maternal NOAEL was 10 mg/kg/day. The developmental NOAEL was 100 mg/kg/day. The maternal LOAEL was 30 mg/kg/day, based on increased maternal liver weights at 30 and 100 mg/kg/day. Fenamidone demonstrates no potential to cause developmental toxicity in mammals.

A 2–generation definitive reproduction study was conducted with rats administered (orally) in the diet fenamidone at dose levels of 0, 3.9, 63.8, 328.3 mg/kg/day (males) and 0, 5.15, 84.4, 459.6 mg/kg/day (females). The NOAEL for maternal and off-spring toxicity was 5.15 mg/kg/day. The maternal NOAEL was based on decreased body weight and food consumption. The pup NOAEL is based on F1 pup body weight decrease. The reproductive NOAEL was >328.3 mg/kg/day (males) and >459.6 mg/kg/day (females). Fenamidone is not considered a reproductive toxicant at non-maternally toxic dose levels and shows no evidence of endocrine effects.

4. *Subchronic toxicity*. In a 13–week range-finding study, fenamidone was administered in the diets of male and female rats at dose levels of 0, 4.05, 10.41, 68.27, 343.93 mg/kg/day to males and 0, 4.81, 12, 83.33, 380.68 mg/kg/day to females. The NOAEL is 68.27 mg/kg/day (males) and 83.33 mg/kg/day (females) and the LOAEL is 343.93 mg/kg/day for males and 380.63 mg/kg/day for females based on adaptive liver changes at 68.27 mg/kg/day and increased liver and thyroid weights at the highest dose tested (HDT). In a 13–week subchronic feeding study, fenamidone was administered in the diet to mice at dose levels of 0, 11.33, 44.5, 220.2, 1,064.3 mg/kg/day to males and 0, 13.7, 54.1, 273.9, 1,375.2 mg/kg/day to females. The NOAEL is 44.5 mg/kg/day (males), and 54.1 mg/kg/day (females), and the LOAEL is 220.2 mg/kg/day (males), and 273.9 mg/kg/day (females) based on 14% increase in liver weight at the high dose. In a 28–day subchronic dermal study, fenamidone was applied to skin of male and female New Zealand white rabbits at doses of 0 or 1,000 mg/kg/day for 6 hours/day, 5 days/week. Treatment produced a slight decrease in food consumption (8–10%), and body weight (6%) in males only. In a 13–week study, fenamidone was administered in the diets of male and female dogs at 0, 10, 100, and 500 mg/kg/day. Based on clinical symptoms at the high dose, the NOAEL is 100 mg/kg/day and the LOAEL is 500 mg/kg/day.

In a subchronic neurotoxicity study, there was no evidence of neurotoxicity when fenamidone technical was administered to rats for 13 weeks at dosage levels up to 5,000 ppm (395.6–414.2 mg/kg/day), the MTD. The

NOAEL for the study was 1,000 ppm (equivalent to 74.2–83.4 mg/kg/day).

5. *Chronic toxicity*. A 1–year oral study was conducted with dogs administered fenamidone at dose levels of 0, 10, 100, and 1,000 mg/kg/day in capsules. The NOAEL is 100 mg/kg/day for both sexes, based on significantly increased liver weights and biliary hyperplasia in the high dose. The LOAEL is 1,000 mg/kg/day.

A 2–year combined chronic toxicity/carcinogenicity study was conducted with fenamidone administered in the diet to rats at doses of 0, 2.83, 7.07, 47.68, 260.13 mg/kg/day (males) and 0, 3.63, 9.24, 60.93, 335.10 mg/kg/day (females). The NOAEL for systemic toxicity is 2.83 mg/kg/day (males) and 3.36 mg/kg/day (females). The LOAEL is 7.07 mg/kg/day (males) 9.24 mg/kg/day (females). No statistically significant linear dose response was observed for any tumor incidence.

A 104–week combined carcinogenicity study in mice was conducted with mice administered fenamidone in the diet at dose levels of 0, 9.5, 47.5, 525.5, 1,100.2 mg/kg/day (males) and 0, 12.6, 63.8, 690.5, 1,393.2 mg/kg/day (females). The NOAEL was 9.5 mg/kg/day (males) and 12.6 mg/kg/day (females). The LOAEL for carcinogenicity was 47.5 mg/kg/day (males) and 63.8 mg/kg/day (females). The NOAEL is based on non-neoplastic liver changes and decreased body weight gain at the top two dose levels. Fenamidone demonstrates no potential for carcinogenic effects in mammals.

6. *Animal metabolism*. Metabolism studies conducted with goat and hen demonstrate that fenamidone is rapidly metabolized and excreted. Residue levels in edible animal tissues (meat, milk and eggs) are negligible and do accumulate in those tissues. The metabolic pathway proceeds via cleavage of the amino-phenyl group and the thiomethyl group with further metabolism by hydroxylation. There is also evidence to that glucuronide and sulfate conjugates are formed.

