

C. 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. Offer alternative ways to improve the notice or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. 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.

III. What Action is the Agency Taking?

EPA is making available to the public the risk assessments that have been developed as part of the Agency's interim public participation process for tolerance reassessment and reregistration. During the next 60 days, EPA will accept comments on the human health and environmental fate and effects risk assessment and other related documents for 2,4-DB and 2,4-DB-DMAS, available in the individual pesticide docket. Like other REDs for pesticides developed under the interim process, the 2,4-DB and 2,4-DB-DMAS RED will be made available for public comment.

EPA and the United States Department of Agriculture have been using a pilot public participation process for the assessment of organophosphate pesticides since August 1998. In considering how to accomplish the movement from the current pilot being used for the organophosphate pesticides to the public participation process that will be used in the future for non-organophosphates, such as 2,4-DB and 2,4-DB-DMAS, EPA and USDA have adopted an interim public participation process. EPA is using this interim process in reviewing the non-organophosphate pesticides scheduled to complete tolerance reassessment and reregistration in 2001 and early 2002. The interim public participation process ensures public access to the Agency's risk assessments while also allowing

EPA to meet its reregistration commitments. It takes into account that the risk assessment development work on these pesticides is substantially complete. The interim public participation process involves: A registrant error correction period; a period for the Agency to respond to the registrant's error correction comments; the release of the refined risk assessments and risk characterizations to the public via the docket and EPA's internet website; a significant effort on stakeholder consultations, such as meetings and conference calls; and the issuance of the risk management decision document (i.e., RED) after the consideration of issues and discussions with stakeholders. USDA plans to hold meetings and conference calls with the public (i.e., interested stakeholders such as growers, USDA Cooperative Extension Offices, commodity groups, and other Federal Government agencies) to discuss any identified risks and solicit input on risk management strategies. EPA will participate in USDA's meetings and conference calls with the public. This feedback will be used to complete the risk management decisions and the RED. EPA plans to conduct a close-out conference call with interested stakeholders to describe the regulatory decisions presented in the RED. REDs for pesticides developed under the interim process will be made available for public comment.

Included in the public version of the official record are the Agency's risk assessments and related documents for 2,4-DB and 2,4-DB-DMAS. As additional comments, reviews, and risk assessment modifications become available, these will also be docketed. The 2,4-DB and 2,4-DB-DMAS risk assessments reflect only the work and analysis conducted as of the time they were produced and it is appropriate that, as new information becomes available and/or additional analyses are performed, the conclusions they contain may change.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: July 22, 2004

Debra Edwards,

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

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0188; FRL-7366-3]

Abamectin; 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-2004-0188, 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:

- Industry (NAICS code 111)
- Crop production (NAICS code 112)
- Animal production (NAICS code 311)
- Food manufacturing (NAICS code 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-2004-0188. 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 St., 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 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.1. 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-2004-0188. 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-2004-0188. 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-2004-0188.

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-2004-0188. Note: Due to renumbering of buildings in area, the street address will change to 1801 South Bell St., as of June 26, 2004. 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 pesticide 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 these pesticide petitions. Additional data may be needed before EPA rules on the pesticide petitions.

List of Subjects

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

Dated: July 9, 2004.

Betty Shackelford,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioners' summary of the pesticide petitions, PP 2H5642 and PP 3E6557, is printed below as required by FFDCA section 408(d)(3). The summary of the pesticide petitions was prepared by Whitmire Micro-Gen Research Laboratories, Inc. and Interregional Research Project Number 4 and represents the view of the pesticide petitioners. The summary of the pesticide petitions 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.

Whitmire Micro-Gen Research Laboratories, Inc.

