

List of Subjects

Environmental protection, Reporting and recordkeeping requirements.

Dated: March 18, 2004.

Susan B. Hazen,

Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

[FR Doc. 04-6698 Filed 3-30-04; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0070; FRL-7348-4]

Carfentrazone-ethyl; Notice of Filing 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 identification (ID) number OPP-2004-0070, must be received on or before April 30, 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:

Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6224; e-mail address: miller.joanne@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-2004-0070. 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 in 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-2004-0070. 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-2004-0070. 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-2004-0070.

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-2004-0070. 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 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 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 pesticide petitions 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 these petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated: March 22, 2004.

Betty Shackelford,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner's summary of the pesticide petitions is printed below as required by FFDCA section 408(d)(3). The summary of the petitions was prepared by the petitioner and represents the view of the petitioner. 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.

FMC Corporation and IR-4

PP 2F6468 and 3E6746

EPA has received pesticide petitions (2F6468 and 3E6746) from FMC Corporation and IR-4, 1735 Market

Street, Philadelphia, PA 19103, and Technology Center, of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of carfentrazone-ethyl (ethyl-alpha-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzene-propanoate) and the metabolite carfentrazone-ethyl chloropropionic acid (alpha-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoic acid) in or on the raw agricultural commodities: Grape at 0.1 part per million (ppm); tuberous and corm vegetables, crop subgroup 1C at 0.1 ppm; citrus, crop group 10 at 0.1 ppm; pome fruit, crop group 11 at 0.1 ppm; stone fruit, crop group 12 at 0.1 ppm; tree nut, crop group 14 at 0.1 ppm; vegetable, root and tuber, crop group 1 at 0.1 ppm; vegetable, leaves of root and tuber, crop group 2 at 0.1 ppm; vegetable, bulb, group 3 at 0.1 ppm; vegetable, leafy, except brassica, group 4 at 0.1 ppm; vegetable, brassica, leafy, group 5 at 0.1 ppm; vegetable, legume, group 6 at 0.1 ppm; vegetable, foliage of legume, group 7 at 0.1 ppm; vegetable, cucurbit group 9 at 0.1 ppm; berry group 13 at 0.1 ppm; herbs and spice group 19 at 0.1 ppm; rapeseed, seed at 0.1 ppm; rapeseed, Indian at 0.1 ppm; mustard seed, Indian at 0.1 ppm; mustard seed, field at 0.1 ppm; mustard seed, black at 0.1 ppm; flax, seed at 0.1 ppm; sunflower, seed at 0.1 ppm; safflower, seed at 0.1 ppm; crambe, seed at 0.1 ppm; borage, seed at 0.1 ppm; strawberry at 0.1 ppm; sugarcane at 0.1 ppm; peanut at 0.1 ppm; grass, forage, fodder, and hay, group 17 at 0.1 ppm; vegetables, crop group 8 at 0.1 ppm; okra at 0.1 ppm; tropical tree fruit at 0.1 ppm; pistachio at 0.1 ppm; lingonberry at 0.1 ppm; juneberry at 0.1 ppm; salal at 0.1 ppm; kiwi fruit at 0.1 ppm; pomegranate at 0.1 ppm; fig at 0.1 ppm; olive at 0.1 ppm; date at 0.1 ppm; banana at 0.1 ppm; persimmon at 0.1 ppm; pawpaw at 0.1 ppm; cacao at 0.1 ppm; palm heart at 0.1 ppm; tea at 0.1 ppm; Indian mulberry at 0.1 ppm; vanilla at 0.1 ppm; coconut at 0.1 ppm; coffee at 0.1 ppm; ti at 0.1 ppm; wasabi at 0.1 ppm; stevia at 0.1 ppm; cactus at 0.1 ppm; strawberry pear at 0.1 ppm; guayule at 0.1 ppm; kava at 0.1 ppm; sweet sorghum at 0.1 ppm; and horseradish at 0.1 ppm; almond hulls at 0.2 ppm; and grass, forage, fodder, and hay, group 17 at 12 ppm. EPA has determined that the petitions contain data or information regarding the

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

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of carfentrazone-ethyl in plants is adequately understood. Corn, wheat, radish, and soybean metabolism studies with carfentrazone-ethyl have shown uptake of material into plant tissue with no significant movement into grain, root, or seeds. All four plants extensively metabolized carfentrazone-ethyl and exhibited a similar metabolic pathway. The residues of concern are the combined residues of carfentrazone-ethyl and carfentrazone-ethyl-chloropropionic acid.

2. *Analytical method.* There is a practical analytical method for detecting and measuring levels of carfentrazone-ethyl and its metabolites in or on food with a limit of quantitation (LOQ) that allows monitoring of food with residues at or above the levels set or proposed in the tolerances. The analytical method for carfentrazone-ethyl involves separate analyses for the parent and its metabolites. The parent is analyzed by gas chromatography/electron capture detector (GC/ECD). The metabolites are derivatized with boron trifluoride and acetic anhydride for analysis by gas chromatography/mass spectrometry (GC/MSD) using selective ion monitoring.

