to establish, modify, or revoke a tolerance, the Agency consider '' available information'' concerning the cumulative effects of a particular pesticide residue and ''other substances that have a common mechanism of toxicity.'' EPA stated in the **Federal Register** (FR) document published April 7, 1999, (64 FR 16843) (FRL–6070–6) that it does not have, at this time, available data to determine whether abamectin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment.

E. Safety Determination

1. *U.S. population*. Using the exposure assumptions described above and based on the completeness and reliability of the toxicity data base, Whitmire Micro-Gen has calculated aggregate exposure levels for this chemical. The calculations show that chronic dietary exposure is below 100% of the RfD and the predicted acute exposure is below 100% of the acute RfD for all subpopulations. Use on herb crop subgroup 19A (except chives) is not expected to have an impact on these calculations. Chronic exposure through the consumption of drinking water has been estimated to be well below any level of concern. Acute exposure to residues of abamectin in drinking water has been estimated to be above the drinking water level of comparison DWLOC for children (1–6 years old) but the certainty of this calculation is low due to the uncertainty on the amount of runoff from strawberry plant beds covered in plastic mulch and the uncertainty on the amount of degradation of abamectin on black plastic as compared to soil. Whitmire Micro-Gen concludes that there is a reasonable certainty that no harm will result from aggregate exposure to abamectin residues.

2. *Infants and children*. The Food Quality Protection Act FQPA (Public Law 104–170) authorizes the employment of an additional safety factor of up to 10X to guard against the possibility of prenatal or postnatal toxicity, or to account for an incomplete data base on toxicity or exposure. EPA has chosen to retain the FQPA safety factor for abamectin based on several reasons including evidence of neurotoxicity, susceptibility of neonatal rat pups, similarity to ivermectin, lack of a developmental neurotoxicity study, and concern for exposure to infants and children. It is the opinion of Whitmire Micro-Gen that a 3X safety factor is more appropriate for abamectin at this time. EPA has evaluated abamectin repeatedly since its introduction in 1985 and has found repeatedly that the level of dietary exposure is sufficiently low to provide ample margins of safety to guard against any potential adverse effects of abamectin. In addition, valid exposure studies demonstrate there is no exposure via indoor applications of abamectin products. Whitmire Micro-Gen states that the data base for abamectin is complete and that the developmental neurotoxicity study is a new and not yet initially required study. Additionally, there is much more information regarding human risk potential than is the case with most pesticides, because of the widespread animal-drug and human-drug uses of ivermectin, the closely related analog of abamectin.

It is the opinion of Whitmire Micro-Gen that the use of a full 10X safety factor to address risks to infants and children is not necessary. The established chronic endpoint for abamectin in the neonatal rat is overly conservative. Similar endpoints for ivermectin are not used by the Food and Drug Administration (FDA) to support the allowable daily intake for ivermectin residues in food from treated animals. No evidence of toxicity was observed in neonatal rhesus monkeys after 14–days of repeated administration of 0.1 mg/kg/day HDT and in juvenile rhesus monkeys after repeated administration of 1.0 mg/kg/day HDT. The comparative data on abamectin and ivermectin in primates also clearly demonstrate the dose response for exposure to either compound is much less steep than that seen in the neonatal rat. Single doses as high as 24 mg/kg of either abamectin or ivermectin in rhesus monkeys did not result in mortality; however, this dose was more than 2 times the LD_{50} in the adult rat and more than 20 times the LD_{50} in the neonatal rat. The absence of a steep dose-response curve in primates provides a further margin of safety regarding the probability of toxicity occurring in infants or children exposed to abamectin compounds. The significant human clinical experience and widespread animal drug uses of ivermectin without systemically toxic, developmental, or postnatal effects supports the safety of abamectin to infants and children.

F. International Tolerances

Abamectin is a broad spectrum insecticide used throughout the world to control pests of livestock, crops, ornamental plants and turf, and household, commercial and industrial use areas. There is no codex maximum residue limit MRLs for abamectin in or on food products in food handling establishments or on herbs. Therefore, international harmonization is not an issue at this time.

[FR Doc. 04–16852 Filed 7–27–04; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0177; FRL–7365–2]

Carfentrazone-ethyl; 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 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–2004–0177, must be received on or before August 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: 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); and
- Pesticide manufacturing (NAICS).

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–2004–0177. 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, 1801 Bell Street, 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–2004–0177. 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–2004–0177. 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–2004–0177.

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, 1801 Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0177. 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 assignedto this action in the subject line on the first page of your response. You may also provide thename, 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: July 9, 2004.