Interregional Research Project Number 4

PP 2H5642 and PP 3E6557

EPA has received a pesticide petition (PP 2H5642) from Whitmire Micro-Gen Research Laboratories, Inc., 3568 Tree Court Industrial Boulevard, St. Louis,

MO 63122. EPA has also received a pesticide petition (PP 3E6557) from Interregional Research Project Number 4, 681 U.S. Hwy. #1 South, North Brunswick, NJ 08902-3390. These pesticide petitions propose, pursuant to FFDCA section 408(d), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of abamectin (avermectin B₁) and/or its delta 8,9-isomer as follows:

1. PP 2H5642, which was submitted by Whitmire Micro-Gen Research Laboratories, Inc., proposed establishment of a tolerance for food products in food handling establishments at 0.001 parts per million (ppm).

2. PP 3E6557, which was submitted by Interregional Research Project Number 4, proposed establishment of a tolerance for herb crop subgroup 19A (except chives) at 0.03 ppm.

EPA has determined that the pesticide 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 pesticide petitions. Additional data may be needed before EPA rules on the pesticide petitions.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of abamectin in plants is adequately understood and the residues of concern include the parent insecticide abamectin (also referred to as avermectin B₁ which is a mixture of a minimum of 80% avermectin B_{1a} and a maximum of 20% avermectin B_{1b}) and the delta 8,9-isomer of the B_{1a} and of the B_{1b} components of the parent insecticide.

2. *Analytical method.* The analytical methods involves homogenization, filtration, partition, and cleanup with analysis by high performance liquid chromatography (HPLC)-fluorescence detection. The methods are sufficiently sensitive to detect residues at or above the tolerances proposed. All methods have undergone independent laboratory validation as required by PR Notice 96-1.

3. *Magnitude of residues.* Residue studies were submitted for food handling establishments and for basil (the representative crop for herb crop subgroup 19A (except chives)). Results from the studies demonstrate that the highest residues found will not exceed the proposed tolerances when abamectin is applied following the proposed use directions.

B. Toxicological Profile

1. *Acute toxicity.* The data base includes the following studies:

i. A rat acute oral study with a lethal dose (LD)₅₀ of 4.4 to 11.8 milligram/kilogram (mg/kg) males and 10.9 to 14.9 mg/kg females.

ii. An acute oral toxicity in the CF-1 mouse with the delta 8,9-isomer has LD₅₀ greater than 80 mg/kg.

iii. A rabbit acute dermal study with a LD₅₀ >2,000 mg/kg.

iv. A rat acute inhalation study with a LC₅₀ >5.73 mg/Liter.

v. A primary eye irritation study in rabbits which showed irritation.

vi. A primary dermal irritation study in rabbits which showed no irritation.

vii. A primary dermal sensitization study in guinea pigs which showed no skin sensitization potential.

viii. An acute oral toxicity study in monkeys with a no observed adverse effect level (NOAEL) of 1.0 mg/kg based upon emesis at 2.0 mg/kg.

2. *Genotoxicity.* The Ames assays conducted with and without metabolic activation were both negative. The V-79 mammalian cell mutagenesis assays conducted with and without metabolic activation did not produce mutations. In an alkaline elution/rat hepatocyte assay, abamectin was found to induce single strand DNA breaks without significant toxicity in rat hepatocytes treated *in vitro* at doses greater than 0.2 millimeter (mm). This *in vitro* dose of 0.2 mm is biologically unobtainable *in vivo*, due to the toxicity of the compound. However, at these potentially lethal doses, *in vivo* treatment did not induce DNA single strand breaks in hepatocytes. In the mouse bone marrow assay, abamectin was not found to induce chromosomal damage. There are also, many studies and a great deal of clinical and follow-up experience with regard to ivermectin, a closely similar human and animal drug.