3. *Magnitude of residues.* Trials were conducted on several crop groups listed above. Carfentrazone-ethyl (Aim effective concentration (EC), Aim estimated water (EW), or Aim herbicide) was applied as a broadcast application to soil at a target rate of 0.032 lb active ingredient/acre 24–48 hours prior to planting. The second application was a post-emergent banded application at a target rate of 0.064 lb active ingredient/acre within 12–24 hours of harvest with a hooded sprayer to the row middles with the hood riding along the soil surface. Treated and untreated mature samples were collected at crop maturity. Additional samples from one trial each of several crops were collected to establish a residue decline pattern. Additional samples from one trial each of several crops were collected for processing studies for subsequent analysis of processed parts. Residues of carfentrazone-ethyl and its metabolites in the crop group samples were detected in low levels ranging from not detected (ND) to 0.06 ppm with a pre-harvest

interval (PHI) of 1–day. Residues were not found in the exaggerated rate samples, and therefore, processing was not conducted for most of the crops. Residue values <0.05 ppm are estimated values less than the LOQ and greater than the limit of detection (LOD) (0.01–0.02 ppm).

For berries, trials were conducted as follows: For blueberry, the first application of carfentrazone-ethyl (aim EC, Aim EW or Aim herbicide), was a dormant post-direct application to the base of tree trunks at a targeted rate of 0.032 lb active ingredient/acre and the second application was an indirect hooded sprayer application at a target banded rate of 0.064 lb active ingredient/acre 12–24 hours prior to harvest for a total of 0.096 lb active ingredient/acre. For blackberry (Aim EC) and raspberry (Aim EW) carfentrazone-ethyl was applied four times as a post-direct application each at a target rate of 0.1 lb active ingredient/acre for a total of 0.4 lb active ingredient/acre with a PHI of 15 days. Treated and untreated mature samples were collected at crop maturity. Additional samples from one blueberry trial were collected to establish a residue decline pattern. Residues were not detected (<0.01 ppm) in any of the samples.

For grape, tuberous, and corm vegetables, citrus fruits, pome fruits, stone fruits, tree nuts, and grass, trials were conducted as follows: Carfentrazone-ethyl (aim EC, Aim EW or aim herbicide) was applied three times as a broadcast foliar application at a target rate of 0.031 lb active ingredient/acre for a total target rate of 0.093 lb active ingredient/acre. Additional samples were collected from one trial each to establish a residue decline pattern and for processing studies. For grass, forage samples were collected on 0 day, hay was cut on 0 day and dried for 0–14 days after the third application of the test substance. The maximum total residue for carfentrazone-ethyl and its major metabolites in/on forage and hay was 5.59 and 10.64 ppm, respectively. Low level residues were found in the control samples in 7 of the 12 trials ranging from an estimated 0.02 ppm to 0.07 ppm. Residues of carfentrazone-ethyl and its metabolites in the crop/group samples were detected in low levels ranging from ND to <LOQ except for residues of almond hulls. Residue values <0.05 ppm are estimated values less than the LOQ and greater than the LOD (0.01–0.04 ppm). Raw agricultural commodities were harvested at the appropriate time and subsequent analyses determined that the residues of carfentrazone-ethyl and its

metabolites would not exceed the proposed tolerances.

B. Toxicological Profile

1. *Acute toxicity.* Carfentrazone-ethyl demonstrates low oral, dermal, and inhalation toxicity. The acute oral lethal dose (LD)₅₀ value in the rat was greater than 5,000 milligrams/kilogram (mg/kg), the acute dermal LD₅₀ value in the rat was greater than 4,000 mg/kg and the acute inhalation lethal concentration (LC)₅₀ value in the rat was greater than 5.09 milligrams/Liter (mg/L/4h). Carfentrazone-ethyl is non-irritating to rabbit skin and minimally irritating to rabbit eyes. It did not cause skin sensitization in guinea pigs. An acute neurotoxicity study in the rat had a systemic no observed adverse effect level (NOAEL) of 500 mg/kg based on clinical signs and decreased motor activity levels; the NOAEL for neurotoxicity was greater than 2,000 mg/kg highest dose tested (HDT) based on the lack of neurotoxic clinical signs or effects on neuropathology.

2. *Genotoxicity.* Carfentrazone-ethyl did not cause mutations in the Ames assay with or without metabolic activation. There was a positive response in the chromosome aberration assay without activation but a negative response with activation. The mouse micronucleus assay (an *in vivo* test which also measures chromosome damage), the chinese hamster ovary/hypoxanthine guanine phosphoribosyl transferase (CHO/HGPRT) forward mutation assay and the unscheduled deoxyribonucleic acid (DNA) synthesis assay were negative. The overwhelming weight of the evidence supports the conclusion that carfentrazone-ethyl is not genotoxic.

