

amended the Federal Food, Drug, and Cosmetic Act, Congress directed EPA to develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have hormonal effects in humans. In 1996, EPA chartered a scientific advisory committee, the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), under the authority of the Federal Advisory Committee Act (FACA) to advise it on establishing a program to carry out Congress' directive. EDSTAC recommended a multi-step approach including a series of screens (Tier I screens) and tests (Tier II tests) for determining whether a chemical substance may have an effect in humans similar to that produced by naturally occurring hormones. EPA adopted almost all of EDSTAC's recommendations in the program that it developed, the Endocrine Disruptor Screening Program (EDSP), to carry out Congress' directive.

EDSTAC also recognized that there currently are no validated test systems for determining whether a chemical may have an effect in humans that is similar to an effect produced by naturally occurring hormones. Consequently, EPA is in the process of developing and validating the screens and tests that EDSTAC recommended for inclusion in the EDSP. In carrying out this validation exercise, EPA is working closely with, and adhering to the principles of the Interagency Coordinating Committee for the Validation of Alternate Methods (ICCVAM). EPA also is working closely with the Organization for Economic Cooperation and Development's (OECD) Endocrine Testing and Assessment Task Force to validate and harmonize endocrine screening tests of international interest.

Finally, to ensure that EPA has the best and most up-to-date advice available regarding the validation of the screens and tests in the EDSP, EPA formed the Endocrine Disruptor Methods Validation Subcommittee (EDMVS) of the National Advisory Council for Environmental Policy and Technology (NACEPT). EDMVS provides independent advice and counsel to the Agency through NACEPT, on scientific and technical issues related to validation of the EDSP Tier I screens and Tier II tests, including advice on methods for reducing animal use, refining procedures involving animals to make them less stressful, and replacing animals where scientifically appropriate.

The EDMVS has held six meetings since its establishment in September 2001.

The objectives of the first meeting, which was held in October 2001, (docket control number OPPT-42212D) were for EPA to provide:

1. An overview of EPA's Endocrine Disruptor Program.
2. Background information on test protocol validation and approaches.
3. For the EDMVS to develop a clear understanding of their scope, purpose, and operating procedures.

4. The EDMVS and the EDSP to determine the next steps.

The objectives of the December 2001 meeting (docket control number OPPT-42212E) were for the EDMVS to provide input and advice on:

1. EDMVS's mission statement and work plan.
2. The *in utero* through lactation assay detailed review paper.
3. The pubertal assay study design for the multi-dose and chemical array protocols.
4. The mammalian one-generation study design.

The objectives of the March 2002 meeting (docket control number 42212F) were for the EDMVS to provide input and advice on:

1. EPA's implementation process and practical aspects of validation.
2. The *in utero* through lactation assay protocol.
3. The fish reproduction assay detailed review paper.
4. Special studies, the fathead minnow assays, vitellogenin assay, and avian dosing protocol.
5. The steroidogenesis detailed review paper.
6. The aromatase detailed review paper.
7. A proposed standard suite of chemicals for testing in the Tier I screening assays.
8. The current efforts related to evaluating the relevance of animal data to human health.
9. EPA's approach to addressing low dose issues.

The objective of the June 2002 teleconference meeting (docket ID number OPPT-2002-0020) was for the EDMVS to provide input and advice on the steroidogenesis detailed review paper.

The objectives of the July 2002 meeting (docket ID number OPPT-2002-0029) were:

1. To review the screening criteria, recommended by EDSTAC and adopted by EDSP for screens.
2. To receive an update of the NICEATM estrogen and androgen receptor binding efforts.

3. To discuss and provide advice on general dose setting issues; and to provide comments and advice on:

- A pubertal--special study--restricted feeding.
- A mammalian 2-generation draft PTU special study.
- An amphibian metamorphosis detailed review paper.
- An invertebrate detailed review paper.

The objective of the December 2002 teleconference meeting (docket ID number OPPT-2002-0059) was for the EDMVS to provide input and advice on the Tier II fish life cycle assay detailed review paper.

### III. Meeting Objectives for the June 5-6, 2003 Meeting

The objectives of the June 5-6, 2003 (docket ID number OPPT-2003-0016) are for EDMVS to provide input and advice on:

1. The Tier II Mammalian 2-generation special study on the one-generation extension results.
2. The Tier I steroidogenesis (sliced testes) study results.
3. To provide the status of the Tier I study results of the aromatase placental tissue study.