3. *Reproductive and developmental toxicity.* In a 2-generation study in rats the NOAEL was established at 0.12 mg/kg/day in pups based upon retinal folds, decreased body weight (bwt), and mortality. The NOAELs for systemic and reproductive toxicity were 0.4 mg/kg/day. In the 2-generations reproduction study in rats with the delta 8,9-isomer, the NOAEL was 0.4 mg/kg/day and the lowest observed adverse effect level (LOAEL) was greater than 0.4 mg/kg/day highest dose tested (HDT). In an oral developmental toxicity study in the CF-1 mouse the maternal NOAEL was 0.05mg/kg/day based upon decreased body weights and tremors. The fetal NOAEL was 0.20 mg/kg/day based upon cleft palates. In an oral developmental

toxicity study with the delta 8,9-isomer in CF-1 mice the maternal NOAEL was 0.10 mg/kg/day based upon decreased body weights. The fetal NOAEL was 0.06 mg/kg/day based upon cleft palate. In an oral developmental toxicity study in rabbits the maternal NOAEL was 1.0 mg/kg/day based upon decreased body weights and tremors. The fetal NOAEL was 1.0 mg/kg/day based upon clubbed feet. In an oral developmental toxicity study in rats the maternal and fetal NOAEL was 1.6 mg/kg/day, the HDT. In an oral developmental toxicity study with the delta 8,9-isomer the maternal NOAEL in CF-1 mice that expressed P-glycoprotein was greater than 1.5 mg/kg/day, the highest and only dose tested. No cleft palates were observed in fetuses that expressed normal levels of P-glycoprotein, but fetuses with low or no levels of P-glycoprotein had increased incidence of cleft palates.

4. *Subchronic toxicity.* Subchronic toxicity studies included the following:

i. A rat 8-week feeding study with a NOAEL of 1.4 mg/kg/day based upon tremors.

ii. A rat 14-week oral toxicity study with a NOAEL of 0.4 mg/kg/day, the HDT.

iii. A dog 12-week feeding study with a NOAEL of 0.5 mg/kg/day based upon mydriasis.

iv. A dog 18-week oral study with a NOAEL of 0.25 mg/kg/day based upon mortality.

v. A CD-1 mouse 84-day feeding study with a NOAEL of 4 mg/kg/day based upon decreased body weights.

5. *Chronic toxicity.* A rat 53-week carcinogenicity feeding study was negative for carcinogenicity, with a NOAEL of 1.5 mg/kg/day based upon tremors. A CD-1 mouse 94-week carcinogenicity feeding study was negative for carcinogenicity, with a NOAEL of 4 mg/kg/day based upon decreased body weights. A dog 53-week chronic feeding study was negative for carcinogenicity, with a NOAEL of 0.25 mg/kg/day based upon mydriasis.

6. *Animal metabolism.* Rats were given oral doses of 0.14 or 1.4 mg/kg bwt/day of abamectin or 1.4 mg/kg bwt/day of the delta 8,9 isomer. Over 7-days, the percentages excreted in urine were 0.3-1% of the administered dose of abamectin and 0.4% of the dose of the isomer. The animals eliminated 69-82% of the dose of abamectin and 94% of the dose of isomer in feces. In rats, goats, and cattle, unchanged parent compound accounted for up to 50% of the total radioactive residues in tissues. The 24-hydroxymethyl derivative of abamectin was found in rats, goats, and cattle treated with the compound and in rats treated with the delta 8,9 isomer,

and the 3''-O-demethyl derivative was found in rats and cattle administered abamectin and in rats administered the isomer.

7. *Metabolite toxicology.* There are no metabolites of concern based on a differential metabolism between plants and animals. The potential hazard of the 24-hydroxymethyl or the 3''-O-demethyl animal metabolites was evaluated in toxicology studies with abamectin photolytic break-down product, the delta 8,9-isomer.

8. *Endocrine disruption.* There is no evidence that abamectin is an endocrine disrupter. Evaluation of the rat multi-generational study demonstrated no effect on the time to mating or on the mating and fertility indices, suggesting no effects on the estrous cycle, on mating behavior, or on male or female fertility at doses up to 0.4 mg/kg/day, the HDT. Furthermore, the range finding study demonstrated no adverse effect on female fertility at doses up to 1.5 mg/kg/day, the HDT. Similarly, chronic and subchronic toxicity studies in mice, rats, and dogs did not demonstrate any evidence of toxicity to the male or female reproductive tract, or to the thyroid or pituitary (based upon organ weights and gross and histopathologic examination). In the developmental studies, the pattern of toxicity observed does not seem suggestive of any endocrine effect. Finally, experience with ivermectin in breeding animals, including sperm evaluations in multiple species, shows no adverse effects suggestive of endocrine disruption.