3. *Reproductive and developmental toxicity.* Carfentrazone-ethyl is not considered to be a reproductive or a developmental toxin. In the 2-generation reproduction study, the no observe effect level (NOEL) for reproductive toxicity was greater than 4,000 ppm (greater than 323 to greater than 409 mg/kg/day). In the developmental toxicity studies, the rat and rabbit maternal NOELs were 100 mg/kg/day and 150 mg/kg/day, respectively. The developmental NOEL for the rabbit was greater than 300 mg/kg/day, which was the HDT and for the rat the NOEL was 600 mg/kg/day based on increased litter incidences of thickened and wavy ribs at 1,250 mg/kg/day. These two findings (thickened and wavy ribs) are not considered adverse effects of treatment but related delays in rib development which are generally believed to be reversible.

4. *Subchronic toxicity.* The 90-day feeding studies were conducted in mice, rats, and dogs with carfentrazone-ethyl. The NOEL for the mouse study was 4,000 ppm (571 mg/kg/day), for the rat study was 1,000 ppm (57.9 mg/kg/day for males; 72.4 mg/kg/day for females) and for dogs was 150 mg/kg/day. A 90-day subchronic neurotoxicity study in the rat had a systemic NOEL of 1,000 ppm (59.0 mg/kg/day for males; 70.7 mg/kg/day for females) based on decreases in body weights, body weight gains and food consumption at 10,000 ppm; the neurotoxicity NOEL was greater than 20,000 ppm (1,178.3 mg/kg/day for males; 1,433.5 mg/kg/day for females) which was the HDT.

5. *Chronic toxicity.* Carfentrazone-ethyl is not carcinogenic to rats or mice. A 2-year Combined Chronic Toxicity/Oncogenicity study in the rat was negative for carcinogenicity and had a chronic toxicity NOEL of 200 ppm (9 mg/kg/day) for males and 50 ppm (3 mg/kg/day) for females based on red fluorescent granules consistent with porphyrin deposits in the liver at the 500 and 200 ppm levels, respectively. An 18-month oncogenicity study in the mouse had a carcinogenic NOEL that was greater than 7,000 ppm (>1,090 mg/kg/day for males; >1,296 mg/kg/day for females) based on no evidence of carcinogenicity at the HDT. A 1-year oral toxicity study in the dog had a NOEL of 50 mg/kg/day based on isolated increases in urine porphyrins in the 150 mg/kg/day group (this finding was not considered adverse). Using the Guidelines for Carcinogen Risk Assessment, carfentrazone-ethyl should be classified as group "E" for carcinogenicity--no evidence of carcinogenicity--based on the results of carcinogenicity studies in two species. There was no evidence of carcinogenicity in an 18-month feeding study in mice and a 2-year feeding study in rats at the dosage levels tested. The doses tested are adequate for identifying a cancer risk. Thus, a cancer risk assessment is not necessary.

6. *Animal metabolism.* The metabolism of carfentrazone-ethyl in animals is adequately understood. Carfentrazone-ethyl was extensively metabolized and readily eliminated following oral administration to rats, goats, and poultry via excreta. All three animals exhibited a similar metabolic pathway. As in plants, the parent chemical was metabolized by hydrolytic mechanisms to predominantly form carfentrazone-ethyl-chloropropionic acid, which was readily excreted.

7. *Endocrine disruption.* An evaluation of the potential effects on the endocrine systems of mammals has not

been determined; however, no evidence of such effects was reported in the chronic or reproductive toxicology studies described above. There was no observed pathology of the endocrine organs in these studies. There is no evidence at this time that carfentrazone-ethyl causes endocrine effect.

C. Aggregate Exposure

1. *Dietary exposure—i. Acute dietary.* Based on the available toxicity data, EPA has established an acute reference dose (RfD) for carfentrazone-ethyl of 5 mg/kg/day. The acute RfD for carfentrazone-ethyl is based on acute neurotoxicity study in rats with a threshold NOEL of 500 mg/kg/day and an uncertainty factor (UF) of 100.

