3. By hand delivery or courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2003–293. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed 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 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 your estimate.

5. Provide specific examples to illustrate your concerns.

6. Offer alternatives.

7. Make sure to submit your comments by the comment period deadline identified.

8. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. What Action is the Agency Taking?

For the herbicide sodium acifluorfen, the Agency is announcing the availability of the reregistration eligibility decision (RED) document and supporting technical documents. EPA has assessed the risks associated with the use of sodium acifluorfen, reassessed the tolerances for sodium acifluorfen, and reached a reregistration eligibility decision. The Agency has determined that all currently registered uses of sodium acifluorfen are eligible for reregistration, provided that all the conditions identified in the RED document are satisfied, including the implementation of risk mitigation measures through label amendments. The RED document also describes the tolerance reassessment decision for sodium acifluorfen.

The sodium acifluorfen RED and supporting technical documents were developed using a public participation process designed to increase transparency and maximize stakeholder involvement and to provide numerous opportunities for public comment. The Agency is therefore issuing this RED for sodium acifluorfen as a final document with a 30–day public comment period, which is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the RED. Unless substantive information is received during the comment period, which indicates that the Agency's assessments must be refined and that additional risk mitigation is warranted, this RED will be considered to be a final decision.

List of Subjects

Environmental protection, Pesticides, Sodium acifluorfen.

Dated: January 13, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 04–1549 Filed 1–27–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0375; FRL–7337–3]

Fenamidone; 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 ID number OPP–2003–0375, must be received on or before February 27, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; 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 potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2003–0375. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0375. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID number OPP–2003–0375. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2003–0375.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP–2003–0375. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

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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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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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 thatsupport 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 ID 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 FFDCA 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: January 5, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

EPA has received a pesticide petition (1F6300) from Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709 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 fenamidone, 4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-,(S)-, and its metabolites (RPA 412708), (RPA 412636), and (RPA 410193) in or on the raw agricultural commodity vegetable, tuberous and corm, subgroup 1C at 0.05 parts per million (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.

In the **Federal Register** of January 4, 2002 (67 FR 592) (FRL–6812–2) EPA issued a notice of filing of Pesticide Petition (1F6300) from Bayer Crop Science (formerly Aventis Crop Science) at the above address proposing to amend 40 CFR part 180 by establishing tolerances for fenamidone and its metabolites in or on various raw agricultural commodities. EPA has received an amended petition to include the above raw agricultural commodities subgroup. This notice contains information submitted in addition to that contained in the January 4, 2002 notice.

Bayer CropScience

PP 1F6300

A. Residue Chemistry

1. *Plant metabolism.* The plant metabolism of fenamidone (RPA 407213) was evaluated in four distinct crops (lettuce, tomatoes, potatoes, and grapes) and is adequately understood. In all cases, the primary residue was the parent compound. The only significant metabolite was (RPA 410193) (17% of the total radioactive residue (TRR) in grapes, 9% of the total radioactive residue (TRR) in tomatoes, <1% of the total radioactive residue (TRR) in potatoes (haulm or tubers). RPA 412708 and RPA 412636 were minor metabolites reported in the lettuce and potato 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 HR-P polymeric solid phase extraction (SPE) cartridge and an amino SPE cartridge. Residues are quantified by 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.* Eighteen residue trials were conducted with fenamidone on potatoes in 1999. EXP 10623A, a suspension concentrate containing 500 grams (g) fenamidone per liter, was applied as four broadcast applications of 0.268 lb active ingredient/Acre (a.i./A) 300 g a.i./ha each or six broadcast applications of

0.178 lb a.i./A 200 g a.i./ha each, for a maximum seasonal use rate for 1.068 lb a.i./Acre 1,200 g a.i./ha). Applications were made approximately 5 days apart. The target pre-harvest interval (PHI) was 14 days. No quantifiable residues of fenamidone or metabolites were found in any 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 tuber or the potato chips despite the exaggerated application rated. Only parent 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 less than the RAC LOQ of 0.02 ppm.