A list of the EDMVS members and meeting materials are available on our web site (<http://www.epa.gov/scipoly/oscpendo/edmvs.htm>) and in the public docket.

#### List of Subjects

Environmental protection, Endocrine system, Endocrine disruptors, Endocrine disruptor screening program.

Dated: May 9, 2003.

#### Joseph Merenda,

Director, Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances.

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0142; FRL-7308-4]

### Fenhexamid; 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 ID number OPP-2003-0142, must be received on or before June 20, 2003.

**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:** Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; e-mail address: [jackson.sidney@epa.gov](mailto:jackson.sidney@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. 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. 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 28522)

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. 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-2003-0142. 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 EPA's 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 EPA's 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-2003-0142. 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](mailto:opp-docket@epa.gov), Attention: Docket ID number OPP-2003-0142. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

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

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID number OPP-2003-0142.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP-2003-0142. 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: May 9, 2003.

**Debra Edwards,**

*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 Arvesta Corporation, 100 First Street, Suite 1700, San Francisco, CA 94105 and represents the view of Arvesta Corporation. The petitions 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.

#### **Interregional Research Project Number 4**

*PP 2E6463, 2E6496, 3E6532, and 3E6541*

EPA has received pesticide petitions 2E6463, 2E6496, 3E6532, and 3E6541, from the Interregional Research Project Number 4 (IR-4), Center for Minor Crop Pest Management, Rutgers, The State University 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 180.553 by establishing tolerances for residues of fenhexamid, *N*-(2,3-dichloro-4-hydroxyphenyl)-1-methyl-cyclohexane carboxamide, in or on raw agricultural commodities as follows:

1. PP 2E6463 proposes a tolerance in or on kiwifruit (post harvest) at 15.0 parts per million (ppm).

2. PP 2E6496 proposes to establish tolerances in or on cucumber at 2.0 ppm, and vegetable, fruiting, group 8 at 2.0 ppm.

3. PP 3E6532 proposes a tolerance in or on leafy greens subgroup 4A, except spinach, at 30.0 ppm.

4. PP 3E6541 proposes a tolerance in or on fruit, stone, group 12 (post harvest) at 10 ppm.

This action also proposes to further amend 40 CFR 180.553 by deleting the

entry for stone fruit, except plum (fresh prune) tolerance at 6.0 ppm as a higher tolerance of 10 ppm for fruit, stone, group 12 (post harvest) is proposed herein.

#### A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of fenhexamid residues in plants is adequately understood.

2. *Analytical method.* An adequate method for purposes of enforcement of the proposed fenhexamid tolerances in plant commodities is available.

3. *Magnitude of residues.* The magnitude of residues for fenhexamid on the proposed commodities is adequately understood.

#### B. Toxicological Profile

In the **Federal Register** of February 8, 2002 (67 FR 6028) (FRL-6821-2), EPA published the Notice of Filing proposing the establishment of tolerances for residues of fenhexamid on a number of raw agricultural commodities, including caneberry, *et. al.* That publication summarizes in detail the current state of knowledge regarding the toxicological profile of fenhexamid including aggregate exposure assessment and determination of safety. Interested readers are referred to that document for specific information under Unit II.

#### C. Aggregate Exposure

1. *Dietary exposure—i. Food.* Dietary exposure to fenhexamid is limited to the established tolerances for residues of fenhexamid on grapes (at 4.0 ppm), raisins (at 6.0 ppm), strawberries (at 3.0 ppm), almond nutmeat (at 0.02 ppm), almond hulls (at 2.0 ppm), stonefruit (pre-harvest, at 5.0 ppm), pear (at 15 ppm), bushberries (at 5.0 ppm), caneberries (at 20 ppm), and pistachios (at 0.02 ppm); the proposed tolerances in the current submission which are as follows: Cucumber (at 2.0 ppm), crop group 8 (fruiting vegetables, at 2.0 ppm), kiwi (post-harvest, at 15.0 ppm), lettuce (at 30.0 ppm), and crop group 12 (stonefruit, pre-harvest and post-harvest, at 10.0 ppm).

ii. *Drinking water.* Review of the environmental fate data indicates that fenhexamid is relatively immobile and rapidly degrades in the soil and water. Fenhexamid dissipates in the environment via several processes. Therefore, Arvesta Corporation believes that a significant contribution to aggregate risk from fenhexamid in drinking water is unlikely.