ii. *Chronic dietary.* Based on the available toxicity data, EPA has established a RfD for carfentrazone-ethyl of 0.03 mg/kg/day. The RfD for carfentrazone-ethyl is based on a 2-year chronic toxicity/carcinogenicity study in rats with a threshold NOEL of 3 mg/kg/day and an UF of 100. For purposes of assessing the potential chronic dietary exposure, a Tier I dietary risk assessment was conducted based on the Theoretical Maximum Residue Contribution (TMRC) from the established and proposed tolerances for carfentrazone-ethyl. The tolerances are as follows: 0.1 ppm in or on caneberry subgroup; 0.20 ppm in or on corn, field, forage; 0.20 ppm in or on corn, sweet, forage; 0.1 ppm corn, sweet, kernel, plus cob with husk removed; 10 ppm in or on cotton, gin by products; 0.20 ppm in or on cotton, undelinted seed; 0.60 ppm in or on cotton, hulls; 0.35 ppm in or on cotton, meals; 1.0 ppm in or on cotton, refined oil; 1.0 ppm in or on grain, cereal, forage (excluding corn and sorghum); 0.30 ppm in or on grain, cereal, hay; 0.10 ppm in or on grain, cereal, group; 0.30 ppm in or on grain, cereal, stover; 0.1 ppm in or on grain, cereal, straw (excluding rice); 1.0 ppm in or on rice, straw; 0.20 ppm in or on sorghum, forage and 0.1 ppm in or on soybean, seed. (The TMRC is a "worse case" estimate of dietary exposure since it is assumed that 100% of all crops for which tolerances are established are treated and that pesticide residues are present at the tolerance levels). In conducting this exposure assessment, the following very conservative assumptions were made - 100% of soybean, cotton, caneberry, and cereal grains will contain carfentrazone-ethyl residues and those residues would be at the level of the tolerance which result in an over estimate of human exposure.

2. i. *Food.* Dietary exposure from the proposed uses would account for 1.0% or less of the acute population adjusted

dose (PAD) in subpopulations (including infants and children). Dietary exposure from the proposed uses would account for 15% or less of the chronic PAD in subpopulations (including infants and children).

ii. *Drinking water.* Acute drinking water levels of concern (DWLOC) are estimated at 175,000 mg/kg/day, surface water estimated environmental concentration (EEC) at 21.4 parts per billion (ppb) and ground water EEC at 13.4 ppb for U.S. subpopulations - all seasons. Chronic DWLOC is estimated at 998 mg/kg/day, surface water EEC at 20.2 ppb, and ground water EEC at 13.4 ppb for U.S. subpopulations - all seasons.

3. *Non-dietary exposure.* No specific worker exposure tests have been conducted with carfentrazone-ethyl. The potential for non-occupational exposure to the general population has not been fully assessed.

D. Cumulative Effects

EPA is also required to consider the potential for cumulative effects of carfentrazone-ethyl and other substances that have a common mechanism of toxicity. EPA consideration of a common mechanism of toxicity is not appropriate at this time since EPA does not have information to indicate that toxic effects produced by carfentrazone-ethyl would be cumulative with those of any other chemical compounds; thus only the potential risks of carfentrazone-ethyl are considered in this exposure assessment.

E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions described and based on the completeness and reliability of the toxicity data, the aggregate exposure to carfentrazone-ethyl will utilize less than 1% of the acute PAD and less than 15% of the chronic PAD for the U.S. subpopulations. EPA generally has no concern for exposures below 100% of the acute PAD or chronic PAD. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, there is a reasonable certainty that no harm will result from aggregate exposure to residues of carfentrazone-ethyl, including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of carfentrazone-ethyl, EPA considers data from developmental toxicity studies in the rat and rabbit and the 2-generation reproduction study in the rat. The

developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to effects on the reproductive capacity of males and females exposed to the pesticide. Developmental toxicity was not observed in developmental toxicity studies using rats and rabbits. In these studies, the rat and rabbit maternal NOELs were 100 mg/kg/day and 150 mg/kg/day, respectively. The developmental NOEL for the rabbit was greater than 300 mg/kg/day, which was the HDT and for the rat was 600 mg/kg/day based on increased litter incidences of thickened and wavy ribs. These two findings are not considered adverse effects of treatment but related delays in rib development, which are generally believed to be reversible.

In a 2-generation reproduction study in rats, no reproductive toxicity was observed under the conditions of the study at 4,000 ppm, which was the HDT.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base. Based on the current toxicological data requirements, the data base relative to prenatal and postnatal effects for children is complete and an additional UF is not warranted. Therefore at this time, the RfD of 0.03 mg/kg/day is appropriate for assessing aggregate risk to infants and children.

F. International Tolerances

There are no Codex Alimentarius Commission (Codex) maximum residue levels (MRLs) for carfentrazone-ethyl on any crops at this time. However, MRLs for small grains in Europe have been proposed which consist of carfentrazone-ethyl and carfentrazone-ethyl-chloropropionic acid.

[FR Doc. 04-7078 Filed 3-30-04; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0006; FRL-7342-4]

Reynoutria Sachalinensis; 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 identification (ID) number OPP-2004-0006, must be received on or before April 30, 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: Driss Benmhend, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9525; e-mail address: benmhend.driss@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-2004-0006. 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