A single low dose (3 mg/kg), a single high dose (300 mg/kg) and a low dose (3 mg/kg) administered for 15 consecutive days were fed to rats. Fenamidone was relatively well absorbed at a nominal dose of 3 mg/kg in both sexes and intensively metabolized by phase I (oxidation, reduction and hydrolysis) and phase II (conjugation) reactions. The elimination of radiolabeled fenamidone was relatively rapid with the majority of the administered dose being excreted via the biliary route (for the low dose experiments). The comparison of the levels of radioactivity recovered in bile kinetic and ADME studies suggested that a part of the radioactivity excreted via the bile could be reabsorbed and subsequently re-excreted via the urine. High levels of radioactivity measured in blood samples from the tissue kinetics also supported this hypothesis. At the high dose level fenamidone was not very well absorbed: Some 50–60% of the radioactivity was present as parent compound in the feces. Radioactivity was widely distributed in the tissues with predominance in the thyroids, blood, liver, kidneys, fat and pancreas. Fenamidone is therefore expected to be rapidly and extensively metabolized and excreted in mammals.

7. *Metabolite toxicology*. The major dietary metabolites of fenamidone, RPA 412708, RPA 410193 and RPA 412636 were evaluated for mammalian toxicity in an acute oral toxicity study, a 90–day repeated dose study and in genotoxicity tests. The metabolites are considered to be of comparable toxicity to the parent fenamidone.

8. *Endocrine disruption*. Chronic, lifespan, and multi-generational bioassays in mammals and acute and subchronic studies on aquatic organisms and wildlife did not reveal endocrine effects. Any endocrine related effects would have been detected in this definitive array of required tests. The probability of any such effect due to agricultural uses of fenamidone is negligible.

*C. Aggregate Exposure*

1. *Dietary exposure*. Fenamidone is a fungicide with proposed uses on the food crops tomato, potato, head lettuce, leaf lettuce, the bulb vegetable crop group, and the cucurbit crop group. Although quantifiable residues are highly unlikely, wheat tolerances are also proposed to cover any conceivable plant back residues. An import tolerance for wine grapes is also proposed to cover imported wine. There are no residential uses proposed for fenamidone. Therefore the aggregate exposure would consist of any potential exposures to fenamidone residues from the above food crops from drinking water, and from imported wine. The chronic reference dose (RfD) of 0.03 mg/kg bwt/day is based on a NOAEL of 3 mg/kg bwt/day from a 2–year rat chronic study. There are no acute effects of concern for fenamidone and an acute analysis was not conducted.

i. *Food*. Chronic dietary exposure estimates resulting from the proposed and registered uses of fenamidone as listed above are well within acceptable limits for all sectors of the population. Potential dietary exposures from food were estimated using the chronic module of the DEEM™ software system, Version 7.62 (Novigen Sciences, Inc.), and the 1994–96 Department of Agriculture (USDA) consumption data. Anticipated residue values were calculated from the appropriate field trial studies conducted for fenamidone and its metabolites and submitted as part of the fenamidone petition. Processing factors were derived for tomato paste and puree and potato flakes and chips. For this chronic assessment, percent crop treated (PCT) values were estimated for the compound at market maturity. The PCT value for wine grapes is 20%. This assumes that all wine imported into the country (USDA FATUS tables) is made from grapes treated with fenamidone. This over estimates the risk significantly since fenamidone will only be registered on wine grapes in Western European countries. The wheat residue is included at 100% crop treated even though the actual plant back of a wheat crop behind vegetable crops (mostly potato) is estimated at 15%. Using these conservative assumptions, the most highly exposed population was children 1–6 utilizing 1.0% (0.000302 mg/kg/bwt/day) of the chronic RfD. The U.S. population utilized 0.8% (0.000236 mg/kg/bwt/day) of the RfD. Actual exposures are likely to be much less in real world situations because of the many conservative assumptions incorporated in this analysis.

ii. *Drinking water*. EPA's Standard Operating Procedure (SOP) for Drinking Water Exposure and Risk Assessments was used to perform the drinking water assessment. This SOP uses a variety of tools to conduct drinking water assessments, including water models such as SCI-GROW, FIRST, PRZMS/EXAMS, and monitoring data. If monitoring data are not available, then the models are used to predict potential residues in surface and ground water and the highest levels are assumed to be the drinking water residue. In the case of fenamidone, monitoring data do not exist, therefore SCI-GROW and FIRST were used to estimate a water residue. The calculated drinking water levels of comparison (DWLOC) for chronic exposure for all adults and children exceed the drinking water estimated concentration (DWEC) from the models. The chronic DWLOC for adults is 1,042 ppb. The chronic DWLOC for children/toddlers is 297 ppb. The DWEC for the worst case chronic scenario is 20 ppb. The drinking water levels of comparison are based on conservative dietary (food) exposures and are expected to be much higher in real world situations.