C. Aggregate Exposure

1. *Dietary exposure—i. Food.* In support of the petition for tolerance for abamectin in celeriac, the last EPA-approved tolerance, an acute assessment was conducted for avermectin B_{1a} and B_{1b} residues using the Dietary Exposure Evaluation Model DEEM™ and food consumption information from United State Department of Agriculture's (USDA's) 1994-1996 Continuing Survey of Food Intake by Individuals (CSFII). Acute dietary exposure to the adult male subpopulation was compared to an acute reference dose (RfD) of 0.0025 mg/kg/day based on a NOAEL of 0.25 mg/kg/day from a 1-year dog study and a 100X uncertainty factor (UF). For all other populations (containing females, infants and children) an acute population adjusted dose (PAD) of 0.00083 mg/kg/day was used and reflects an appropriate 300X UF. This tier 3 probabilistic analysis included the entire distribution of field trial residues and percent of crop treated information was incorporated by adding zeroes into the residue distribution file (RDF)

representing the percent of crop not treated. Non-detected residues of avermectin B_{1a} were entered into the software as $\frac{1}{2}$ the limit of quantitation ($\frac{1}{2}$ limit of quantitation (LOQ) and non-detected residues of avermectin B_{1b} were entered in as $\frac{1}{4}$ LOQ since the production ratio of B_{1a}: B_{1b} is 80:20. The acute dietary exposure results for the male (20 + years) population shows that 2.6% of the acute RfD was utilized at the 99.9th percentile of exposure. For the general U.S. population at the 99.9th percentile, exposure was 13.2% of the acute PAD. The most sensitive subpopulation was non-nursing infants (<1-year old) with 39.3% of the acute PAD at the 99.9th percentile.

For the male subpopulation, chronic exposure was compared to the chronic RfD of 0.0012 mg/kg/day from a 2-generation reproduction study in rats and a 100X UF. A 300X UF was utilized for populations containing females (13 + years old) and infants and children and the exposures were compared to a PAD of 0.0004 mg/kg/day. Residue values, taken from field trials conducted at maximum application rates and minimum pre-harvest intervals (PHI), were averaged and incorporated into the assessment. Residue values were adjusted with percent of crop treated information. For the male population (both 13–19 years and 20 + years), exposure was 0.3% of the chronic RfD. The chronic exposure results indicate that the U.S. population utilizes 1.3% of the chronic PAD. The most sensitive subpopulation was non-nursing infants with 2.9% of the chronic PAD. These results are conservative in that residue values were generated from field trials with maximum application rates and minimum post PHI. In addition, a significant reduction in residues would be expected as abamectin-treated commodities travel through food commerce, food preparation and storage.

Food handling establishment studies indicate that residue of abamectin in food is not expected from this use. While residues of abamectin in herbs up to tolerance levels are likely, the exceedingly small proportion of herbs in the diet limits exposure via this food group. Thus the chronic dietary risk assessment will not be impacted by these additional uses.

ii. *Drinking water*—a. *Acute exposure*. The estimated maximum concentration of abamectin in surface water is 0.88 parts per billion (ppb) (peak estimated environmental concentration (EEC) value from EPA's Pesticide Root Zone Model (PRZM)/EXAMS). This is an estimated environmental concentration based on the use of abamectin on

strawberries (the maximum use rate on registered and proposed uses). Use rates for crops on the current petition are all below the maximum use rate for strawberries. Whitmire Micro-Gen believes the estimates of abamectin exposure in water derived from the PRAM/EXAMS models are significantly overstated. EPA noted that the certainty of the concentrations estimated for strawberries is low, due to uncertainty on the amount of runoff from plant beds covered in plastic mulch and uncertainty on the amount of degradation of abamectin on black plastic compared to soil. Although, there is a high degree of uncertainty to this analysis, this is the best available estimate of concentrations of abamectin in drinking water.