Betty Shackleford,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summary of the petitions were 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

2F6468, 3E6746, 3E6554, 4E6814 and 3F6584

EPA has received pesticide petitions (2F6468, 3E6746, 3E6554, 4E6814 and 3F6584) 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-α-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 (α, 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: Acerola at 0.1 parts per million (ppm); Almond hulls at 0.2 ppm and grass, forage, fodder and hay, group 17 at 12 ppm; Hops at 0.05 ppm; Avocado at 0.1 ppm; Atemoya at 0.1 ppm; Banana at 0.1 ppm; Berry group 13 at 0.1 ppm; Birida at 0.1 ppm; Borage, seed at 0.1 ppm; Cacao at 0.1 ppm; Cactus at 0.1 ppm; Canistel at 0.1 ppm; Cherimoya at 0.1 ppm; Citrus, crop group 10 at 0.1 ppm; Citrus cultivars and/or hybrids of grapefruit and pummelo, including Uniq fruit at 0.1 ppm; Coconut at 0.1 ppm; Coffee at 0.1 ppm; Crambe, seed at 0.1 ppm; Custard apple at 0.1 ppm; Date at 0.1 ppm; Feijoa at 0.1 ppm; Fig at 0.1 ppm; Fish at 0.2 ppm; Flax, seed at 0.1 ppm; Grape at 0.1 ppm; Grapefruit at 0.1 ppm; Guava at 0.1 ppm; Guayule at 0.1 ppm; Herbs and spice group 19 at 0.1 ppm; Horseradish at 0.1 ppm; Ilama at 0.1 ppm; Indian Mulberry at 0.1 ppm; Jabotica at 0.1 ppm; Juneberry at 0.1 ppm; Kava at 0.1 ppm; Kiwi fruit at 0.1 ppm; Lingonberry at 0.1 ppm; Lychee at 0.1 ppm; Longan at 0.1 ppm; Mango 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; Okra at 0.1 ppm; Olive at 0.1 ppm; Palm Heart, leaves at 0.1 ppm; Passionfruit at 0.1 ppm; Papaya at 0.1 ppm; Pawpaw at 0.1 ppm; Peanut at 0.1 ppm; Persimmon at 0.1 ppm; Pistachio at 0.1 ppm; Pome fruit, crop group 11 at 0.1 ppm; Pomegranate at 0.1 ppm; Pulasan at 0.1 ppm; Pummelo at 0.1 ppm; Rambutan at 0.1 ppm; Rapeseed, Indian at 0.1 ppm; Rapeseed, seed at 0.1 ppm; Safflower, seed at 0.1 ppm; Salal at 0.1 ppm; Sapodilla at 0.1 ppm; Sapote, black at 0.1 ppm; Sapote, mamey at 0.1 ppm; Shellfish at 0.2 ppm; Sorghum, sweet, stalks at 0.1 ppm; Sorghum, sweet, syrup at 0.1 ppm; Soursop at 0.1 ppm; Spanish lime at 0.1 ppm; Star apple at 0.1 ppm; Starfruit at 0.1 ppm; Stone fruit, crop group 12 at 0.1 ppm; Strawberry at 0.1 ppm; Strawberrypear at 0.1 ppm; Stevia at 0.1 ppm; Sugar apple at 0.1 ppm; Sugarcane at 0.1 ppm; Sunflower, seed at 0.1 ppm; Ti, leaves at 0.1 ppm; Tea at 0.1 ppm; Tree nut, crop group 14 at 0.1 ppm; Tuberous and corm vegetables, crop subgroup 1C at 0.1 ppm; Vanilla at 0.1 ppm; Vegetable, brassica, leafy, group 5 at 0.1 ppm;

Vegetable, bulb, group 3 at 0.1 ppm; Vegetable, cucurbit group 9 at 0.1 ppm; Vegetable, foliage of legume, group 7 at 0.1 ppm; Vegetables, Fruiting, Group, crop group 8 at 0.1 ppm; Vegetable, leaves of root and tuber, group 2 at 0.1 ppm; Vegetable, leafy, except brassica, group 4 at 0.1 ppm; Vegetable, legume, group 6 at 0.1 ppm; Vegetable, root and tuber, group 1 at 0.1 ppm; Wasabi, roots at 0.1 ppm; and Wax jambu at 0.1 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 supports granting of the petitions. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of 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 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 parent and its metabolites. The parent is analyzed by gas chromatography/electron capture detection (GC/ECD). The metabolites are derivatized with boron trifluoride and acetic anhydride for analysis by gas chromatography mass spectrometry detection (GC/MSD) using selective ion monitoring.