2. *Non-dietary exposure.* There is no significant potential for non-occupational exposure to the general public. The proposed uses are limited to agricultural and horticultural use.

#### D. Cumulative Effects

Consideration of a common mechanism of toxicity is not appropriate at this time since it has a unique mode of action. Moreover, there is no significant toxicity observed for fenhexamid. Even at toxicology limit doses, only minimal toxicity is observed for fenhexamid. Therefore, Arvesta Corporation concludes that only the potential risks of fenhexamid are considered in the exposure assessment.

#### E. Safety Determination

1. *U.S. population.* Considering that the percent of the chronic population adjusted dose (cPAD) utilized by all current uses (almonds, bushberries, caneberries, grapes, pear, pistachios, raisins, pre-harvest stonefruit, and strawberry) is estimated to be 7% in the **Federal Register** of April 18, 2002 (67 FR 19114) (FRL-6829-9); considering also the proposed tolerances, proportion of the crops treated and their importance in the diet, the percent of the cPAD utilized by the proposed uses is estimated to 14%. Therefore, Arvesta Corporation believes that the estimates of dietary exposure indicate adequate safety margins for the overall U.S. population.

2. *Infants and children.* Considering that the percent of the cPAD utilized by all current uses (almonds, bushberries, caneberries, grapes, pear, pistachios, raisins, pre-harvest stonefruit, and strawberry) is estimated to be 66% (infants) and 17% (children) (67 FR 19114, April 18, 2002); considering also the proposed tolerances, proportion of the crops treated and their importance in the diet, the percent of the cPAD utilized by the proposed uses is estimated to 11% (infants) and 13% (children). Therefore, the estimates of dietary exposure indicate adequate safety margins for children. In assessing the potential for additional sensitivity of infants and children to residues of fenhexamid, the available developmental toxicity and reproductive toxicity studies and the potential for endocrine modulation by fenhexamid were considered. Developmental toxicity studies in two species indicate that fenhexamid does not impose additional risks to developing fetuses and is not a teratogen. The 2-generation reproduction study in rats demonstrated that there were no adverse effects on reproductive performance, fertility, fecundity, pup survival, or pup development at non-maternally toxic levels. Maternal and developmental no observed adverse effect levels (NOAELs) and lowest observed adverse effect

levels (LOAELs) were comparable, indicating no increase in susceptibility of developing organisms. No evidence of endocrine effects was noted in any study. It is therefore concluded by Arvesta Corporation that fenhexamid poses no additional risk for infants and children and no additional uncertainty factor is warranted.

#### F. International Tolerances

International tomato tolerances are in effect in France, Germany, Greece, Italy, Slovenia, Spain, Turkey (1 ppm), and other European countries (2 ppm). Kiwi tolerances are as follows: Greece, Italy, and Slovenia (10 ppm). Stonefruit tolerances already exist in the U.S. for pre-harvest applications as well as in Canada (6 ppm), Austria (cherry, 5 ppm; plum, 2 ppm); Belgium (cherry, 5 ppm); Germany and Slovenia (cherry, 5 ppm; peach and plum, 2 ppm), Italy (cherry, 5 ppm; apricot, peach, and plum 2 ppm); Japan (peach, 1 ppm), Switzerland (cherry, 2 ppm) and the United Kingdom (plum, 1 ppm), and other European countries (peach and plum, 1 ppm; cherry, 5 ppm).

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### ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0167; FRL-7306-9]

#### Carbofuran; Receipt of Applications for Emergency Exemption, Solicitation of Public Comment

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

**ACTION:** Notice.

**SUMMARY:** EPA has received specific exemption requests from the Texas Department of Agriculture; the Oklahoma Department of Agriculture, Food, and Forestry; and the Louisiana Department of Agriculture and Forestry to use the pesticide flowable carbofuran (Furadan 4F Insecticide/Nematicide) (EPA Reg. No. 279-2876) to treat up to 1.8 million acres of cotton in Texas; 100,000 acres of cotton in Oklahoma; and 500,000 acres of cotton in Louisiana to control cotton aphid. The Applicants propose the use of a chemical which has been the subject of a Special Review within EPA's Office of Pesticide Programs, and is intended for a use that could pose a risk similar to the risk posed by uses evaluated under the Special Review. The granular formulation of carbofuran was the subject of a Special Review between the years of 1986-1991, which resulted in a negotiated settlement whereby most of