Based on the EPA's "Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments" document (December 2, 1997), the acute drinking water levels of comparison (DWLOC_{acute}) were calculated for abamectin. For the adult male subpopulation, the DWLOC_{acute} was determined based on an acute RfD of 0.0025 mg/kg/day based on a NOAEL of 0.25 mg/kg/day from a 1-year dog study and a 100X UF. For all other populations (containing females, infants, and children), the DWLOC_{acute} was determined based on a population adjusted dose PAD of 0.00083 mg/kg/day and reflects an appropriate 300X UF. The acute dietary exposure results for the male (20 + years) population shows an exposure estimate of 0.000066 mg/kg bwt/day at the 99.9th percentile of exposure, thus a DWLOC_{acute} of 85 for this subpopulation. For the general U.S. population at the 99.9th percentile, an exposure estimate of 0.000110 mg/kg bwt/day was determined, thus a DWLOC_{acute} of 25. The most exposed subpopulation was non-nursing infants (<1 year old) with an exposure estimate of 0.000327 mg/kg bwt/day at the 99.9th percentile, thus a DWLOC_{acute} of 3 for this subpopulation. Based on this analysis, abamectin EECs do not exceed the calculated acute DWLOCs. Based on a maximum EEC of 0.88 ppb, acute exposure through the consumption of drinking water is below 19% of the acute population adjusted dose for all subpopulations.

b. *Chronic exposure*. The estimated maximum concentrations of abamectin in surface and ground water are 0.37 ppb (mean of annual values from PRZM/EXAMS) and 0.002 ppb screening concentration in ground water (SCI-GROW), respectively. These are EECs based on the use of abamectin on strawberries (the maximum use rate on registered and proposed uses). Use rates

for crops on the current petition are all below the maximum use rate for strawberries. The chronic drinking water levels of comparison (DWLOC_{chronic}) were calculated for abamectin. For the adult male subpopulation, the DWLOC_{chronic} was determined based on the chronic RfD of 0.0012 mg/kg/day from a 2-generation reproduction study in rats and a 100X uncertainty factor. A 300X UF was utilized for populations containing females (13 + years old) and infants and children and the DWLOC_{chronic} was determined based on a population-adjusted dose PAD of 0.0004 mg/kg/day. The chronic dietary exposure results for the male (13–19 yrs and 20 + years) population shows an exposure estimate of 0.000004 mg/kg bwt/day, thus a DWLOC_{chronic} of 42 for this subpopulation. For the general U.S. population, an exposure estimate of 0.000005 mg/kg bwt/day was determined, thus a DWLOC_{chronic} of 14. The most exposed subpopulation was non-nursing infants (<1 year old) with an exposure estimate of 0.000012 mg/kg bwt/day, thus a DWLOC_{chronic} of 2.3 for this subpopulation. Based on this analysis, abamectin EECs do not exceed the calculated DWLOCs. Based on a maximum EEC of 0.37 ppb, chronic exposure through the consumption of drinking water is below 16% of the chronic population adjusted dose for all subpopulations.

2. *Non-dietary exposure*. Abamectin's registered residential uses include indoor crack/crevice and outdoor application to lawns. For lawn uses, EPA conducted a risk assessment for adult applicators and post-application exposure to abamectin using the EPA's draft Standard Operating Procedures (SOPs) for residential exposure assessments. The highest predicted exposure, oral hand to mouth for children, resulted in a calculated margin of exposure (MOE) of 14,000. For children's post-application exposure to abamectin from indoor crack/crevice products, valid exposure studies demonstrate there is no exposure and therefore no risk for indoor residential scenarios. Short- and intermediate-term risk for the registered uses do not exceed EPA's level of concern.

i. *Chronic exposure and risk*. Chronic exposures for the residential uses are not expected.

ii. *Short-term and intermediate-term exposure and risk*. Risk for the registered uses do not exceed EPA's level of concern.

D. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA 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 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 LD₅₀ in the adult rat and more than 20 times the LD₅₀ 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.

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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