3. *Magnitude of residues*. Trials were conducted on several on several crop groups listed above. Carfentrazone-ethyl (Aim EC, Aim EW or Aim Herbicide) was applied as a broadcast application to soil at a target rate of 0.032 pounds active ingredient per acre (lbs ai/A) 24–48 hours prior to planting. The second application was a post-emergent banded application at a target rate of 0.064 lb ai/A within 12–24 hours of harvest with a hooded sprayer to 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 ND to 0.06 ppm with a 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 limit of quantitation (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 ai/A and the second application was an indirect hooded sprayer application at a target banded rate of 0.064 lb ai/A 12-24 hours prior to harvest for a total of 0.096 lb ai/A. 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 ai/A for a total of 0.4 lb ai/A 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 ai/A for a total target rate of 0.093 lb ai/A. 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 seven of the twelve 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). RAC 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.

No residues of carfentrazone-ethyl were found in any fish tissue sample at any time. The maximum total residue of carfentrazone-ethyl chloropropionic acid in the fish tissues were 0.17 ppm.

B. Toxicological Profile

1. *Acute toxicity*. Carfentrazone-ethyl demonstrates low oral, dermal and inhalation toxicity. The acute oral LD_{50} value in the rat was greater than 5,000 milligrams/kilogram (mg/kg), the acute dermal LD_{50} value in the rat was greater than 4,000 mg/kg and the acute inhalation LC_{50} value in the rat was greater than 5.09 mg/Liter (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 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) based on the lack of neurotoxic clinical signs or effects on neuropathology.

2. *Genotoxicty*. 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 CHO/HGPRT forward mutation assay and the Unscheduled 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 NOAEL 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 NOAELs were 100 mg/kg/day and 150 mg/kg/day, respectively. The developmental NOAEL for the rabbit was greater than 300 mg/kg/day, which was the HDT and for the rat the NOAEL 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*. Ninety-day feeding studies were conducted in mice, rats and dogs with Carfentrazone-ethyl. The NOAEL 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 NOAEL 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 NOAEL was greater than 20,000 ppm (1178.3 mg/kg/day for males; 1433.5 mg/kg/day for females) which was the highest dose tested.

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 NOAEL 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 NOAEL that was greater than 7,000 ppm (>1,090 mg/kg/day for males; >1296 mg/kg/day for females) based on no evidence of carcinogenicity at the highest dose tested. A 1–Year Oral Toxicity study in the dog had a NOAEL 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, the EPA has established an acute Reference Dose (aRfD) for carfentrazone-ethyl of 5 mg/kg/day. The aRfD for carfentrazone-ethyl is based on acute neurotoxicity study in rats with a threshold NOAEL of 500 mg/kg/day and an uncertainty factor of 100.

ii. *Chronic dietary*. Based on the available toxicity data, the 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 NOAEL of 3 mg/kg/day and an uncertainty factor of 100. For purposes of assessing the potential chronic dietary exposure, a Tier 1 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 and0.1 ppm in or on soybean, seed. (The TMRC is a ''worse case'' estimate of dietary exposure since it is assumed that 100 percent 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. *Food*. Dietary exposure from the proposed uses would account for 1.0% or less of the aPAD in subpopulations (including infants and children). Dietary exposure from the proposed uses would account for 15% or less of the cPAD in subpopulations (including infants and children).

3. *Drinking water*. Acute DWLOC is estimated at 175,000 mg/kg/day, surface water 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.

4. *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 aPAD and less than 15% of the cPAD for the US subpopulations. EPA generally has no concern for exposures below 100 percent of the aPAD or cPAD. 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 two-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 NOAELs were 100 mg/kg/day and 150 mg/kg/day, respectively. The developmental NOAEL for the rabbit was greater than 300 mg/kg/day, which was the highest dose, tested 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 two-generation reproduction study in rats, no reproductive toxicity was observed under the conditions of the study at 4,000 ppm, which was the highest dose tested.

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 pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database relative to pre-natal and post-natal effects for children is complete and an additional uncertainty factor 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.

3. *Population adjusted dose (aPAD and cPAD).* Using the conservative exposure assumptions described above, the percent of the aPAD that will be utilized by aggregate exposure to residues of carfentrazone-ethyl for non-nursing infants (<1 year old) would be < 1% (aPAD) and < 10% (cPAD); for children 1–6 years of age would be < 1% (aPAD) and < 15% (cPAD), (the most highly exposed group). 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 to infants and children from aggregate exposure to the residues of carfentrazone-ethyl including all anticipated dietary exposure.

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.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0197; FRL–7366–2]

Spiromesifen; 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–2004–0197, must be received on or before August 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: Thomas C. Harris, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9423; e-mail address: *harris.thomas@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food processing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturers (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 identification (ID) number OPP–2004–0197. 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. Note: Due to renumbering of buildings in area, the street address will change to 1801 South Bell Street as of June 26, 2004. 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