2. *Non-dietary exposure*. Fenamidone products are not labeled for residential

uses (food or non-food), thereby eliminating the potential for residential exposure or non-occupational exposure.

*D. Cumulative Effects*

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. There is no available data to determine whether fenamidone 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, fenamidone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance petition, therefore, it has not been assumed that fenamidone has a common mechanism of toxicity with other substances.

*E. Safety Determination*

1. *U.S. population.* Using the assumptions and data described above, based on the completeness, and reliability of the toxicity data, it is concluded that chronic dietary exposure to the proposed uses of fenamidone will utilize at most 0.8% of the chronic reference dose for the U.S. population. The actual exposure is likely to be much less as more realistic data, and models are developed. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risk to human health. Drinking water levels of comparison based on the dietary and aggregate exposures are greater than highly conservative estimated levels, and would be expected to be well below the 100% level of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure (food and drinking water) to residues of fenamidone.

2. *Infants and children.* The relevant toxicity studies as discussed in the toxicology section above show no extra sensitivity of infants and children to fenamidone, therefore, the food quality protection act (FQPA) safety factor can be removed. Using the assumptions and data described in the exposure section above, the percent of the chronic RfD that will be used for exposure to residues of fenamidone in food for children 1–6 (the most highly exposed subgroup) is 1.0% (0.000302 mg/kg/bwt/day). Infants utilize 0.2% (0.000056 mg/kg/bwt/day) of the chronic RfD. There are no non-dietary concerns for infants and children. As in the adult situation, drinking water levels in comparison are higher than the worst case drinking water estimated concentrations, and are expected to use well below 100% of the reference dose, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of fenamidone.

*F. International Tolerances*

To date, no Codex, Canadian or Mexican tolerances exist for fenamidone.

[FR Doc. 02–224 Filed 1–3–02; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–7125–7]**

### Valley Chemical Superfund Site/ Greenville, Mississippi; Notice of Proposed Settlement

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of proposed settlement.

**SUMMARY:** Under section 122(h)(1) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Environmental Protection Agency (EPA) has proposed to amend the Agreement for Recovery of Response Costs, CERCLA Docket No. CER–04–2001–3755, in settlement of claims for response costs at the Valley Chemical Superfund Site (Site) located in Greenville, Mississippi, with Valley Chemical Company. EPA will consider public comments on the proposed settlement amendment for thirty days. EPA may withdraw from or modify the proposed settlement amendment should such comments disclose facts or considerations which indicate the proposed settlement amendment is inappropriate, improper, or inadequate. Copies of the proposed settlement amendment are available from: Ms. Paula V. Batchelor, U.S. Environmental Protection Agency, Region IV, Waste Management Division, 61 Forsyth Street, SW., Atlanta, Georgia 30303, (404) 562–8887.

Written comment may be submitted to Mr. Greg Armstrong at the above address within 30 days of the date of publication.

Dated: December 18, 2001.

**James T. Miller,**

*Acting Chief, CERCLA Program Services Branch, Waste Management Division.*

[FR Doc. 02–220 Filed 1–3–02; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

**[PB–402404–CN; FRL–6811–5]**

### Lead; Requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities; Authorization of the Cherokee Nation's Lead-Based Paint Activities Program

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice; final approval.

**SUMMARY:** On November 19, 1999, the Cherokee Nation of Oklahoma submitted an application for EPA approval to administer and enforce training and certification requirements, training program accreditation requirements, and work practice standards for lead-based paint activities in target housing and child-occupied facilities under section 402 of the Toxic Substances Control Act (TSCA). Notice of the receipt of the Cherokee Nation's application, a solicitation for public comment regarding the application, and background information supporting the application were published in the **Federal Register** of January 25, 2000. Today's notice announces the approval of the Cherokee Nation's application, and authorization of the Cherokee Nation's lead-based paint program for Cherokee Nation's Tribal Trust Lands in Oklahoma, effective October 15, 2001, in lieu of the corresponding Federal program under section 402 of TSCA.

**DATES:** Lead-based paint activities program authorization was granted to the Cherokee Nation effective on October 15, 2001.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey Robinson, Regional Lead Coordinator, Environmental Protection Agency, Region VI, 6PD-T, 1445 Ross Avenue, Suite 1200, Dallas, TX 75202–2733. Telephone: 214–665–7577, e-mail address: robinson.jeffrey@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Pursuant to Title IV of TSCA, Lead Exposure Reduction, 15 U.S.C. 2681-2692, and regulations promulgated thereunder, States and Tribes that choose to apply for lead-based paint activities program authorization must submit a complete application to the