B. Toxicological Profile

1. *Acute toxicity.* A complete battery of acute toxicity studies for fenamidone has been conducted. The acute oral toxicity study in rats resulted in a lethal dose $(LD)_{50}$ of <5,000 milligrams/kilogram (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 lethal concentration $(LC)_{50}$ of >5 milligrams/Liter (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. *Genotoxicity.* 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 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 adverse 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 maternal LOAEL was 30 mg/kg/day, based on increased maternal liver weights at 30 and 100 mg/kg/day. Fenamidone demonstrates no 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 offspring 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. 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 and 414.2 mg/kg/day), the maximum tolerance dose (MTD). The NOAEL for the study was 1,000 ppm (equivalent to 74.2 and 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, 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 dosed 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 s 2.83 mg/kg/day (males) and 3.36 mg/kg/day (females). The LOAEL is 7.07 mg/kg/day (males and 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, 535.5, 1,100.2 mg/kg/day (males) and 0, 12.6, 63.8, 680.5, 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 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 1 oxidation, reduction and hydrolysis and 2 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 absorption, distribution, metabolism and excretion (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 registered for use on head and leaf lettuce, and has been proposed previously to support uses on the bulb vegetable crop group, potatoes, and the cucurbit crop group. Wheat tolerances were also proposed to cover any potential plant-back residues. An import tolerance for wine grapes was also proposed to cover potential residues in 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 acute reference dose (aRfD) of 0.13 mg/kg/day is based on a NOAEL of 125 mg/kg/day from the neurotoxicity study in rat and a 10X database uncertainty factor (UF) recently applied by the Agency for lack of a developmental neurotoxicity study. The chronic reference dose (cRfD) of 0.002 mg/kg/day from the 2–year rat chronic study and the UF of 10X.

i. *Food.* Acute and chronic dietary analyses were conducted to estimate exposure to potential fenamidone residues in/on the crops and crop groups of tuberous and corm vegetables, head and leaf lettuce, onions and bulb vegetables, cucurbits and tomatoes as target crops, and wheat as a rotational crop. Tier III analysis were conducted for both the acute and chronic scenarios using the DEEM™ Exponent, Inc. software. The acute dietary exposure estimates at the 95th percentile of exposure for the U.S. population was 5.5% of the acute Reference Dose (aRfD). The U.S. population subgroup with the highest exposure was toddlers 1–2 years at 9.3% of the aRfD. Chronic dietary exposure estimates from potential residues of fenamidone for the U.S. population was 8.0% of the chronic RfD. The sub-population with the highest exposure was children 1–6 years at 10–2% of the RfD.

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 available monitoring data. If monitoring data are not available, then the models are used to predict potential residues in surface water 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 acute and chronic exposure for all adults and children exceed the modeled drinking water estimated concentration (DWEC). The acute DWLOC values are 4,301 parts per billion (ppb) for the general population and 1,179 ppb for infants and children, compared to the worst-case acute DWEC of 50 ppb. The chronic DWLOC values are 27 ppb for the general population and 29 ppb for infants and children, compared to a worst-case chronic DWEC of 11 ppb. These drinking water levels of comparison are based on conservative dietary (food) exposures and are typically expected to be much higher under actual use scenarios.

2. *Non-dietary exposure.* Fenamidone is not registered for residential uses (food or non-food), thereby eliminating any 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, the dietary exposure from the proposed uses of fenamidone will utilize at most 8.0% of the aRfD or cRfD for the U.S. population. 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 of food and drinking water to residues of fenamidone.

2. *Infants and children.* In consideration of the toxicology data base as discussed above, EPA has determined that there is no extra

sensitivity of infants and children, and therefore, the default FQPA safety factor can be removed. However, the Agency has applied a data base uncertainty factor of 10X to account for the current lack of developmental neurotoxicity study. Using the assumptions and data described in the exposure section above, the percent of the aRfD and cRfD that will be used for exposure to residues of fenamidone in food for infants and children (the most highly exposed subgroups) is 10.2%. There are no non-dietary concerns for infants and children. As with adults, drinking water levels of comparison are higher than the worst-case drinking water estimated concentrations and are expected to use well below 100% of the reference dose.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0407; FRL–7339–6]

Cyfluthrin; Notice of Filing of Pesticide Petitions 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 pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2003–0407, must be received on or before February 27, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal Production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide Manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2003–0407. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper